Access to Medicine Index 2018

access to medicine index

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ACCESS TO MEDICINE FOUNDATION

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We would like to thank the many other experts who contributed their views to the development of this report (see Appendix XVI).

ACCESS TO MEDICINE FOUNDATION

The Access to Medicine Foundation is an independent non-profit organisation based in the Netherlands. It aims to advance access to medicine in low- and middle-income countries by stimulating and guiding the pharmaceutical industry to play a greater role in improving access.

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How to radically ramp up access to healthcare

How can we radically ramp up access to healthcare worldwide? This 6th Access to Medicine Index shows where pharmaceutical companies are currently focusing their efforts to improve access. The Index is a guide to what is working, and a tool for inspiring further action.

Public health has seen massive gains in the past decades. Yet, millions of people still face uncertainty when it comes to the supply and affordability of health products. This is not only a problem for people in resource-limited settings, but it is today a global issue. The challenges are complex, going beyond the persistent challenges posed by infectious killers and the rise of lifestyle diseases. Climate change is already affecting the supply of medicines to island nations and isolated communities. With 70% of the world in close contact with animals, zoonotic diseases are sadly part of everyday life for many people.

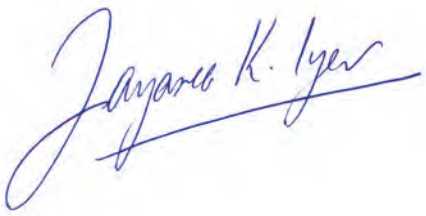
The power of priority setting

When there are competing global issues, we know that priority-setting works. It is 40 years since world leaders agreed that primary healthcare is key to improving health for all people. This commitment has been renewed this year in Kazakhstan to ensure no one is left behind. More people are signing up to these priorities, with the SDGs providing a framework for organisations working to improve all health. Governments are advancing universal health coverage (UHC) and implementing national action plans to address areas such as comprehensive cancer care. At the Access to Medicine Foundation, we clarify the priorities for pharmaceutical companies, as innovators and top producers, to improve access to medicine. Each Index reports in detail how companies are performing against these priorities.

The risk of a retreat

In 2018, we find that every single company evaluated is taking greater steps than before, albeit at different paces. The current range of practices and initiatives includes many good examples and ones that are being successfully expanded to cover more people. Most activity we see is being taken by just a few companies, where any retreat could have a catastrophic impact on access and yet many countries and communities have yet to be reached. To close the gaps that remain, a greater diversity of companies must get involved and stay engaged for the long haul.

The question I am asked most often in our work is 'how can the best pharmaceutical innovations reach the most people?' The 106 countries covered by the Index are home to 77% of all people alive today. The global reach of the pharmaceutical industry means that much more can be done. This new Index sets out which steps still need to be taken, and highlights the urgency of greater collaborative action.



Jayasree K. Iyer
Executive Director
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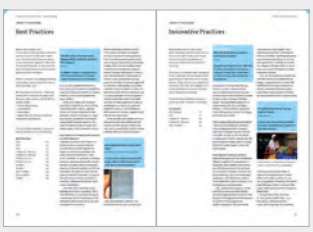

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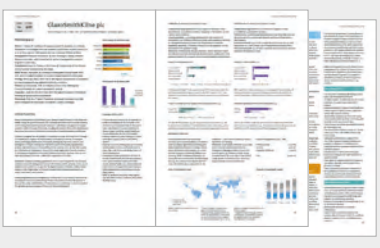


Executive Summary

INTRODUCTION

Globally, two billion people cannot access the medicines they need, with millions in low- and middle-income countries dying each year from diseases because the vaccines, medicines and diagnostic tests that they need are either unavailable or unaffordable. Pharmaceutical companies control products that can greatly alleviate disease burdens; they also have the expertise to meet the need for new and adapted innovative products; the power to address the affordability of those products through more refined access strategies; and the ability to strengthen supply chains and support healthcare infrastructures. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine.

For more than a decade, the Access to Medicine Foundation has worked to stimulate change within pharmaceutical companies. Every two years, it publishes its Access to Medicine Index, which analyses the top 20 research-based pharmaceutical companies and ranks them according to their efforts to improve access to medicine in developing countries. A total of 69 indicators make up a framework within which company performances relating to 77 diseases, conditions and pathogens in 106 low- and middle-income countries can be compared.

The Index analysis brings out best practices and examples, highlights areas where progress has been made and areas where critical action is required. The Index also acts as a benchmark where companies can compare their own contributions to improving access to medicine with their peers. While companies are held to a single standard, they are different in the way they operate and in their portfolio of investigational and marketed products. The Index is a relative ranking: scores cannot be directly compared between Indices.

The methodology is updated every two years in line with developments in access to medicine following a wide-ranging multi-stakeholder dialogue. For the first time this year, the Index examines company efforts to increase access to cancer products. Also for the first time, the Index zeroes in on 53 products on the market that it considers particularly critical candidates for company access initiatives and evaluates what companies are doing to facilitate their affordability and supply. These are products that are on patent, first-line therapies and on the World Health Organization Model List of Essential Medicines (EML).

This report outlines the key findings and overall ranking analysis of the 2018 Access to Medicine Index before presenting a detailed analysis of company performances and rankings in each of the seven areas of corporate activity it focuses on. The report concludes with detailed, tailored company report cards that explain each company's performance, highlight industry-leading practices and company-specific opportunities to improve access to medicine.

KEY FINDINGS

- Most priority R&D projects are being conducted by five companies: GSK, Johnson & Johnson, Merck KGaA, Novartis and Sanofi. Such concentration is also seen in the industry's overwhelming focus on five of the 45 priority diseases – malaria, HIV/AIDS, tuberculosis, Chagas disease and leishmaniasis– targeting that reflects international donor priorities.
- Access initiatives for cancer focus on pricing but have limited reach, mainly for small population groups and fewer than five key countries on average. Meanwhile, access planning for cancer products in the pipeline lags far behind that for communicable disease candidate products and plans are less comprehensive.
- The majority of the 53 key on-patent products have an access initiative attached to them, but these are limited in scope, with pricing schemes being applied in fewer than five countries where greater affordability is a priority. Many of these key products with access initiatives are for diseases prioritised by global health donors or international procurers.

2018 ACCESS TO MEDICINE INDEX – OVERALL RANKING

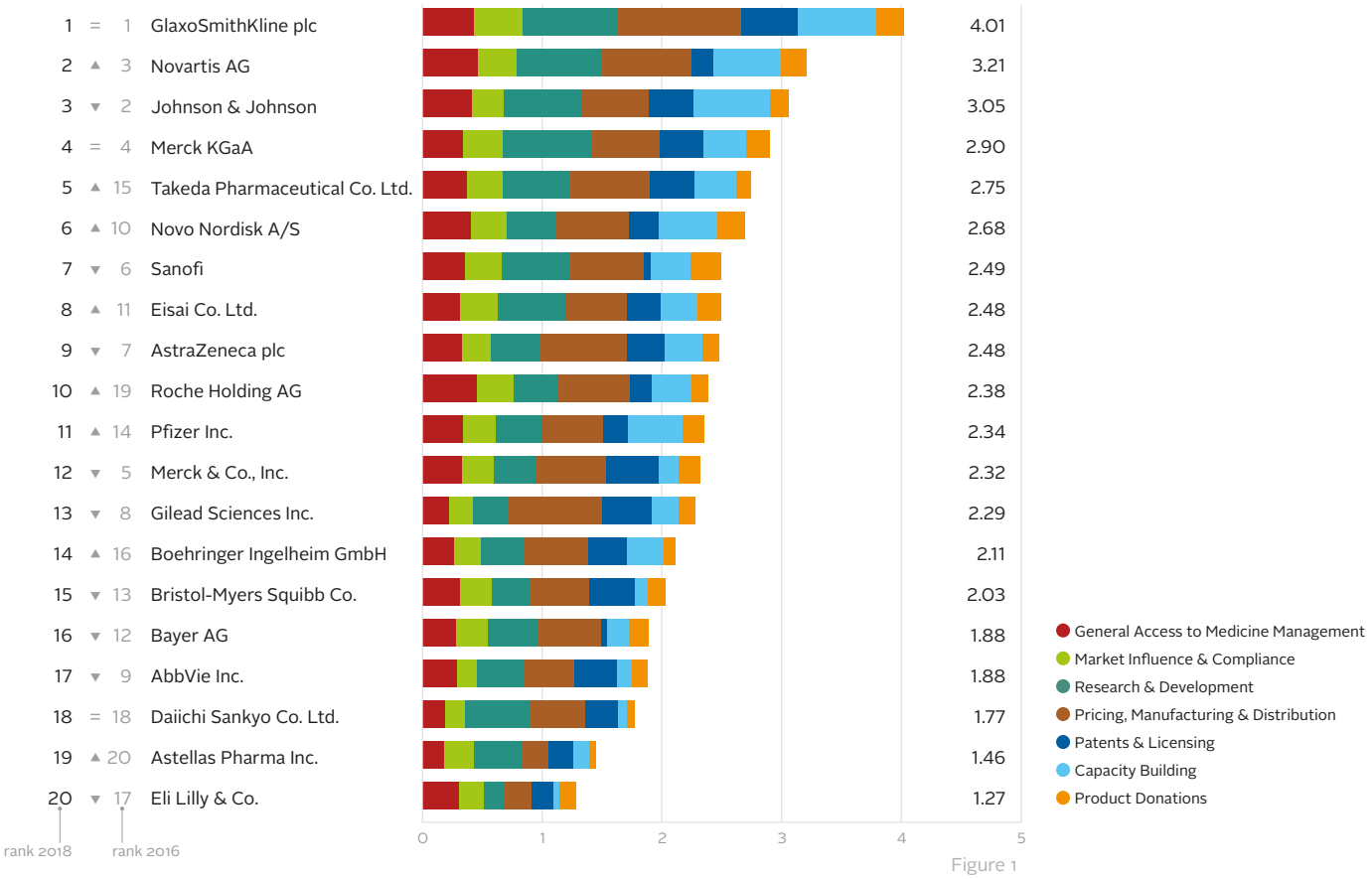


Figure 1

2018 RANKING ANALYSIS

The pharmaceutical industry continues to mature in its approach to access to medicine, with three companies issuing new or strengthened access strategies since the 2016 Index, with pricing strategies that set different prices for different segments of a country's population (intra-country pricing) becoming more sensitive to different population's abilities to pay, and more transparency over what products are under patent where. However, key areas for access continue to lag behind, such as planning for access during the late stage of development and filing for registration of newly launched products in the majority of priority countries.

All companies assessed are pursuing access initiatives to some degree. However, a handful of them account for the bulk of the activity to address access to medicine in low- and middle-income countries. This reliance on a concentrated group to drive most of the activity makes the access ecosystem fragile; if any of them changed direction to focus exclusively on commercial markets in high-income countries, a large proportion of the contributions of the R&D-based industry to access to medicine would be at risk.

At the top of the Index is GSK in first place, followed by Novartis, Johnson & Johnson and Merck KGaA. These leaders most consistently invest in projects and initiatives that the global health community has identified as pressing priorities. Takeda has climbed the furthest since 2016, jumping 10 places to rank 5th. It leads a broad, mid-ranking pack of companies with close scores; this means small shifts in performance in this pack would lead to large changes in ranking. Three of the lowest-ranking companies – AbbVie, Daiichi Sankyo and Astellas – have yet to set an access strategy.

EXECUTIVE SUMMARY

TOP FINDINGS PER TECHNICAL AREA

The Index measures company performance in seven main areas of activity.

GENERAL ACCESS TO MEDICINE MANAGEMENT

- More companies make access a strategic issue; two further companies have aligned access strategies with corporate strategies, taking the total to 14.
- Access is also being given higher priority internally, with the number of companies assigning direct board-level responsibility increasing from 6 to 11.
- 5 companies actively measure impact, while 11 report a general commitment to measuring it in the future.

MARKET INFLUENCE & COMPLIANCE

- More companies have stepped away from using only sales-based performance incentives and bonuses for sales agents.
- 16 companies extend their anti-corruption and/or ethical marketing policies to cover third parties.
- Only three companies demonstrated evidence of all components of an internal control framework, newly looked for in 2018.

RESEARCH & DEVELOPMENT

- Almost one quarter of R&D projects target priority product gaps.
- One in five late-stage candidates have access plans in place. For late-stage cancer projects, this drops to less than one in twenty.
- More projects target neglected tropical diseases (NTDs) today than in 2016, but only four NTD candidates have moved along the pipeline in the last two years.
- Most companies score well for establishing and enforcing codes of conduct governing clinical trials.

PRICING, MANUFACTURING & DISTRIBUTION

- The proportion of products with equitable pricing strategies has grown from 33% in 2014 and 2016 to 43%, with prices within countries becoming more tailored according to need.
- Companies have so far filed products in less than a quarter of the possible priority countries in need of medicine.
- More than half of the companies are taking action to align supply with demand in countries in scope.

PATENTS & LICENSING

- The majority of companies improve in at least one area. In particular, public disclosure of patent status information has improved significantly since 2016, with 17 companies placing such information in the public domain.
- 15 companies make a public commitment not to enforce patents in Least Developed Countries and low-income countries, up from 13 companies in 2016.
- There have been few improvements in voluntary licensing since 2016. Two* new compounds have been licensed and licensing practices remain limited to HIV/AIDS and hepatitis C.

CAPACITY BUILDING

- Initiatives commonly fell short on measuring progress and outcomes, but 5 companies show evidence of measuring the impact of their initiatives.
- Most activity is centred around strengthening local health systems, with initiatives covering 80 countries.
- The majority of initiatives are active in sub-Saharan Africa. Kenya has the most initiatives in this region, likely because of the prioritisation of healthcare from the Kenyan government and high activity from NGOs and other partners. It is also a rapidly growing healthcare market.

PRODUCT DONATIONS

- Half of donation programmes for neglected tropical diseases are explicitly committed to continuing until the disease in question is eradicated or eliminated.
- Donation programmes for cancer address narrower patient populations than other programmes.
- Seven donation programmes for non-communicable diseases apply a range of transition planning approaches for diseases which require long-term or ongoing treatment.

Raising the bar

The 2018 Index identified 45 best and innovative practices across each of the Technical Areas it measures. These practices are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

In Zambia, GSK's Live Well equips community health entrepreneurs to provide last-mile access.

Researchers at Sanofi have developed an oral cholera vaccine which is considered a priority R&D project.

GSK's HALOW works to improve access to healthcare services for garment workers in Bangladesh.

In DREAMS, Johnson & Johnson engages with local young women through workshops aiming to reduce HIV infections.

Treatment for lymphatic filariasis is provided during an annual drug administration in Tanzania.

INTRODUCTION

How can progress in access to medicine be sustained?

The constitution of the World Health Organization (WHO) asserts that all people have the right to the highest attainable standard of health, yet access to medicine continues to be out of reach for an estimated two billion people. New and complex health challenges continue to emerge, demanding sustained commitment and deeper cooperation across the ecosystem of global health stakeholders, as well as wider adoption of proven solutions.

Increasing access depends on a range of factors and involves action from a variety of parties. The pharmaceutical industry, in collaboration with the global health community, plays a critical role in responding to defined priorities for global health, developing much-needed innovative products, expanding access to those products that already exist and forging new partnerships to promote sustainable, long-term access to medicines.

Global health challenges are evolving

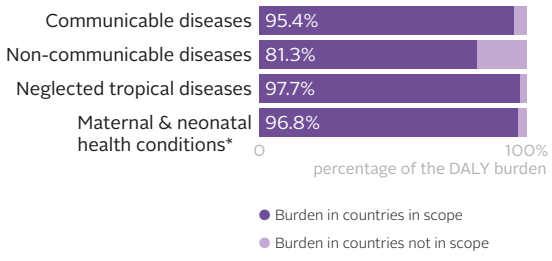
The growth in development aid for health has slowed since 2010 as donor government budgets have tightened. This is particularly concerning for low-income countries that rely heavily on aid to provide health services to their populations.[1] Low-income countries are being hit the hardest: in these countries, government health expenditure as a percentage of GDP has been in decline in recent years, resulting in more needing to be done with less.[2] In 2015, the UN agreed the Sustainable Development Goals, including global health targets such as the elimination of major disease epidemics and the reduction in the burden of childhood obesity.[3]

Progress in global health is not inevitable. In 2017, improvements in the global mortality rate was less pronounced than in earlier years; in some countries, mortality rates are stagnating or worsening. In 2017, non-communicable diseases (NCDs) accounted for 73.4% of deaths, an increase of 22.7% since 2007.[4] The rise is due, in part, to rapid urbanisation, worsening diets and increasingly sedentary lifestyles.[5]

Meanwhile, the scale of antimicrobial resistance, which already causes more than 700,000 deaths each year worldwide, is growing.[6] In addition, new public health crises have posed further challenges to global health and put more pressure on already strained health systems and families paying out of pocket for health services. For instance, new Ebola outbreaks occurred in the Democratic Republic of Congo in 2018. They were contained more quickly than the 2014-2016 West Africa Ebola outbreak was[7], in part due to quicker response times and the use of innovative medicine and vaccine candidates. Yet, infections were confirmed in high-conflict areas, creating significant new challenges for health services.[8] Also in 2018, just weeks after 47 African governments pledged to end cholera outbreaks by 2030, Zimbabwe declared a state of emergency due to a cholera outbreak.[9] To help address current and future global health issues, governments and regulators – as well as stakeholders from the public and private sectors – need to develop, support and implement innovative practices to reach more people in need.

Figure 2. Low- and middle-income countries face the bulk of disease burden.

'Disease burden' describes how severely a population is impacted by a disease or condition, for example, in terms of years of life lost due to premature death and years of healthy life lost due to disability (DALYs). Across all diseases and conditions in scope, people in low- and middle-income countries face almost the total burden. Behind these numbers are millions of people who cannot rely on access to affordable, quality medicine.



*For maternal & neonatal health conditions, mortality was used as an indicator of global burden.

Progress is being made

Despite significant global health challenges, milestones have been reached. These demonstrate that effective approaches are being developed and applied and exemplify the impact that international collaboration and coordination can have on the health of billions. For example, child mortality dropped by almost 50% between 1990 and 2013.[10]

There has been a 48% decline in AIDS-related deaths since the peak of the HIV/AIDS epidemic in 2005, and more than half of all people living with HIV/AIDS are accessing antiretroviral therapy.[11] In 2015, 71% of countries had a national action plan addressing cancer, up from 50% in 2010,[12] and WHO member states endorsed a set of measures in 2017 to improve cancer control.[13] Vaccine campaigns are enabling movement towards elimination of polio in Haiti, meningitis in 26 countries in sub-Saharan Africa and hepatitis B in China.[14]

New global health conventions and commitments – including the 2017 London Summit on Family Planning and the 2018 UN High Level Meeting on Ending Tuberculosis, as well as the UN High-Level Meeting on Non-Communicable Diseases – are helping to set additional priorities, with the goal of inspiring global action.

Recent innovations

New medicines and vaccines also continue to reach the market, including new treatments that make country-by-country elimination of hepatitis C now possible. Immunotherapy has become a clinically validated treatment for many cancers,[15] contributing to a 23% reduction in cancer mortality since 1991 in the United States.[16] Collaboration to limit antimicrobial resistance is also strengthening, with multiple initiatives established in recent years, such as the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) and the Global Antibiotic Research and Development Partnership (GARDP) in the field of R&D. New vaccine developments are helping countries to better prepare for and respond to future disease outbreaks, including Ebola.

Critical role for pharmaceutical companies

In 2018, the need for all stakeholders to take action on access to medicine remains clear, with each having their own roles and responsibilities. This includes the scientific research community, local governments, public health and regulatory agencies, overseas development agencies, philanthropists, multi-lateral agencies and the non-profit sector including product development partnerships. Pharmaceutical companies, with the resources and the knowledge to develop and supply new medicines at scale, have a responsibility to ensure these are made available to people regardless of their socioeconomic standing. Pharmaceutical companies have the power to address affordability by refining their access strategies; and the ability to strengthen supply chains and support healthcare infrastructures. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine.

Novartis leverages mobile technology in capacity building initiatives such as telemedicine to improve care.

Blood samples are tested in a mobile clinic as part of Bayer's donation programme which provides free treatment for patients infected with human African trypanosomiasis.

The 20 companies in the 2018 Index account for approximately 70% of global pharmaceutical revenue. In 2016, global pharmaceutical sales were USD 768 billion, and are expected to reach USD 1.06 trillion by 2022 (growing 6.5% year on year).[17] The global market for anti-infectives is projected to grow by 5.1% between 2016 and 2022 to USD 90.9 billion.[17] Emerging economies accounted for 23% of global spending on pharmaceuticals in 2015, and is expected to account for 25% by 2020.[18] The size of the pharmaceutical market in low-income countries is comparatively stable.

Pharmaceutical companies manufacture almost all medicines and vaccines available today.[18] The industry continues to consolidate, particularly in anti-infectives. In 2018, for example, Novartis ended its antibacterial research (licensing three projects), following a similar decision by AstraZeneca, and Sanofi outlicensed the development of its anti-infective medicines.[19]

The Access to Medicine Index

For a decade, the Access to Medicine Index has worked to stimulate change within pharmaceutical

companies. The Index analyses 20 of the top research-based pharmaceutical companies in low- and middle-income countries and ranks them according to their efforts to improve access to medicine. It identifies best practices, highlights where progress is being made and uncovers where critical action is still required. In this way, the Index provides an incentive and a guide for pharmaceutical companies to do more for people who still lack access to medicine.

Over the past decade, the Access to Medicine Foundation has developed a robust process for building consensus among a wide range of stakeholders on what society expects of pharmaceutical companies regarding access to medicine in low- and middle-income countries. These expectations are then translated into metrics that form the basis of the methodology for the Access to Medicine Index. The Index methodology is updated every two years in line with developments in access to medicine following a wide-ranging multi-stakeholder dialogue coordinated by the Access to Medicine Foundation. The dialogue involves NGOs, governments, the industry and multilateral organisations, in order to build consensus on how and where pharmaceutical companies can and should be improving access to medicine.

How the Index responds to global challenges

As a result, the Index methodology has evolved continually since the first Access to Medicine Index was published in 2008. For example, the disease scope has been adjusted in line with changing views on which diseases should be prioritised for improving access to medicine. In 2008, the Index focused mainly on neglected tropical diseases as defined by WHO, expanding to include high-burden diseases, including non-communicable diseases, in 2010. The latest refinement in this direction is the inclusion of cancer in the 2018 Access to Medicine Index. The geographic scope has also been refined, to ensure it covers countries where greater access to medicine is needed most. Many countries have moved into higher World Bank classifications over the lifespan of the Index: 72% of the world's poor now live in middle-income countries.[20] To adapt to these demographic changes, the 2014 Index adopted measures of human development and inequality in its country inclusion framework, to bring some higher-income countries with high levels of inequality into the scope of the Index. At the same time, company business models are also evolving and accounting for a growth in the middle class in, for example, emerging markets. The Index continues to raise the bar, measuring companies on their ability to both increase access for the new middle classes, as well as to ensure the most marginalised populations are not left behind.

The 2018 Index measures 20 companies. The methodology comprises 69 indicators and covers 106 countries and 77 diseases, conditions and pathogens. The Foundation will use this latest Index to provide guidance to pharmaceutical companies on where the priorities lie and how they can improve current practices with the many solutions and opportunities identified in the Index.

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2018 Access to Medicine Index

The 2018 Access to Medicine Index provides a finely detailed picture of how 20 of the world's largest pharmaceutical companies' take action to address access to medicine. The Index reports on these companies' access-related policies and practices based on an analysis of 69 indicators, concerning 106 low- and middle-income countries and 77 diseases, conditions and pathogens.

The Index is used as a tool for driving change in the pharmaceutical industry. It identifies best practice, tracks progress and shows where critical action is still needed.

This first section of the report provides the core analyses of how the 20 companies in scope performed, with Key Findings, the 2018 overall Index ranking, and a visual breakdown of their R&D pipelines and marketed products.

KEY FINDINGS

- Five companies are developing 63% of urgently needed medicines.
- Access initiatives for cancer products focus on pricing.
- 53 products are critical candidates for companies' access initiatives. Most have access initiatives, but these are limited in reach.

2018 INDEX RANKING

- Progress led by a handful of companies, including in pricing and R&D.
- The 2018 Access to Medicine Index overall ranking.

PIPELINE & PORTFOLIO ANALYSIS

- Products for non-communicable diseases dominate the pipeline and portfolio.
- Gap analysis: which diseases have treatments on the market or promise in the pipeline?
- Breakdown: a closer look at company pipelines and portfolios.
- Market approvals since 2016: which diseases account for most new treatments?

KEY FINDING 1: R&D

Five companies are carrying out 63% of the most urgently needed R&D projects.

IN BRIEF

- ▶Pharmaceutical R&D priorities have been identified for people in low- and middle-income countries.
- ▶The priorities span 45 diseases, conditions and pathogens, with different products needed per disease, such as medicines or diagnostics.
- ▶Companies are responding to priority setting; priority R&D accounts for one quarter of all R&D projects analysed.
- ▶63% of priority R&D projects are being developed by five companies: GSK, Johnson & Johnson, Merck KGaA, Novartis and Sanofi.
- ▶Priority R&D projects mainly focus on 5 diseases: malaria, HIV/AIDS, tuberculosis, Chagas disease and leishmaniasis.
- ▶Many diseases with priority gaps, such as Burili ulcer and syphilis, remain unaddressed by the companies evaluated.

Most of the R&D projects (63%) for diseases listed as global priorities are being conducted by five companies: GSK, Johnson & Johnson, Merck KGaA, Novartis and Sanofi. The global health community has identified specific medicines, vaccines, diagnostic tests or other products that are needed as a priority by people living in low- and middle-income countries. The Index terms R&D into these needs as 'priority R&D'. The need for priority R&D has been identified for 45 diseases, conditions and pathogens, with different sets of gaps per disease (see figure 5).

Priority R&D represents one quarter of the total R&D pipeline analysed by the Index (298 out of 1,314 projects). The industry's engagement in priority R&D is overwhelmingly focused on five diseases: 144 of the projects in the priority R&D pipeline target malaria, HIV/AIDS, tuberculosis, Chagas disease and leishmaniasis. These diseases include the leading causes of death in low- and middle-income countries. All five of these diseases have global health donors or product development partnerships behind them. Overall, almost two thirds of priority R&D projects are being developed in collaboration with other organisations.

Many priority product gaps go unaddressed

A total of 91 of the 139 identified gaps are unaddressed, and 16 prioritised diseases have no projects at all (see figure 5). The average number of projects across the 45 diseases, conditions and pathogens is only two. Diseases with the least attention here include several haemorrhagic fevers, several parasitic worm diseases, syphilis, Buruli ulcer, cholera and diarrhoea caused by *E. coli*. Some of these are rarer diseases, while others have weaker global health community push and donor support.

For malaria, there is at least one project for each gap identified. For both tuberculosis and HIV/AIDS, there is one gap left unaddressed by the 20 companies. Coverage of product gaps for leishmaniasis and Chagas disease is more patchy, with four out of nine product gaps being addressed.

Specific product gaps have not been established to address antibiotic resistance. The industry has 40 such projects in the pipeline, including 13 new antibiotics, 22 vaccines (mostly for pneumonia) and a new diagnostic test for the superbug MRSA.

WHAT NEXT?

The pipelines for malaria, HIV/AIDS, tuberculosis, Chagas disease and leishmaniasis show that the combination of (1) prioritising gaps, (2) donor funding and (3) research collaboration can be successful in engaging pharmaceutical companies in priority R&D. However, the model is currently being applied to only a handful of diseases. The next challenge for donors, research organisations and the pharmaceutical industry is to extend this model to other prioritised diseases. The global health community can also address the current lack of a list of R&D priorities for non-communicable diseases, such as cancer, heart disease and diabetes to ensure that products moving through the pipeline are adequately tailored to the particular needs of low- and middle-income countries. Getting more companies involved in priority R&D would not only increase the numbers of products being developed, but would also reduce the negative impact of individual companies deciding to halt or reduce their engagement in such R&D.

Many priority product gaps go unaddressed

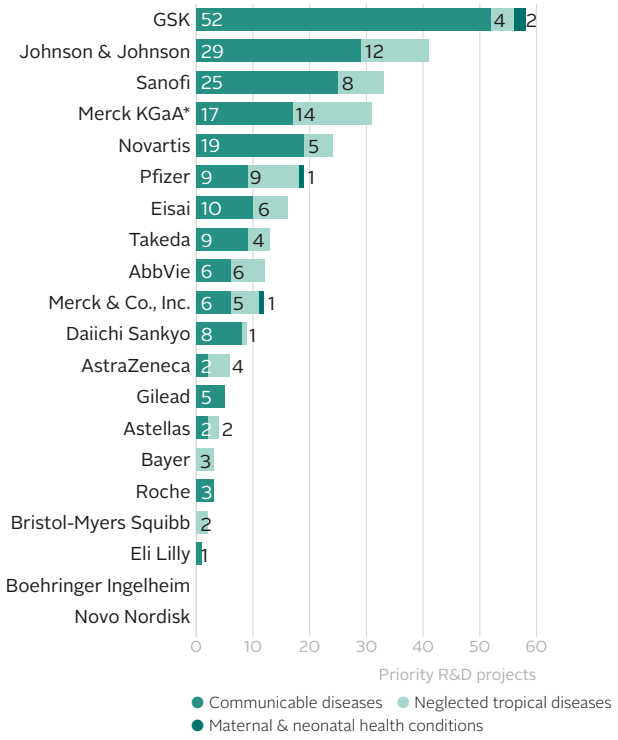
The table shows which products are urgently needed by people living in low- and middle-income countries, as identified by WHO and Policy Cures Research. Diseases with the most unaddressed gaps are at the top. The zeroes represent gaps that receive no attention from companies in scope. A total of 91 of the 139 gaps are unaddressed. Figure 5

>10 projects
5-10 projects
1-4 projects
0 projects
No priority

Diseases, conditions and pathogens	Gaps Remaining	Product types: Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (Reproductive Only)
Crimean-Congo haemorrhagic fever (CCHF)	5	0	0	0	0		0	
Rift Valley fever (RVF)	5	0	0	0	0		0	
Severe fever w thrombocytopenia syndr. (SFTS)	5	0	0	0	0		0	
Arenaviral haemorrhagic fevers (incl. Lassa fever)	4	0	0	0	0			
Coronaviruses**	4	0	0	0	0			
Nipah	4	0	0	0	0			
Buruli ulcer	3	0	0		0			
Leishmaniasis	3	13	0	0	0			
Marburg	3	0	1	0	0			
Onchocerciasis	3	10	0		0		0	
Strongyloidiasis***	3	0	0		0			
Zika	3	0	2	0	0		1	
Chagas disease	2	13	0	1	0		2	
Cholera	2	0	1		0			
Contraceptive methods	2	0						0
Cryptosporidiosis	2	4	0		0			
Ebola	2	3	4	0	0			
Enteroaggregative *E. coli*	2		0		0			
Hookworm diseases***	2	0	0					
Human African trypanosomiasis	2	6	0		0		1	
Lymphatic filariasis	2	3			0		0	
Non-typhoidal *S. enterica*	2	0	1		0			
Schistosomiasis	2	8	0		3		0	
Syphilis	2	0						0
Taeniasis/cysticerosis	2	0					0	
Trachoma	2		0		0			
Typhoid and paratyphoid fever	2	0	1		0			
Viral hepatitis C (genotypes 4-6)	2	3	0		0			
Cryptococcal meningitis	1	0						
Dengue	1	9	3		0		1	
Enterotoxigenic *E. coli* (ETEC)	1		1		0			
Giardiasis (lambliasis)	1				0			
HIV/AIDS	1	24	3	1	5	0		
Leprosy	1	1			0			
Leptospirosis	1				0			
N. meningitidis (meningitis)	1		3		0			
Respiratory syncytial virus (RSV)	1	0	8					
Rheumatic fever	1		0					
S. pneumoniae (lower respiratory infections)	1		6		0			
S. pneumoniae (meningitis)	1		3		0			
Shigellosis	1	5	3		0			
Tuberculosis	1	26	2	0	3			
Ascariasis***	0	1						
Group B *Streptococcus*	0		2					
Influenza	0		8					
Malaria	0	43	3		2		2	
Postpartum haemorrhage	0	2						
Rotaviral gastroenteritis	0		2					
Trichuriasis***	0	1						

Five companies are developing most priority R&D

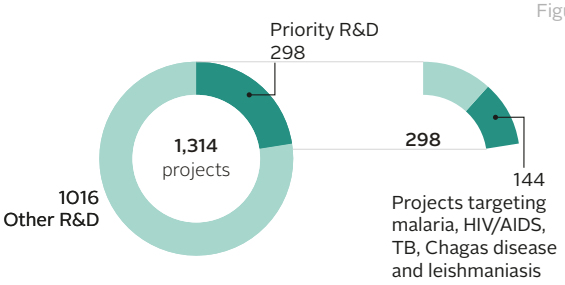
The chart compares the pipelines of priority R&D projects for each of the 20 companies evaluated. The top five companies account for almost 63% of these. Figure 3



Priority R&D represents almost one quarter of the total R&D pipeline

The Index identified 1,314 projects for diseases in scope. Almost one quarter comprises priority R&D, mainly targeting just five diseases: malaria, HIV/AIDS, tuberculosis, Chagas disease and leishmaniasis.

Figure 4



*Includes one project that targets both communicable diseases and neglected tropical diseases. This project was counted once for each disease category.

**Coronaviruses include Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus (SARS-CoV).

***Types of soil-transmitted helminthiases

KEY FINDING 2: CANCER

Access initiatives for cancer products focus on pricing, mainly for small populations.

IN BRIEF

- ▶Most of the 20 companies are marketing cancer medicines on the WHO EML: 72 medicines in total.
- ▶For 57% of these cancer products, companies have an access initiative in place, mainly pricing strategies.
- ▶Yet pricing initiatives for cancer products on the market have limited reach, covering fewer than 5 key countries on average.
- ▶Access planning for cancer R&D projecs in the pipeline lags behind planning for other types of R&D.
- ▶Access plans for cancer R&D projects are much less comprehensive - mostly registration commitments, in China and Brazil.

Cancer is taking an increasing toll in low- and middle-income countries, where more than half of deaths due to cancer now occur.[1] The Index examines company efforts to increase access to cancer products for the first time this year, focusing on cancer medicines deemed by the World Health Organization to be essential for all healthcare systems.*

In this first assessment, the Index compares cancer products on the 2017 WHO Model List of Essential Medicines (EML)[2] with other WHO EML products, such as HIV/AIDS medicines and antibiotics. It found that around the same proportion of cancer products on the WHO EML have access initiatives attached to them as products for other diseases do, with initiatives in place for just over half of products (57% vs 54% respectively).

The largest proportion of access initiatives for cancer involve pricing initiatives. However, they generally have limited coverage aiming to reach fewer people than initiatives for other WHO EML products. Pricing initiatives on average apply in fewer than five priority countries**, most commonly middle-income countries such as Egypt, Pakistan and Mexico. Conversely, for communicable disease products on the WHO EML, equitable pricing initiatives are applied to many low-income countries in South Asia and sub-Saharan Africa. Moreover, no cancer medicine is covered by voluntary licensing. Pricing and licensing are core tools for improving access to medicine.

Initiatives mainly focus on pricing

All access initiatives evaluated for cancer products were either pricing or donations initiatives. In both categories, initiatives can take the form of Patient Assistance Programmes (PAPs), where products are made available at low or no cost and target smaller groups of patients per programme (compared to, e.g., donations programmes targeting neglected tropical diseases). These programmes are supported by ancillary activity involving, for example, the training of healthcare workers, patient education, and screening and diagnostic services, thereby recognising the need to strengthen health systems ill-equipped to manage cancer care. No cancer medicines are covered by licences. However, two companies, GSK and Merck KGaA, have stated they are open to using voluntary licensing for cancer medicines in the future.

Which companies market the most cancer products on the WHO EML?

Out of the 20 companies evaluated, 14 market a total of 72 cancer medicines that are on the WHO EML (see figure 8). Novartis markets the largest proportion of these, including half of the cancer products that have an access initiative. The remaining products with pricing initiatives are spread between seven other companies.

Access planning for cancer products is lagging

The Index has also assessed whether companies plan ahead during development to make future products more accessible in low- and middle-income countries. By this measure, access planning for new products for non-communicable diseases – and particularly cancer – lags far behind planning for communicable disease products (see figure 7). The access plans are mostly commitments to register new products in low- and middle-income countries, overwhelmingly in China and occasionally in Brazil. Some access plans also involve commitments to flexible pricing in key countries, but the impact of those commitments is unclear, as most companies did not reveal where and to what extent they will apply.

Plans for donation programmes cover one cancer medicine: Novartis' chronic myeloid leukaemia treatment nilotinib (Tasigna®), which was recently approved for use in children one year of age and older. The company uses a combination of pricing mechanisms and donations to address access to the medicine in India, Pakistan, Egypt and China.

*There are 27 cancer types in scope for the 2018 Access to Medicine Index: 17 for the R&D analysis (based on the top 10 highest global incidence rates, highest incidence in countries in scope and highest proportion of global incidence in countries in scope), and 19 for the areas of analysis relating to pricing, patenting and donations (i.e., cancer with products on the WHO EML).

**Priority countries are disease-specific subsets of countries with a particular need for access to relevant products (see Appendix VI).

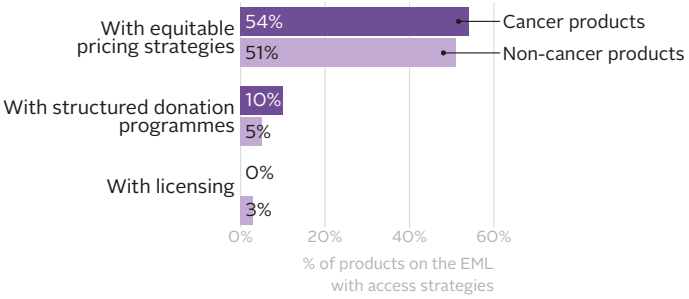
It works with the Max Foundation to donate and distribute Tasigna® in 40 additional low- and middle-income countries.

WHAT NEXT?

Pharmaceutical companies can work with national governments and partners to expand pricing schemes, particularly for poorer patients, and donation programmes where appropriate. Companies are also strongly urged to begin systematically planning ahead during clinical development to ensure successful products can be made widely available more quickly in low- and middle-income countries. They can pioneer voluntary licensing for cancer medicines, and establish multi-sector capacity building partnerships. A 2017 study by the Access to Medicine Foundation found that the companies evaluated are carrying out many diverse capacity building initiatives related to cancer care.[3] The 2018 Index confirms this finding; most initiatives examined for health systems strengthening focus on cancer. Many health systems, particularly in low- and middle-income countries, lack the infrastructure and investments to be able to offer the full complex range of cancer care services.[4] Health systems in developing countries also need to be sufficiently strengthened by governments and their partners before sustainable health outcomes for cancer patients can be achieved.

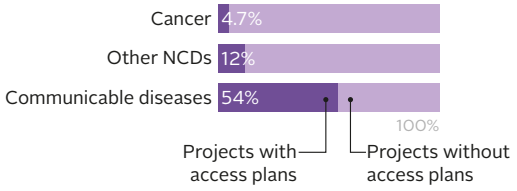
Access initiatives mainly focus on pricing, for cancer and other EML products

The graph compares the proportion of products covered by different types of access initiatives. It looks at products on the 2017 WHO Model List of Essential Medicines (EML), comparing cancer products with non-cancer products, such as HIV/AIDS medicines and antibiotics. Figure 6



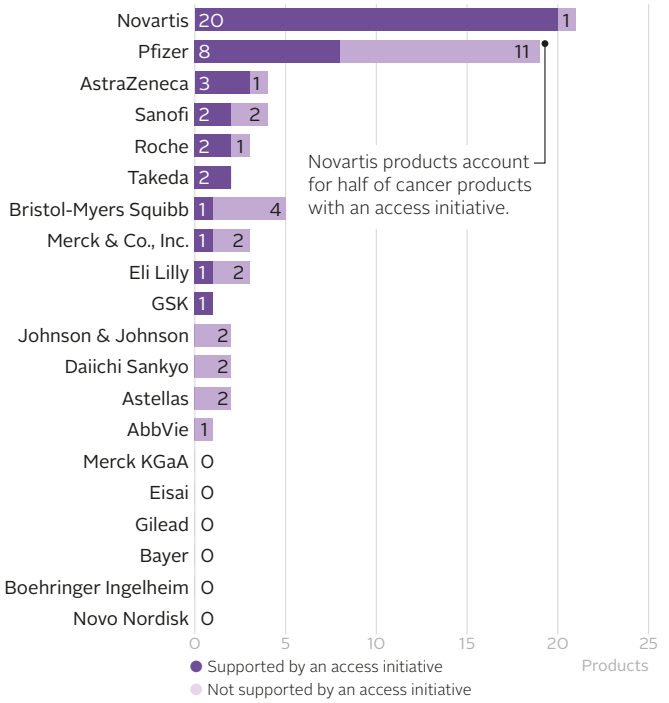
Access planning for cancer products in development is lagging

The graph shows the proportion of late-stage R&D projects supported by access plans (Phase II onwards). It compares the proportion for cancer projects with those for other non-communicable diseases and for communicable diseases. Access planning for cancer products lags far behind planning for communicable disease products. Figure 7



Overall, 14 companies market 72 cancer medicines on the EML

The chart compares the number of cancer medicines on the EML in each company's portfolio, and shows what proportion of these medicines are supported by an access initiative (pricing or donations). Figure 8



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KEY FINDING 3: ON-PATENT PRODUCTS

Majority of key on-patent products have access initiatives, but these are limited in reach.

IN BRIEF

►The Index identifies 53 products that are critical candidates for companies' access initiatives.

►These products are
a) on-patent
b) first-line therapies
c) essential medicines
d) indicated for a disease in scope

►Of these, 37 (70%) are covered by at least one access initiative. Yet most initiatives are limited in scale and reach.

►Most are pricing strategies, and apply in fewer than five of the countries where greater affordability is a priority.*

►Many products with access initiatives are for diseases targeted by donors and other global health actors.

►Some examples of broad-based or nuanced strategies stand out.

From the 20 companies evaluated, the Index has identified 53 products that are critical candidates for companies' access initiatives. The Index uses four criteria: being on-patent, being a first-line therapy, and being designated as an essential medicine by the World Health Organization, as well as targeting a disease in scope. The 53 products are mainly medicines for HIV/AIDS or hepatitis C, and vaccines, including the measles-mumps-rubella-varicella vaccine. The remaining products are varied, including essentials such as inhalable medicines for people with asthma. The Index found that 37 of the products (70%) are covered by at least one such initiative. Yet most of these initiatives are limited in scale and reach.

Most initiatives are limited in scope

Patents give their owners control over a product's price as well as where and in what volumes it is available. The decisions pharmaceutical companies take have a larger impact on public health when patents cover first-line therapies on the WHO Model List of Essential Medicines (EML). First-line therapies are generally needed in higher volumes, as they are the treatments doctors turn to in the first instance, while products on the WHO EML are seen as essential for healthcare systems.

The Index conducted a specific analysis to investigate what companies are doing to facilitate affordability and supply of these products, examining pricing, licensing and donation programmes. It found that 37 of the products (70%) are covered by at least one such initiative. Yet most of these are limited in scale and reach.

Most of the initiatives involve using different prices for different populations. Per disease, the Index has identified 13 countries on average as priority targets for companies to apply pricing strategies.* Most pricing strategies in this analysis are applied in fewer than five of the countries where greater affordability is a priority.

Drivers for action

Many products with access initiatives are for diseases targeted by donors and other global health actors, such as HIV/AIDS and hepatitis C or neglected tropical diseases, or are vaccines that are the focus of large international programmes to improve immunisation coverage. Two such products stand out for their comparatively broad-based access initiatives: emtricitabine/tenofovir disoproxil fumarate (Truvada®) for HIV/AIDS and sofosbuvir (Sovaldi®), a treatment for hepatitis C. Both are marketed by Gilead. The medicines have stratified pricing schemes applying in all countries considered a priority, and are licensed for local generic-version manufacture in more than 100 countries. There is a donation programme for emtricitabine/tenofovir disoproxil fumarate (Truvada®) in Kenya. However, it should be noted that the affordability of sofosbuvir (Sovaldi®) has been called into question, particularly for poorer populations in wealthier countries.[1]

There are also companies applying initiatives for diseases not widely prioritised by the global health community. For example, AstraZeneca has a particularly nuanced access strategy for its cholesterol-lowering drug, rosuvastatin (Crestor®). Its strategy can take account of individual people's ability to pay in Brazil. The strategy segments the population into several groups, with the poorest paying the least. Another example is GSK's salbutamol sulfate (Ventolin®), used in inhalers for asthma and chronic obstructive pulmonary disorder. The product is covered by particularly flexible pricing strategies in 11 out of 16 priority countries. The strategy is global and allows GSK to apply a single, locally adjusted price across specific country markets, taking account of locally relevant factors (such as disease burden, healthcare system and funding). GSK and Gilead account for more than half (23 out of 37) of the products with access strategies.

*Priority countries are disease-specific subsets of countries with a particular need for access to relevant products (see Appendix VI).

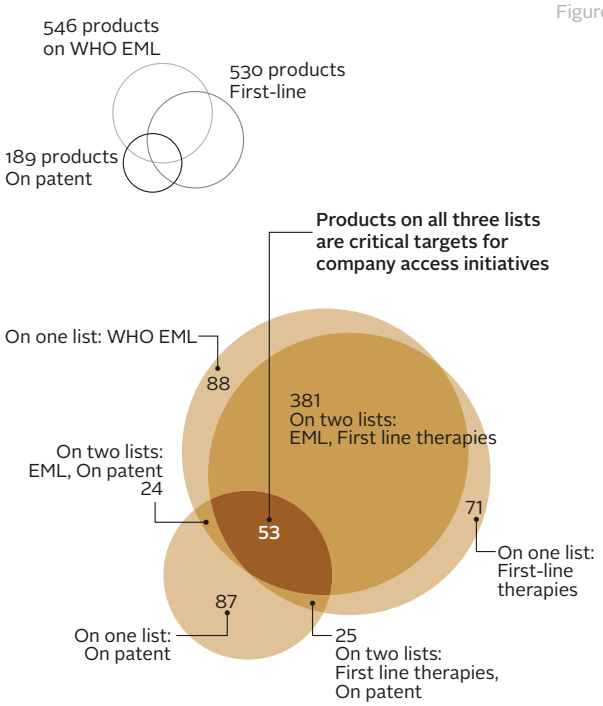
WHAT NEXT?

There are 16 on-patent first-line therapies that are on the EML and that currently have no pricing, voluntary licensing or structured donation programmes in place. These products include contraceptive methods and devices such as drospirenone/ethinylestradiol (Yasmin®), as well as a palliative treatment for advanced prostate cancer, leuprolide acetate (Eligard®). Companies are urged to develop and implement access initiatives for these products, starting with countries where greater access is deemed a priority. Companies can also evaluate opportunities to expand access initiatives already in place for products in this group to additional countries, so that more people can benefit, recognising that, as patent owners, they are in a strong position to influence who gains access to these important products, as well as a responsibility to take positive action.

53 products are critical candidates for companies' access initiatives

The 20 companies have 53 on-patent**, first-line therapies on the WHO Model List of Essential Medicines (EML) for the diseases in scope. Companies have considerable influence over the affordability, accessibility and availability of patented products.[2] First-line therapies are generally needed in higher volumes, as they are the treatments doctors turn to first after diagnosis. Medicines on the WHO EML are considered essential for all healthcare systems.

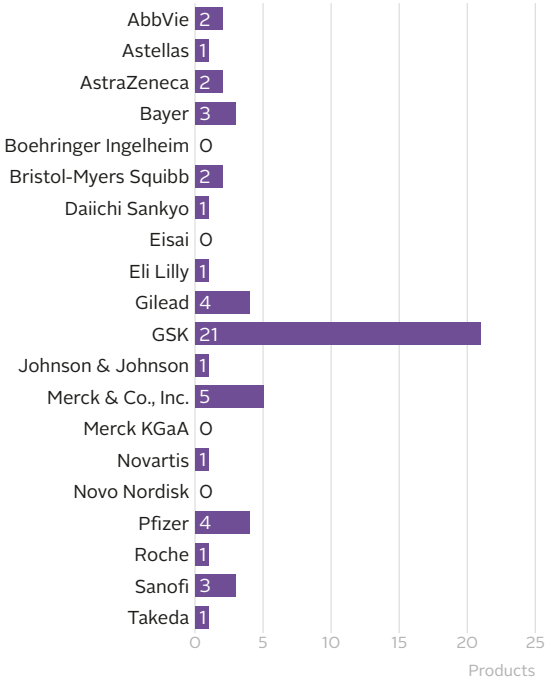
Figure 9



Which companies control the 53 products?

The chart compares the number of on-patent first-line therapies on the EML held by each of the 20 companies evaluated.

Figure 10



**The numbers used for this analysis include unique product counts. Patented products developed and marketed by multiple companies, were only counted once in this Venn diagram. When analysing the total number of access initiatives covered by products in the Index (1036), individual companies are evaluated for their respective access initiatives for a given product for which they have marketing rights. Patent status is determined based on data available from the US FDA and Health Canada. See Appendix IX.

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THE 2018 ACCESS TO MEDICINE RANKING

Progress led by handful of companies, including in pricing and R&D

IN BRIEF

▶The companies continue to mature in their approaches to access to medicine, making improvements in areas such as strategy, pricing, patent transparency.

▶All 20 companies are pursuing access initiatives to some degree. However, in many areas evaluated, a handful of companies account for most activity.

▶Key areas for access continue to lag behind: in access planning, licensing and registration in priority countries.

▶Models for good practice have emerged in these areas also; e.g., five companies now plan ahead systematically during development.

▶Emerging markets get most attention for pricing and registration. Capacity building focuses in sub-Saharan Africa.

The pharmaceutical industry continues to mature in its approach to access to medicine, with more companies assigning responsibility for access initiatives at the board level, three companies issuing new or strengthened access strategies since the 2016 Index, and pricing strategies that set different prices for different segments of a country's population (intra-country pricing) are becoming more sensitive to different population's abilities to pay.

Many companies have also become more transparent about what products are under patent and where, with 17 out of the 20 now revealing this information. This compares with only four companies in 2016 and one in 2014. This shift has been influenced by years of external pressure and provides much needed clarity for international procurers supplying medicines to low-resource countries.

Core groups of companies account for most activity

All companies assessed are pursuing access initiatives to some degree. However, a handful of them account for the bulk of the activity to address access to medicine in low- and middle-income countries. For instance, the majority of the R&D efforts that the global health community considers a priority is being performed by just five companies, while one-third of such priority R&D projects are carried out by a single company. Meanwhile, the increase identified in segmented pricing is being driven by just five of the companies, as is the application of access plans to candidate products in the pipeline.

These companies aren't always the same ones in every area important for access to medicine, but those that rank at the top of the Index are consistently among the small group dominating these areas. This reliance on a concentrated group to drive most of the activity makes the access ecosystem fragile; if any of these companies changed direction to focus exclusively on commercial markets in high-income countries, a large proportion of the contributions of the R&D-based industry to access to medicine would be at risk.

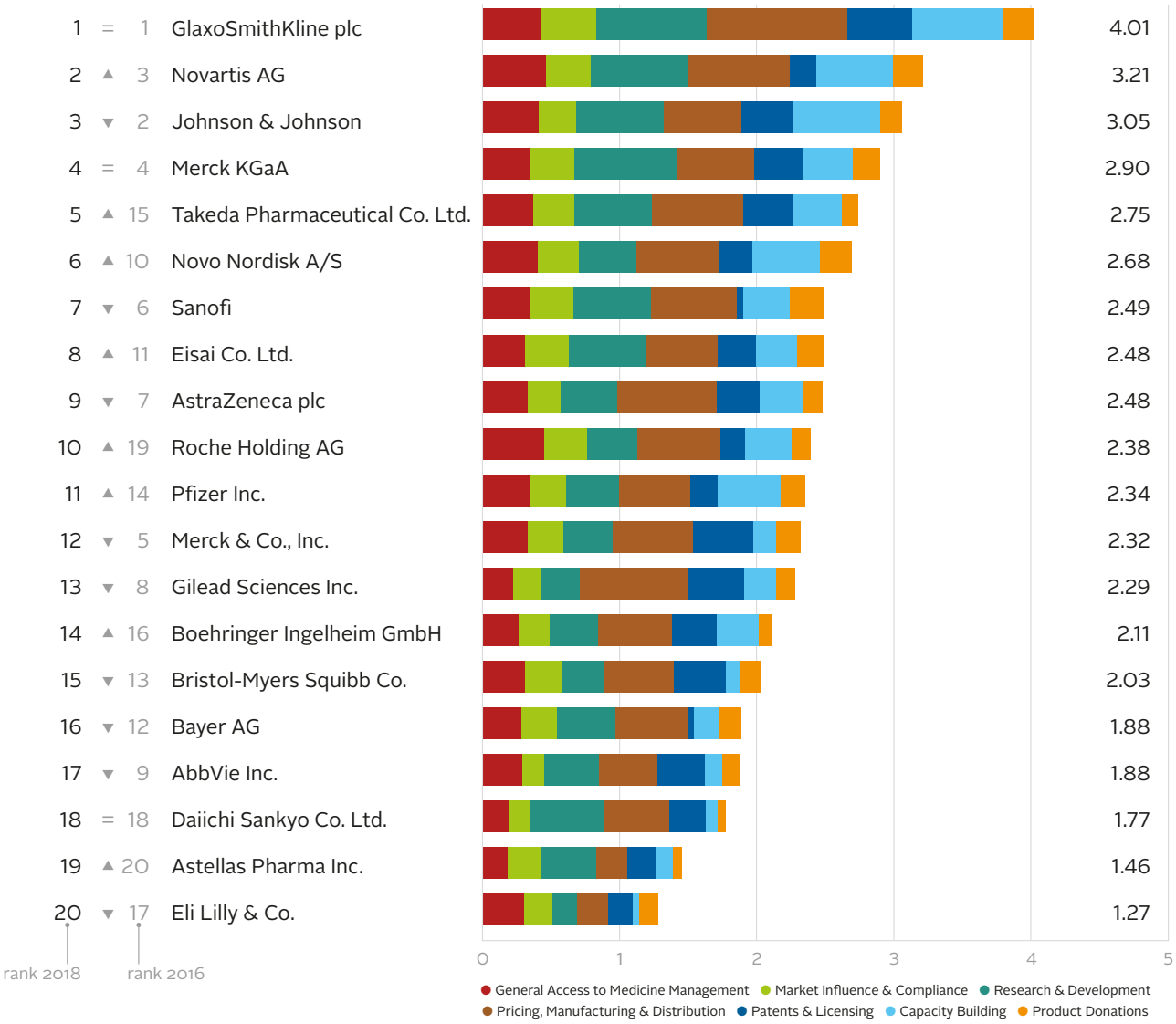
Models for good practice emerge

Key areas for access continue to lag behind, however models for good practice have emerged. Only 1 out of 5 candidate products in the late stage of development, across all disease categories, have access plans attached to them, such as registration plans for low- and middle-income countries and commitments to affordability. Nevertheless, five companies now have strong processes for systematically developing access plans. Voluntary licensing is broadly a success story in increasing access to medicine; the full range of antiretrovirals recommended for people living with HIV/AIDS is now available for generic manufacture, whether under patent or not. Nevertheless, licensing remains confined to few diseases (HIV/AIDS and hepatitis C). In addition, less than one-quarter of recently launched products have been filed for registration in the majority of countries the Index identifies as being particularly in need of them.

Disease and country focus

Emerging markets such as China, Brazil and India continue to get significant attention, particularly when it comes to the implementation of segmented pricing and product registration filings, and to transferring knowledge, expertise and other capacities to support the local manufacture of pharmaceutical products. Capacity building initiatives to strengthen health systems and supply chains are particularly concentrated in sub-Saharan Africa. When it comes to specific diseases, malaria, HIV/AIDS and tuberculosis, along with Chagas disease and leishmaniasis, get the most attention when it comes to priority R&D, while products for diabetes, HIV/AIDS, cancer, heart disease and lower respiratory infections are the most frequent targets of registration filings.

THE 2018 ACCESS TO MEDICINE INDEX – OVERALL RANKING



HANDFUL OF COMPANIES CARRY OUT MOST ACTIVITY

In many areas, such as R&D and pricing, a handful of companies account for the bulk of the activity to address access to medicine in low- and middle-income countries. All companies assessed are pursuing access initiatives to some degree.

FOUR LEADERS CONSISTENTLY INVEST IN ACCESS INITIATIVES

The four leaders – GSK, followed by Novartis, Johnson & Johnson, and Merck KGaA – frame access as a business proposition and most consistently invest in projects and initiatives that the global health community has identified as pressing priorities.

BIGGEST RISER LEADS TIGHTLY RANKED MIDDLE-PACK

Takeda has climbed the furthest since 2016, jumping 10 places. It performs particularly well in R&D and pricing. It leads a broad, mid-ranking pack of companies with close scores; this means small shifts in performance would lead to large changes in ranking.

EMERGING MARKET FOCUS

Emerging markets such as China, Brazil and India draw significant attention, particularly in pricing and registration, and to transferring expertise and other capacities to local pharmaceutical manufacturers. Capacity building generally is focused in sub-Saharan Africa.

ABOUT OUR DATA

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. In 2018, three companies declined to provide data to the Access to Medicine Index: AbbVie, Eli Lilly and Merck & Co., Inc. Of these three, Merck & Co., Inc. has placed substantially more information in the public domain since 2016. The Index credits companies for placing information in the public domain that can support access to medicine, for example, information used by procurers and governments.

FOUR LEADERS CONSISTENTLY OUTPERFORM PEERS ONCE AGAIN

The 2018 Index is led by **GSK**, followed by **Novartis**, **Johnson & Johnson**, and **Merck KGaA**. These are the same four companies that led in 2016. They most consistently invest in projects that the global health community has identified as pressing priorities with either no or low commercial incentive. They frame access as a business proposition, and all are among the leaders in multiple areas of evaluation.

GSK retains first place for the sixth consecutive Index. It continues to outpace peers, supported by and building on its long-standing foundation of projects, initiatives and policies. GSK leads in 5 out of 7 of the areas that the Index analyses. During the period of analysis, GSK has shown itself to currently be the most access-oriented company in the Index.

Novartis rises one place to take second rank, having climbed every Index since 2012. Over the period of analysis, the company has expanded the scope of its access efforts, embodied in the Novartis Access Principles, which promises to integrate access-oriented thinking across the company's pipeline. Its pipeline covers both non-communicable diseases such cancer and COPD and communicable diseases such as malaria.

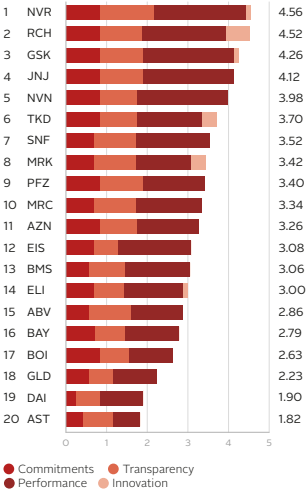
Johnson & Johnson remains in the top three companies for the fourth consecutive Index. The company remains an access leader, with a robust internal structure for ensuring coherent, senior governance of access in selected disease areas, and a strong approach to capacity building that aligns with stakeholder expectations. The company has expanded its global health focus since 2016, for example to newly include mental health.

Merck KGaA holds fourth place for the second consecutive Index. Since 2016, it has created the Merck Global Health Institute and launched a new business model, Curafa™, addressing primary healthcare in Kenya. The company has particular strength in targeting R&D priorities and in the systems it has in place to minimise the risk of corruption and unethical marketing.

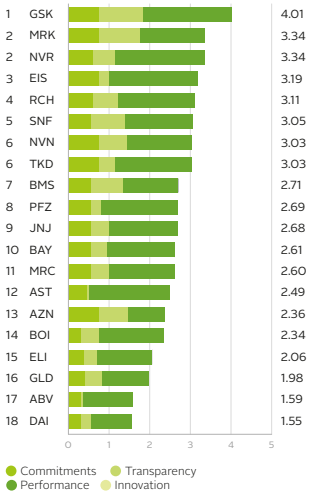
RANKINGS PER AREA

The Index evaluates companies' performances in seven areas of corporate behaviour that can impact access to medicine. The Index uses dense ranking: all 20 companies are ranked, companies that compare equally receive the same ranking number.

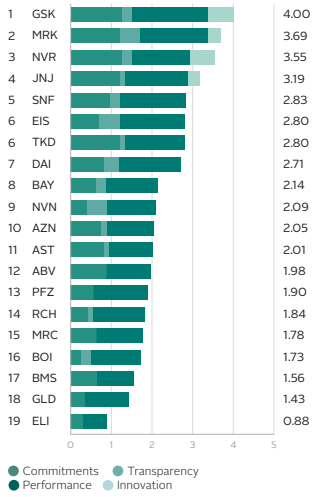
General Access to Medicine Management



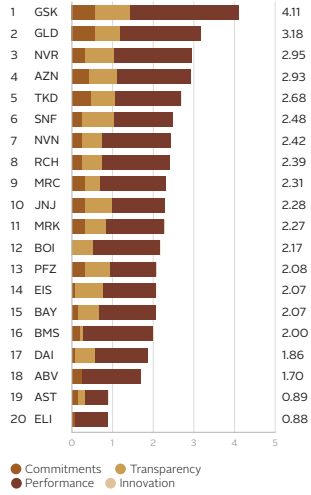
Market Influence & Compliance



Research & Development



Pricing, Manfacturing & Distribution



DIVERSE STRENGTHS FROM MIDDLE-RANKING COMPANIES RESULT IN CLOSE COMPETITION

Following the top-ranked group of companies are **Takeda** and **Novo Nordisk**, in 5th and 6th place respectively. They lead a broad mid-ranking pack of companies stretching to Bristol-Myers Squibb in 15th place. **Takeda** has climbed the most in rank since the 2016 Index after jumping 10 places and performs particularly well in two core areas the Index evaluates – R&D and pricing. Fractionally behind **Takeda**, **Novo Nordisk** takes a particularly high-quality approach to capacity building, including its efforts to increase children's access to diabetes care.

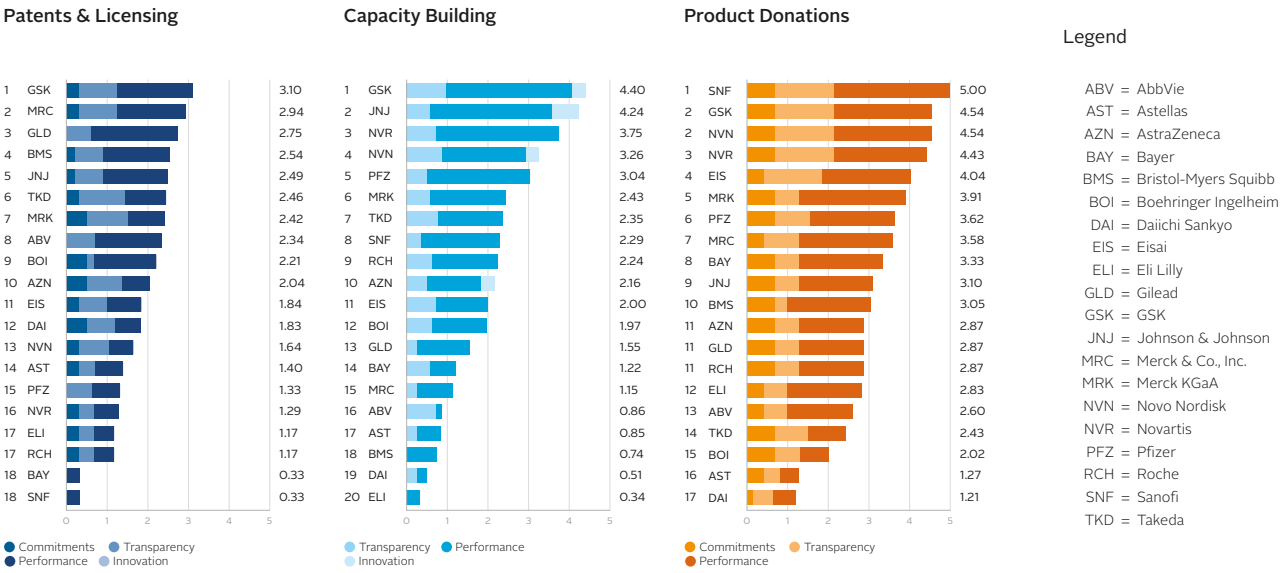
Scores are particularly densely packed between **Sanofi** in seventh place and **Gilead** in 13th place. This group has similar scores but for very different reasons; the strengths and weaknesses are diverse, with each company choosing to focus its efforts more or less in different areas the Index measures. With scores this close, comparatively small shifts in performance can trigger a significant rise or fall in rank.

Following closely behind are **Boehringer Ingelheim** and **Bristol-Myers Squibb**, in 14th and 15th place respectively. **Boehringer Ingelheim** has pulled out of the lower rankings of the Index with a strengthened access strategy but is held back by a comparatively poor performance in attaching access plans to products in its pipeline.

OF THE FIVE LOWEST-RANKING COMPANIES, THREE HAVE YET TO SET STRATEGIES

The tail of the Index is populated by a group of five companies, comprising **Bayer**, **AbbVie**, **Daiichi Sankyo**, **Astellas** and **Eli Lilly**. Of these five, only **Bayer** and **Eli Lilly** have strategies in place for improving access to medicine, leaving **Astellas**, **Daiichi Sankyo** and **AbbVie** as the three remaining companies out of the 20 evaluated in the Index yet to develop an overarching approach for their access activities. These three companies tend to engage in access initiatives on an ad hoc basis. All the companies in this lowest-ranking group placed in the bottom quartile in at least three out of the seven areas of evaluation.

Bayer, ranked 16th, placed in the bottom quartile in three areas. **AbbVie** fell eight places to rank 17th, with scores in the bottom quartile in four areas. **Daiichi Sankyo**, which ranks 18th, places in the last quartile of five areas. Although it rose one place to 19th in this Index, **Astellas** placed in the bottom quartile in four of the areas of evaluation and in the bottom half of the remaining three. **Eli Lilly** falls 3 places to rank 20th. Its performance is relatively weak across all of the seven areas the Index evaluates, and is less transparent than its peers across multiple measures. The company holds the last position in three of the areas.



PIPELINE & PORTFOLIO ANALYSIS

Products for non-communicable diseases dominate the pipeline and portfolio.

When pharmaceutical companies take action to improve access to medicine, it has the largest impact on their own products. The Index has identified which products those are – including future products still in development – for 20 of the world's largest research-based pharmaceutical companies. The Index compiled products and R&D projects for 77 high-burden diseases, conditions and pathogens, including diseases with the largest global impact on health, such as malaria and tuberculosis, and diseases that overwhelmingly affect people living in low to middle-income countries, such as infections caused by parasitic helminths or sandfly bites.

Pipeline: 1,314 projects in development
- 945 projects target NCDs
- 615 for cancer
- 42 for HIV/AIDS
- 31 for tuberculosis
- 4 for neonatal sepsis

Portfolio: 1,036 products already available
- 672 products are for NCDs
- 201 for heart disease (ischaemic and hypertensive)
- 109 for cancer
- 76 for HIV/AIDS
- 24 contraceptive methods
- 8 for soil-transmitted helminthiases

Figure 11. Cancer accounts for a major proportion of R&D projects

The chart compares the size of the collective pipepline with the size of the collective portfolio, by type of disease. Collectively, the 20 companies have more products and R&D projects for non-communicable diseases (NCDs), than for all other disease types examined. Cancer accounts for the majority of NCD R&D projects while products for cardiovascular health and cancer make up large proportions of the collective portfolio. Cancer is newly in scope in 2018.

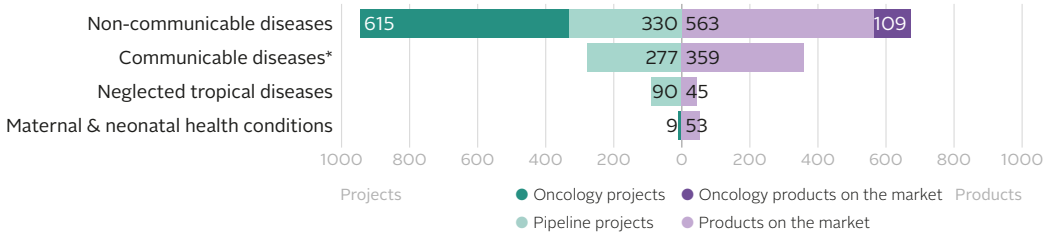


Figure 11a. Pipeline: 6.8% of projects target NTDs

Most companies evaluated have signed the 2012 London Declaration to Combat Neglected Tropical Diseases.

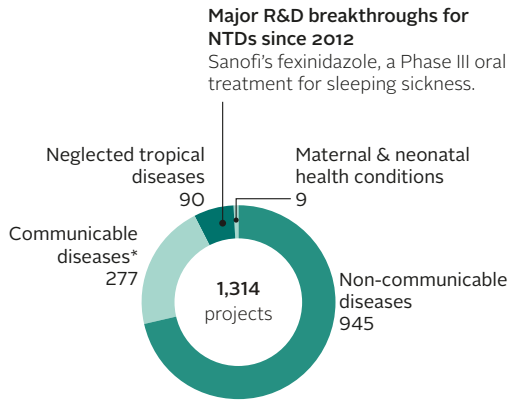
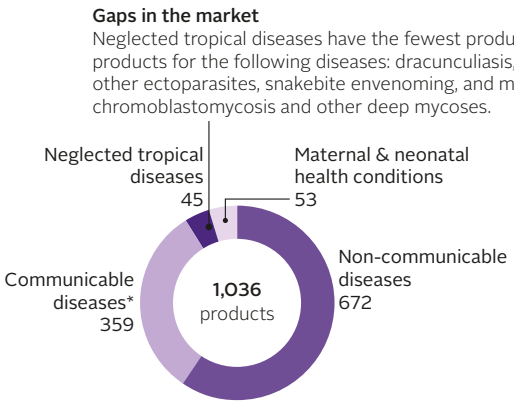


Figure 11b. Portfolio: 4.3% of products target NTDs

Neglected tropical diseases affect the poorest populations most severely, particularly where sanitation is poor.



*The 11 communicable diseases with the highest DALY burdens in countries in scope of the 2018 Index. The R&D pipeline includes 10 further diseases and 12 pathogens. Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II for more detail.

Projects and products falling into multiple disease categories are counted twice.

PIPELINE & PORTFOLIO ANALYSIS

Gap analysis: which diseases have treatments on the market or promise in the pipeline?

The diseases and conditions examined by the Index pose a far higher burden to people living in low- to middle-income countries than to people living in the rest of the world. Per disease, the Index has assessed whether the 20 companies in scope are developing and marketing products that could treat these diseases and conditions.

Figure 12a. R&D for 22 priority diseases

The Index also covers 22 diseases, conditions and pathogens that are only included in its R&D analysis. These are 22 of the 45 diseases flagged as priorities for global health.

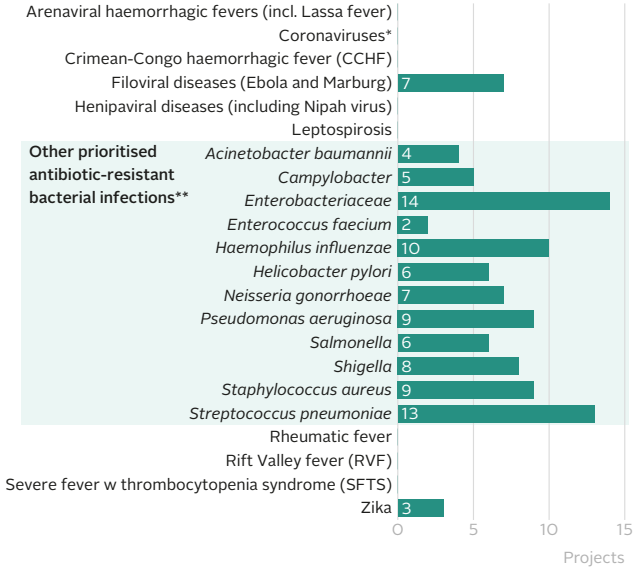
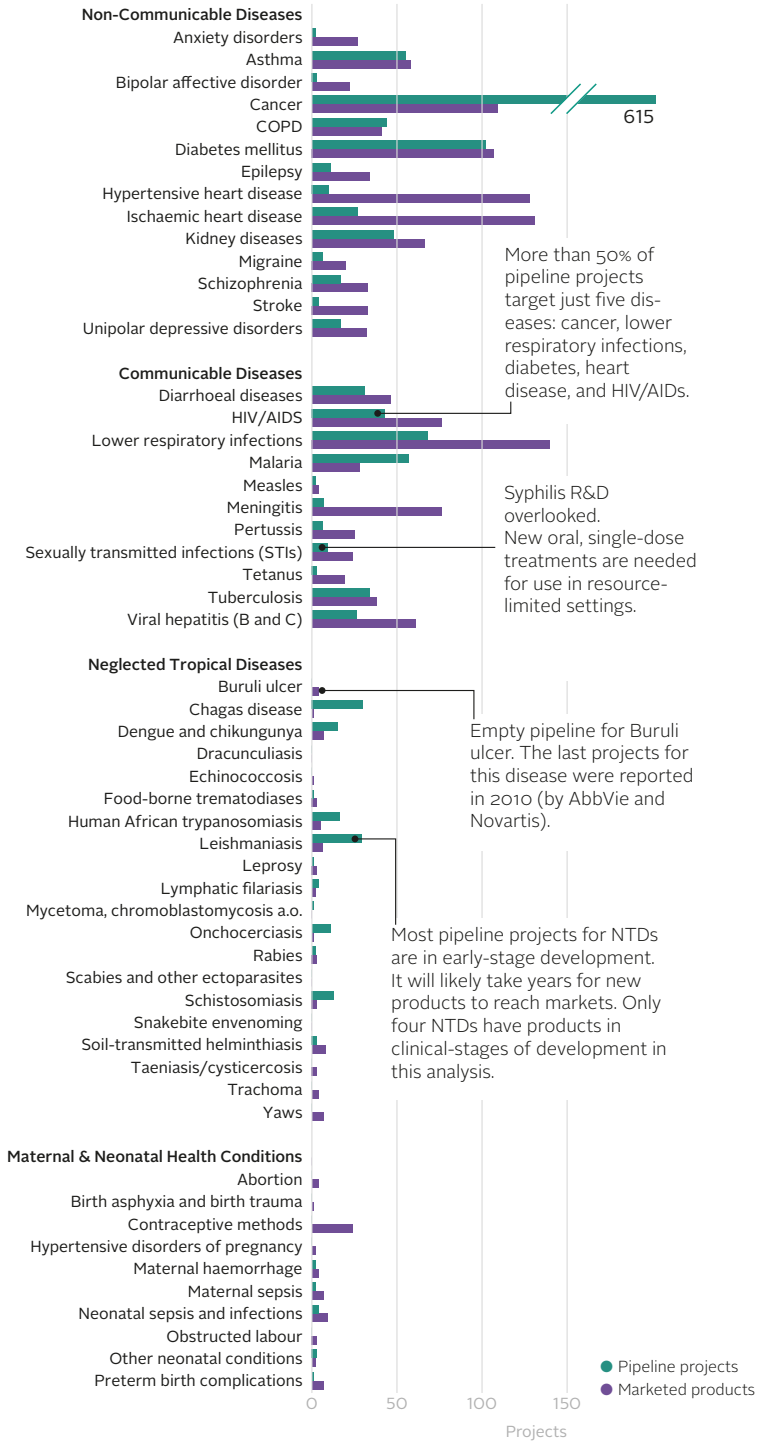


Figure 12b. Mapping the pipeline and the market

The 20 companies evaluated in the 2018 Index are mostly focused on a small group of diseases: cancer, lower respiratory infections, diabetes mellitus, heart disease, and HIV/AIDS. The least attention is being paid to maternal and neonatal health conditions and to neglected tropical diseases.



*Coronaviruses include Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome coronavirus (SARS-CoV).

**Includes 12 antibiotic-resistant priority pathogens identified by WHO for which new treatments are urgently needed. For AMR see Appendix IV. Tuberculosis is assessed as a separate disease.

PIPELINE & PORTFOLIO ANALYSIS

Breakdown: a closer look at company pipelines and portfolios

The Index has analysed the size and contents of companies' pipelines and portfolios to reveal their focus on diseases and conditions that disproportionately affect countries in scope. Most companies are targeting R&D priorities (here termed 'priority R&D'), and all companies produce at least some medicines and/or vaccines identified by the World Health Organization (WHO) as essential to the running of a modern healthcare system.

Figure 13. Pipeline analysis shows most companies are developing urgently needed new products

The chart compares the sizes of companies' pipelines for diseases in scope. To guide companies on which products are urgently needed, WHO and Policy Cures Research have published lists of R&D priorities. 18 out of 20 companies are developing priority R&D projects.

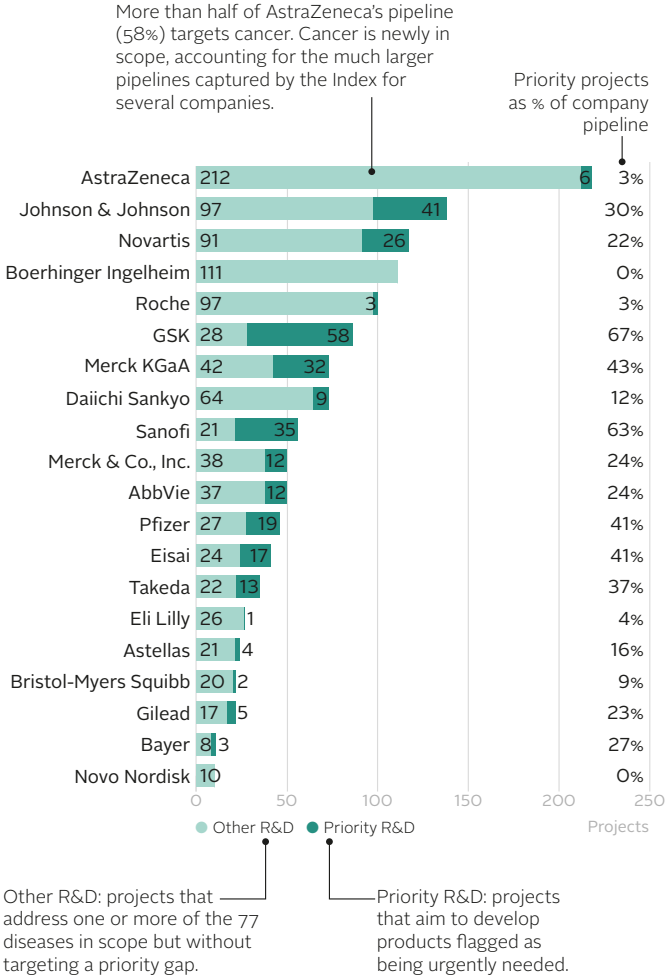
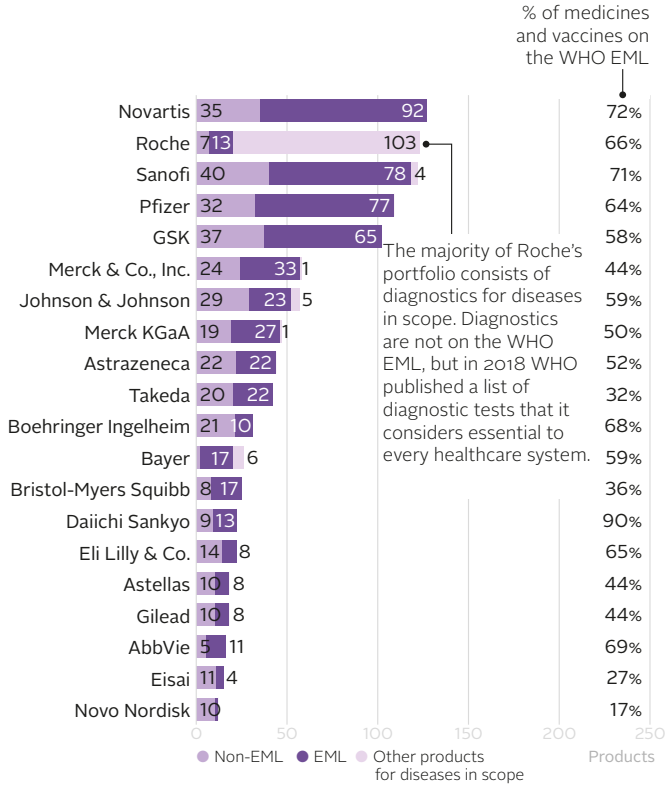


Figure 14. Portfolio analysis shows all companies have essential medicines or vaccines

The chart compares the sizes of companies' portfolios of products for diseases in scope. The 2017 WHO Model List of Essential Medicines (EML) identifies those medicines and vaccines seen as critical for all modern healthcare systems. All of the companies in the 2018 Index have at least some products on the EML. Overall, 60% of the medicines and vaccines in the portfolio are on the EML.



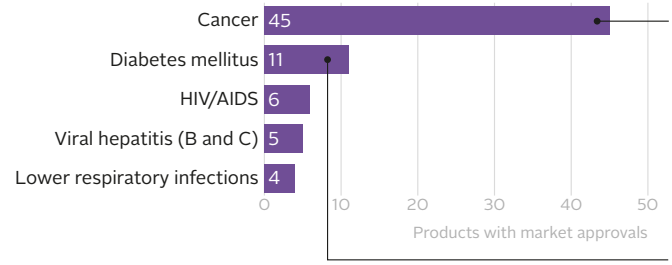
PIPELINE & PORTFOLIO ANALYSIS

Market approvals since 2016: which diseases account for most new treatments?

During the period of analysis, 19 companies received at least one regulatory approval by the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) or the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for a product targeting a disease in scope. These approvals account for 66 products with 80 new indications, targeting 14 diseases in scope. The FDA, EMA and PMDA are responsible for protecting public health by ensuring the efficacy, safety and quality of medicines or medical products for market use. Approvals by these agencies are greatly respected by other countries and often pave the way for them to begin approving products for their own populations.

Figure 15. Cancer gains the most market approvals

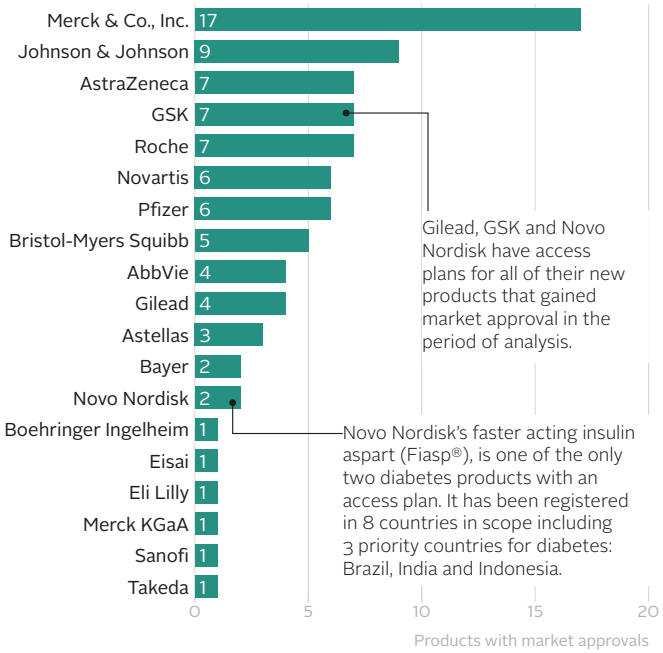
This chart shows the five diseases that gained most new treatments since 2016. Cancer and diabetes account for more than half of all market-approved indications. There was only one approval for a neglected tropical disease and no new approvals for products for maternal & neonatal health conditions from the 20 companies in scope in the last two years.



Ensuring access
Currently, around 65% of cancer deaths occur in low- and middle-income countries, where cancer rates are also rising. New products need access strategies to make them more available, accessible and affordable. Five newly approved cancer products have plans to improve access. E.g., Roche's pertuzumab (Perjeta®), approved as an adjuvant treatment for HER2-positive breast cancer has equitable pricing commitments.

Only two (out of 11) new diabetes products that gained market approval, both from Novo Nordisk, are supported by access plans, specifically commitments to file the products for registration in low- and middle-income countries.

Figure 16. Merck & Co., Inc. and Johnson & Johnson have the most new product approvals



Gilead, GSK and Novo Nordisk have access plans for all of their new products that gained market approval in the period of analysis.

Novo Nordisk's faster acting insulin aspart (Fiasp®), is one of the only two diabetes products with an access plan. It has been registered in 8 countries in scope including 3 priority countries for diabetes: Brazil, India and Indonesia.

▸Two new products for bacterial infections reach the market

- One new antibiotic, Pfizer's ceftazidime/avibactam (Zavicefta®), is used to overcome antibiotic resistance in bacteria that have developed beta-lactamases.
- Merck & Co., Inc.'s bezlotoxumab (Zinplava™) is a monoclonal antibody that can be used to prevent recurrent *Clostridium difficile* infections in adult patients receiving traditional antibiotics such as oral vancomycin and metronidazole.

▸New paediatric treatments from four companies

- GSK has four paediatric products for HIV/AIDS and lower respiratory infections.
- Johnson & Johnson contributes one with its chewable mebendazole (Vermox™ Chewable) tablet for roundworms and whipworms.
- Merck & Co., Inc. contributes one approval, raltegravir (Isentress®) for the treatment of HIV/AIDS in newborns weighing at least two kilograms.
- Eisai's perampanel (Fycompa®) is a monotherapy used for epileptic patients 12 years of age and older.

Technical Areas

The Access to Medicine Index uses an analytical framework of 69 indicators to capture and compare company action in 106 low-and middle-income countries and 77 diseases, conditions and pathogens. The framework is constructed along seven areas of focus, called Technical Areas. These areas cover the range of company activities that experts consider most relevant to access to medicine.

GENERAL ACCESS TO MEDICINE MANAGEMENT
Achieving greater access to medicine requires companies to view access to medicine as a strategic issue and to manage it as such, with clear goals and objectives and commitment from top management.

MARKET INFLUENCE & COMPLIANCE
Companies operate in an environment where the pressure to maintain profits and a fiercely competitive landscape can increase the temptation to engage in inappropriate, unethical behaviour. Strong policies and procedures for ensuring compliance are critical for mitigating this risk.

RESEARCH & DEVELOPMENT
There is a huge demand for R&D that meets the needs of people living in low- and middle-income countries. For example, new products are needed for infectious diseases such as malaria, as well as for tropical parasitic diseases. Large R&D-based pharmaceutical companies are best placed to develop such products and bring them to market.

PRICING, MANUFACTURING & DISTRIBUTION
Affordability depends on who is going to pay – the patient, government or another stakeholder in the local healthcare system. In low-income countries, up to 70% of spending on medicines may be made out of pocket. Different populations have different incomes and expenses. Companies must recognise this when pricing their products.

PATENTS & LICENSING
How companies manage their intellectual property (IP) impacts the availability and affordability of medicines. This has been demonstrated by the game-changing engagement between R&D-based manufacturers and generic medicine manufacturers in the global market for HIV/AIDS medicines. Companies have an obligation to manage their IP rights responsibly.

CAPACITY BUILDING
Some of the biggest barriers to access to medicine relate to gaps in local pharmaceutical and health systems. Companies can draw on their capabilities and expertise to increase the availability of quality-assured, safe and effective medicine, while helping to build and strengthen future markets.

PRODUCT DONATIONS
Donations of medicines and vaccines are an important tool for improving access to medicine in specific circumstances, such as to control, eliminate or eradicate diseases impacting the poorest populations in the world. To safeguard the access that donations bring, it is essential that companies remain engaged until eradication or elimination targets are achieved, or work with governments on transition plans for when the programme ends.

Each Technical Area includes a ranking of how the companies performed, a breakdown of industry activity and complete overviews of best and innovative practices. Key areas of analysis, i.e., R&D and pricing, include leading graphics illustrating major trends and developments.

A General Access to Medicine Management

CONTEXT

As pharmaceutical companies search for new opportunities in low- and middle-income countries, they have a responsibility to also increase access to their products for people on lower incomes. Achieving this balance requires companies to view access to medicine as a strategic issue, and to manage it as such. To give scope and direction to their access to medicine activities, companies need clear access-to-medicine strategies supported by strong rationales and commitment from top management. Companies are more likely to achieve long-term access goals if they formulate measurable objectives supported by time-bound targets that are monitored on a regular basis.

HOW WE MEASURE

For its analysis in this area, the Index reviews documentation and data submitted by companies directly to the Index, alongside publicly available information. Public sources include company websites, where information is expected to be in the public domain, and other sources such as public reports on access-to-medicine initiatives as disclosed through the Access Observatory.

WHAT WE MEASURE

The Index examines how companies govern, plan for and manage the achievement of access-related objectives. It looks at three main areas:

1 **Access-to-medicine strategy**: looking for clear strategies with long-term goals, supported by a global health rationale and aligned with corporate strategies.
2 **Managing for access-to-medicine outcomes:** assessing companies' policies and practices for working on, incentivising and monitoring progress toward access-linked goals, including measuring impact.
3 **Stakeholder engagement:** whether companies engage with a wide range of stakeholders in developing their access strategies; and whether companies disclose this information.

TOP INSIGHTS

▶5 companies pull ahead in access management in 2018, with 2 clear frontrunners.

▶More companies make access a strategic issue; two further companies have aligned access strategies with corporate strategies, taking the total to 14.

▶Access is also being given higher priority internally, with companies assigning direct board-level responsibility increasing from 6 to 11.

▶5 companies actively measure impact, while 11 companies report a general commitment to measure impact in the future.

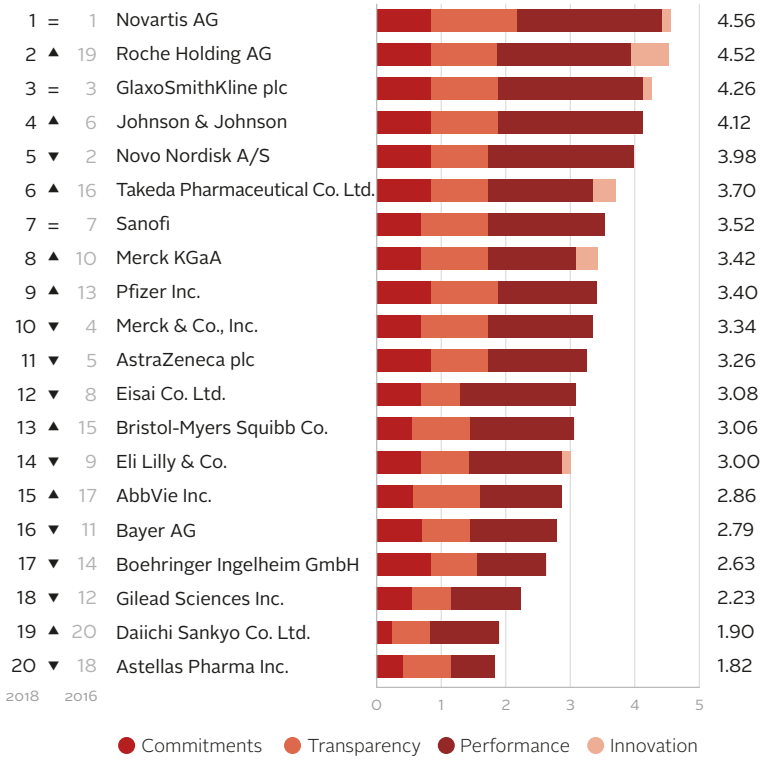
IN THIS CHAPTER

HOW COMPANIES COMPARE

Roche joins leading group in high-scoring area

- There are now five leaders with two companies out in front.
- Novartis retains 1st place, but is now closely followed by Roche (2nd). GSK remains in 3rd.
- Companies score comparatively highly in this area, with half scoring 3 or above.
- Clear divides have opened up between the highest-ranking companies (Novartis to Novo Nordisk), those in the middle (Takeda to Boehringer Ingelheim) and those lower down. In 2016, companies were more tightly packed.
- There are three laggers, although Astellas and Daiichi Sankyo lag noticeably behind Gilead.

Figure 17. Company ranking: General Access to Medicine Management



Leaders have commercially aligned strategies

There are five companies pulling ahead in 2018, with three newcomers in the group and two front-runners (Novartis and Roche).

These five have (1) company-wide strategies for improving access to medicine, with clear objectives aligned to corporate strategies; (2) solid approaches to stakeholder engagement; (3) typically disclose both their selection process and the stakeholders they engage with; and (4) have systems for incorporating perspectives from local stakeholders into strategies.

Novartis (1st) leads once again. It meets all Index criteria on transparency in this area, including public disclosure of commitments, measurable objectives and performance information. It is deploying an innovative business model, Novartis Access, that focuses on products for non-communicable diseases (NCDs) in 24 resource-limited countries.

Roche (2nd) rises 17 places, improving its score across the board. It has reviewed its access strategy, now including an Access Planning Framework, which focuses on awareness and diagnosis. Roche's innovative Global Access Program aims to expand sustainable access to diagnostic HIV/AIDS testing in endemic countries.

GSK (3rd) performs well in managing access-to-medicine outcomes, but is less transparent than leaders in publishing information about stakeholder selection. It has scaled up its innovative programme (Live Well) in Zambia for recruiting and training local community health entrepreneurs, who become 'last-mile' distribution agents and contribute to strengthening the national health system.

Johnson & Johnson (4th) is close behind GSK. Like other leaders, it has put structures in place to incentivise senior managers to deliver results for access initiatives over the long term.

Novo Nordisk (5th) remains in the leader group. It continues to perform well in multiple areas, but has been outpaced by the other leaders.

Climbers renew access strategy and assign top responsibility

In 2018, two companies make significant rises through the ranks.

Roche rises 17 (to 2nd), driven by increasing transparency, a renewed access-to-medicine strategy, and innovative model focused on HIV/AIDS diagnosis.

Takeda rises 10 (to 6th), as it newly assigns responsibility at board level for its access strategy, and improves its governance structures. It also receives credit for innovative work with the Cancer Alliance in Nairobi.

Eli Lilly falls 5 (to 14th), as it is affected by an overall lack of transparency across several areas of measurement. For example, it no longer provides evidence of sharing its stakeholder selection process.

Gilead falls 6 to (18th), out of the mid-ranking group. It is overtaken by peers in several areas. For example, it still does not demonstrate evidence of having direct board responsibility for its access approach.

Mid-ranking companies are tightly packed

Companies ranked between 6th and 17th place (Takeda to Boehringer Ingelheim) are clustered, all scoring within one point. These companies all perform less well than leaders in disclosing information about stakeholder engagements: i.e., their selection processes and/or the groups they engage with.

Most mid-ranking companies generally perform less well when it comes to publicly reporting how they manage access-to-medicine outcomes.

None of the three lowest-ranking companies Gilead (18th), Daiichi Sankyo (19th) and Astellas (20th) demonstrate having access-related incentives for senior management that are based on long-term performance. Gilead does not publish any information relating to stakeholder engagement, while Daiichi Sankyo and Astellas do not publish their stakeholder selection processes. These three generally perform poorly compared to other companies on transparency measures.

INDUSTRY ACTIVITY PER TOPIC

Pro-access governance becoming standard practice

Increasingly, pharmaceutical companies are entering markets in low-and middle-income countries as they represent key frontiers for growth. Correspondingly, they bear an increasing responsibility to expand access to their products for people on lower incomes. To achieve a balance, companies need to develop strategies that provide for access to medicine, and to integrate these with their core business and manage their implementation. The Index takes a closer look at new and scaled up business models which can improve access for the poorest, while generating a revenue stream.

The Index considers how companies plan, manage, govern and achieve their objectives for access to medicine. To increase the likelihood that a strategy will achieve its long-term goals, companies need to set objectives for the medium-term, with time-bound, measurable targets that are monitored regularly. To boost the likelihood of long-term engagement, at least senior management should also be incentivised against the achievement of long term, rather than solely short-term goals.

Engaging with local stakeholders helps companies to identify risks and opportunities for access, and to tailor access strategies to meet local needs more closely. The Index analyses how companies engage with stakeholders, both local and global, to share knowledge and identify access-related challenges and opportunities. The Index also looks to see whether companies incorporate views of stakeholders in planning access strategies, and assesses levels of transparency about stakeholder interaction.

When companies engage in access-related activities, they also need to develop ways to manage outcomes. The Index assesses performance and management systems, and structures that provide governance and incentives.

The Index looks for companies to develop and implement clear, long-term strategies for how they will improve access to medicine. A first step is to identify specific objectives relating to access. Companies then need to underpin these objectives with a strong business rationale and align them with core business, to ensure the access strategy will be sustainable and enduring. Objectives might be included, for example, in overarching corporate strategies and processes. Companies that demonstrate this alignment thereby indicate that they consider access to medicine to be relevant to their own sustainability and growth in the long term.

ACCESS-TO-MEDICINE STRATEGY

Leaders view access as a business matter

The integration of access strategies into core business models can enhance the sustainability of access-to-medicine initiatives. As companies recognise low- and middle-income country markets as new frontiers for growth, they also recognise that improving access to medicine presents a business opportunity. Access initiatives offer potential for a company to enter, understand and develop new markets and ultimately reach more people.

There are benefits in both directions—when pharmaceutical companies take steps to improve access to medicine in low- and middle-income countries, both the company and the country can benefit. Such actions can provide the country (and its populations) with improved healthcare by addressing local needs. At the same time, such steps can enable companies to further develop their businesses in key emerging markets. This situation is often referred to as providing shared value.

A large proportion of companies in scope (14) have access strategies aligned with their corporate strategies. These 14 companies acknowledge the importance of including access in their core business: i.e., addressing new markets in low- and middle-income countries, and increasing access to medicine.

The majority of companies in scope (17/20) report having access-to-medicine strategies in place. Three of them (Bayer, Bristol-Myers Squibb and Gilead) demonstrate evidence of having an

IN BRIEF

▶More companies are making access a strategic issue. 14 companies now have access strategies aligned with their corporate strategies, up from 12 in 2016.

▶17 companies now have some form of access strategy. All 20 companies are running one or more access-to-medicine initiatives.

▶Access is also being given higher internal priority by more companies. 11 companies have now assigned responsibility for access to medicine to the Board, up from 6 in 2016.

▶15 companies disclose some information about stakeholder engagement, with 6 companies publicly disclosing their processes for selecting stakeholders.

access strategy linked to a business rationale; they appear to be considering how access-to-medicine strategies might represent a way to enter new markets, but do not yet provide evidence that their access approach is clearly aligned with their core business strategies.

Boehringer Ingelheim, Pfizer and Roche announced a review of their access-to-medicine strategies since 2016. Boehringer Ingelheim reviewed its strategic approach to access to healthcare which is based on three pillars: availability, sustainable access models and innovative solutions for awareness and adherence. Pfizer reviewed its strategy during the establishment of its Patient & Health Impact division in 2017, committing to developing commercially viable models to provide sustainable access for all patients. Roche reviewed its approach after creating its Access Planning Framework in 2015, enabling the company to adapt its access to medicines and diagnostics strategies for each country it operates in.

Bayer, however, no longer provides evidence that its current access activities are aligned to its corporate strategies. Two further companies, Bristol-Myers Squibb and Gilead, have strategies to increase access to medicine, but do not explicitly link these to their commercial strategy. Three companies (AbbVie, Astellas and Daiichi Sankyo) continue to lack evidence of an overarching strategy, but are involved in access initiatives.

MANAGEMENT OF ACCESS STRATEGY

Over 50% of board committees are responsible for access

To implement access strategies successfully, companies need to establish good management policies and practices. This involves assigning responsibility for access to medicine at board level, and putting in place long-term access-related incentives for employees, as part of performance management.

By monitoring and measuring outcomes and impact of access-to-medicine activities, companies can generate the information necessary to ensure they make progress. The Index assesses whether progress is being tracked against defined goals, and impact assessments to be conducted. It also looks for companies to make results publicly available.

By assigning direct responsibility for access strategies at board level, companies can increase the degree to which they initiate, prioritise, monitor and achieve access-related objectives. In 9/20 companies in scope, board members are indirectly responsible for access strategies, i.e., responsibility for access lies at the executive level. An individual or committee responsible for the company's access-to-medicine strategy will, for example, report to the board while not being part of the board.

Just over half the companies (11) have direct board-level responsibility for access. Among these companies, since 2016, four companies (Bayer, Boehringer Ingelheim, Novo Nordisk and Takeda) newly established direct board-level responsibility for access. This may involve a board member sitting on an access-to-medicine committee to ensure accountability at the highest level.

PERFORMANCE MANAGEMENT

Most companies monitor access performance

Of companies in scope, 17 have a performance management system that measures whether the company reaches its objectives for access-to-medicine initiatives. Systems range from monitoring and evaluation dashboards to partner-supplied data and reports on progress. Johnson & Johnson and Roche represent best practice in this area. Johnson & Johnson tailors its performance management system to each of its access-to-medicine initiatives. For example, its Janssen/Global Commercial Strategy Organization (GCSO) has a Market Access product dashboard which includes all products which fall under the umbrella of that organisation, and summarises progress on different metrics across this range (see page 38 for more detail).

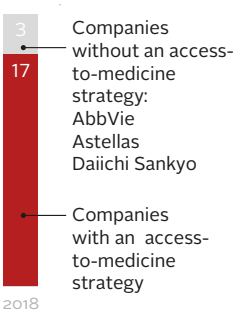
Roche tailors its Patient Access Dashboard to each initiative across markets. This provides a clear overview and description of its objectives, strategies, milestones, activities, resources, potential hurdles and stakeholders. Three companies (Astellas, Bayer and Gilead) do not yet report having an access-specific performance management system in place to measure performance of their access-to-medicines activities.

Do companies measure impact?

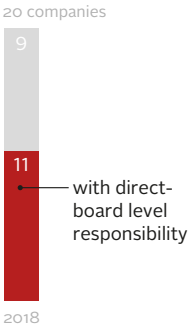
For the first time, the Index assesses how companies are making moves towards measuring the impact of their access-to-medicine strategies and initiatives. By monitoring and measuring outcomes and impact, companies track and evaluate the progress of initiatives, and this can make success more likely. The Index sees 'impact' as the long-term result of a company's activities on the communities it intends to support. At the same time, it should be acknowledged that (with other factors and influences acting upon results) impacts may be beyond the direct control of a project or initiative.

A large proportion of companies in scope

Strategies for access still lacking



Majority of companies assign top-level accountability



(16; all except AbbVie, AstraZeneca, Boehringer Ingelheim and Gilead) mention impact assessments. Five have disclosed information that they are already assessing the impact of at least one access-to-medicine initiative, while a further 11 companies have made a general commitment to doing so in the future, e.g., through their participation in a new initiative: Access Accelerated. Access Accelerated was formed in 2017 as a partnership working to address NCDs and works with Boston University to develop frameworks for measuring the impact of access initiatives which fall under its umbrella. Fifteen companies in scope participate in Access Accelerated.

The five companies who have gone the furthest are already collecting data that will contribute to an understanding of the impact of their initiatives: GSK, for example, reports using a monitoring and evaluation system to measure progress and impact, twice a year, in its partnership with Save the Children. Johnson & Johnson's logic model for its New Horizons initiative (which enhances access to appropriate paediatric HIV/AIDS treatment and care in a sustainable way) includes an assessment of impact. Merck & Co., Inc. demonstrates evidence of good practice, conducting impact assessments for its Informed Push Model initiative; and Novo Nordisk commissioned an impact assessment from University College London for its Base of the Pyramid initiative in Kenya. Novo Nordisk stated that its impact evaluation highlighted where the initiative was successful, and where improvements are needed. Novartis reports measuring impact (using Boston University's framework) for its initiative Novartis Access.

Employee incentives are used as a strategic tool

Companies need to incentivise employees to achieve access-related goals and objectives. The Index looks for internal structures that enable companies to reward employees for delivering initiatives effectively, helping to improve access to medicine.

The Index expects companies to have incentive structures in place for all staff to reward the effective delivery of access initiatives in countries in scope (i.e., for employees as well as for senior management). Companies are also expected to incentivise senior management to achieve long-term access-related goals and results.

Currently, only six companies in scope (Bayer, GSK, Johnson & Johnson, Novartis, Novo Nordisk and Roche) demonstrate specific incentive structures for senior management to reward longer-term results. Employees of GSK, for example, participate in an overall performance share plan that links the proportion and value of bonuses to long-term results (arising over three or more years). These results include those arising from its access-to-medicine strategy. Fourteen companies in scope demonstrate having an internal structure that offers incentives for performance in access-to-medicine initiatives, as well as in other areas. Sanofi, for example, sets annual objectives for its employees and rewards them through salary increases and bonuses when objectives are met. It also recognises employee performance in access-to-healthcare programmes. 17 companies (all except Bayer, Daiichi Sankyo and Gilead) in scope demonstrate having a general or access-specific performance management system that monitors outcomes of their access-related initiatives.

5 companies taking steps to measure impact:
- GSK
- Johnson & Johnson
- Merck & Co., Inc.
- Novartis
- Novo Nordisk

PUBLIC REPORTING

Greater transparency needed for accountability

By disclosing information about their access-to-medicine objectives, activities and progress, companies help to ensure they remain accountable to external stakeholders in their commitments. Most companies (13) appear to publicly disclose at least their commitments and performance information; fewer companies also publicly disclose clear objectives and measurable targets or progress.

Johnson & Johnson represents best practice (see page 38) in publicly reporting on its access-to-medicine outcomes through its robust performance management system that enables it to track its objectives, how local access strategies are implemented, and how activities progress. It sets specific goals and measurable targets aligned with the United Nations Sustainable Development Goals (SDGs) and has its own Health for Humanity goals aiming to address global health challenges by 2020. Johnson & Johnson gives detailed information about the outcomes of its initiatives contributing to access to healthcare, making this information publicly available. Johnson & Johnson's online scorecard of all access-to-medicine initiatives dating from 2016 lists its goals, progress and other details, including quantitative and qualitative targets.

STAKEHOLDER ENGAGEMENT

Two companies stand out for their local stakeholder engagement policies

When companies develop and implement access strategies, they engage with a range of external stakeholders, including universities, industry peers, patient groups, government agencies, employees, and non-governmental organisations. Stakeholders may be local, national or global. Through dialogue

with stakeholders, companies share knowledge and build understanding of the needs of populations they aim to support through access activities. The Index looks for evidence of systems to enable and facilitate dialogue with stakeholders, and for processes through which companies take account of new knowledge and perspectives, and incorporate this to inform their access strategies. It also considers the degree to which companies disclose information about how they select and engage stakeholders. This kind of disclosure enhances transparency and helps ensure accountability. All companies in scope report that they engage with stakeholders on their strategies and approaches for improving access to medicine. The range of types of engagement is wide. Novartis and Novo Nordisk, for example, are part of The Defeat-NCD Partnership, which combines the efforts of multiple stakeholders such as WHO, civil society groups, academics, multilateral agencies, philanthropic foundations, governments and private sector organisations.

To engage effectively and credibly with local stakeholders, companies need clear engagement policies. The Index looks for evidence of policies outlining how companies will engage responsibly with local stakeholders. Most companies did not report this level of detail. Two companies stand out: AstraZeneca and Eisai. Both have policies describing their specific approach for responsible engagement with stakeholders. AstraZeneca, for example, has a global policy on ethical interactions and anti-bribery/anti-corruption. Eisai's policy concerns promoting mutual respect and trust with business partners, including patients, employees and healthcare professionals.

Public reporting on stakeholder engagement varies

Public disclosure of stakeholder engagement information can help companies to stay accountable, providing insight into the depth, breadth and quality of a company's engagements, and revealing how such engagement informs company policy.

All companies publicly disclose which stakeholder groups they engage with. Most of them (15) also publicly disclose information about stakeholder engagement activities. However, despite overall progress in public reporting, many companies do not meet deeper expectations for transparency about stakeholder engagement. Only two companies (Novartis and Roche) publicly disclose the full range of information looked for by the Index. Six companies (Bayer, Johnson & Johnson, Merck KGaA, Novartis, Novo Nordisk and Roche) publicly disclose their process to select stakeholders.

Novartis publicly states that it engages with certain stakeholders (such as patient groups) to build a better understanding of their needs. It uses interviews to create a materiality assessment and establish an overview of stakeholder priorities. It then groups priorities and uses these to inform strategy, identify possible bottlenecks, and establish metrics to measure how the initiative performs.

INNOVATIVE BUSINESS MODELS

Business models scale up to take on more markets

The industry appears to be making positive moves to overcome local challenges in low- and middle-income country markets via locally tailored business models. The healthcare landscape in low-and middle-income country markets can be vastly different to higher-income markets due to a lack of infrastructure and resources. For this reason, companies need to also consider how they address these constraints beyond product-based initiatives such as pricing, licensing and donations. Locally-tailored business models, which incorporate training for healthcare workers and health financing, can help companies overcome these barriers. Since 2014, companies in scope appear to be making positive moves in this direction. The Index has observed that companies are increasingly considering low- and middle-income populations as target markets, and that these models in some cases can be successfully scaled up. New pilots and expansion of existing business models are evidence of this.

6 companies publish their stakeholder selection process:
- Bayer
- Johnson & Johnson
- Merck KGaA
- Novartis
- Novo Nordisk
- Roche

In 2018, the Index highlighted six new or expanding inclusive business models (see page 42 further details). Five of these are scale-ups (one of which, the Roche Global Access Program, was evaluated for the first time in the 2018 Index). One business model was newly launched during the period of analysis. The 2014 Index highlighted six similar business models, while seven were highlighted in 2016. Four innovative business models evaluated in the 2016 Index have been scaled up since they were first noted by the Index. These include the Novartis Access (expanding its activities from 2 to 5 countries, including Uganda, Rwanda and Pakistan in 2017) and ComHIP programmes (from operating in 2 districts in Ghana in 2015 to a third district in 2017); GSK/Barclays' Live Well initiative (scaling up the number of community health entrepreneurs recruited and trained from four to 20 rural and semi-rural communities located in Zambia since 2016); and Eli Lilly's LEAP (extending the reach of its insulin products in China from initially targeting smaller communities in six north-eastern Chinese provinces, to nearly

4 business models highlighted in 2016 have scaled up by:
- GSK
- Eli Lilly
- Novartis

As part of GSK's Live Well initiative, community health entrepreneurs provide last-mile distribution of consumer health goods.

half of China's 32 provinces in 2018). These are encouraging signs that these models can and are being successfully sustained over the longer-term.

The 2018 Index newly highlights two innovative models (page 44) for low- and middle-income country markets from Merck KGaA and Roche. Merck KGaA's new Curafa™ project is a collaborative initiative that looks to open facilities to make primary healthcare available, train community health workers, and strengthen referral processes in communities. The facilities will provide each of five essential elements: pharmacy and nursing services, access to medication, awareness and education about health, digital health solutions, and financing for healthcare.

Roche's Global Access Program (GAP) aims to expand affordable access to quality diagnostic testing for countries hardest hit by HIV/AIDS. It combines pricing approaches with capacity building and diagnostics R&D. Notably, it has scaled up to 82 countries where cost is a barrier to patient treatment, e.g., offering affordable diagnostic products for early infant diagnosis.

GENERAL ACCESS TO MEDICINE MANAGEMENT

Best Practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations (see page 40).

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness
- Sustainability
- Replicability
- Alignment with external standards/ stakeholder expectations

The 2018 Index identified four best practices in this area, from three companies.

JOHNSON & JOHNSON, ROCHE

Leading examples of platforms to track access activities

GLOBAL

Systems that enable them to track how local access strategies are implemented, and how activities progress.

Johnson & Johnson represents best practice for its transparency in publicly disclosing access-to-medicine outcomes. With Roche, it also represents best practice for robust performance management in access activities.

How does Johnson & Johnson track access activities?

Since 2016, Johnson & Johnson publishes all its goals and targets for access, and progress made. For example, on its goal to deliver innovative healthcare access and trainings to impact a billion lives in underserved areas, it reports being on track to make HIV/AIDS therapy accessible to a total of 130,000 adults and 5,000 children by 2020. So far under this programme, 38,500 adults and 630 children have received HIV/AIDS treatment.

In its transparency in providing information about its progress, Johnson & Johnson also meets external stakeholders' expectations for public reporting, enabling accountability for its activities. It commits to the UN Sustainable Development Goals and has measurable targets: Health for Humanity goals, incorporating access-related objectives. Through these, the company demonstrates that it considers access to be relevant for its own sustainability.

As well as being transparent, Johnson & Johnson has a robust performance management system to monitor and measure the outcomes and progress of its access-to-medicine activities. This system, which the company adapts to each of its working groups on access-related strategies, collect information about medicines covered by the company's GCSO through its includes its Market Access Product Dashboards. For at least one access initiative (New Horizons, advancing HIV care for children), Johnson & Johnson uses a logic model framework (a tool for performance management) and an impact assessment plan.

How does Roche track access activities?

Like Johnson & Johnson, Roche stands out in performance management for access. It too has an analytics system (its 'Patient Access Dashboard') that supports the identification of access-related challenges and relevant stakeholders to engage with to provide access plans that are specific to each country; it also underpins internal goals by tracking outcomes of activities.

One goal was to increase access to treatment for people with HER2+ breast cancer and blood cancers. Using its system to test access across 14 low- and middle-income countries, Roche achieved its goal before the end of the set period. It has since extended its country scope and aims to scale up to reach a new goal and continue to expand.

What makes this a best practice?

Both Roche and Johnson & Johnson aim to create value in global access to medicine, with systems that enable them to track how local access strategies are implemented, and how activities progress. These 'dashboards' gather best practice and incentivise employees to consider access challenges across operations: such joined-up thinking makes success more likely toward addressing unmet needs of patients globally.

JOHNSON & JOHNSON

Global Public Health expands for better delivery of access to healthcare

GLOBAL

A multidisciplinary unit with a strong business rationale for its access-to-medicine strategy.

Johnson & Johnson represents best practice with its Global Public Health business unit dedicated to access.

Launched in 2016, the unit aims to address unmet health needs across the world, and focuses on areas including multidrug resistant tuberculosis (MDR-TB), HIV/AIDS, neglected tropical diseases and mental health. It seeks to cover all processes relating to access to medicine, from R&D to supply chains.

How is Global Public Health improving access?

Operating in settings in which resources are limited, including countries in scope of the Index, the unit works end-to-end from development to market, aiming to make access to care both responsive to need, affordable and sustainable. It has, for example, established operations in sub-Saharan African countries, with two regional offices in Kenya and Ghana. These will oversee the development and distribution of medicines for diseases that disproportionately affect those living in Africa, such as HIV/AIDS.

What makes this a best practice?

Johnson & Johnson presents a strong business rationale for its access-to-medicine strategy, consolidated in its Global Public Health unit, and has integrated this into its overall corporate strategy.

Johnson & Johnson aims to scale up Global Public Health to reach more people. The unit adds clear value to access efforts, by promoting initiatives for better delivery of access to healthcare across the world, and in particular in Africa.

NOVARTIS

Leading approach to measuring impact

GLOBAL

A developed, tested and applied methodology for measuring impact on society in financial, environmental and social (FES) terms.

Since 2016, Novartis has been exploring and developing an approach that allows it to quantify, measure and value the impacts its activities (and related initiatives) make on society in financial, environmental and social (FES) terms. The approach also enables Novartis to assess the impacts of its social activities on communities.

What is the value of measuring impact?

'Social impact valuation' can be used to gauge the impact a business' activities make on human capital, the impact of its products on society, or the impact of its initiatives to strengthen healthcare systems and improve access to medicines. Impact measurement offers Novartis the possibility of tailoring its access initiatives and its work to strengthen healthcare systems. In doing so, this approach represents good practice.

Novartis has developed, tested and applied its FES methodology since 2016. As impact evaluation is still a nascent field, Novartis is working to incentivise external partners and stakeholders to encourage them to engage in this area by sharing their findings and promoting dialogue.

What makes this a best practice?

Novartis demonstrates best practice in access governance and in stakeholder engagement. This will not only bring benefits to the company, for example enabling it to tailor cost-effective operations; it will also help facilitate access to medicine in the places where Novartis operates. The company states its commitment to developing this approach and improving the way access issues are governed.

ROCHE

Comprehensive overview of stakeholder engagement

GLOBAL

Only company in scope to share publicly, via its website, a clear overview of the way it engages with each specific stakeholder.

Roche represents best practice with its commitment to work at policy level to promote and influence access to medicine issues.

How does Roche engage with stakeholders?

In its 2015 code of conduct, Roche shares its priority to engage with stakeholders, aiming to address challenges related to responsible business, and provide quality access to all patients worldwide. It uses informal methods of communication and formal, structured engagements to embed this approach into its daily business. It cooperatively develops solutions to foster local engagement and works with relevant stakeholders to have a global impact with its products.

Its clear, transparent disclosure of how it engages with various different parties constitutes a strong model meeting all the criteria looked for by the Index. This approach helps take into account different perspectives to inform access-related practices.

What makes this a best practice?

In the Index, Roche stands out as being the only company in scope to share publicly a clear and comprehensive overview of the way it engages with each specific stakeholder. Roche discloses stakeholder groups it engages with, listing on its website all collaborations including patient organisations, healthcare professionals, government departments, trade associations, scientists and local organisations.

Roche states that innovation, for the most part, comes from sources outside the company; therefore it reports having multi-stakeholder dialogue and considers their needs. With that recognition

comes the understanding that engaging with all relevant stakeholders provides a vital way to make activities sustainable. Initiatives for engagement include the introduction of a systematic process to apprehend stakeholders' concerns at a local level and incorporate them in the company's global priority strategies. This can enable the company to specifically target local needs in terms of access to medicine. Roche meets all the criteria looked for by the Index relating to public reporting on stakeholder engagement.

GENERAL ACCESS TO MEDICINE MANAGEMENT

Innovative Practices

ABOUT INNOVATIVE PRACTICES

Many challenges exist for healthcare systems in low- and middle-income countries such as patchy healthcare services, poor infrastructure, and lack of resources.

The Access to Medicine Index recognises those companies that are trialing unique approaches to overcome some of these barriers. These practices are classified as innovative. The Index also highlights previously identified innovations that have been scaled up or expanded.

The 2018 Index identified eight innovations in this area, including six innovative business models (summarised in the next sextion, page 42).

ROCHE

Systematic approach to identify access challenges

GLOBAL

A comprehensive Access Planning Framework to determine current access levels in countries, and how its initiatives contribute to access.

In 2015, Roche created and began to roll out its Access Planning Framework.

Access to healthcare is a multidimensional challenge, with local access often closely linked with the way a local healthcare system works. Through its framework, Roche is focusing on providing locally tailored access plans in four key areas: awareness, diagnosis, healthcare capacity and funding.

How does the framework support Roche's access efforts?

To address these areas and find solutions, Roche is working to build an understanding of the reasons why people in particular countries and regions lack access to opportunity for diagnosis and medicines. Using a systematic approach, it analyses each of the countries in scope where it operates, aiming to identify relevant stakeholders such as local communities or healthcare professionals, and capture specific issues of access, such as gaps in infrastructure, cultural barriers and financial constraints.

Roche then creates a detailed, comprehensive access plan for each country. Plans become part of its Access Planning Framework, and are embedded in the company's overall business strategy. By the end of 2017, it had plans in place for more than 70 countries in scope. To support the continuance of its Framework, Roche consequently developed a comprehensive Patient Access

Dashboard aimed at assessing, at a country level, current access levels, and how its strategies and initiatives contribute to improve access.

In addressing obstacles to diagnosis and treatment, Roche seeks to benefit those in low- and middle-income countries with health problems, improving their journeys to gain care. By working systematically to identify the particular challenges that exist at national and regional levels around how patients interact with healthcare systems, Roche represents innovation in this area.

TAKEDA

Diverse stakeholders come together for the Cancer Alliance

SUB-SAHARAN AFRICA

Cross-sector partnership with local stakeholders – represents a new, regionally focused approach to integrate and improve the provision of cancer services.

In 2017, Takeda established the Cancer Alliance for sub-Saharan Africa. The alliance – a partnership with other pharmaceutical companies, government agencies, NGOs and non-profit organisations – represents a new, regionally focused approach to integrate and improve the provision of cancer services across sub-Saharan Africa (SSA). It demonstrates best practice by aiming to ensure that it is a local initiative with local ownership. It does this by pooling existing knowledge, capabilities and resources from a diverse group of local stakeholders to focus on access to oncology treatments in SSA.

Efforts to improve access to medicine in Africa have focused on communicable diseases including HIV, tuberculosis and malaria, contributing to a decline in ratios of mortality.[1] In contrast, the threat of cancer is on the rise, with deaths associated with cancer increasing.

How does the Cancer Alliance work to improve access to cancer care?

As a single independent, not-for-profit entity, the Cancer Alliance was founded to address barriers to treatment, raise standards of health, prevent the duplication of effort, promote collaboration (both local and international), and eradicate a 'silo' mentality. Through these efforts, Takeda and its partners hope to improve the coordination of cancer care throughout sub-Saharan Africa.

Specifically, the alliance is working to increase access to diagnosis and make high-quality medicines more affordable. It plans to expand transport to healthcare facilities, and improve community and patient knowledge (by providing education about types of cancer, covering topics such as screening, treatment, counselling and nutrition).

It will also work to increase skills among healthcare practitioners, recruit and retain specialised healthcare professionals, collect and disseminate data, and influence public policy and legislation. In particular, it plans to develop Nairobi (Kenya) into a centre of excellence and treatment hub, improving transport links to facilitate treatment across the region.

To provide governance and measure impact, the Cancer Alliance has established reporting deadlines and assessment protocols. It will also monitor progress and impact through partnerships with the Kenya Medical Research Institute (KEMRI), community health worker programmes, and an online platform (in development).

GENERAL ACCESS TO MEDICINE MANAGEMENT – INNOVATIVE BUSINESS MODELS

Business models that aim to include the poor are expanding

Hundreds of millions of people worldwide must pay directly for their medicines and healthcare, yet also live on low incomes and have little money left over after living expenses.[2] The conventional pharmaceutical business model does not include such populations in its customer base.

An 'inclusive' business model is one that explicitly aims to include people living on very low incomes in its customer base in order to improve access to specific medicines or other health products. These models can be either cost-neutral or, ideally, commercially sustainable. These business models receive credit in the Index as evidence of a business model innovation.

Tailored approaches

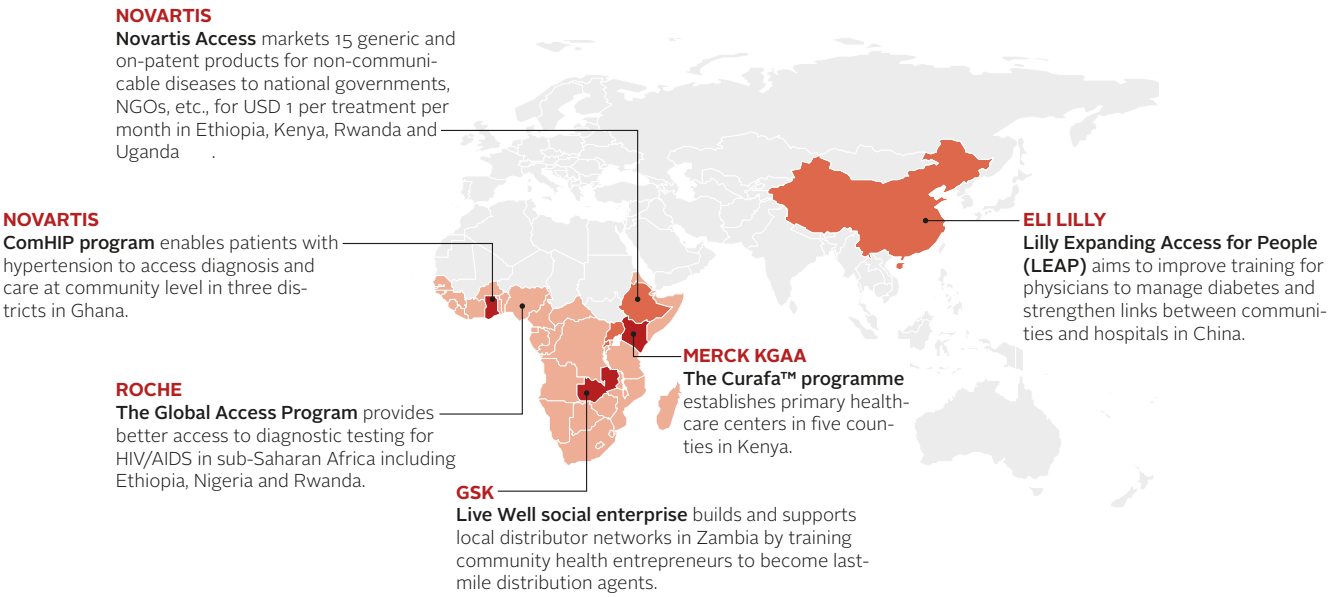
Five companies are expanding commercial opportunities in a variety of ways, indicating that tailored approaches are required, based on specific, local conditions as well as on the company's product portfolio, strategic focus and capabilities. It is encouraging to see that pilots from previous cycles are expanding to include more countries, more patients and more products.

'Inclusive' business models see poorer populations as part of a sustainable market for medicines and health products. Such models can have a particular impact on access in emerging and frontier markets, which often have weaker health systems. These business models go beyond pricing, licensing and donations initiatives, recognising that conditions and circumstances in low-and middle-income country markets can be vastly different. These differences are mainly due to a lack of healthcare infrastructure and trained health workers. In order to make business models work, these constraints must be taken into account and addressed.

Table 1. Six innovative and inclusive business models in 2018
In 2018, the Index has identified inclusive business models that are either new in 2018 or have been scaled up since 2016. Five of these models are scaled-up models. One has been newly launched since 2016.

Eli Lilly	Lilly Expanding Access for People (LEAP)	**Scale-up**: To 14 provinces in China; from 13 in 2016
GSK	Live Well social enterprise	**Scale-up**: To 20 communities in Zambia, from four in 2016
Merck KGaA	Curafa™ programme	**Newly launched**: in 2018, in five counties in Kenya
Novartis	ComHIP program	**Scale-up**: To three districts in Ghana, from two in 2016
Novartis	Novartis Access	**Scale-up**: To five countries (Pakistan, Uganda, Rwanda); from two in 2016 (Ethiopia, Kenya).
Roche	Global Access Program	**Scale-up**: To 82 countries and more products for HIV/AIDS testing; and to hepatitis C testing.

Figure 17a. Six innovative business models helping to improve access



ELI LILLY
Lilly Expanding Access for People (LEAP) builds capacity in diabetes care in China

Aim: To improve community-based care, by strengthening linkages between communities, township clinics and larger teaching hospitals, and empowering people to manage their disease.
Model: Training for primary care physicians in China to increase their confidence and skills in managing diabetes across all stages of the disease.
Partners: International Diabetes Center for specific capacity building aspects.
Scale-up: To 14 provinces in China; from 13 in 2016

Eli Lilly's LEAP builds capacity of primary care physicians to manage patients' diabetes.

In 2015, Eli Lilly launched its Lilly Expanding Access for People (LEAP) initiative targeting diabetes in China's emerging middle class. Of 400 million people globally who live with diabetes, one in four lives in China.[3]

How is LEAP addressing diabetes care in China?

In communities where LEAP operates, some patients can access basic diabetes medicines including human insulins, but the healthcare clinics where they typically seek care are often under-equipped to provide the right support and quality care for diabetes, which is a lifelong disease. Many healthcare practitioners working in these clinics lack the confidence and capability to effectively manage diabetes, especially when it involves the prescription of insulin. Under LEAP, Eli Lilly aims to ensure that primary care physicians receive improved training to increase their confidence and skills to manage diabetes across all stages of the disease. The programme also aims to improve community-based care by strengthening linkages between community and township clinics with diabetes experts and larger teaching hospitals, and empowering people to manage their disease with the support of Lilly Diabetes Educators. In this way, through LEAP, Eli Lilly aims to address what it sees as a gap in community diabetes care. LEAP uses a 'shared value' approach, looking to develop future markets while strengthening local economies, marketplaces and communities, and working to increase the number of people it serves with its core business model by expanding access to its products and services, specifically among China's middle class.

LEAP began initially by targeting smaller communities in six northeastern Chinese provinces, where local healthcare clinics lacked the capability to deal with diabetes effectively, especially in the prescription of insulin. LEAP trains primary care physicians, increasing skill and building confidence in overseeing all stages of disease. Partnering with government departments, LEAP works to improve community-based care, strengthening links between clinics and hospitals, using diabetes educators to increase knowledge, and supporting patients.

How has this business model been scaled up?

In LEAP's first two years, its team collected data relating to impacts on Eli Lilly's business in China. By 2016, LEAP was working with around 5,000

community organisations, and had helped around 20,000 people to start insulin therapy. By early 2018, it extended its reach to nearly half of China's 32 provinces, teaching self-management skills to more than 33,000 people, training 40,000 primary care doctors, and introducing insulin products to 165,000 patients. This was achieved with 100 Eli Lilly diabetes care partners and educators in collaboration with the International Diabetes Center to deliver the training curriculum for primary care physicians. The company now has around 200 dedicated personnel working with LEAP and plans to extend the initiative to more provinces.

GSK
Live Well social enterprise model builds and supports local distributor networks in Zambia

Aim: Improve affordability and supply, by addressing constraints in local supply chains linked to the high cost of borrowing.
Model: Network of local outlets for health products run by community members; financial assistance (lower interest rates on bank loans) for these and their upstream wholesalers, provided savings are shared with purchasers.
Partners: Barclays, a UK-based multinational investment bank and financial services company.
Scale-up: To 20 communities in Zambia, from four in 2016

In Zambia, GSK's Live Well equips community health entrepreneurs to provide last-mile access.

In 2015, GSK and Barclays, together with other partners, began to pilot their Live Well initiative across four sites in Zambia. Run by GSK and local partners, Live Well raises awareness of health issues, increases access to products that benefit health, and provides local people with opportunities to earn income and gain skills. Now scaled up, it aims to reach a million people in Zambia.

The initiative acknowledges that, in Zambia, the health system depends on thousands of community volunteers to plug the gaps. Live Well recruits and trains 'community health entrepreneurs' (CHEs) who become last-mile distribution agents, promoting healthcare and selling products in underserved rural and semi-rural communities. They sell oral health, pain control, contraceptive and other health-related products, together with goods such as cooking stoves.

How does Live Well work?
Each CHE receives training in business, financial management, basic healthcare and product knowledge, equipping them to educate and inform communities they visit. Each one earns a small profit margin on sales. Overall, the initiative aims to strengthen Zambia's health system. In places where unemployment is often high, it offers workers a way to generate income, and aims to motivate them to help improve the health of others.

Live Well also tackles constraints in the supply chain that stem from high borrowing costs. Previously, wholesalers and distributors took out bank loans and passed on costs to customers and patients. With Barclays and other stakeholders, GSK set up affordable financing arrangements for wholesalers and distributors who share savings with patients. This led to the creation of a private supply chain, incorporating a network of social enterprise health outlets run by individuals from communities to provide access to healthcare. Such outlets also provide jobs, helping to increase economic prosperity.

The Live Well partnership was designed to align with the Zambian government's national health plan. With a business model based on 'shared value', it involves: contributing to local economic prosperity, creating new sources of revenue for companies, and selling health products. GSK, in turn, benefits from selling products through health outlets and reaching new markets and customers.

How has this business model been scaled up?
By the end of 2016, GSK and Barclays have invested GBP 7 million in providing Live Well with financial support and on-the-ground resources over a 3-year period. Live Well now reaches 45,000 people each month. Since 2016, the initiative has trained a further 385 CHEs, bringing the total number to 432. It is reported that the initiative has helped distribute more than 200,000 health products to around 660,000 people since its inception. The number of communities served has also grown from the initial 4 pilot sites to 20 in the last two years.

The consulting firm Accenture conducted an impact assessment for Live Well. Preliminary analysis shows that, overall, CHEs generate at least 10% of their household income through Live Well activities. In a survey undertaken by Live Well in March 2018, 24% of 70 CHEs interviewed said they generated more than USD 70 per month through Live Well activities.

MERCK KGaA

Curafa™ programme establishes primary healthcare centers in Kenya

Aim: To bring integrated range of affordable healthcare services, including nursing and pharmacy, to underserved populations.
Model: Local primary healthcare facilities that provide pharmacy and nursing services, prescription and over-the-counter medications, and access to insurance schemes and healthcare financing.
Partners: Amref Health Africa.
Scale-up: Not applicable (established in 2018).

Merck KGaA's Curafa™ facilities offer a range of services and resources for rural communities.

Curafa™ is a healthcare platform based on an innovative business model, targeting underserved populations in remote areas of Kenya. The initiative is being piloted by Merck KGaA, which leads a multi-partner collaboration with Amref Health Africa along with government and development agencies, NGOs and private healthcare innovators.

Established in early 2018, Curafa™ plans to increase awareness, availability, accessibility and affordability for healthcare and medicine, and to help healthcare providers collaborate in improving quality of life for people with health issues. The initiative looks to open facilities that make primary healthcare available, train community health workers on key health issues, and strengthen referral processes in communities.

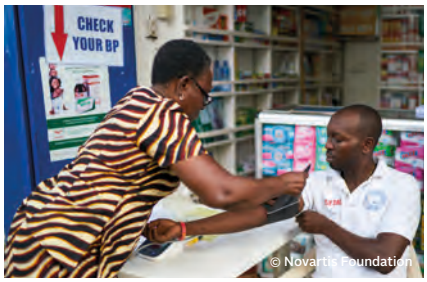
What does the Curafa™ model offer?
Initially, Curafa™ is setting up five primary healthcare facilities in the Kenyan counties of Kiambu, Kajiado, Machakos, Makueni and Mombasa. These will each provide each five essential elements: pharmacy and nursing services, prescription and over-the-counter medications, digital health solutions (for example, using online services to offer consultation and diagnosis for certain diseases), insurance schemes and financing for healthcare, and facilities such as WiFi and social spaces. Each facility will offer a pharmaceutical clinical service, giving access to over-the-counter and prescription medicines, and consumables. Facilities will look to raise awareness of health, and Curafa™ has initiated a process to train 45 community health workers to spot signs of hypertension, asthma, diabetes, trachoma, dengue fever and cholera.

The five pilot facilities will also offer online primary health services, including opportunities to consult doctors remotely. Planned digital solutions include electronic tablets loaded with artificial intelligence software, to be used by individuals for diagnosis with support from nurses. Facilities will make available financing solutions such as health insurance, and communications services (internet and WiFi, cell-phone charging, television and radio). Merck KGaA estimates its initial Curafa™ facilities will be sustainable within five years.

NOVARTIS

ComHIP enables patients to access diagnosis and care at community level in Ghana

Aim: To improve the control of hypertension, by making services more accessible, and empowering individuals to manage their hypertension.
Model: Public-private partnership that embeds services for hypertension control and self-management in local communities via 'local private medicinal' shops
Partners: Novartis Foundation, Ghana Health Service and US-based development organisation FHI 360, supported by the Ghana School of Public Health, the London School of Hygiene & Tropical Medicine, and VOTO Mobile, a Ghana-based social enterprise.
Scale-up: To three districts in Ghana, from two in 2016



Novartis' ComHIP works with private medicinal shops to offer blood pressure screenings.

In 2015, the Novartis Foundation – part of Novartis' philanthropic organisation established an initiative in Ghana to test an innovative healthcare model for the control and self-management of hypertension. A major risk factor for cardiovascular diseases, hypertension affects as many as 36% of Ghana's adults.[4] While awareness of the condition has increased, control of hypertension remains poor.[4]

How does this model improve access to hypertension care?
The Community-based Hypertension Improvement Project (ComHIP) set out to test the benefits of enabling patients to access diagnosis and care at community level through local healthcare workers and businesses, rather than

at hospitals, which can be distant and overcrowded. The test included comparing conventional methods of hypertension care (where hypertension care is coordinated among primary healthcare providers and pharmacists, along with specialists if needed), with an innovative approach. The approaches were tested in two districts close to urban centres in Ghana.

The innovative approach worked with local private medicinal shops (often a first stop for healthcare locally) to offer blood pressure screening, and to dispense medicines. With around 20 shops for every hospital, the aim was to maximise convenience and increase opportunities for diagnosis. This district also facilitated the use of digital health tools: by health workers to help make decisions and ensure connections; and by patients to manage progress and keep track of appointments.

How has this business model been scaled up?

In April 2017, a team from LSHTM and FHI 360 published an evaluation of ComHIP's model, based on the responses of some 2,400 people. With support from Novartis and other partners, Ghana Health Service is now taking the lead to expand the model; it is rolling out ComHIP in a third district in Ghana, while continuing to operate the model in the original two districts. The design of this intervention implementation study and subsequent publication of the ComHIP evaluation paper demonstrates a commitment to implementing programmes using a sound evidence base.

The Novartis Foundation also has a second innovative healthcare model for hypertension in Vietnam, through its Ho Chi Minh City Communities for Healthy Hearts Program since 2016.

NOVARTIS

Novartis Access uses portfolio approach to address affordability for products for non-communicable diseases

Aim: To reach 20 million patients per year by 2020, supplying more than 5 billion tablets per year to these markets.
Model: Portfolio of 15 on- and off-patent products for non-communicable diseases (NCDs) marketed to national governments, NGOs and other stakeholders in the public sector, for USD 1 per treatment per month, supported by capacity building.
Partners: Local NGOs for specific capacity building aspects.
Scale-up: To three additional countries within the period of analysis; from two in 2016

A supply chain worker in Kenya checks the shipment of medicines from Novartis Access.

Novartis Access focuses on making treatments for major chronic diseases both affordable and available in lower-income countries. In the healthcare industry, it represents a first, using a portfolio approach that covers 15 of the company's medicines (including some that are protected under patent) that treat NCDs such as diabetes, respiratory illness, breast cancer and cardiovascular disease.

How does the Novartis Access model work?

Novartis Access offers access to this portfolio to governments, NGOs and other stakeholders in the public sector at a price of USD 1 per treatment per month. Novartis Access also incorporates capacity building activities. These include community awareness and community-level screening of non-communicable diseases and subsequent understanding metrics such as blood pressure and blood sugars. Through its implementing partner NGOs, it trains pathologists and laboratory technicians to increase capacity and quality of diagnostics for breast cancer, provide training on guidelines for diabetes, hypertension, asthma and heart disease.

With each party that wants to buy medicines, Novartis negotiates the size of the basket (i.e., the number of treatments bought overall). This allows Novartis to focus on integrating its supply chain horizontally, coordinating the supply of multiple treatments to individual purchasers. One key benefit of the approach is that it gives governments the opportunity to buy medicines covering a range of common conditions at a subsidised price.

Novartis launched the Novartis Access portfolio in Kenya and Ethiopia in 2015, addressing the high prevalence of NCDs in these countries and aiming to expand access to treatment. Since launch, Novartis Access has delivered more than 800,000 treatments in these countries. Partnering with governments and NGOs, Novartis Access continues to create capacity and capability to deliver better outcomes for patients. Through 2017, for example, it expanded its activities to include awareness raising, improving diagnosis, healthcare worker training, supply chain integrity and distribution.

How has this business model been scaled up?

Novartis is now preparing to roll out the initiative to new countries. During the period of analysis, in 2017, Novartis signed agreements with three further governments (Uganda, Rwanda and Pakistan). It is now in advanced discussions to offer Novartis Access to 10 more countries in Asia and Africa, and longer term it hopes to offer Novartis Access in 30 further countries, not only in Africa and Asia but also in Latin America and Europe. It has already filed 502 product submissions with health authorities in 24 countries, gaining 221 approvals to date. Novartis is measuring

impact of this initiative in collaboration with Boston University.

ROCHE
Global Access Program expands access to diagnostic testing for HIV/AIDS in 82 countries

Aim: Expand sustainable access to quality diagnostic testing for countries hardest hit by HIV/AIDS.
Model: Public-private partnership that embeds services for hypertension control and self-management in local communities via 'local private medicinal' shops
Partners: UNAIDS, the Clinton Health Access Initiative (CHAI), the President's Emergency Plan for AIDS relief (PEPFAR), and the Global Fund.
Scale-up: To 82 countries, with expand access to HIV and hepatitis C diagnostics.

Through GAP, Roche is expanding access to the plasma separation card for HIV viral load testing.

How is this model improving access to HIV testing?

Roche is a market leader in HIV viral-load testing. It launched its Global Access Program (GAP) in 2014 to expand sustainable access to quality HIV testing in countries hardest hit by the virus. Some 35 million people live with HIV/AIDS globally.[5] Roche's systems provide laboratories with very efficient solutions for routine molecular testing, offering performance, flexibility and automation.

The programme, created by Roche in partnership with UNAIDS, CHAI, PEPFAR, and the Global Fund, contributes to the overall UNAIDS 90-90-90 goals. These envisage that by 2020, 90% of people with HIV will know their status, 90% of those who know their status will receive treatment, and 90% of those treated will have a suppressed viral load.

On launching the GAP in 2014, Roche aims to expand access to one of its HIV diagnostics through a special pricing scheme for qualifying organisations in eligible countries. Since then, the GAP has increased access to HIV viral load tests and early infant diagnostics at substantially reduced prices in sub-Saharan Africa and other countries with a high burden of disease.

How has this business model been scaled up?

In July 2016, Roche expanded GAP to include the latest high-throughput automated platforms for low- and middle-income countries. In 2017, Roche reports that more than 10 million viral load tests were performed on its platforms, a 19% increase from 2016, and 2.5 times higher since 2014 when the programme initially began. Working with CHAI, Roche now offers special access pricing for diagnostic products for early infant diagnosis and viral load testing for qualifying government and NGO organisations in 82 eligible countries.

Collaborating with governments, international agencies, local healthcare facilities and communities, GAP builds and equips laboratories, trains healthcare workers, diagnoses and monitors people living with HIV/AIDS, and innovates in research and development. In early 2018, for example, Roche launched its plasma separation card, a stable, easy-to-use sample collection device for HIV plasma viral load testing. This does not need refrigeration during transport to the lab, and is increasing access to testing for those in remote areas, even areas of extreme heat and humidity.

Roche has extended this model to other health initiatives. Drawing on shared HIV expertise with CHAI and Duke Health, it launched the Quick Start Program to address hepatitis C, and committed to reduce costs of diagnostics and treatment for people living with hepatitis C in health facilities enrolled in the programme. Working with the governments of Ethiopia, Indonesia, Myanmar, Nigeria, Rwanda and Vietnam, this initiative has set itself the aim of curing 25,000 people who have hepatitis C, within two years.

GAP is combining sustainable pricing policies with innovative research and development to make diagnostic tests more usable. It represents best practice, and has demonstrated its ability to scale up in countries where price is a barrier to treatment.

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B Market Influence & Compliance

CONTEXT

Pharmaceutical companies operate in an environment where the pressure to maintain profits and a fiercely competitive landscape can increase the temptation to engage in inappropriate, unethical behaviour. Such activities risk harm and a negative impact on access to medicine: for example, by misrepresenting medicine efficacy and safety and offering inappropriate incentives to doctors, increasing the risk of irrational prescribing decisions. Strong policies and procedures for ensuring compliance are critical for mitigating this risk.

HOW WE MEASURE

The Index examines policies for compliance and internal control disclosed by companies for assessment, including supporting documents that demonstrate how they are implemented. The Index looks for public information regarding the financial support of patient organisations and payments made to healthcare practitioners. The Index conducts an independent search for evidence of breaches of industry codes and national laws relating to marketing and corruption in low- and middle-income countries, using, for example, the US Foreign & Corrupt Practices Act and the UK Bribery Act.

WHAT WE MEASURE

The Index looks at policies for ensuring ethical behaviour, including on market influencing, and processes for enforcing compliance, across two areas:

1 **Ethical marketing and anti-corruption:** policies to mitigate corrupt behaviour and unethical marketing such as sales incentives; evidence of breaches of codes and national laws; and an evaluation of internal control frameworks to prevent and mitigate corruption, bribery and unethical behaviour.
2 **Responsible lobbying:** how companies may seek to influence government policies linked to access. The Index looks at memberships, political contributions, responsible engagement and conflict of interest policies.

TOP INSIGHTS

▶ The three leaders have all risen since 2016. GSK rises to 1st from 9th. Merck KGaA and Novartis rise to 2nd from 11th and 15th, respectively.

▶ More companies have stepped away from using only sales-based performance incentives and bonuses for sales agents.

▶ 16 companies extend their anti-corruption and/or ethical marketing policies to cover third parties.

▶ Two additional companies ban political financial contributions, bringing the number taking this step to five.

▶ Only three companies were found to demonstrate evidence of all components of an internal control framework, newly looked for in 2018.

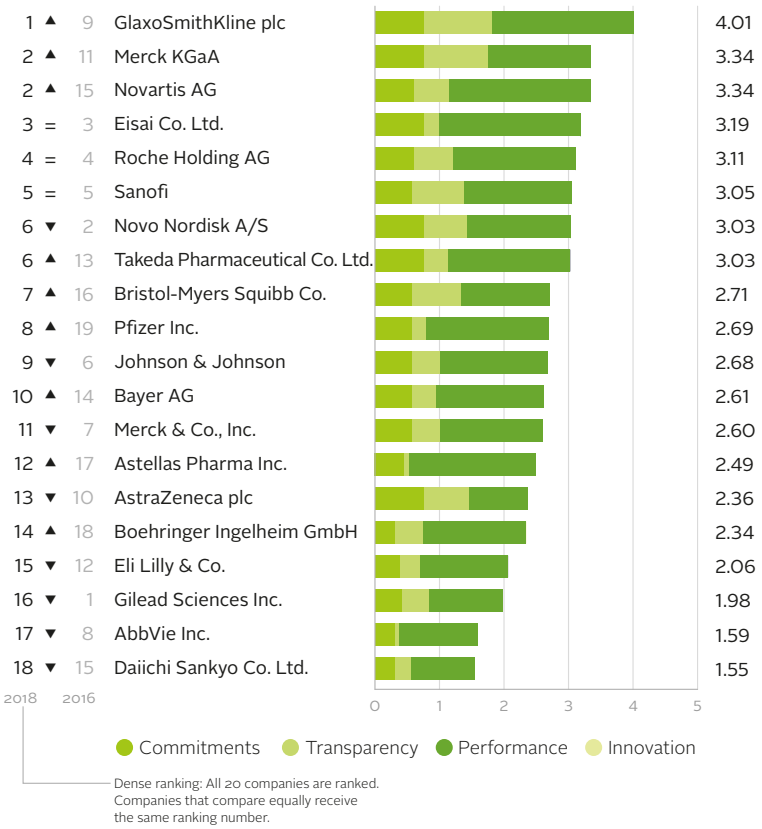
IN THIS CHAPTER

HOW COMPANIES COMPARE

Leaders demonstrate strong, transparent approaches to compliance

- GSK rises to 1st from 9th in 2016, with clear lead over other companies. Merck KGaA and Novartis both climb to joint 2nd place, from 11th and 15th places, respectively.
- The middle-ranks have two tightly clustered groups of companies. The higher-scoring group includes five companies – Eisai (3rd) to Takeda (6th). The other also has five – Bristol-Myers Squibb (7th) to Merck & Co., Inc. (11th).
- Rankings in this area reflect the strength of companies' internal control frameworks for ensuring compliance, their use of enforcement processes, and the decoupling of incentives for sales staff on sales targets.

Figure 18. Company ranking: Market Influence and Compliance



Three new leaders: GSK, Merck KGaA, Novartis

GSK, Merck KGaA and Novartis lead. They are among top performers in several areas: (1) codes for ethical marketing and anti-corruption, and (2) formal processes to enforce compliance for third parties, (3) disclosing lobbying positions with market influence, (4) having whistleblower policies in place, and (5) signing the UN Global Compact, which calls companies to align strategy and operations with universal principles for human rights, labour, environment and anti-corruption, and advance societal goals. They also have strong internal control frameworks for ensuring compliance, including auditing of third parties, and systems for continuously monitoring compliance.

GSK (1st) scores significantly more highly than other companies. Alongside Astellas and Novartis it is one of only three companies to demonstrate having all internal control framework components looked for by the Index. GSK also publishes information about its institutional memberships and the financial contributions it makes to patient organisations. In addition, during the period of analysis, GSK had a policy which prohibited payments to healthcare professionals to attend or speak at conferences.

Merck KGaA and Novartis (both 2nd) are slightly ahead of the next five companies, all with close-clustered scores. Like GSK, both companies have decoupled sales agent incentives from sales targets. For transparency in market influence, Merck KGaA scores significantly more highly than lower-ranked companies. Novartis presents all elements of an internal control framework as looked for by the Index.

Movement due to policy changes and transparency – not misconduct

In 2018, the Index is concerned with breaches in compliance occurring only in countries in scope, not globally as in 2016. One company (AstraZeneca) was found to have been the subject

of a breach, previously unidentified by the Index, in a country in scope. As such, rankings in this area tend to reflect companies' performances in policy, level of disclosure and internal control, and less so on the incidence of misconduct. As a result, companies with no breaches in 2016 that did not make strong improvements in other areas have moved down the ranks: Eisai (3rd) is an exception.

GSK rises 8 (to 1st), with evidence of strong policy commitments, transparency related to market influence, and with no evidence of misconduct.

Merck KGaA rises 9 (to 2nd) by including non-sales-related incentives for its employee, thereby improving its approach to mitigating the risks of unethical marketing. Similarly, Novartis (2nd) has separated sales agents' incentives from sales targets.

Gilead falls 15 (to 16th), performing comparatively poorly in key differentiating metrics: transparency, sales incentives and internal controls.

Middle groups need more stringent controls to ensure compliance

Middle-ranking companies are less likely than higher performers to disclose the financial contributions they make to organisations that may influence access to medicine in countries in scope. They are also less likely to disclose political contributions in countries in scope.

They report fewer components of internal control frameworks to prevent and mitigate corruption, bribery and unethical behaviour. Although many have an audit and reviewing mechanism, most lack one or more of the additional components that the Index looks for.

The higher group of mid-ranking companies – Eisai (3rd) to Takeda (6th) – all report having a code for ethical marketing and anti-corruption consistent with industry standards, with training for employees. They also have formal processes in place to ensure third-party compliance with these standards. Along with Novartis, Eisai, Roche and Takeda newly report having incentives for sales agents that are not solely based on sales targets. Eisai, Roche and Sanofi kept similar rankings as in 2016.

The lower group of mid-ranking companies – Bristol-Myers Squibb (7th) to Merck & Co., Inc. (11th) – deliver varying performances across multiple indicators. They demonstrate comparatively limited transparency in areas such as policy and financial contributions.

Eli Lilly and Gilead sit at the lower end of the second (lower) mid-ranking group. All their incentives for sales agents are based on sales targets, and neither discloses financial contributions to organisations through which they may influence policy in countries in scope.

The two companies ranking lowest in this area lack transparency across multiple indicators. While AbbVie and Daiichi Sankyo demonstrate frameworks for internal control, these include only auditing and review mechanisms, which neither company reports applying to third parties.

INDUSTRY ACTIVITY PER TOPIC

Most companies extend compliance standards to cover third parties

Pharmaceutical companies operate in an environment where the pressure to maintain profits and a fiercely competitive landscape can increase the temptation to engage in inappropriate, unethical behaviour. Such activities risk harm and a negative impact on access to medicine: for example, by misrepresenting medicine efficacy and safety and offering inappropriate incentives to doctors, increasing the risk of irrational prescribing decisions. Strong policies and procedures for ensuring compliance are critical for mitigating this risk.

ETHICAL MARKETING & ANTI-CORRUPTION

Most companies extend policies to third parties

Corrupt behaviour and unethical marketing can have direct consequences on access to medicine, including misdirecting national health budgets and promoting the irrational use of medicines.[1] Companies can limit the risk of misconduct by setting, monitoring and enforcing stringent standards of behaviour across their company employees and associates, as well as by changing their sales incentive structures.

All companies have a code of conduct for anti-corruption and for ethical marketing. However, the depth and quality of these differ widely. For example, GSK reports having standards on anti-bribery and corruption, gifts, hospitality and entertainment, as well as a network of principles throughout GSK where anti-bribery and corruption controls are embedded. The company also has a Code of Practice for Promotion & Scientific Engagement; and reports that conform to international standards.[2, 3] Eli Lilly has its Red Book Code of Business Conduct, which describes a set of principles for ethical marketing, but it does not provide the same consistency with industry and international standards that all its peers demonstrate, through committing to align their policies with standards such as those ones set by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the Pharmaceutical Research and Manufacturers of America (PhRMA), or WHO Ethical Criteria for Drug Promotion. Most companies (16) ensure their anti-corruption and/or ethical marketing policies cover both employees and third parties.

Greater insight into marketing practices, but from low base

As in previous years, pharmaceutical companies remain rather silent about their marketing and promotional practices in low- and middle-income countries, more specifically, whether or not payments are made to healthcare professionals in countries in scope of the Index, for example to attend and/or speak at conferences. Within these countries, there is often weak or limited government regulation and enforcement, that leaves less assurance that ethical marketing policies are being implemented and that financial relationships with healthcare professionals are appropriate.

Disclosures of payments made to healthcare professionals are generally limited to countries outside the scope of the Index—where regulations or industry guidance expects such disclosure.

Companies that are publicly traded on a US exchange stock market or do business in the USA, including all 20 companies in the Index, are legally required in the USA to publicly disclose 'transfers of value' or payments made to healthcare professionals.

In countries in scope of EFPIA, the EFPIA Federation's member companies (including 17 companies in the Index, all excepted Gilead, Daiichi Sankyo and Eisai), certify their commitment to the EFPIA Disclosure Code,[4] which expects members to indicate the amounts and names of recipients of payments. Such data are published on the companies' websites and includes the country where the payment was made. There is little evidence, however, to indicate which of these payments are made to healthcare professionals in low- and middle-income countries. While publicly traded

IN BRIEF

▶ The Index examines companies' policies for compliance and internal control to ensure ethical behaviour and enforce compliance.

▶ Almost all companies report clear internal policies on anti-corruption and unethical marketing. Most also demonstrate evidence that these standards are applied to 3rd parties.

▶ Few companies have policies for prohibiting or disclosing payments to healthcare professionals in low- and middle-income countries.

▶ Compliance measures appear to be mostly passive in nature. Only 3 companies have all components that the Index looks for in companies' internal frameworks for ensuring compliance.

▶ More companies have stepped away from using sales volume as a basis for sales agents' bonuses.

companies must accurately record payments under US and European law and international accounting standards (for example, the International Financial Reporting Standards),[5] information on payments is not required to be disaggregated per country or payee.

Notably, however, Roche discloses that it tracks the following activities in countries in scope of the Index for all products via dedicated monitoring systems: (1) payments made to healthcare professionals for speaking engagements; (2) meals, accommodation and transportation provided to healthcare professionals attending medical education, events or meetings, as well as hospital visits; (3) and grants, sponsorships and donations. Roche, in indicating that it holds such disaggregated information internally, shows that it could choose to disclose this information publicly in the future. AstraZeneca recently announced that it will disclose such payments to healthcare professionals in all countries in which it operates, whether or not it is legally obliged to do so. The company publicly shared plans to disclose payments for the first 11 countries across Latin America, Asia Pacific, North Africa, and the Middle East by the end of 2019.[6]

During the 2018 period of analysis, GSK stood out as the only company that prohibited payments to healthcare professionals that it had invited to attend and/or speak at medical conferences. The company also limited the direct financial support for healthcare practitioners attending such conferences. Yet, in October 2018, following the period of analysis, the company resumed the payment of healthcare professionals for certain circumstances.[7]

Incentives move away from sales targets

There is a growing shift away from rewards pegged primarily against sales targets. Nine companies, up from seven in 2016, now have incentives that are not wholly linked to sales. One common alternative is to reward technical knowledge rather than sales. By minimising the focus on sales volume, there is less incentive for sales agents to behave unethically by mis-selling or overselling products. Roche and Takeda are the only two companies to newly adopt non-sales-related targets for their sales personnel in this cycle. Roche has incorporated non-financial metrics relating to diversity, sustainability, and the environment to its annual bonus plan. Takeda has implemented incentive programmes based on multiple elements focused on both quantitative and qualitative performance. Incentives now involve personal, team and country achievements, plus commercial and non-commercial performance such as technical and product knowledge. In emerging markets, Takeda's sales agents can receive compensation based on both qualitative and quantitative goals in line with each country in which it operates. Qualitative goals can include non-financial qualities such as knowledge checks, call metrics, message recall and product awareness.

The other seven companies with such incentives are AstraZeneca, Eisai, GSK, Merck KGaA, Pfizer, Novartis, and Novo Nordisk. Two companies have improved existing incentives for sales agents since 2016: Merck KGaA and Novartis. In 2018, Merck KGaA increased its emphasis on the non-financial component of its incentive plan. Similarly, Novartis has increased the weight of fixed pay in overall compensation for field force staff, while reducing the variable component.

Leading practice in this area comes from GSK, as for the past three years sales agents' rewards are not solely based on sales targets. GSK now evaluates and rewards its sales employees and associates based on performance, technical knowledge and the quality of services delivered to healthcare professionals in support of patients' healthcare. This policy change arose during the company's U.S Securities and Exchange Commission (SEC) investigation for corrupt practice in China by both its Chinese subsidiary and a China-based joint venture partner, for which GSK,

Most compliance policies extend to third parties

9 companies demonstrate non-sales-related incentives

Table 2. How do companies monitor compliance?

In 2018, the Index newly looks for a strong internal control framework for ensuring compliance: i.e., processes for checking and detecting non-compliance. The framework must be supported by rigorous monitoring and auditing, as well as risk assessments that identify companies' vulnerabilities for fraud. Three companies—Astellas, GSK, and Novartis, are leading in this area by including the components for an effective framework.

Control structure	No. of companies	Companies
Audits	20	All
Audits by external specialists	18	AbbVie, Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myer Squibb, Daiichii Sankyo, Eisai, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc., Novo Nordisk, Novartis, Pfizer, Roche, Sanofi, Takeda
Audits covering third parties	17	Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myer Squibb, Eisai, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novo Nordisk, Novartis, Pfizer, Roche, Sanofi, Takeda
Continuous monitoring system for compliance (other than auditing)	9	Astellas, AstraZeneca, Eli Lilly, GSK, Johnson & Johnson, Merck KGaA, Novartis, Roche, and Takeda
Procedures for segregation of duties.	8	Astellas, Bayer, Eisai, GSK, Novartis, Pfizer, Roche, Sanofi.
Fraud-specific risk assessments	6	Astellas, AstraZeneca, Eisai, GSK, Novartis, and Sanofi

as parent company and indirect owner of 55% of the joint venture, was legally liable.[8]

RESPONSIBLE LOBBYING

More companies ban political contributions

It is commonly understood that pharmaceutical companies will seek to influence government policy on issues concerning access to medicine, directly or indirectly, at bilateral and multilateral levels often via their trade associations. The Index assess whether companies clearly disclose their policy positions, their memberships of organisations through which they may choose to exert influence, and payments made to such organisations. Such transparency is essential to determine the degree to which a governmental position reflects corporate lobbying, thus enabling public scrutiny of a company's influence and potentially greater fulfilment of national public health needs.

Most companies (19) publish policy positions on key access to medicine, vaccines, and further access to healthcare topics. AbbVie is the only company that does not publicly disclose such policy positions. Six companies have policies for responsible engagement with stakeholders that include guidance on, for example, the level of payments that may be made to patient organisations. Only one company (Roche) has a policy in place to mitigate conflicts of interest that may arise through such engagement.

There has been a small increase in the number of companies, from two to five, that expressly forbid political financial contributions to countries in scope; Bristol-Myers Squibb, Eli Lilly, and Merck KGaA, join GSK and Novo Nordisk who have already disclosed such policies. Some companies (Gilead, Daiichi Sankyo, Johnson & Johnson, Takeda) reported that despite the absence of a prohibiting policy, they did not make such contributions in countries in scope during the period of analysis.

All companies disclose whether they are members of organisations that may influence access-to-medicine policies in countries in scope (also disclosing which organisations). Such organisations may be trade associations, patient organisations, trade- and healthcare professional associations. However, only half of the companies (10 - AbbVie, Bristol-Myers Squibb, GSK, Johnson & Johnson, Merck & Co. Inc., Merck KGaA, Novartis, Novo Nordisk, Roche and Sanofi) publicly disclose the financial contributions they have made to such organisations.

Further, regarding socially responsible practices, one additional company (Eisai) has signed the United Nations Global Compact since 2016. It encourages businesses to adopt sustainable and socially responsible policies, and to report on their implementation. AbbVie, Boehringer Ingelheim, Gilead and Roche are the only four companies in scope yet to join the initiative.

ENSURING COMPLIANCE

More stringent controls required to ensure compliance

Companies are expected to set standards for good conduct at the highest levels and actively enforce rigorous standards of behaviour across their operations. In 2018, the Index newly looks for a strong internal control framework for ensuring compliance: i.e., processes for checking and detecting non-compliance. The framework must be supported by rigorous monitoring and auditing, as well as risk assessments that identify companies' vulnerabilities for fraud.

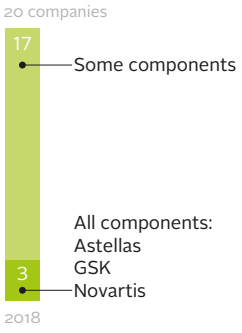
Despite an expectation of pro-active control and risk-minimisation, compliance measures identified by the 2018 Index appear to be mostly passive in nature. Companies disclose reporting mechanisms rather than processes for actively capturing non-compliance. For example, all companies report having whistle-blower procedures, which suggests that most companies expect employees to report instances of non-compliance.

While the presence of such procedures is positive, - and indeed a basic expectation for companies -, this approach alone cannot be sufficient to pro-actively detect non-compliance. Employees may not be trained, for example, to notice and report non-compliance in a timely fashion; how the company mitigates the risk that employees may blackmail non-compliant peers instead of whistle-blowing; and whether employees can fill in for trained specialists in identifying non-compliance; among others. Therefore, in addition to mechanisms such as whistle-blower procedures, codes of conduct, and relevant employee trainings, the Index newly looks for four key components of an internal control framework (see table 2).

Only three companies, Astellas, GSK, and Novartis, demonstrate evidence of having all four components. Six companies have two or more components, in addition to their auditing mechanism as looked by the previous Index, with a fraud-specific risk assessment and monitoring system for compliance being the most common combination. Additionally, the majority of companies (16 , with the exception of AbbVie, Astellas, Boehringer Ingelheim, and Daiichi Sankyo) report having measures to ensure third-party compliance with ethical marketing and anti-corruption standards.

5 companies ban political financial contributions

3 companies with comprehensive frameworks for compliance.



Industry engagement in auditing has clearly improved since 2014. In 2018, all companies audit compliance of their ethical marketing and anti-corruption code in all countries in which the companies operate; 17 companies have extended these audits to third-parties; while 18 companies report conducting audits via external specialists to ensure independence.

Overall, the total number of companies that perform compliance audits on their ethical marketing and anti-corruption policies has risen from eight in 2012 to 20 in 2018 (15 companies in 2014; 20 in 2016). The number of companies that reported using external specialists for these audits was eight in 2016; and 18 in 2018 (with Merck KGaA and Eli Lilly lagging behind).

Companies are using systems other than auditing to monitor compliance. These include fraud-specific risk assessments, a monitoring system separate from audits, and policies for segregating duties.

One new breach identified

In 2016, the Index began to analyse breaches of ethical marketing and anti-corruption laws and codes wherever they occurred globally. In 2018, the Index adopted a narrower scope and searched for breaches occurring in countries within the scope of the Index. Within the period of analysis two cases involving China, settled under US law, were identified. Both involved alleged improper payments to government officials (who were healthcare professionals) in violation of the Foreign Corrupt Practices Act of 1977 (FCPA) and the Securities and Exchange Act that require publicly traded companies to record and account company financial transactions.[9, 10] The cases concerned the Chinese and Russian subsidiaries of AstraZeneca,[11] and the Chinese subsidiary and a joint venture partner of GSK. The case concerning GSK had previously been reported in the 2016 Index in terms of fines issued by Chinese authorities. No additional breaches by other companies were identified by public sources, however it is important to note that this is not an indication of the absence of such breaches. Many low- and middle-income countries often do not have the regulatory or law enforcement capacity to impose measures against unethical marketing or corruption and thus cases are much more difficult to detect. Indeed, most breaches identified in previous Indices occurred in high-income countries outside of the scope of the Index.

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MARKET INFLUENCE & COMPLIANCE

Best Practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations.

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness,
- Sustainability,
- Replicability,
- Alignment with external standards/ stakeholder expectations.

The 2018 Index identified one best practice from three companies for this area. No innovative practices were identified.

ASTELLAS, GSK, NOVARTIS

Three companies incorporate framework of strict guidelines to reduce non-compliance

GLOBAL

Astellas, GSK and Novartis incorporate comprehensive frameworks to manage risk, comply with laws and regulations, ensure reliable financial reporting, and regularly track compliance.

Researchers agree that the true scope and cost of global health corruption is largely unknown. Corruption can be invisible, difficult to detect and highly politicised. It is recognised however that corruption can harm people in various ways: by forcing populations in low and middle-income countries to make sub-optimal choices, such as purchasing medicines from unqualified or illegal sellers in order to save money; by compromising access when medicines are simply unavailable in the public health system; and by having to purchase less-affordable medicines in the private health sector. In low- and middle-income countries, up to 70% of spending on medicines may be made out of pocket.[12] Inflated or unexpected healthcare expenses can result in catastrophic impacts on household budgets.

Why are internal control frameworks needed?

When companies enter low-and middle income country markets, which are more likely to have weaker regulatory or judicial controls, they are at a heightened risk of corrupt acts occurring, and must take greater responsibility to minimise these risks. With a comprehensive internal control framework, a company can reduce the risk of non-compliance with ethical standards. Companies are expected to put in place mechanisms that will enable them to assess diverse elements (such as industry challenges, the regulatory environment, stakeholders' needs, and risk-management priorities) and understand their impact.

What makes these three companies stand out for best practice?

Three companies in scope, Astellas, GSK and Novartis, report having every component of internal control framework newly looked for by the Index in 2018. These include the following: a fraud-specific risk assessment (which proactively identify vulnerabilities for fraud and actual cases), a monitoring system for compliance (which constitutes a rigorous and continuous process to mitigate risk of non-compliance), an auditing and review mechanism (which can apply to third parties in all countries the companies operate; and involve both internal and external resources), and procedures for segregation of duties (which ensure that decisions made are checked by another party, e.g. between management tasks and authorisation tasks, custody of assets and verification tasks, and accounting tasks and payment tasks).

In particular, Astellas reports that its framework is subject to an annual audit, which occurs in part through its internal mechanisms and in part through an external audit firm.

GSK distinguishes itself by describing effective risk management processes to comply with laws and regulations, and to be reliable in its financial reporting. Novartis has its Financial controls Manual and a Financial Risk Assessment to identify the overall financial risk status of their associates.

All three companies demonstrate having a comprehensive framework, monitoring and tracking whether they are complying with laws and regulations, and assuring the reliability of their financial information.

C Research & Development

CONTEXT

There is huge demand from the global health community for R&D that targets the needs of people living in low- and middle-income countries. Specifically, products are needed for high-burden diseases, neglected tropical diseases, and adapted products that are simpler to administer or more effective for specific populations. To highlight the most urgent of these gaps, WHO and Policy Cures Research have published five lists of priority targets for pharmaceutical R&D.

HOW WE MEASURE

The 2018 Index research covers all diseases in the following five lists of priority R&D targets. The Index uses these lists to identify which companies align their R&D activities with defined global health priorities and to assess the industry's responsiveness to these calls for action.

1 Policy Cures Research G-FINDER neglected diseases, products and technologies (2017),[1]
2 Policy Cures G-FINDER reproductive health areas, products and technologies (2014),[2]
3 WHO R&D Blueprint (2017),[3]
4 WHO Initiative for Vaccine Research gaps (2017),[4]
5 WHO priority pathogens list for R&D of new antibiotics (2017).[5]

WHAT WE MEASURE

The Index assesses companies' efforts to engage in R&D for 77 diseases, conditions and pathogens including those identified as priority R&D targets in the aforementioned lists.

1 **Product development:** which products are in the pipeline for diseases in scope, and which R&D priorities are being targeted.
2 **Planning for access:** planning ahead to ensure new products can swiftly be made available and accessible for communities in need. Such plans are referred to as 'access plans'.
3 **Clinical trial conduct:** whether companies have policies for ensuring clinical trials are conducted ethically and for providing trial participants with post-trial access to candidate medicines.

TOP INSIGHTS

▶ Almost one quarter (23%) of R&D projects target priority product gaps.

▶ One in five (19%) late-stage candidates have access plans in place. For late-stage cancer projects, this drops to less than one in twenty.

▶ Most companies score well for their codes of conduct governing clinical trials and for how these codes are enforced.

▶ More projects target neglected tropical diseases (NTDs) than in 2016, but only four NTD projects moved along the pipeline since 2016.

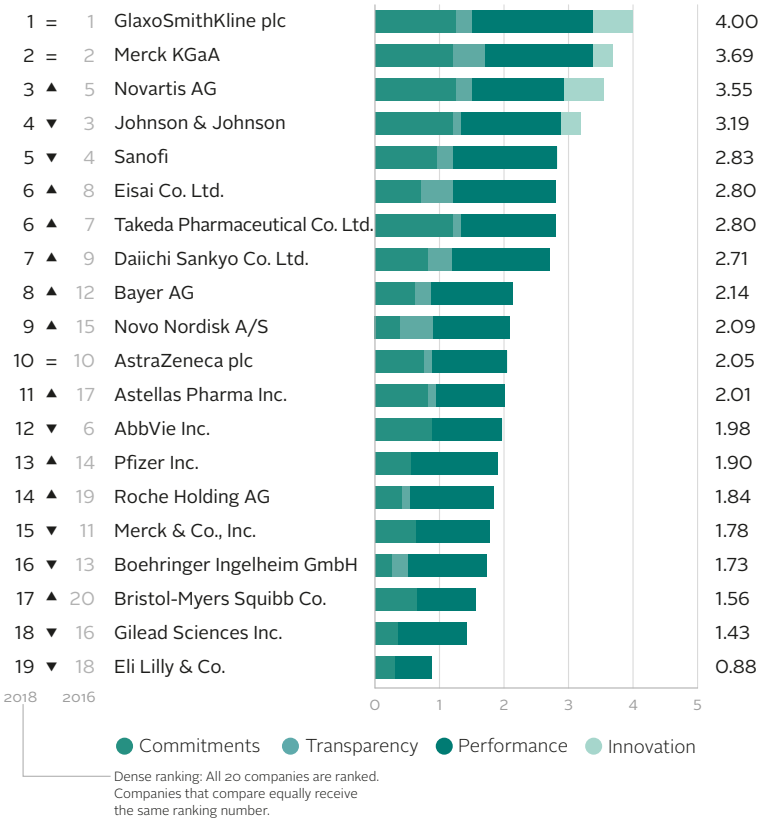
IN THIS CHAPTER

HOW COMPANIES COMPARE

Top four extend lead by performing well in access planning and priority R&D

- GSK extends its lead, followed once again by Merck KGaA in 2nd. Novartis rises to 3rd.
- The group divides into four groups: four clear leaders (GSK to Johnson & Johnson), a closely packed upper-middle group of four (Sanofi to Daiichi Sankyo), a large lower-middle group (Bayer to Boehringer Ingelheim) and a lagging group of three.
- The distance between the highest and lowest scores has widened (by 0.8) since 2016.
- Nearly three quarters of companies have processes to establish access plans during development, but quality varies.
- Most companies score well for their codes of conduct governing clinical trials and for how these codes are enforced.

Figure 19. Company ranking: Research & Development



Leaders systematically plan for access

The four top-ranked companies have pulled further ahead in 2018. Novartis edges into 3rd as Johnson & Johnson falls to 4th. The four stand out for having innovative practices and are generally among the top performers in: (1) having detailed, concrete commitments to R&D for diseases and countries in scope; (2) planning for access during development; (3) pipeline size; and (4) R&D for priority targets.

GSK leads; 67% of its pipeline targets R&D priorities, and it has an innovative integrated Global Health R&D Unit that systematically plans for access for clinical candidates.

Merck KGaA (2nd); 43% of its pipeline targets R&D priorities. Its innovative Merck Global Health Institute is dedicated to developing affordable and available therapies for infectious diseases, including malaria and schistosomiasis.

Novartis (3rd) has an innovative approach to systematically developing access strategies for all new medicines via the Novartis Access Principles. It also commits to evaluating trial participants' need for further medication once clinical trials are completed.

Johnson & Johnson (4th) has the largest pipeline of the four (2nd largest overall). Its Innovation Center actively seeks partnerships to accelerate development of affordable novel therapies for diseases that disproportionately affect countries in scope.

Top 10 typically perform well in priority R&D and access planning

Companies in the top 10 typically have strong commitments to R&D for diseases in scope, are more engaged in priority R&D and plan for access for late-stage candidates. The top five performers in R&D are also the top five companies by number of priority R&D projects in the pipeline.

Roche rises 5 (to 14th), with a new, clear policy on providing clinical trial participants with post-trial access to candidate medication. It invests a comparably higher proportion of its revenue into R&D for diseases in scope.

AbbVie falls 6 (to 12th) due to a lack of transparency and/or detail in several areas, including its process to establish access plans during development and its policy on post-trial access.

Remaining companies falter in planning for access

The upper-middle group (Sanofi in 5th to Daiichi Sankyo in 7th) includes strong performers in priority R&D and applying access plans to late-stage R&D, but in order to be leaders they must strengthen their commitments, especially their processes to develop access plans and commitments for post-trial access.

Most companies in the large lower-middle group (Bayer in 8th to Boehringer Ingelheim in 16th) perform less well in: (1) planning for access; (2) policies for providing post-trial access to candidate medication; and (3) R&D for priority targets.

The lowest three companies (Bristol-Myers Squibb, Gilead and Eli Lilly) perform poorly across multiple indicators. They do not disclose their R&D investments to the Index and have small pipelines. They are the only companies that did not provide detailed information on how they audit and monitor clinical trials for unethical conduct.

AbbVie, Eli Lilly and Merck & Co., Inc. drop to lower ranks largely due to generally low transparency in several key areas, with Merck & Co., Inc. the most publicly transparent of these three.

INDUSTRY ACTIVITY PER TOPIC

Almost one quarter of R&D projects target a priority product gap

There is huge demand from the global health community for R&D that targets the needs of people living in low- and middle-income countries: needs for new products for high-burden diseases and neglected tropical diseases (NTDs), and to adapt products so they are simpler to administer or more effective for specific populations. There are many diseases without adequate or effective treatments available, or where the products are not sufficiently tailored to meet the needs of people living in low- and middle-income countries. Pharmaceutical companies have much to add in this space. Addressing such 'product gaps' is a core expertise of the industry. Every company in the Index, regardless of its size or therapeutic focus, for example, can play an important role in addressing the need for new pharmaceuticals.

The 2018 Access to Medicine Index assesses companies' efforts to engage in R&D for 77 diseases, conditions and pathogens that have the greatest burdens in low- and middle-income countries and/or the greatest need in terms of new and adapted products. This includes looking at their commitment to R&D for global health, pipeline size and focus, whether they work in collaboration and whether they plan ahead to ensure access to successful products.

This disease scope includes 45 diseases, conditions and pathogens that have been flagged as particular R&D priorities regarding global health. The 2018 Index has conducted a specific analysis to assess which of these priorities are being addressed by the 20 companies evaluated. This is termed 'priority R&D' by the Index.

R&D COMMITMENTS

Leaders match R&D commitments to public health needs

The Index assesses whether companies have committed to conducting R&D to improve access to medicine for people living in low- and middle-income countries. These commitments are the first step to making health products available in these countries. Out of the 20 companies, 13 have made such commitments, and they operationalise them through R&D strategies that take public health needs into account, with a system for setting targets and evaluating progress over time. The 13 companies are AbbVie, Astellas, AstraZeneca, Bayer, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, GSK, Johnson & Johnson, Merck KGaA, Novartis, Sanofi and Takeda.

Merck KGaA, for example, makes a detailed commitment and also invests a comparably high proportion of its annual revenue into R&D for diseases in scope. It also has many projects targeting priority R&D including involvement in all twelve schistosomiasis projects reported to the Index (one of which is being developed in collaboration with Astellas), and many that are supported by access plans.

PIPELINES

Most projects target cancer and other NCDs

The Index captured 1,314 R&D projects for the 77 diseases in scope. Almost three quarters (945) are for cancer and other non-communicable diseases (NCDs). The five diseases with the most R&D projects are cancer, diabetes mellitus, lower respiratory infections, malaria and asthma. Three of these diseases (diabetes mellitus, lower respiratory infections and malaria) have been in the top five diseases by number of R&D projects since 2014. Cancer, newly in scope for the 2018 Index, takes the lead spot in the top 5. Almost half of the 1,314 projects target cancer (615).

Twenty diseases out of 77 are not being addressed at all by the companies in the 2018 Index. For most of the unaddressed diseases, products are available, although efficacy varies, including products being marketed by the twenty companies in scope. However, nearly half of the unaddressed diseases are NTDs (eight out of 20) including diseases and conditions for which the companies in scope have no products available (e.g., dracunculiasis, scabies and other

IN BRIEF

▶ The Index has identified 1,314 R&D projects for the 77 diseases, conditions and pathogens in scope. Almost three quarters are for cancer and other NCDs.

▶ 5 companies account for the bulk of R&D projects: AstraZeneca, Boehringer Ingelheim, Johnson & Johnson, Novartis and Roche.

▶ 20 diseases, including 8 NTDs, have empty pipelines from the companies evaluated.

▶ Companies are responding to calls for urgently needed R&D: almost one quarter of R&D projects target R&D priorities.

▶ Access planning still covers a low proportion of projects. Only 1 in 5 late-stage candidates have access plans in place. For late-stage cancer projects, this drops to less than 5%.

ectoparasites and snakebite envenoming).

Nevertheless, there is a clear increase in the number of projects targeting NTDs. There are 38 additional R&D projects for NTDs in 2018 and 90 projects in total. The majority are in discovery or pre-clinical development for both years (37/51 in 2016, 69/90 in 2018). R&D projects for NTDs mostly target the same six diseases: Chagas disease, leishmaniasis, human African trypanosomiasis, dengue, schistosomiasis and onchocerciasis. Many projects target more than one of these six diseases.

Although there are more projects for many diseases, the number of projects for maternal & neonatal health conditions (MNH) has diminished. The 2018 Index identified nine projects for MNH conditions. This is three fewer projects than in 2016. One third (4/12) of the projects for maternal and neonatal health were in pre-clinical development in 2016, with none in discovery. The same proportion (3/9) of MNH projects are in discovery or pre-clinical development in 2018.

Five companies account for more than 50% of all projects that are reported to the Index. These companies are AstraZeneca, Boehringer Ingelheim, Johnson & Johnson, Novartis and Roche. Three of these five companies (AstraZeneca, Boehringer Ingelheim and Roche) focus almost exclusively on NCDs, while Johnson & Johnson and Novartis are developing more diverse pipelines with a comparably high proportion of projects targeting communicable diseases* and NTDs.

More projects in the pipeline since 2016

There are 50 diseases evaluated in 2018 that were also evaluated in 2016. The number of R&D projects targeting these 50 diseases has risen from 420 to 687. Of these 50 diseases, around half (27) have larger pipelines than in 2016, most notably for diabetes mellitus, asthma and malaria.

PRIORITY R&D

Almost all companies are active in priority R&D

As in 2016, the Index finds that pharmaceutical companies are answering calls to carry out urgently needed R&D for people in low- and middle-income countries, termed here 'priority R&D'. Of the 77 diseases examined by the Index, 45 have priority product gaps, as identified on five priority R&D lists currently published and accepted by the global health community (see Appendix IV). Thirty-two of these diseases are being targeted, with the companies developing 298 projects for priority product gaps. This number includes some projects that involve multiple companies in scope. In absolute terms, there are 272 priority R&D projects.

GSK is carrying out the most (58) priority R&D projects, followed by Johnson & Johnson with 41 projects, and Sanofi with 35. These three companies, together with Merck KGaA and Novartis, account for almost two thirds of priority R&D projects. Measured as a proportion of their pipelines, GSK leads with 67% targeting priority R&D, followed by Sanofi and Merck KGaA (63% and 42%, respectively).

Priority R&D accounts for almost one quarter (23%) of all R&D projects in scope. Nearly all companies (18) are conducting priority R&D projects. The majority of these projects target a small subset of these diseases including malaria, HIV/AIDS and tuberculosis, as well as two NTDs, Chagas disease and leishmaniasis.

Of the 45 diseases and conditions identified as having a priority product gap, 13 of these are not being addressed by the companies in scope. These include identified gaps for hormone-free and long-acting contraceptive methods and single-dose oral treatments for syphilis, as well as reproductive health devices for both contraceptive methods and syphilis.[2]

Priority R&D is primarily focused on the development of new medicines (70%) rather than other product gaps, including diagnostics. Of the 272 priority R&D projects, 180 are medicines, while preventive vaccines make up the next largest portion of priority products (66). A much smaller number of products (15) are diagnostics that are being developed to address priority gaps (six of which are being developed by Merck KGaA). For example, Johnson & Johnson is developing a point-of-care diagnostic product to measure HIV viral load that aims to provide a fast, simple and affordable device for regular viral load tests.

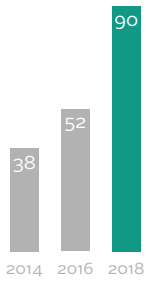
R&D IN COLLABORATION

Partnerships continue to drive access

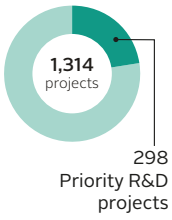
R&D partnership models, such as product development partnerships (PDPs), continue to emerge and expand, drawing on both public and private funds to pool the risks of R&D and share the benefits. Close to a third (420/1,314) of R&D projects are being developed in partnerships. A quarter of partnerships (27%) involve explicitly access-oriented organisations such as the Drugs for Neglected Diseases initiative (DNDi) and the Medicines for Malaria Venture (MMV), or funding bodies such as the Bill & Melinda Gates Foundation and the Wellcome Trust. These organisations can provide funding, resources or expertise, and they incorporate pro-access clauses into contracts with private sector partners to ensure that products are accessible and affordable upon market approval.

Almost 3/4 of the total R&D projects are for NCDs.

52 additional R&D projects for NTDs since the 2014 Index



Almost 1/4 of the pipeline matches R&D priorities



*The 11 communicable diseases with the highest DALY burdens in countries in scope of the 2018 Index. The R&D pipeline includes 10 further diseases and 12 pathogens. Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II for more detail.

Most projects associated with such partners are in early stages of development (88/113). The companies developing the most projects through partnership are Johnson & Johnson, GSK and AstraZeneca. For example, Johnson & Johnson is partnered with a number of government, private and philanthropic partners including the Walter Reed Army Institute of Research in the USA to develop a therapeutic vaccine for the treatment of HIV/AIDS. GSK is developing an inhaled, heat-stable oxytocin product for the treatment of post-partum haemorrhage in partnership with Monash University (Melbourne, Australia). AstraZeneca is developing two monoclonal antibodies for the treatment of lower respiratory infections caused by *Pseudomonas aeruginosa* and *Staphylococcus aureus* through the Innovative Medicines Initiative (IMI).

PIPELINE MOVEMENT

Projects for NTDs progress more slowly

A project's movement along the pipeline from one stage to another can be an indication of multiple factors, including the specific disease target as well as technical, ethical and practical challenges. For example, movement between clinical stages can be slower for NTDs due to unique difficulties conducting clinical trials such as small patient populations, inadequate access to endemic areas and challenging logistics. Further, the failure rate of pharmaceutical R&D is well known to be high. Movement does also give some indication of how efficient a company's R&D activities are, as well as how quickly new high-need products may be available.

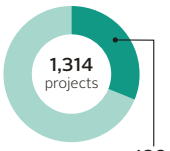
The Index finds that movement through the pipeline varies substantially from company to company. Six companies have moved 20% or more of their pipeline projects from one stage to the next since 2016. The six companies are Bristol-Myers Squibb, Eisai, GSK, Novo Nordisk, Pfizer and Takeda. With the exception of GSK, these companies tend to have small to mid-sized pipelines. Three of these companies (GSK, Eisai and Takeda) have made detailed commitments to conduct R&D to improve access, and they have also dedicated a comparably large proportion of their pipelines to R&D priorities. Novo Nordisk and Bristol-Myers Squibb have relatively small pipelines that are exclusively or almost exclusively focused on NCDs; pipeline movement thus is strongly linked to projects with higher potential commercial incentive.

On average, the 20 companies have moved a sixth (17%) of their pipeline projects from one phase of development to the next since 2016. The majority of projects (725/1314) remain at the same stage of development from 2016 to 2018, while 220 projects were specified as new projects initiated between 2016 and 2018. The remaining projects do not have a reported 2016 phase of development or they do not follow the same clinical development stages, in the case of diagnostics.

In total, 179 projects have moved from one phase of development to the next, with nearly half (80) moving from pre-clinical to clinical phase. Only four projects that moved target NTDs, and only two target maternal and neonatal health conditions. A comparable proportion of projects for NCDs and communicable diseases advanced in the pipeline, although 54/68 projects that advanced from clinical development to applying for market approval target non-communicable diseases.

*Includes projects for which companies did not report a phase of development for 2016 and products that do not follow the standard development phases (e.g., diagnostics).

Nearly 1/3 of R&D projects are in partnership



420
Collaborative R&D projects

ACCESS PLANNING

Earlier planning for access needed

Companies can put plans in place during product development to ensure people gain more rapid access to new products at more affordable prices following market entry. For example, companies can plan to register products in countries in scope, to apply for WHO prequalification and to ensure pro-access licensing and affordability and supply commitments are in place. The establishment of a structured process to develop access plans can help ensure these become a standard practice.

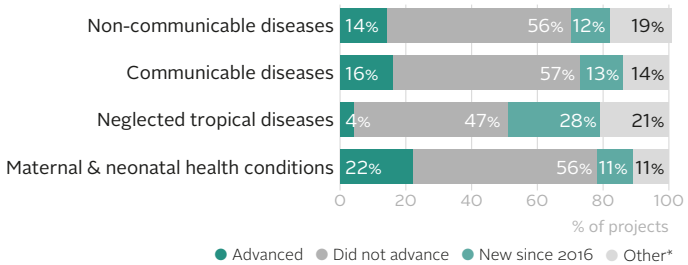
Five companies have strong processes in place with clear timelines to consider and develop access plans for all research projects targeting diseases in scope in which they are active: GSK, Johnson & Johnson, Merck KGaA, Novartis and Takeda. GSK, for example, considers access throughout development and begins to incorporate access plans, including registration strategies, patent waivers and non-exclusive voluntary licensing, into its projects in Phase II. These plans are

Five companies account for two thirds of the late-stage R&D projects with access plans:

- GSK
- Sanofi
- Novartis
- Johnson & Johnson
- Daiichi Sankyo

Figure 20. Pipeline movement by disease category

The chart shows the proportion of projects, in each disease group, that have moved from one phase of development to the next; 179 projects have moved, with nearly half (80) moving from pre-clinical to clinical phase. Four projects that moved target NTDs. Two target maternal and neonatal health conditions.



informed by the unique populations in need and geographic locations where the product will be deployed. GSK's Emerging Access teams work with R&D leads prior to market registration to implement equitable pricing strategies. The remaining 15 companies do not consider access for all projects in scope during development and have either no or only general processes in place to develop access plans for R&D projects, usually on a case-by-case basis or not until after the drug has been approved.

Companies have access plans in place that cover 213 R&D projects, up from 128 in 2016. Nearly three quarters (14 companies) of the industry have incorporated access plans into at least one in-house R&D project. Most access plans identified by the 2018 Index are currently in the form of commitments, rather than concrete strategies or agreements. The five companies with strong access-planning processes in place also lead when it comes to putting access plans in place; these companies together account for 108 out of 213 projects with access plans. For example, Takeda has established registration and equitable pricing strategies, and plans to apply for WHO prequalification for its Phase III dengue vaccine TAK-003, with the intent of making it available to all in need wherever they live.

To ensure that their products reach patients in low- and middle-income countries, companies are expected to have access plans in place by late-stage development (Phase II onwards). By incorporating access plans early on, companies can ensure broader access to more people when the product is launched. Without careful planning, delays between market approval and product launch can extend the period of time during which critical products are not available to the most vulnerable patients living in low- and middle-income countries. However, under one fifth (96/496) of late-stage R&D projects in scope have access plans in place. This proportion is substantially lower for late-stage cancer projects: less than 5% of late-stage projects have access plans in place. To that end, planning for access earlier is an area where companies can continue to improve.

In 2018, there are more R&D projects with access plans in earlier phases of development (108, up from 49). Notably, Gilead has equitable pricing and registration strategies, as well as plans for non-exclusive voluntary licensing and to apply for WHO prequalification, for its Phase I clinical candidate, vesatolimod, for the treatment of HIV/AIDS.

R&D INVESTMENTS

Clarity around R&D investments remains low

Broadly, pharmaceutical companies in scope are not publicly transparent at the disease or project level regarding their investments in R&D. Greater industry-wide transparency could provide valuable information on the costs of R&D as well as highlight the areas receiving little attention or funding, paving the way for more collaboration. Novo Nordisk publishes R&D investments as an aggregate of the two diseases for which it conducts R&D, diabetes mellitus and obesity, the latter of which is not within the scope of the Index. The remaining companies do not publish their R&D investments by disease.

CLINICAL TRIAL ETHICS

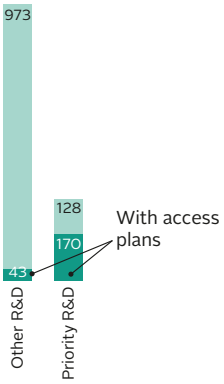
Strong ethical policies; post-trial access lags

Companies are responsible for ensuring that their clinical trials are conducted ethically and to high quality standards. Increasingly, clinical trials are conducted in multiple locations and regions, in countries where regulatory oversight may be weak, and by third-party clinical research organisations (CROs). Working with CROs can save companies time and money while bringing local capacity and expertise on board. However, adding layers of management to global clinical trials raises questions about safety and quality. Good oversight is crucial to prevent misconduct.

Strict adherence to globally agreed upon clinical trial standards helps ensure the ethical treatment of clinical trial participants. Enforcement mechanisms for ethical clinical trial conduct are generally weaker in low- and middle-income countries, raising the expectation that companies publicly commit to adhering to globally agreed standards for all trials. In turn, companies must ensure clinical trials are conducted ethically and to high standards in practice. The Index also examines whether companies have transparent policies in place to ensure post-trial access to treatments tested in clinical trials in countries in scope.

Almost all companies (17) have detailed policies in place that are aligned with the Declaration of Helsinki as well as Good Clinical Practice guidelines. Both documents provide international standards for ethical clinical trial conduct. These companies' policies also impose expectations of high ethical conduct on third-party partners running clinical trials and incorporate auditing and disciplinary actions should bad practice take place. The remaining three companies (Bristol-Myers Squibb, Eli Lilly and Gilead) have clinical trial conduct policies in place that incorporate components of Good Clinical Practice guidelines and the Declaration of

Companies have access plans in place for a total of 213 R&D projects



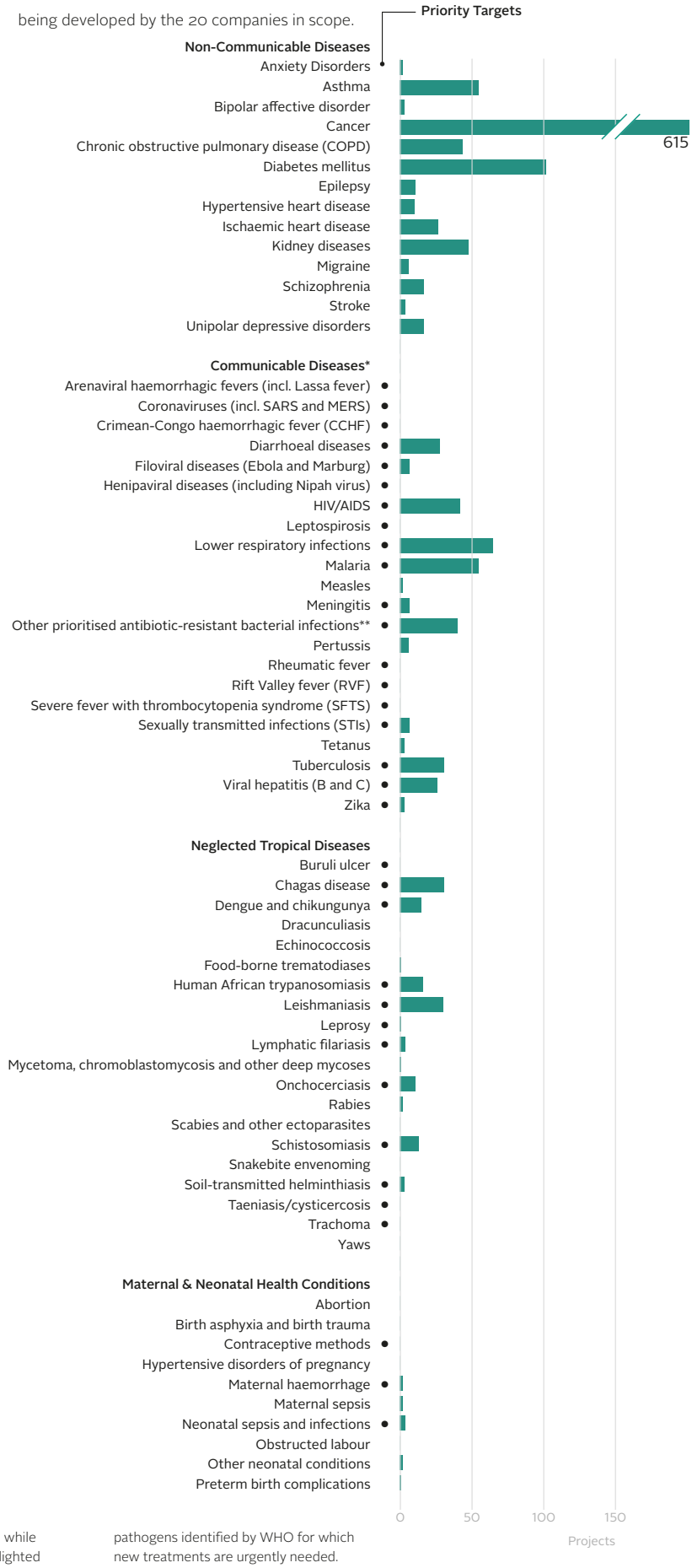
Helsinki, but their processes for auditing and monitoring clinical trials and taking disciplinary action are not as detailed.

Providing clinical trial participants with continued, or post-trial, access to medicine once the trials have ended is key to ensuring that those patients who contribute to studies receive the treatment that they need. Removing access to investigatory health products when no suitable alternatives are available can cause serious health complications in patients with uncontrolled diseases. As health systems in low- and middle-income countries are often less developed, it is essential that the companies themselves provide post-trial access within these countries.

When it comes to providing trial participants with this access, 14 companies have policies in place. However, they vary in their level of rigour: few are publicly available, and few are supported by a concrete example of where post-trial access has been provided in a country in scope. Of these 14 companies, 13 also commit to registering tested products in all countries where clinical trials have been conducted, after the product receives approval from a stringent regulatory authority. Only three companies – GSK, Novartis and Roche – meet all criteria looked for by the Index here, including a transparent, public policy on post-trial access and an example of the policy being used in at least one country in scope. The best policy is from Novartis. This policy was recently implemented to provide post-trial access to all clinical trial participants for whom there is evidence of a continued clinical benefit and no comparable or satisfactory alternative treatment options available, or if the investigatory compound has demonstrated superiority to other therapies. The remaining six companies (AbbVie, Astellas, Bayer, Boehringer Ingelheim, Daiichi Sankyo and Gilead) had no clear policy on providing post-trial access.

Figure 21. What is in the pipeline?

This figure shows the spread of R&D projects being developed by the 20 companies in scope.



*The 11 communicable diseases with the highest DALY burdens in countries in scope of the 2018 Index. The R&D pipeline includes 10 further diseases and 12 pathogens.

Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II for more detail.

**Includes 12 antibiotic-resistant priority pathogens identified by WHO for which new treatments are urgently needed. Tuberculosis is assessed as a separate disease.

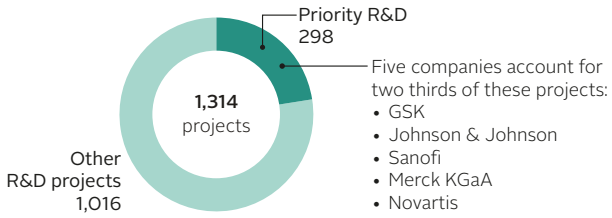
PRIORITY R&D

Are pharmaceutical companies responding to calls for urgently needed R&D?

Globally, two billion people cannot access the medicines they need, with millions in low- and middle-income countries dying each year from diseases because the vaccines, medicines and diagnostic tests that they need are either ineffective or completely lacking.[6] Diseases can have an effective cure available and still face product gaps – such as syphilis, where the development of a single-dose oral treatment would enable governments to bring this disease quickly under control during outbreaks. WHO and Policy Cures Research, an independent R&D-focused policy group, have published lists of the most urgently needed new products – here termed priority product gaps. Without action by large research-based pharmaceutical companies, there is little chance that these products will be developed and commercialised. This analysis looks at which of these gaps are being addressed by the 20 companies assessed by the 2018 Index.

Figure 22. A quarter of R&D projects target R&D priorities

The 20 companies in scope are developing 1,314 R&D projects for the diseases in scope. Almost one quarter (23%) target a priority product gap, such as an urgently needed medicine or vaccine, as identified by WHO and Policy Cures Research.



A small proportion of projects are being worked on by multiple companies in scope. In figures 22, 23 and 24 these are counted twice to enable the size of company pipelines to be compared.

Figure 23. Two thirds of priority R&D projects are collaborative

Almost two thirds of priority R&D projects are being developed in collaboration.

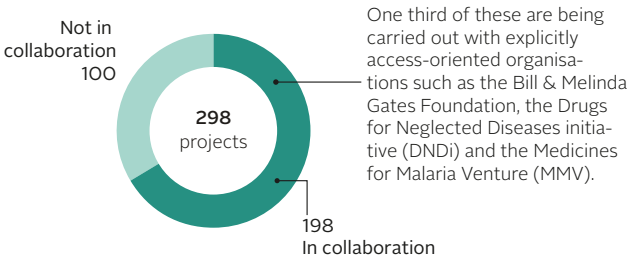
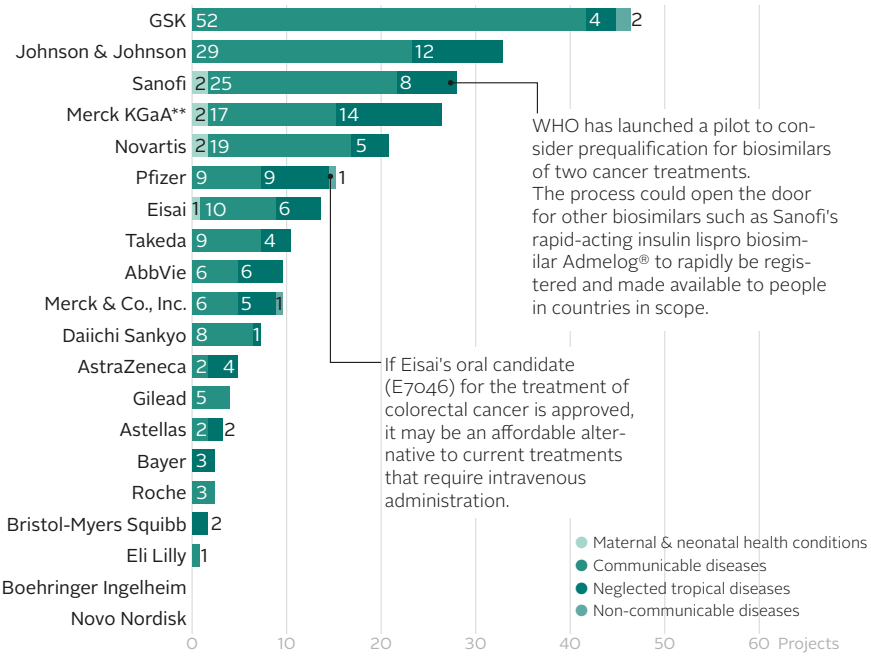


Figure 24. Companies largely focus on priorities for communicable diseases

The chart compares companies' pipelines of projects targeting R&D priorities. Most companies focus on communicable disease* priorities (mainly HIV/ AIDS, malaria and tuberculosis), as well as some neglected tropical diseases (NTDs) (mainly Chagas disease and leishmaniasis). Only three companies are conducting priority R&D for maternal & neonatal health conditions. No list has yet been published that identifies priority R&D product gaps for non-communicable diseases (NCDs). Novo Nordisk and Boehringer Ingelheim only conduct R&D for NCDs. Five companies submitted projects targeting NCDs that demonstrated potential to meet the specific needs of people living in low- and middle-income countries.



*The 11 communicable diseases with the highest DALY burdens in countries in scope of the 2018 Index. The R&D pipeline includes 10 further diseases and 12 pathogens.

Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II for more detail.

**Includes one project that targets both communicable diseases and NTDs. This project was counted once for each disease category.

PRIORITY R&D

Priority R&D focuses on five diseases

Out of the 77 diseases, conditions and pathogens in scope, more than half (45) have been flagged as priorities for R&D. The 20 companies are developing projects for 32 of these diseases, although the majority of projects focus on just five diseases: HIV/AIDS, malaria and tuberculosis (TB) as well as two NTDs, Chagas disease and leishmaniasis. Projects for these five diseases account for one half of the 272 R&D projects for priority product gaps. A small proportion of these 272 projects are being worked on by multiple companies.

Figure 25. Five diseases are main focus of priority R&D

The chart shows which diseases are the focus of most priority R&D projects. 137 out of 272 projects target five out of 45 diseases that have been identified as priorities. WHO estimates that the top three, HIV/AIDS, malaria and TB, accounted for more than 3 million deaths in 2016.[7-9]

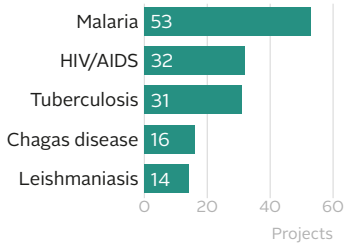
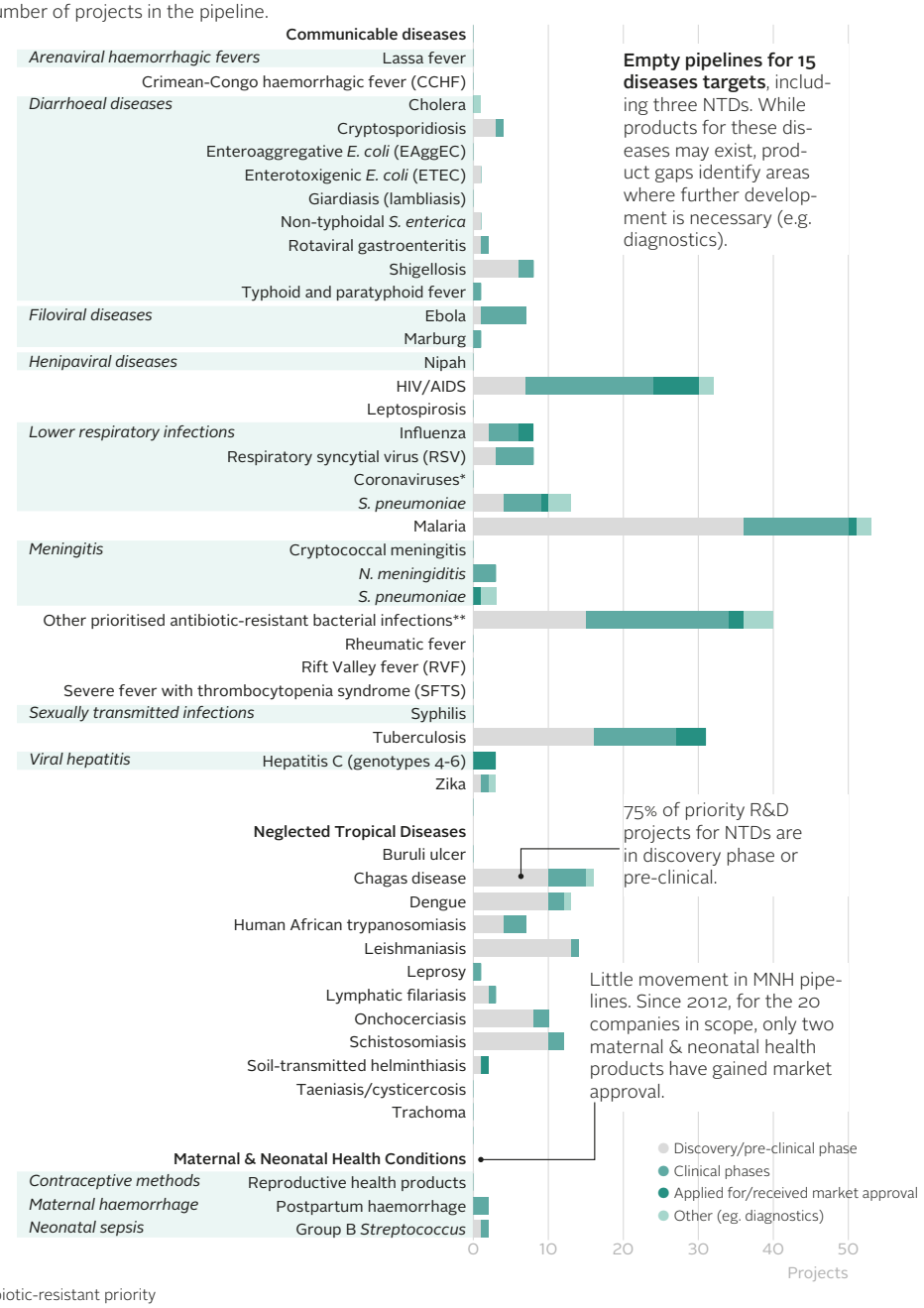


Figure 26. There are projects in the pipeline for 32 out of 45 diseases flagged as R&D priorities

This figure shows the 45 diseases that have been flagged as priorities for R&D, and the number of projects in the pipeline.



▸Two companies lead R&D for paediatric health

More than 30 projects target paediatric healthcare. Many of these projects are being developed by GSK and Johnson & Johnson. This includes paediatric versions of GSK's tafenoquine (Krintafel™) for the treatment of *Plasmodium vivax* malaria and Johnson & Johnson's bedaquiline (Sirturo®) for the treatment of multidrug-resistant tuberculosis.

*Coronaviruses include Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus (SARS-CoV).

**Includes 12 antibiotic-resistant priority pathogens identified by WHO for which new treatments are urgently needed. Tuberculosis is assessed as a separate disease.

PRIORITY R&D

Multiple priority R&D gaps are going unaddressed

The Index looked at whether the 20 companies in scope are developing products that are urgently needed by people living in low- and middle-income countries – termed 'priority R&D'. There are various types of product gaps – for some diseases, new medicines are needed, for others, it may be vaccines or diagnostics that are the most urgent priority. In total, there are 139 separate priority product gaps identified by WHO and Policy Cures Research for 45 diseases, conditions and pathogens. This analysis looks at the different product gaps, per disease, that are being targeted by the 20 companies in scope. It shows which proportion of gaps that are being targeted, and which types of gaps get most attention. For the majority of diseases, there is at least one product gap that is not being addressed by this group.

▶What are priority product gaps?

The Index uses five globally accepted lists of products that are urgently needed, spanning 139 priority product gaps. They have been published by either WHO or Policy Cures Research. These lists call for new products for HIV/AIDS and malaria, where vaccines are urgently sought, as well as for NTDs such as soil-transmitted helminthiasis, which affects 1.5 billion children and adults,[10] and conditions such as maternal haemorrhage. To date, no globally recognised list has been developed that identifies priority product gaps for NCDs such as cancer and diabetes. R&D projects that address these gaps are known as 'priority R&D'.

The five lists of priority product gaps are:

- Policy Cures Research G-FINDER neglected diseases, products and technologies (2017);[1]
- Policy Cures G-FINDER reproductive health areas, products and technologies (2014);[2]
- WHO R&D Blueprint (2017);[3]
- WHO Initiative for Vaccine Research gaps (2017);[4] and
- WHO priority pathogens list for R&D of new antibiotics (2017).[5]

Figure 27. One third of gaps are being targeted

The 20 companies in scope are addressing 48 out of 139 priority product gaps. That means many much-needed medicines, vaccines and diagnostics are likely not being developed, unless they are in early stages of development by, for example, academic research groups or others in the private sector, especially diagnostics companies.

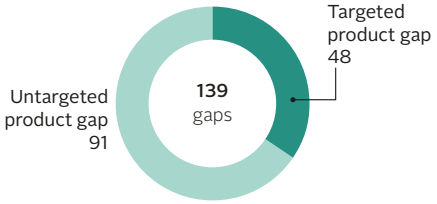


Figure 28. Diagnostics get least attention

The chart shows how many gaps have been identified for each type of product and what proportion have projects in the pipeline. Around half the gaps for medicines and vaccines are being targeted, compared to only four (11%) for diagnostics. Many companies in scope have expertise in diagnostics and could offer much in this area.

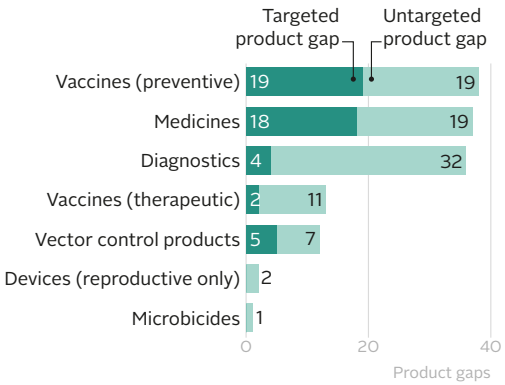


Figure 29. Many priority product gaps go unaddressed

The table shows which products are urgently needed by people living in low- and middle-income countries, as identified by WHO and Policy Cures Research. Diseases with the most unaddressed gaps are at the top. The zeroes represent gaps that receive no attention from companies in scope. A total of 91 of the 139 gaps are unaddressed.

Diseases, conditions and pathogens	Gaps Remaining	Product types: Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (Reproductive Only)
Crimean-Congo haemorrhagic fever (CCHF)	5	0	0	0	0		0	
Rift Valley fever (RVF)	5	0	0	0	0		0	
Severe fever w thrombocytopenia syndr. (SFTS)	5	0	0	0	0		0	
Arenaviral haemorrhagic fevers (incl. Lassa fever)	4	0	0	0	0			
Coronaviruses*	4	0	0	0	0			
Nipah	4	0	0	0	0			
Buruli ulcer	3	0	0		0			
Leishmaniasis	3	13	0	0	0			
Marburg	3	0	1	0	0			
Onchocerciasis	3	10	0		0		0	
Strongyloidiasis**	3	0	0		0			
Zika	3	0	2	0	0		1	
Chagas disease	2	13	0	1	0		2	
Cholera	2	0	1		0			
Contraceptive methods	2	0						0
Cryptosporidiosis	2	4	0		0			
Ebola	2	3	4	0	0			
Enteroaggregative *E. coli*	2		0		0			
Hookworm diseases**	2	0	0					
Human African trypanosomiasis	2	6	0		0		1	
Lymphatic filariasis	2	3			0		0	
Non-typhoidal *S. enterica*	2	0	1		0			
Schistosomiasis	2	8	0		3		0	
Syphilis	2	0						0
Taeniasis/cysticerosis	2	0					0	
Trachoma	2		0		0			
Typhoid and paratyphoid fever	2	0	1		0			
Viral hepatitis C (genotypes 4-6)	2	3	0		0			
Cryptococcal meningitis	1	0						
Dengue	1	9	3		0		1	
Enterotoxigenic *E. coli* (ETEC)	1		1		0			
Giardiasis (lambliasis)	1				0			
HIV/AIDS	1	24	3	1	5	0		
Leprosy	1	1			0			
Leptospirosis	1				0			
N. meningitidis (meningitis)	1		3		0			
Respiratory syncytial virus (RSV)	1	0	8					
Rheumatic fever	1		0					
S. pneumoniae (lower resp.iratory infections)	1		6		0			
S. pneumoniae (meningitis)	1		3		0			
Shigellosis	1	5	3		0			
Tuberculosis	1	26	2	0	3			
Ascariasis**	0	1						
Group B *Streptococcus*	0		2					
Influenza	0		8					
Malaria	0	43	3		2		2	
Postpartum haemorrhage	0	2						
Rotaviral gastroenteritis	0		2					
Trichuriasis**	0	1						

Apart from a few exceptions, such as malaria medicines, the number of projects targeting each gap on average is low. Given the high failure rate of pharmaceutical R&D, more projects are needed to ensure effective new products become available. Projects that are being developed by multiple companies are counted once.

▶Behind the numbers

- **The majority of projects** are for medicines, despite there being similar numbers of diseases with medicine or preventive vaccine gaps.
- **Four fixed-dose combinations** and a neonatal indication for HIV/AIDS have gained market approval from a stringent regulatory authority since 2016.
- Around **600 million people** are estimated to be infected with hookworm globally.[11] Children and pregnant women are high-risk groups for hookworm infections. Johnson & Johnson has tested chewable mebendazole (Vermox™ Chewable) tablets to treat children for two parasitic worms, but not yet for hookworm.
- **Two companies** (Pfizer and GSK) are developing vaccines against group B *Streptococcus*, a leading cause of neonatal sepsis and meningitis responsible for an estimated 147,000 stillbirths and infant deaths a year globally.[12] Pfizer's candidate is now in phase I of clinical-stage development.

>10 projects
5-10 projects
1-4 projects
0 0 projects
No priority

*Coronaviruses include Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus (SARS-CoV).
**Types of soil-transmitted helminthiases

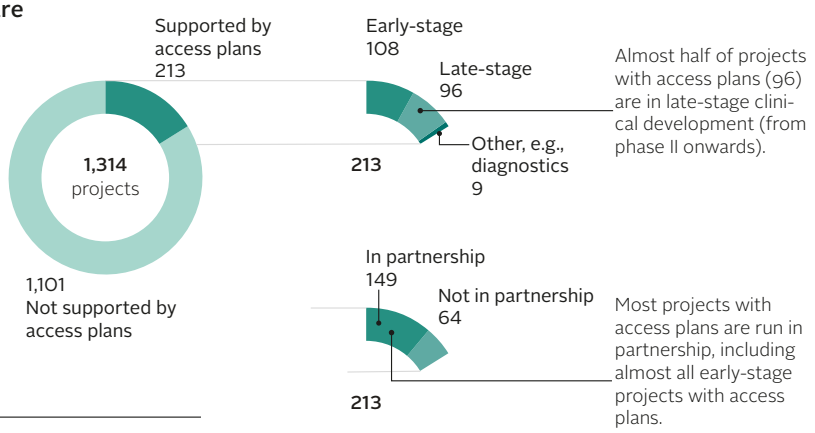
ACCESS PLANNING

Are pharmaceutical companies planning to make new products quickly accessible?

New medicines and other life-saving products must be made rapidly available to people who need them, wherever they live. This requires advance planning. Before new products are approved for sale, companies can put access plans in place, such as pricing commitments or licensing arrangements, to accelerate the speed at which products become accessible. The Index examines whether companies are planning ahead in this way, and what these access plans look like.

Figure 30. Overall, 16% of R&D projects are supported by access plans

The Index identified 1,314 R&D projects for the 77 diseases in scope. Of these, 213 projects (16%) have access plans in place. When looking solely at late-stage R&D projects, just 19% of these projects are supported by access plans.



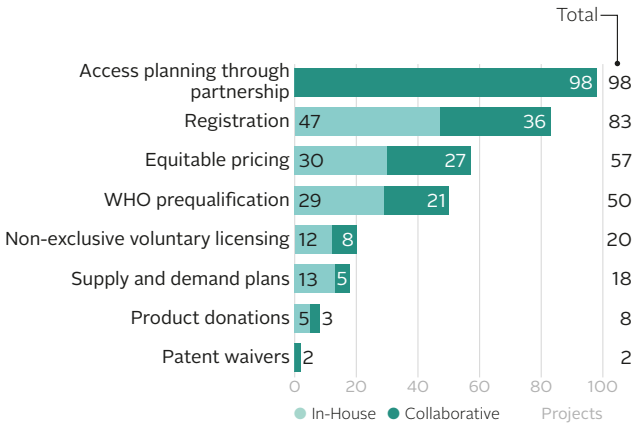
▶What is an access plan?

Access plans comprise concrete tactics to address issues related to access, especially affordability and availability. Projects that have equitable pricing strategies, wide-spread registration strategies and non-exclusive voluntary licensing agreements in place have the best outlook for access.

What	How
Registration preparation	Commit to filing products in all countries where there is a need, and prepare registration dossiers in parallel with EMA, FDA or PMDA approval.
Non-exclusive voluntary licensing	Voluntarily enter licensing agreements under pro-access terms to facilitate generic entry.
Patent waivers	Publicly waive patent rights and pledge not to enforce patent rights in specific territories.
Supply and demand plans	Plan for and align with other actors along supply chains to ensure the timely supply of quality product and prevent stock-outs.
WHO prequalification	Submit products to WHO's prequalification process to allow for UN procurement and accelerate registration process in countries with weak national regulatory authorities.
Equitable pricing strategies	Set prices within the ability of specific populations to pay, with reference to a range of socioeconomic factors.
Product donation plans	Identify populations with no capacity to pay for the new product and prepare to donate as appropriate, working with local partners.
Access planning through partnership	Conduct R&D with organisations that explicitly commit to using access plans to make health products widely available.

Figure 31. Partnerships continue to drive access planning

The chart shows which types of access plans are most often in place. Projects are more likely to have access plans when they are being developed with organisations that explicitly commit to making health products available in low- and middle-income countries. More than half of projects with access plans are run through such partnerships.



ACCESS PLANNING

Which companies plan ahead for access?

Companies are expected to establish access plans for projects that are in Phase II clinical development and onwards, referred to as 'late-stage candidates'. This analysis focuses specifically on which companies are planning ahead, looking at the proportion of their late-stage pipelines that are supported by access plans.

Figure 32. Access planning for NCDs lags behind others

This chart shows the percentage of late-stage R&D projects (Phase II onwards) that have access plans for each disease category. Projects that target more than one disease category are counted more than once.

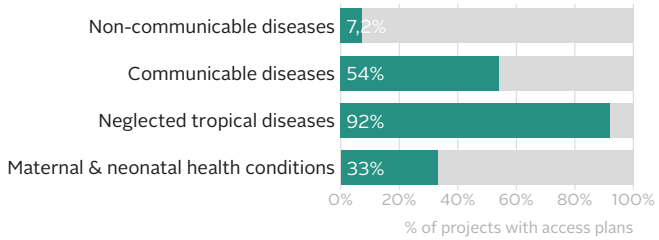
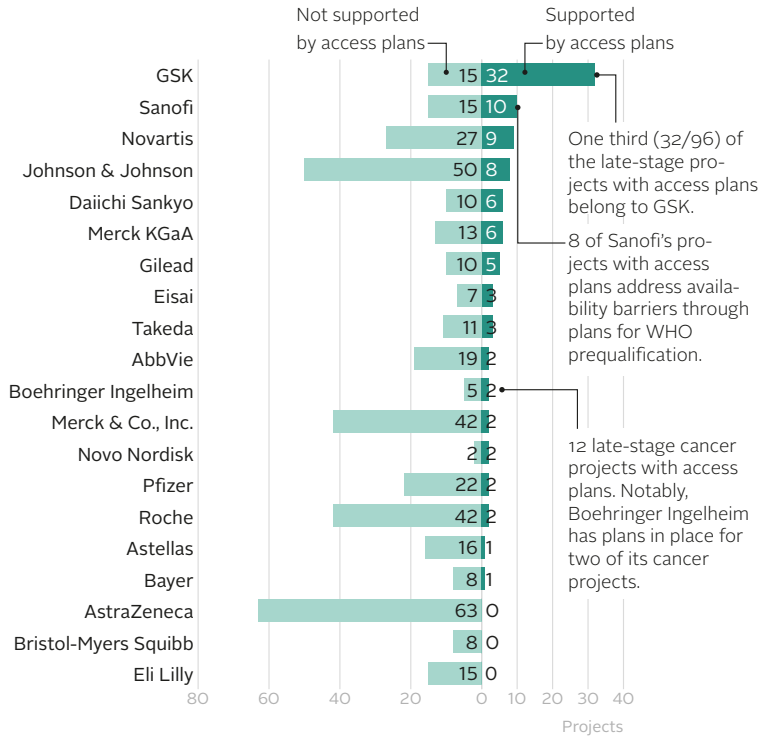


Figure 33. Five companies account for nearly 60% of late-stage R&D projects with access plans



▸The first new treatment for *Plasmodium vivax* malaria in 60 years.
GSK's tafenoquine (Krintafel™) was approved just after the period of analysis for the 2018 Index. However, GSK developed a comprehensive access plan during development to ensure that the drug is available as quickly as possible now that it has received approval. This includes a partnership with a quality, low-cost manufacturer; not-for-profit pricing; patent waivers; and implementation studies in Brazil, Ethiopia and Thailand. After these studies are completed, GSK will seek to make the drug available to all patients who need it through partnerships with access-oriented partners including the Medicines for Malaria Venture (MMV) and the Bill and Melinda Gates Foundation.

▸How firm are access plans?
Generally, access plans first take the shape of commitments made during early stages of development before being turned into concrete strategies or agreements. Most access plans identified by the 2018 Index are currently in the form of commitments. This is a necessary first step, and now efforts must be made to ensure these commitments are turned into action.

For example, Merck & Co., Inc. has committed to making its investigational Ebola vaccine (rVSV-ZEBOV) available to Gavi-eligible countries at the lowest possible access price. This vaccine could be instrumental in preventing future Ebola outbreaks, provided this commitment translates into equitable pricing.

RESEARCH AND DEVELOPMENT

Best practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations (see page 73).

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness,
- Sustainability,
- Replicability,
- Alignment with external standards and stakeholder expectations.

The 2018 Index identified four best practices in this area, from three companies.

GSK, SANOFI

Largest proportion of pipelines dedicated to priority R&D projects

GLOBAL

More than 60% of GSK's and Sanofi's pipelines focus on diseases for which products including vaccines, medicines and diagnostics are urgently needed, yet either ineffective or lacking.

There are many diseases without adequate or effective treatments available, or where the products are not sufficiently tailored to meet the needs of people living in low- and middle-income countries. Pharmaceutical companies have much to add in this space. Addressing such 'product gaps' is a core expertise of the industry. In 2018, the Index has deepened its analysis of R&D that addresses such gaps, looking specifically at the diseases listed on five priority R&D lists currently published and accepted by the global health community from WHO and Policy Cures Research (see Appendix IV). This is termed 'priority R&D' by the Index.

Two companies stand out among pack

GSK and Sanofi demonstrate best practices in this area. Both are leaders by the proportion of priority R&D projects in their pipelines to address specific gaps identified by WHO and Policy Cures Research, an independent R&D-focused policy group.

How does GSK demonstrate best practice?

GSK has 86 projects in its R&D pipeline for diseases in scope, and 58 of these (around 67%) address priority R&D gaps. The majority relate to products for HIV/AIDS and priority pathogens (specific strains of bacteria that have demonstrated resistance to certain antibiotics, making treatment particularly difficult, see Appendix IV). Other projects address malaria and maternal and neonatal health conditions, including maternal and neonatal sepsis and maternal haemorrhage.

Of GSK's 58 priority projects, 34 are medicines, 23 are preventive vaccines and one is a vector control project for malaria. Two projects cover multiple product types.

To close product gaps and to achieve a public health impact, companies must keep priority R&D projects moving through the pipeline. They also need to establish access plans to ensure people can access and afford products in countries in scope as soon as possible.

GSK performs well in both progressing projects through the pipeline and establishing access plans for its priority R&D projects. Of its 58 priority R&D projects, 34 (58.6%) have access plans in place, with 15 progressing in the pipeline during the period of analysis. Four of these have received market approval: two influenza vaccines with paediatric indications, a multi-dose pneumococcal polysaccharide conjugate vaccine (Synflorix®), and the first single-tablet, two-drug complete antiretroviral therapy: dolutegravir/rilpivirine (Juluca®). A fifth project, tafenoquine (Krintafel™) for *Plasmodium vivax* malaria, was submitted for market approval during the period of analysis and received this on 20 July 2018. All five products address critical health needs in low- and middle-income countries, and in each case, plans have been made during R&D to help ensure these products will be accessible. For example, dolutegravir/rilpivirine (Juluca®) has registration and equitable pricing strategies, and GSK plans to apply non-exclusive royalty-free voluntary licensing to the product.

How does Sanofi demonstrate best practice?

Sanofi also performs well in ensuring that its priority R&D projects have access plans in place during development. Of its 56 R&D projects, 35 (62.5%) are priority projects addressing specific product gaps identified by WHO and Policy Cures Research, with an emphasis on lower respiratory infections, tuberculosis and malaria. Seven projects target nseases (NTDs), particularly Chagas disease, leishmaniasis and human African trypanosomiasis. Like GSK, Sanofi's 35 priority projects target a range of diseases and product types: 19 are for medicines, and 16 are for preventive vaccines.

Researchers at Sanofi have developed an oral cholera vaccine which is considered a priority R&D project.

Two fifths (14/35) of Sanofi's priority R&D projects are late-stage, including seven Phase III clinical candidates. One of these clinical candidates is fexinidazole, which could become the first oral treatment of human African trypanosomiasis caused by *Trypanosoma brucei gambiense*, as a result of a 10-year collaboration with the Drugs for Neglected Diseases initiative (DNDi).

Sanofi has established access plans for 21 of its 35 priority R&D projects. In the majority of cases, these include plans to apply for WHO prequalification. One example of the way Sanofi makes effective use of WHO prequalification for priority R&D projects is its oral cholera vaccine Shanchol™. While this has not yet received approval from a stringent regulatory authority such as the FDA, Sanofi has shipped more than 12 million doses of the vaccine globally since receiving WHO prequalification in 2011.[13] Data from WHO prequalification has played an important role in countries' decisions to allow the vaccine to be used by its citizens. With updated WHO approval in February 2018, the vaccine can now be kept in conditions that limit the need to maintain a cold chain, which can be particularly challenging in resource-limited settings.

GSK

Plans ahead for largest proportion of pipeline

GLOBAL

GSK leads in planning ahead to make future products accessible. It has covered the largest proportion of late-stage projects with access plans.

Several companies have committed to improving access by integrating dedicated access plans into their R&D projects. These include registration in countries in scope, to ensure the product is approved for use in these countries; WHO prequalification, which verifies the quality and safety of a product; equitable pricing strategies, which price products based on a population's ability to pay; and voluntary licensing agreements, which can facilitate generic entry and market competition, leading to more affordable pricing and increased supply.

Out of all the companies that have made commitments to improving access, GSK has risen to become the industry leader by transforming commitment into action.

What makes this a best practice?

Stakeholders such as product development partnerships look to pharmaceutical companies to establish access plans for any drugs in Phase II (late-stage) onwards. GSK has the largest proportion of late-stage R&D projects with access plans in place (32/47); it also has some of the most comprehensive access plans of all companies evaluated. Together, these will help to ensure that critical products are available and affordable in countries in scope.

Most companies apply access plans to late-stage projects through registration commitments or plans to apply for WHO prequalification. These steps are crucial in providing access to new products, but they are not sufficient to ensure products will be both available and affordable. Access plans also need to integrate key provisions such as equitable pricing strategies and licensing and supply agreements.

Of GSK's 32 late-stage projects with access plans in place, 27 have more than one unique component, such as a commitment or strategy, and some have as many as four different types.

How is GSK planning for access during development?

One example is cabotegravir. GSK is developing this Phase III HIV integrase inhibitor as a long-acting injectable drug for pre-exposure prophylaxis (PrEP) of HIV; it is also collaborating with Johnson & Johnson to develop a combination long-acting injectable of cabotegravir with rilpivirine as treatment and PrEP. For the two projects associated with this clinical trial candidate, GSK has put in place a range of access components, including equitable pricing strategies, a commitment to register in countries in scope, and plans to apply for WHO prequalification and to establish non-exclusive voluntary licensing.

One Phase III study (Antiretroviral Therapy as Long-Acting Suppressor, or ATLAS) achieved its primary endpoint for non-inferiority of the dual injectable therapy in maintaining viral suppression in HIV-1-infected adults, given once-monthly, when compared to a three-drug, daily oral regimen.[14] By offering an injection that is only required once a month, GSK aims to address key adherence issues, including missed doses, that are associated with current HIV/AIDS therapies and PrEP.

NOVARTIS

R&D unit dedicated to adaptive R&D aims to improve efficacy, safety and access

GLOBAL

Unique R&D unit dedicated to adapting existing medicines to meet the specific needs of people living in low- and middle-income countries.

What makes this a best practice?

Novartis' working group for adaptive R&D, established in 2016, is a best practice in adapting R&D for use in low- and middle-income countries. This dedicated research unit scrutinises whether the company's existing medicines offer new opportunities for improved efficacy, safety and access in countries in scope of the Index.

The working group is endorsed by Novartis' highest level of company governance and has been incorporated into objectives for its Head of Global Drug Development. This working group spans multiple research teams and seeks to identify and activate opportunities in three main areas: reformulating existing medicines; expanding a drug's scope of use and the range of people it can treat (for example, children and older patients); and researching new areas (such as genetic polymorphisms) to better adapt products. Periodically, the working group systematically reviews the company's entire portfolio to identify these opportunities.

How is this best practice addressing local needs?

By using systematic portfolio reviews, the working group has already identified multiple opportunities to adapt existing medicines to meet the needs of patients of low- and middle-income countries. Since 2017, when a review took place, the group has initiated a number of R&D adaptations for countries in scope. These include development of an expanded indication for clofazimine (Lamprene®), an anti-leprosy drug, to treat multidrug-resistant tuberculosis and of a long-acting, solid dispersible formulation of the antimalarial drug lumefantrine (a component of Coartem®) that is child-friendly and taken once-daily.

This best practice builds on Novartis' previous good record in adaptive R&D. In 2009, the company launched a dispersible form of artemether-lumefantrine (Coartem® Dispersible) that it co-developed with the Medicines for Malaria Venture (MMV). Since this launch, an estimated 350 million treatments of this product have been delivered to 50 malaria-endemic countries.[15]

NOVARTIS

Detailed commitment to providing post-trial access, goes further than peers

GLOBAL

Detailed and thought-through policy for providing investigational products to all clinical trial participants until the product is commercially available.

When people participating in clinical trials lose access to promising experimental treatments or comparable therapies, they may experience devastating health effects, especially for chronic diseases, e.g., HIV/AIDS. For vulnerable populations in low- and middle-income countries, without the means to access alternative treatments, this loss may be especially difficult and could lead to relapse or other worsening conditions. 'Post-trial access' describes the continued provision of a product to clinical trial participants after a trial has concluded.

Ensuring access after clinical trial completion

To address this issue, Novartis has taken a new position on post-trial access, publishing this position in August 2018. In a comprehensive, public policy on post-trial access, the company commits to provide free post-trial access to all patients who participate in and complete a confirmatory Novartis-sponsored clinical trial and meet certain criteria: there must be evidence of continued clinical benefit to the patient, and he or she must give consent to continue treatment. There must also be a lack of available alternative treatment options that are comparable or satisfactory. Finally, local laws and regulations must allow post-trial access to take place.

What makes this a best practice?

Novartis' new policy goes into greater depth than the post-trial access policies of its peers. It also contains a greater range of patient groups eligible for continued treatment. The 2018 Index finds that 14 companies have (or make available) a post-trial access policy, although they vary in their level of rigour. Those companies that do have post-trial access policies often stipulate that for participants to continue to receive treatment, they must demonstrate a life-threatening or serious illness, one for which no alternative treatments are available.

Novartis considers all patients for post-trial access

Although it requires the absence of a comparable or satisfactory alternative for treatment, Novartis considers all patients for post-trial access, regardless of the severity of disease. Its policy includes additional protection: if withdrawal of treatment might lead to substantial harm or relapse, Novartis will provide post-trial access, even where alternative marketed therapies are available.

In a further provision, when clinical trial results demonstrate the superiority of a product under investigation, Novartis commits to offering this product to all trial participants until the product becomes available commercially, or accessible locally. In September 2018, Novartis was conducting at least 90 clinical trials in 19 countries in scope, which highlights the potential reach of this policy. [16]

RESEARCH AND DEVELOPMENT

Innovative practices

ABOUT INNOVATIVE PRACTICES

Many challenges exist for healthcare systems in low- and middle-income countries such as patchy healthcare services, poor infrastructure and lack of resources.

The Access to Medicine Index recognises those companies that are trialing unique approaches to overcome some of these barriers. These practices are classified as innovative. The Index also highlights previously identified innovations that have been scaled up or expanded.

The 2018 Index identified four innovations in this area, from four companies.

GSK

Global Health R&D Unit to simulate collaboration

GLOBAL

Targeted open innovation incubators and research units with focus on R&D for conditions unique or endemic to low- and middle-income countries.

Open innovation can better advance technology and ideas by looking outside an organisation's boundaries to share expertise and know-how. This type of innovation can be especially useful for R&D for diseases with little commercial incentive to develop new products, such as NTDs, particularly if companies have extensive compound libraries and other potentially untapped resources. Several pharmaceutical companies have established research units and incubators for open innovation, allowing others to utilise these resources and address a range of diseases while promoting collaboration.

What makes this an innovation?

GSK goes a step further. Its Global Health R&D Unit, established in 2017, combines several distinct models of open innovation, with a specific focus on R&D for conditions unique or endemic to low- and middle-income countries. GSK has been evolving these models for several years, and they are now part of a dedicated unit, under a single leadership team.

GSK's global health R&D unit oversees three leading initiatives. The first is the Tres Cantos Open Lab Foundation (TCOLF), a specialist research centre in Spain, which since 2010 has enabled independent researchers to access GSK facilities, resources and expertise to advance research into diseases relevant to low- and middle-income countries.

A second initiative, Trust in Science, aims to build R&D capacity. A third initiative is the global health R&D catalyst unit, which oversees GSK's Africa NCD Open Lab and its maternal and neonatal health R&D unit.

Through these initiatives, GSK seeks to address diseases that have a disproportionate effect on people living in countries in scope. As part of this, it has committed to incorporating access plans into projects associated with these initiatives, including not-for-profit pricing, sharing of the intellectual property derived from initiatives, and the application of royalty-free voluntary licences to medicines such as dolutegravir (Tivicay®), which treats HIV infection.

Expanding resources and knowledge

GSK is expanding its Global Health R&D Unit to address further global health needs. In 2017, for example, TCOLF added shigellosis, a priority R&D target, to the list of diseases for which it supports research. Trust in Science is extending its work to new countries in scope of the Index. Since 2011, GSK has also partnered with the World Intellectual Property Organization (WIPO), working to advance access to intellectual property including compounds and patent-associated experimental data to accelerate R&D for NTDs and other high-burden communicable diseases. Through its Global Health R&D Unit (which incorporates access plans, operates under a single management and includes all disease categories within the scope of the Index), GSK has brought a fresh approach to open innovation.

JOHNSON & JOHNSON

Cross-sector partnership drives early-stage R&D

GLOBAL

Extensive financial and on-site resources to enable groups behind early-stage projects to overcome limitations associated with development.

Johnson & Johnson uses unique partnerships to accelerate early-stage R&D for critical diseases.

Johnson & Johnson Innovation is an initiative that catalyses R&D by investing in, and partnering with, a wide range of external organisations and research teams across sectors. Johnson & Johnson has run its innovation initiative for several years, but in 2016, it announced an expansion through a new global public health strategy. With this strategy, it seeks partnerships to advance R&D for tuberculosis; HIV/AIDS; maternal, newborn and child health; and other areas of global public health concern, including NTDs.

The initiative works, in part, by enabling groups behind promising early-stage projects, particularly in academic and start-up environments, to overcome the sizeable costs and limitations associated with developing these projects. By reaching out to potential collaborators, and providing partners with financial investments and the use of its facilities, Johnson & Johnson has succeeded in accelerating a number of early-stage projects for global health priorities.

Through its incubator division JLABS, for example, the company awarded a six-month residency at its US-based incubator in Houston, Texas, to an entire research group from Rio de Janeiro, Brazil. This project in 2016, under Johnson & Johnson's 'Latin America QuickFire Challenge', focused on isolating or developing anti-Zika monoclonal antibodies as a potential treatment for Zika.[17] Because of the substantial size and scale of Johnson & Johnson's resources, the R&D projects it selects have significant potential to advance knowledge at a much faster rate.

What makes this an innovation?

The company's model differs from other open innovation and incubator models by giving chosen partners (with work ranging from early-stage to clinical phase initiatives) access to its extensive financial and on-site resources. Selected partners benefit from being able to use its compound libraries and research capabilities. These partners include a variety of public and private laboratories including universities and the National Institute of Allergy and Infectious Diseases (Maryland, USA). Overall, it aims to use incubation and early-stage investment to establish unique cross-sector partnerships and to accelerate R&D for global health needs.

By actively seeking out cross-sector partnerships and by funding promising early-stage projects to address global health issues, Johnson & Johnson has developed an innovative approach to quickly advancing R&D for diseases in scope. In combination with JLABS, its global health innovation model continues to accelerate the development of early-stage projects around the world.

MERCK KGaA

Merck Global Health Institute partners up to accelerate R&D for bacterial infections, schistosomiasis and malaria

GLOBAL

Institute setting up R&D partnerships to develop projects to target bacterial infections, schistosomiasis and malaria in low- and middle-income countries.

In 2017, Merck KGaA launched Merck Global Health Institute, as part of its new corporate affairs function. The overall mission of this institute is to develop health solutions – through R&D, capacity building and access planning – focused on controlling and eliminating infectious diseases that severely impact children, and to contribute to the United Nations Sustainable Development Goals. It focuses on developing, producing and distributing new products to address malaria, schistosomiasis and bacterial infections, including antimicrobial-resistant bacteria, in low- and middle-income countries. The scope of disease may expand as the institute grows.

The Merck Global Health Institute is developing new diagnostics for key malaria biomarkers.

How does the institute accelerate R&D for infectious diseases?

To accelerate innovation in R&D, the institute seeks to establish partnerships with a range of public and private partners, such as universities, access-oriented organisations and major funding bodies around the world, including those in low- and middle-income countries. Since April 2017, it has established more than 30 partnerships to develop projects for target diseases. As these diseases are disproportionately present in low- and middle-income countries, the institute also incorporates access plans into each project to address barriers to availability and affordability. These plans include commitments to ensure sufficient supply and low-cost manufacturing processes, meant to reduce overall patient costs, as well as plans to apply for WHO prequalification, among others.

The institute has already begun developing new diagnostic devices for schistosomiasis and has continued to develop a paediatric formulation of praziquantel for the treatment of schistosomiasis. It has also initiated several new projects for malaria including cell-based diagnostic assays to identify sub-clinical levels of *Plasmodium*

falciparum and *Plasmodium vivax* biomarkers in potential malaria patients.

What makes this an innovation?
The institute is fully incorporated into Merck KGaA, whose financial support contributes not only to the initiative's long-term sustainability, but also to the achievement of its goals. This level of integration makes the initiative unique, as most companies' global health R&D initiatives operate as separate units that seek external funding.

NOVARTIS

Novartis Access Principles to establish access plans during development

GLOBAL

A systematic approach to developing access strategies for each new medicine during development.

Novartis has established a systematic approach to develop access strategies for each of its new medicines during development. As it is developing products that target some of the most pressing needs in low- and middle-income countries, establishing access strategies for all new medicines could have a significant impact in these countries. In 2017, senior leaders at Novartis approved the Novartis Access Principles, and it was implemented in 2018.

What are the Access Principles?
Previously, pharmaceutical companies have focused on establishing access plans only for R&D projects developed in partnership. However, stakeholders now expect companies to establish access plans for in-house R&D projects too. The new Novartis Access Principles are designed to streamline this process to increase the success of access strategies and to provide accountability for access. Through this approach, Novartis' global, regional and country teams establish strategies for access once a clinical candidate enters later stages of clinical development (usually at Phase IIb). These teams then update these strategies as the clinical candidate progresses toward market approval.

Stakeholders expect companies to establish access plans for pipeline projects from at least Phase II of clinical development on. Novartis' new principles align with this timeline, with its access strategies including plans for registration, pricing and licensing, among others. Novartis will develop strategies for all of its innovative medicines as well as biosimilars developed by Sandoz, its generics division, with separate strategies for its adaptive R&D projects.

What makes this an innovation?
A number of companies have processes enabling them to consider and develop access plans across pipelines. However, Novartis is the first to commit fully to establishing access strategies across its pipeline regardless of disease type, signalling a unique willingness to consider access for diseases with high and low commercial potential for use in countries in scope.

In putting in place company-wide access strategies, and to ensure these are implemented, Novartis has created accountability with both a structured timeline and through the endorsement of these principles by senior leadership. While it will take time to see the effect of these principles for new medicine launches, Novartis will use key performance indicators to measure impact in expanding access to medicine for the first two years following launch.

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D Pricing, Manufacturing & Distribution

CONTEXT

Pharmaceutical companies continue to enter low- and middle-income country markets – home to the majority of the world's poorest people. Whether products are available and affordable to the people who need them in these markets depends on the choices companies make when registering, pricing and distributing their products. Affordability depends on who is going to pay – whether it is the patient or another stakeholder in the local healthcare system. In low-income countries, up to 70% of spending on medicines may be made out of pocket.[1] Different populations and groups have different incomes and expenses, and it is important for pharmaceutical companies to recognise this when pricing their products.

HOW WE MEASURE

The 2018 Index looks at registration and pricing practices in relation to specific products and countries:

Priority countries: For each disease in scope, the Index has defined lists of priority countries (see Appendix VI) – those with the greatest need for improved access to affordable products for that disease. Performance in equitable pricing and in registration are compared against these lists.

Equitable pricing strategies: These strategies are graded on whether and how companies take socioeconomic factors into account when determing prices (factors such as household income and mode of health financing).

WHAT WE MEASURE

This Technical Area looks at three areas of behaviour:

1 **Filing for registration:** do companies rapidly file new products for sale in the countries that need them most?
2 **Equitable pricing strategies:** how do companies consider the ability of the governments, global health agencies and individual patients to pay for the product?
3 **Manufacturing & distribution:** do companies adapt product packaging according to local needs in order to facilitate rational use by practitioners and patients; do they support the sufficient and timely supply of their products?

TOP INSIGHTS

▶ The proportion of products with equitable pricing strategies has grown from 33% (in 2014 and 2016) to 43%, with a notable increase in intra-country pricing strategies.

▶ More than half of companies do not disclose specific targets for filing their products for registration within a year of gaining first market approval.

▶ Companies have so far filed products in less than a quarter of the possible priority countries in need of medicine.

▶ More than half of the companies are taking action to align supply with demand in countries in scope.

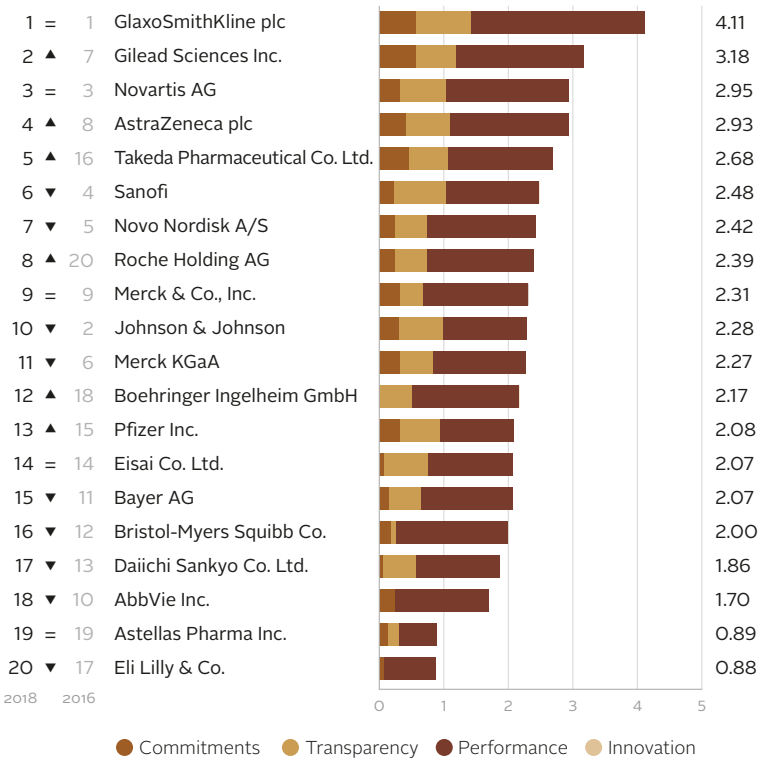
IN THIS CHAPTER

HOW COMPANIES COMPARE

Gilead and Novartis new in leading group; use of equitable pricing improves

- GSK (1st) is a clear leader. It is followed by Gilead (2nd) and Novartis (3rd) in the leading group.
- The top three are followed by two additional companies (AstraZeneca and Takeda) that outperform the rest, and a closely ranked group of 12 companies (Sanofi to Daiichi Sankyo) ahead of three laggards.
- Rankings in this area primarily reflect the depth and breadth of companies' equitable pricing strategies and how far they are being applied in priority countries.*
- More companies are demonstrating progress, both when it comes to considering socioeconomic factors when setting prices, and in the proportion of priority countries covered by equitable pricing strategies.
- Leaders apply more equitable prices and register some new products in priority countries and for higher proportions of their portfolios than their peers.

Figure 34. Company ranking Pricing, Manufacturing and Distribution



Leaders target countries most in need

GSK (1st) is a clear leader. It is followed by Gilead (2nd) and Novartis (3rd) in the leading group. These three are generally top performers in: (1) taking account of multiple socioeconomic factors when setting prices; (2) applying equitable pricing strategies to large proportions of products and/or in priority countries; and (3) filing to register some new products in priority countries.

GSK (1st) held its lead by expanding its equitable pricing strategies to 60% of its products in scope for at least one priority country. Almost all its products in priority countries (96%) are linked to equitable pricing strategies based on multiple socioeconomic factors.

Gilead (2nd) joins the top three, expanding its use of equitable pricing strategies to cover 94% of its relevant products, up from 50%.

Gilead and GSK have both committed to filing all new products for registration in countries in scope within a year of first global product launch with reference to public health needs.

Novartis (3rd) maintains its position of third but improved its performance in equitable pricing, as did its leading peers. In 2018, 57% of Novartis' relevant products are covered by equitable pricing strategies targeting priority countries (compared to 49% in 2016).

Risers apply more equitable pricing strategies

Most movement is at the top and bottom of the ranking. Two companies, Gilead and Takeda moved into the top five by linking more products to equitable pricing strategies covering priority countries.

Many companies (14) improved their use of socioeconomic factors when setting prices and linked more strategies for equitable pricing to priority

*Priority countries are disease-specific subsets of countries with a particular need for access to relevant products (see Appendix VI).

countries than in 2016, contributing to a growth in the average number of factors taken into account per strategy from 0.7 in 2016 to 3 in 2018.

Takeda rises 11 places (to 5th), making a strong pledge to equitable pricing and registration in priority countries, and going from 0 to 10 products with intra-country equitable pricing strategies, all linked to multiple socioeconomic factors.

Roche rises 12 (to 8th), significantly increasing its transparency across all areas.

Johnson & Johnson falls 8 (to 10th). It did not keep up with peers in its use of equitable pricing strategies and socioeconomic factors to set prices, or in widely filing to register its newest products in relevant priority countries.

AbbVie falls 8 (to 18th) primarily due to a drop in transparency.

Middle group expand pricing and registration practices

AstraZeneca (4th) and Takeda (5th) lead the large middle group primarily due to an increase in the consideration of more socioeconomic factors per strategy on average compared to the other middle-ranking companies.

Improvement in the middle group is largely in the scope and scale of equitable pricing strategies and registration practices. E.g., Novo Nordisk (7th) now files to register half of its newest relevant products in the majority of corresponding priority countries. Additionally, it is the only company to file to register all of its new products in at least one priority country. These companies also generally perform above average in aligning supply and demand.

AbbVie (18th), Astellas (19th), and Eli Lilly (20th) perform poorly across many measures. Eli Lilly and AbbVie are markedly less transparent than in 2016. AbbVie edges past its peers to 18th, as it files more of its newly launched products for registration in the majority of corresponding priority countries.

INDUSTRY ACTIVITY PER TOPIC

While registration performances lag, prices within countries become more tailored according to need

Compared to 2016, some companies make commitments to improving equitable pricing strategies and accelerating the registration of new products in countries in the scope of the Index, but broad practical implementation does not always align with these commitments. Specifically, seven pharmaceutical companies have strengthened their commitments to file rapidly to register newly launched products in more countries in scope of the Index. They also commit to provide differential pricing models to products, with the goal of helping create better access to new products in low- and middle-income countries.

Overall, 79% of the companies' newest products* are registered in fewer than half the countries with high need for the treatments in question (termed 'priority countries'**). More products are covered by equitable pricing strategies (44%, up from 33%), yet such strategies are, in general, still not being widely applied in priority countries. For example, Brazil, China and India are targeted by the most equitable pricing strategies (38% of the total number for the top ten countries). However, less than one quarter of priority countries are not targeted by any equitable pricing strategies and are typically smaller markets.

The 2018 Index also found that companies generally take more socioeconomic factors into account when setting prices than in 2016 (three per strategy, up from 0.7, on average). Furthermore, good practice remains focused on only a few diseases; almost half of equitable pricing strategies are linked to communicable diseases, mainly hepatitis C or HIV/AIDS. Strategies often cover products that are already off-patent, limiting access and affordability of many important on-patent products, many of which have no initiatives to improve access at all.

Poorer populations overlooked by registration

Before a medicine can be made available in a country, it must first be approved for sale by the relevant regulatory authority. The Index looks at whether companies have specific, time-bound targets for filing to register new products in low- and middle-income countries. Such targets are especially critical where there is an urgent public health need for a product. Furthermore, by publishing where products are registered, companies can support coordination and collaboration between people working to make products available to the people who need them. Rapid registration also helps secure market access and grow a strong market share.

In 2018, there are five companies that have disclosed specific targets for filing to register products in low- and middle-income countries within one year of their first global launch: Gilead, GSK, Johnson & Johnson, Sanofi and Takeda. Takeda makes the strongest commitment to registration and is also the most recent company to make a pledge via the Index. Takeda has specifically committed to filing submissions for any new medicines globally (and not only in major markets), working in parallel to prepare these submissions as it files for first global market approval. If implemented, the strategy could have a significant impact on access to important products for multiple communicable and non-communicable diseases. Gilead and GSK also make broad commitments, pledging to register all products for diseases in scope in all countries in scope, where possible. Gilead, GSK and Takeda all state that their registration decisions are informed by a public health rationale.

Over half of all companies have still not provided evidence of specific targets for filing to register products within a year of gaining first market approval for high-burden diseases: AbbVie, Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, Eli Lilly, Merck & Co., Inc., Merck KGaA, Novartis, Novo Nordisk, Pfizer and Roche. This suggests that accelerating the filing process for registration in low- and middle-income countries may not be a priority for these companies, a business practice that delays access to the newest

IN BRIEF

- The Index analysed pricing strategies for 1,036 products, and examined registration filings for 187 products.
- Only 21% of products analysed are being widely registered in countries where greater access is urgently needed.*
- Most companies (16) now make at least a general commitment to take affordability into account when setting prices.
- The use of equitable pricing is expanding: from 33% of products in 2016 to 43% in 2018.
- Almost three quarters of equitable pricing strategies now set prices for specific populations, rather than at the national level.
- 6 companies report improving how they adapt their brochure and packaging materials to meet local needs.

*The 2018 Index examines registration filings for of a maximum of ten of each company's most recently approved products for diseases in scope.

**Priority countries are disease-specific subsets of countries with a particular need for access to relevant products (see Appendix VI).

medicines in the countries that need them the most.

Where are products registered?

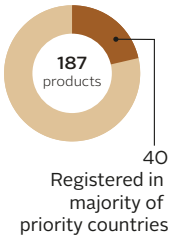
The Index asked companies to report registration data on a maximum of ten of their newest products for diseases in scope. The Index then looked exclusively at whether companies report filing these products for registration where they are most needed (i.e., in priority countries). The highest standard looked for by the Index is whether products are: (a) filed within a year of their first launch; and (b) filed in priority countries in parallel to the submission for first global registration.

Cumulatively, companies have filed at least one product in under half of the possible priority countries. Of the total number of newly launched products reported to the Index (187), almost a quarter (40) have been filed to register in the majority of corresponding priority countries. Of 20 companies, only 12 have registered a portion of their newest products in the majority of corresponding priority countries (one company fewer than in 2016). These companies are: AbbVie, AstraZeneca, Bayer, Bristol-Myers Squibb, Gilead, GSK, Merck & Co., Inc., Novartis, Novo Nordisk, Pfizer, Roche and Sanofi. Of these 12, Bayer and Roche have both registered 70% of their newest products (7 products each) in the majority of priority countries. Novartis has registered 50% in the majority of priority countries. Novo Nordisk is the only company to register all of its new products in at least one priority country.

However, as in 2016, the 20 companies are collectively missing many opportunities to complete this first step in ensuring availability: most (79%) of the companies' 187 newest products are registered in fewer than half of the corresponding priority countries (compared to 78% in 2016). These new medicines often reflect advancements in treatment options that can better meet the needs of patients. In order to ensure these new products are globally accessible and have the greatest impact on public health, companies should aim to ensure rapid access and uptake through the early filing of products for registration.

There are examples of companies participating in specific initiatives to accelerate the registration process. For example, Johnson & Johnson and Pfizer are both involved in the WHO collaborative registration procedure. Specifically, Johnson & Johnson has disclosed its participation in four pilots of the WHO Collaborative Registration Procedure for products already approved by a stringent regulatory authority (i.e., the European Medicines Agency [EMA]). The initiative facilitates broader regional registration through an expedited process. The pilot focused on the registration of etravirine (Intelence® [25 mg tablet]), darunavir (Prezista® [400 mg tablet], [oral suspension]) and bedaquiline (Sirturo® [100 mg tablet]) in several low- and middle-income countries in sub-Saharan Africa (SSA). Similarly, Roche is involved in the Emerging Markets Project, which aims to support local health authorities in low- and middle-income countries to expedite the registration process. The implementation of the newly announced African Medicines Agency may also advance efforts to accelerate the registration of products in Africa through the harmonisation of registration standards across the continent.

21% of new products have been filed to register

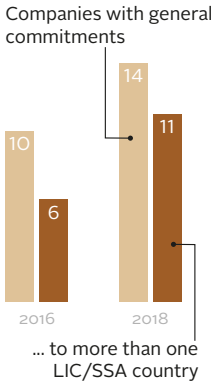


Who reports where products are filed for registration?

In 2018, seven companies share at least some information with the public about the registration status of particular products for diseases in scope, including Eisai, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc., Sanofi and Takeda. Of these, only GSK and Gilead provide detailed information for the majority of their products. Gilead publishes the most detail, providing information including registration status, country registration and registration dates. Eisai, GSK, Sanofi and Takeda have all published additional information since 2016. Merck & Co., Inc. publishes the registration status of some medicines online, including a country list and original approval date. Johnson & Johnson publishes information about the registration status of the majority of its products that target diseases and countries in scope. However, it only provides the country and product name, disclosing only partial information about the majority of its products. Best practice requires companies to disclose detailed information, including registration status, a complete list of country registrations and the date products were approved in each country for all or most products.

The remaining 13 companies do not publish any of this information. Some make it available on request or to specific health authorities. By publishing the registration information of products — a process that requires few company resources — companies may be provided with a broader market share due to additional interested purchasers.

General commitments to register products in LMICs up 20%



7 companies disclose registration data:

- Eisai
- Gilead
- GSK
- Johnson & Johnson
- Merck & Co., Inc.
- Sanofi
- Takeda

PRICING

What is an equitable pricing strategy?

Affordability is a key barrier to access in many low- and middle-income countries. Pharmaceutical companies have a responsibility to commit to and then develop strategies for pricing products

equitably, in order to ensure medicines are affordable for populations in need and not only the wealthy. When setting prices – whether at the individual country level, or for populations within a country – companies are expected to take account of the ability of the purchaser to pay for the product.

The Index has examined how companies consider affordability when setting prices and for how many of their products. It has also looked at where companies apply equitable pricing strategies. For this analysis, companies must provide proof of implementing their strategies by providing price and sales data for their products.

Companies' commitments to improve affordability needs momentum

In 2018, 16 companies make at least a general commitment to taking affordability into account through the application of equitable pricing strategies to a subset of products when setting prices, specifically for people living in low- and middle-income countries. However, the net number of strong commitments is down (from 19 in 2016), and only two companies, Takeda and AstraZeneca, improved the quality and detail of their commitments since 2016. Sanofi and Bayer did not publicly disclose any commitments to equitable pricing in 2018. AstraZeneca makes the broadest commitment, publicly committing to applying equitable pricing models for diseases in scope for which it has products on the market. It specifically covers products for respiratory and cardiovascular diseases with its intra-country strategies and commits to applying them in the majority of countries in scope. The commitment explicitly applies to future products. This is an extension of its previous pledge (i.e., to apply equitable pricing strategies to a minority of its products).

How the Index compares pricing strategies

The Index does not measure whether medicines are affordable: affordability is a measure of each individual's capacity to pay out of pocket for medicines in the private sector with no health insurance, as well as the capacity and budget of government-run health systems and organisations. Instead, the Index explores how pharmaceutical companies consider affordability when setting prices. To make this assessment, it looks at whether companies take specific socioeconomic factors into account when setting prices and for which products. The Index examines two types of equitable pricing strategies with pricing segmentation: inter-country, where one price is set per country; and intra-country, where prices are set for different populations or sectors within a country. The latter is considered most sensitive to people's ability to pay and is more likely to improve affordability. Price segmentation between populations in this way can help open up markets previously believed to be unprofitable. The Index also focuses on whether equitable pricing strategies are being applied in the countries with the highest burden and lowest ability to pay (i.e., in priority countries).

Needs-based pricing has increased

Overall, the proportion of products with equitable pricing strategies has grown from 33% (in 2014 and 2016) to 43% (this represents 447 products out of 1,036, compared to 280 out of 850 in 2016).

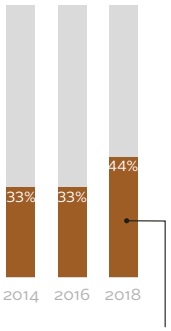
Out of 447 products with equitable pricing strategies, there are 40 oncology products, including 21 covered by strategies that are most sensitive to affordability (i.e., intra-country pricing applied to at least one priority country and with at least one socioeconomic factor considered). Increasing the number of equitable pricing strategies for cancer products is an important step in improving access to affordable cancer care globally. Cancer is newly in scope for the Index in 2018. Even when accounting for the corresponding increase in products in the 2018 analysis, the growth in equitable pricing strategies from 2016 remains significant, at an 11% increase.

Of the 20 companies' most recently launched products, 40 have been filed to register in the majority of possible priority countries. Of these, 22 (55%) have equitable pricing strategies. Overall, and in comparison to 2016, the use of needs-based equitable pricing strategies has improved from 5% to 18%. In 2018, a total of 189 out of 1,036 products (18%) are covered by strategies that: (a) set different prices for different population segments within a country (intra-country equitable pricing); (b) take multiple socioeconomic factors into account when setting prices; and (c) target at least one priority country. Three companies account for 53% of these strategies: Boehringer Ingelheim, Gilead and Novartis.

50% of pricing strategies consider affordability

Almost 50% (447 out of 1,036) of products on the market for diseases in scope are covered by at least one equitable pricing strategy. Of these equitably priced products, 72% (or 324) of strategies apply to priority countries. On average, the strategies for each of these 324 products target just four priority countries. Looking across all 324 products with equitable pricing strategies, companies target on average only 28% of the priority countries.

Products covered by equitable pricing over the years



47 diseases have been in scope since 2014. 44% of products for these diseases have equitable pricing strategies.

Almost three quarters of equitable pricing strategies in 2018 are intra-country equitable pricing strategies (71%, or 317 products). This is a marked rise since 2016 (34%) and 2014 (29%) that cannot only be attributed to the new inclusion of cancer products in this analysis in 2018. Out of the 317 products with intra-country equitable pricing strategies, 29 are for oncology products. The increase in intra-country equitable pricing strategies is strongly accounted for by the five companies that lead in this Technical Area: AstraZeneca, Gilead, GSK, Novartis and Takeda. Together, this group accounts for more than half of all intra-country equitable pricing strategies identified in 2018.

Socioeconomic factors are considered more frequently

Another sign of progress is the growing use in 2018 of socioeconomic factors to inform prices. To ensure affordability, companies need to assess people's ability to pay. This depends on the applied use of multiple socioeconomic factors. Best practice for setting prices is to pay particular attention to such factors and to apply them to prices, with the goal of increasing affordability and access.

The 20 companies are taking such factors into account when setting prices for more products than in 2016: 189 products are linked to intra-country equitable pricing strategies in at least one priority country, that take at least one socioeconomic factor into account, up from 44 products in 2016. Looking at intra-country equitable pricing strategies only, in 2018, 60% of strategies take at least one socioeconomic factor into account (up from 46% in 2016). The factor considered most commonly is disease burden, followed by how the healthcare system is financed and the level of economic and human development. On average, the 20 companies are considering three factors when determining prices (in 2016, this average was 0.7). Takeda stands out with nine equitable pricing strategies that each take five socioeconomic factors into account: disease burden/prevalence, level of inequality, type of healthcare system, public financing systems and cost analysis.

Three companies have provided evidence of the use of specific tools to better determine differential pricing within different populations in individual countries. In 2016, AstraZeneca conducted an in-depth analysis of the abilities of different population segments in a subset of countries to pay for its products. In 2018, the same company provided evidence of the implementation of its Mosaic Segmentation approach, which includes using detailed economic patient profiles based on data provided by an independent third party. It applies this approach to products, for example, for hypertension in Brazil, one of many countries with large socioeconomic disparities and one where many patients pay for medicines out of pocket (Best Practice, see page 90). Takeda has developed a tool for assessing a patient's financial eligibility (ability to pay) through a third party called Axios, which uses a patient financial eligibility tool (PFET) to develop an assessment of patients' ability to pay. This process facilitates prices that better meet individual affordability considerations for patients paying out of pocket for otherwise out-of-reach medicines. Takeda uses this tool to determine prices for expensive products for Hodgkin's lymphoma and inflammatory bowel disease in countries in scope including the Philippines, Thailand and Ukraine. Novartis developed its latest framework – Potential Affordability by Decile methodology – to determine price segmentation and develop patient access programmes for countries in scope. The methodology takes into account income levels by deciles of population and the impact of mark-ups and taxes on ability to pay out of pocket. This granular approach to determine patients' ability to pay has facilitated the development of patient access solutions to decrease mark-up impact and patient support programmes to help improve affordability.

3 factors considered the most when setting prices

- Disease burden
- Healthcare system financing
- Level of economic and human development

Priority country coverage varies widely

While more products are covered by equitable pricing strategies than in 2016, such strategies are in general still not being widely applied in all possible priority countries, which is likely severely restricting access for many patients in need.

There remains significant variation between companies in how broadly they apply equitable pricing strategies in priority countries. For example, in 2018, 17 of Gilead's 18 products for diseases in scope (specifically for hepatitis C and HIV/AIDS) are covered by equitable pricing strategies that all apply in all of the corresponding priority countries. However, six other companies have linked either very few or none of their products for diseases in scope to an equitable pricing strategy that covers a priority country.

MANUFACTURING & DISTRIBUTION

Improvement in manufacturing and distribution practices

In this Technical Area, the Index also looks at companies' manufacturing and distribution practices. It examines three types of behaviour: firstly, whether companies have policies, procedures and resources in place to carry out effective drug recalls; secondly, whether companies facilitate appropriate

use by practitioners and patients by adapting brochures and product packaging; and thirdly, the Index asks how companies support the alignment between supply and demand in low- and middle-income countries.

To protect patients from risks associated with product quality and adverse reactions, companies must carry out product recalls effectively and to stringent standards in low- and middle-income countries. The 2018 Index finds that all 20 companies either improved or maintained the standard of their drug recall systems in the countries in scope. Eight companies now disclose the use of specific tools to track products through the supply chain, specifically in countries in scope of the Index, up from four in 2016: AstraZeneca, GSK, Merck & Co., Inc. and Sanofi were joined by Boehringer Ingelheim, Merck KGaA, Pfizer and Roche in 2018. All companies now have guidelines for drug recalls, which apply to all countries in the scope of the Index where companies have products available.

Companies have a responsibility to support different populations in understanding how to use medicines appropriately. In 2018, GSK performs best in this regard, followed by Johnson & Johnson and Novartis. These companies each adapt materials to meet a range of needs, including language, literacy and cultural (such as halal labelling in predominantly Muslim countries) needs; demographic considerations (such as larger print that is easier to read for older populations); and environmental considerations (such as heat stable packaging). These three companies also aim their adaptations to different levels of the health system, from the dispensary to the healthcare practitioner to the patient. GSK leads the group, as it is the only company to provide evidence of brochure and packaging adaptations that meet all five relevant needs and at various levels of the health system. Six further companies report improvements to how they adapt their materials since 2016 (Bristol-Myers Squibb, Daiichi Sankyo, Gilead, Roche, Sanofi and Takeda). Namely, these companies now make a broader range of adaptations than before.

The Index finds that more than half of the companies are making proactive efforts to align supply with demand in countries in scope. Such efforts can help ensure product integrity, improve production timelines and prevent stock-outs. Specifically, 10 companies (AstraZeneca, Bayer, Eli Lilly, Gilead, GSK, Johnson & Johnson, Novartis, Pfizer, Sanofi and Takeda) have systems in place to align global, regional and country-level supply planning processes with demand for all of the products they market in countries in scope. This system involves 1) making efforts to understand product distribution and demand behaviour in countries in scope, beyond the point of first product handoff; 2) applying this information to ensure sufficient, timely supply to these countries; and 3) specific efforts to address supply to Least Developed Countries (LDCs), low-income countries and/or poor and rural population segments in countries within the Index scope. One company, Merck & Co., Inc., meets the aforementioned criteria but for a subset of products. The other nine companies do not demonstrate specific efforts to address supply to LDCs, low-income countries and/or poor and rural population segments in countries within the Index scope.

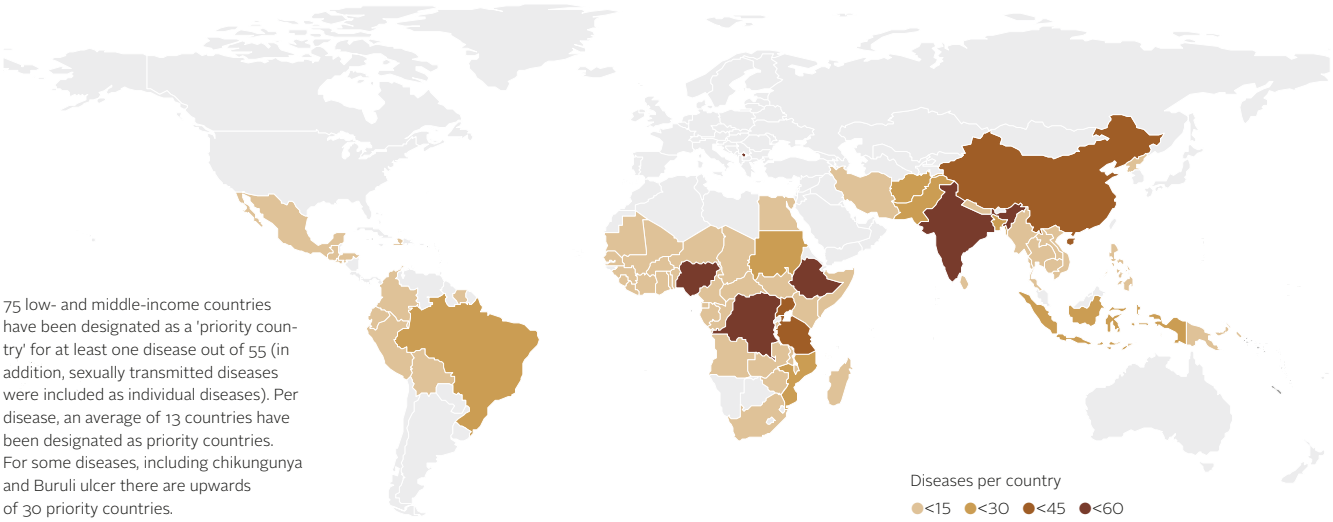
REGISTRATION

Which countries benefit from rapid registration filings?

A product can only be marketed in a country once it is registered for sale. Companies must take this step as rapidly as possible – particularly if a product is innovative or superior to those already on the market. The Index looks for companies to file new products for registration widely and rapidly across low- and middle-income countries, starting where the need is the highest. As the first step in making a product available, registration leads to improved and more equitable access to treatment options and helps prevent disease outbreaks of epidemic and pandemic proportions. It can also enable the improved collection of global epidemiological data, increase global market size and improve market competition.

Figure 35. Which countries urgently need the most products to be registered?

The map shows which countries urgently need the most products to be registered. The darker the country, the more diseases have been identified as being of particular concern to people living there.



75 low- and middle-income countries have been designated as a 'priority country' for at least one disease out of 55 (in addition, sexually transmitted diseases were included as individual diseases). Per disease, an average of 13 countries have been designated as priority countries. For some diseases, including chikungunya and Buruli ulcer there are upwards of 30 priority countries.

▸Defining 'priority countries'

Priority countries are defined by the Index for each disease covered by the scope of the Index. The Index uses these lists to indicate countries with a greater need for improved access to products, per disease, based on data from WHO or the Institute for Health Metrics and Evaluation, adjusted for multi-dimensional inequality, or based on World Bank classification as a low-income country (see Appendix VI).

Figure 36. Five priority countries with the most registration filings

This chart shows the priority countries with the most registration filings. Most products are filed for registration in countries with growing populations and economies.

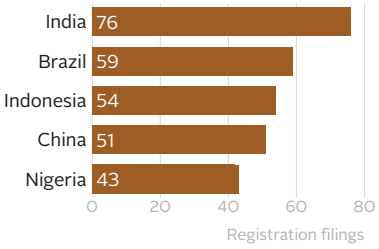
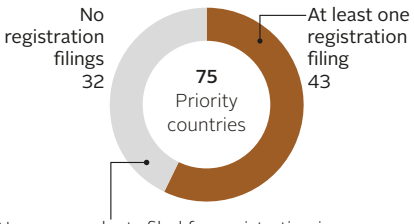


Figure 37. 43% of priority countries lack registration filings

The Index identified 75 countries as being a priority country for at least one disease. 32 of these countries received no registration filings for products for corresponding diseases.



No new products filed for registration in 13/46 sub-Saharan African (SSA) countries in scope. The 150 million people living in these 13 countries do not have access to any new products for priority diseases.[2]

Products analysed: the registration filings of a maximum of ten of each company's most recently launched products for the diseases in scope (187 products; most reached the market since 2008; most are for non-communicable diseases, mainly diabetes and cancer)

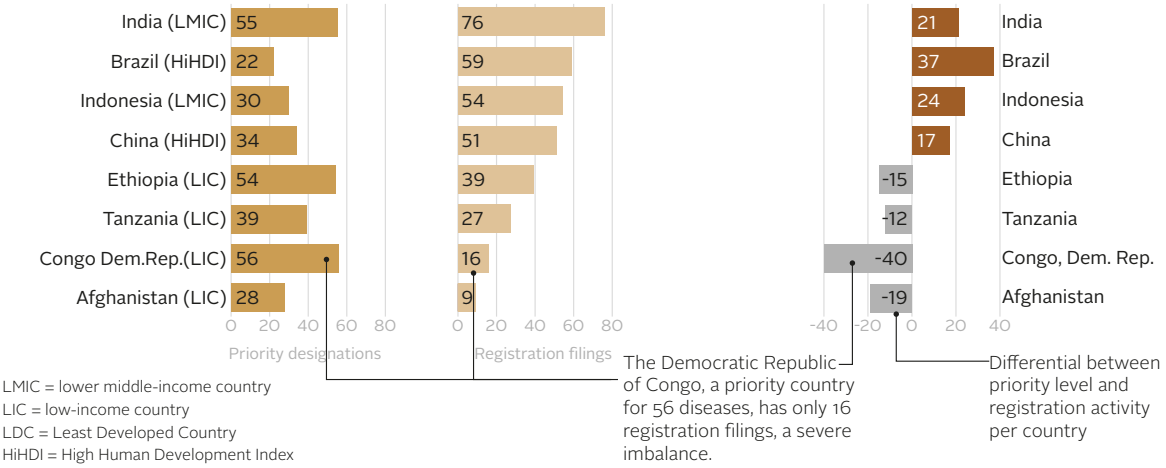
Figure 38. Poorer populations have fewer registration filings

Countries with higher income classifications, including India, generally benefit from more product registrations than lower-income countries, such as the Democratic Republic of Congo. This is despite both being priorities for similar numbers of diseases.

Priority level per country
This chart shows how many times each country is flagged as a registration priority for a specific disease.

Registration activity per priority country
This chart shows how many products have been filed in each priority country.

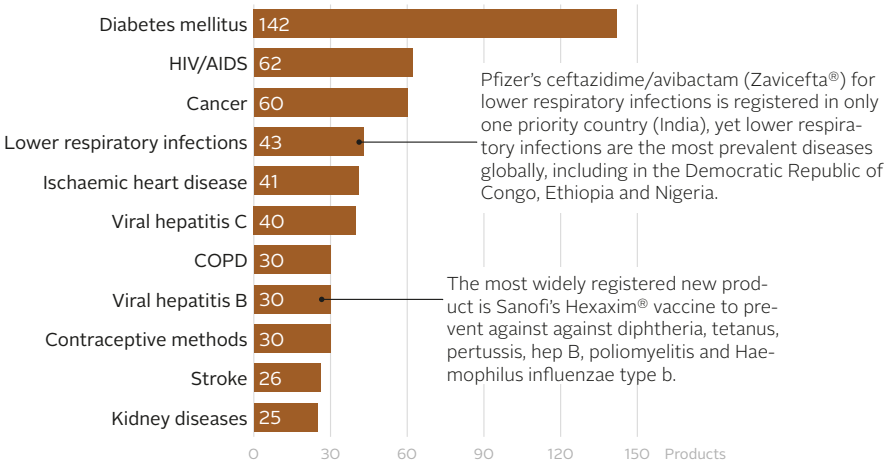
Comparing priority level with registration activity
The chart shows the gap between priority level and registration activity per country. Countries with larger negative differences have a greater imbalance between their need for better access to medicine and the level of products registered there.



LMIC = lower middle-income country
LIC = low-income country
LDC = Least Developed Country
HiHDI = High Human Development Index

Figure 39. New diabetes products filed most widely in priority countries

The chart shows the diseases with the most new products filed for registration in at least one priority country. Diabetes has the most, with 142 filings.



Disincentives to registering products

- Country regulatory systems in need of significant capacity building
- Local regulatory requirements (e.g., local clinical trials and a need for originator product dossiers)
- Poor healthcare infrastructure
- Low volume markets
- Generic equivalents already on the market
- Political instability or conflict
- Economic sanctions

Methods of encouraging registration

- *WHO Collaborative Registration Procedure:* Expedites registration by supporting multiple regulatory authorities.
- *WHO Prequalification:* An alternative route for medicines procured through the UN system for selected diseases.
- *Article 58 (EMA):* Assists regulatory authorities with standard scientific assessments of dossiers.
- *Parallel regulatory submissions:* Companies submit dossiers to both stringent regulatory authorities and health authorities simultaneously.

Many countries in SSA lack swift registration of critical, novel products.

- The newly created African Medicines Agency (AMA) may help expedite the registration process across the continent. Additionally, a coalition of partners established the African Medicines Regulatory Harmonization (AMRH) programme in 2009 to help improve access to medicine by supporting the regulatory environment in Africa, including increased registration capacity and regulatory collaboration between countries.

EQUITABLE PRICING

How many products are linked to fairer pricing strategies?

Affordability is the cornerstone of access to medicine. Targeted pricing strategies that aim to make products affordable for different population segments – including those who are the most economically marginalised – are a crucial component for increasing access to medicine in low- and middle-income countries. Companies must think in terms of patients' or healthcare providers' ability to pay (here termed 'equitable pricing'). This analysis looks at how companies set equitable pricing strategies that target people in countries where the need for greater access is highest.

Ultimately, affordability depends on who is paying and the constraints they face. It matters for both individual patients paying out of pocket and for governments supporting national health systems, and public sector budgets.

To ensure affordability, companies need to assess the affordability of their products for different population segments. This depends on the consideration of multiple socioeconomic factors, including disease burden, healthcare system spending and level of inequality.

The Index cannot assess the affordability of specific products, but it does assess whether and how pharmaceutical companies pricing strategies are likely to ensure greater affordability.

Figure 40. Almost half of products aim to be more affordable

Almost half (43%) of the products for diseases in scope are covered by equitable pricing strategies.

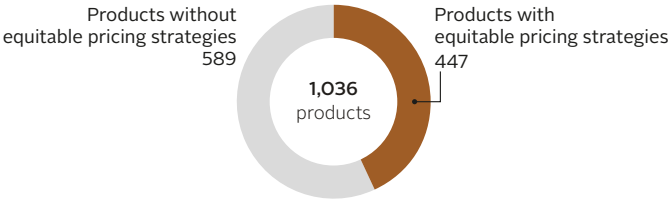
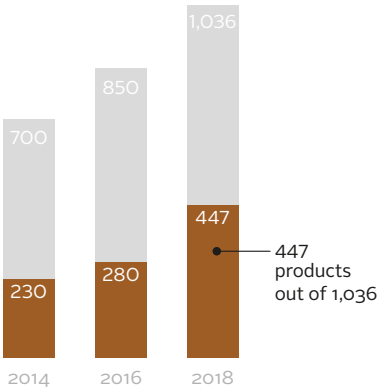


Figure 41. More products are covered by equitable pricing

The proportion of products with equitable pricing strategies has grown from 33% (in 2014 and 2016) to 43%.



▶What is an equitable pricing strategy?

The Index examines two types of equitable pricing strategies:

- Inter-country strategies, where prices are set at the national level based on, e.g., GDP or GNI per capita; and
- Intra-country strategies, where different prices are set within a country for different population segments, e.g., to reflect differences between the private and public sectors. Intra-country strategies are considered more sensitive to people's ability to pay and more likely to lead to lower prices for important products.

Figure 42. Do companies use people's ability to pay to shape pricing strategies?

The figure shows what proportion of equitable pricing strategies meet the different criteria looked for by the Index. One fifth of strategies meet all criteria, including taking at least one socioeconomic factor into account when determining prices. On average, companies are considering three socioeconomic factors when determining prices.

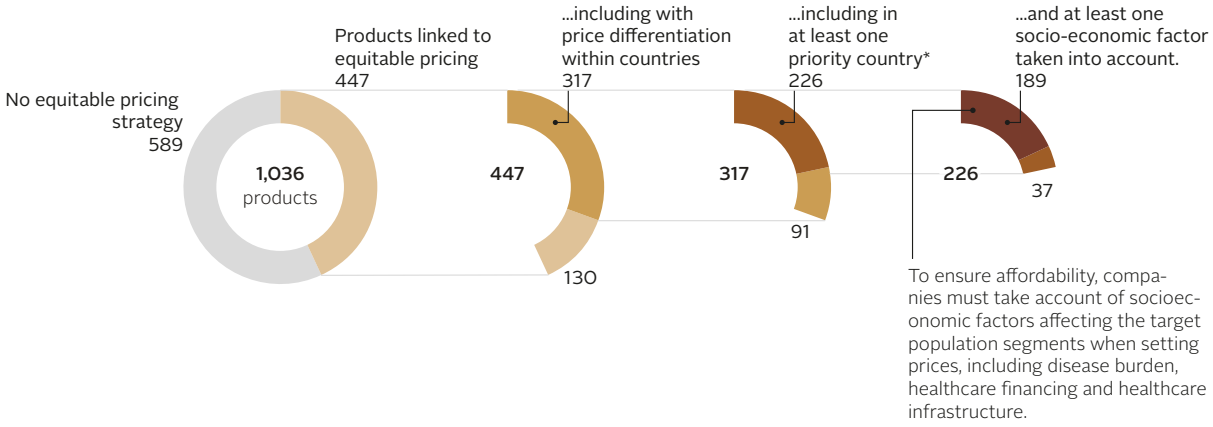


Figure 43. Prices are mostly tailored for emerging markets

The chart shows which countries are covered by more equitable pricing strategies than others. The top three are lower middle-income countries or upper middle income countries with high inequality, representing large markets where some groups have a far higher ability to pay for medicine. Pricing segmentation to ensure affordability for low-income groups is also key.

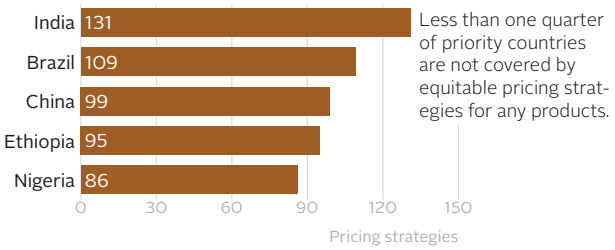
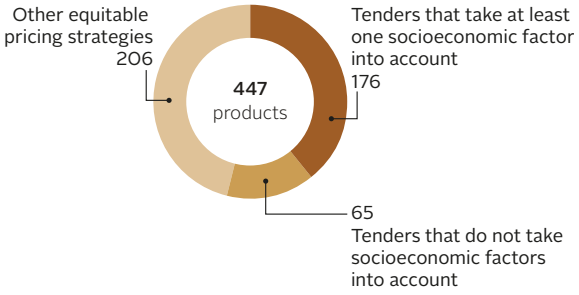


Figure 44. Majority of pricing strategies take the form of tenders

More than half of the equitable pricing strategies identified in 2018 are tenders, which the Index accepts for analysis only when the company reports considering affordability when determining the tender price.



▶Case study: AstraZeneca Mosaic Segmentation

AstraZeneca's new model of price segmentation, the mosaic price segmentation model, employs a third party to determine prices based on individualised socioeconomic profiles. This is an intra-country equitable pricing strategy aimed at improving treatment for heart disease in Brazil, which has a population of 207 million in which inequality is high.[1] The strategy takes multiple socioeconomic factors into account when setting prices for products to treat the disease and creates a variety of price points for various segments of the population (Best Practice, see page 90) .

▶How do tenders impact prices?

A pharmaceutical tender is a method used by governments or other agencies to procure large amounts of medicines or vaccines from particular companies. Issuing a tender typically begins with selecting qualified and interested suppliers based on a variety of factors including price, availability and proposed delivery terms. Open tenders facilitate bidding by all interested suppliers, helping to produce lower prices. Restricted tenders limit this negotiation and are issued, for example, when public health emergencies require immediate procurement. Tenders can help governments and global health stakeholders achieve significant price discounts. However, they do not always promote affordability, particularly when negotiating conditions are limited.

*Priority countries are disease-specific subsets of countries with a particular need for access to relevant products (see Appendix VI).

ACCESS TO KEY PRODUCTS

How do companies use pricing, licensing and donations to improve access to key products?

Low- and middle-income countries are home to the majority of the world's poorest people. Whether medicines, vaccines and other products reach the people who need them in these countries depends on the choices companies make when making them available. The three main tools available to a pharmaceutical company for improving access to specific products are: equitable pricing strategies, licensing and product donations. This section looks at how companies use these tools to make specific products more available, accessible and affordable.

Figure 45. How many products in scope are on-patent, first-line therapies and on the WHO EML?

The diagram shows how many products in the Index analysis fall into specific categories: first-line therapies, products on the 2017 WHO Model List of Essential Medicines (WHO EML) and products that are on patent. Ensuring access to first-line therapies – particularly if they are on the WHO EML and target high-burden diseases – is a priority for healthcare authorities.[3]

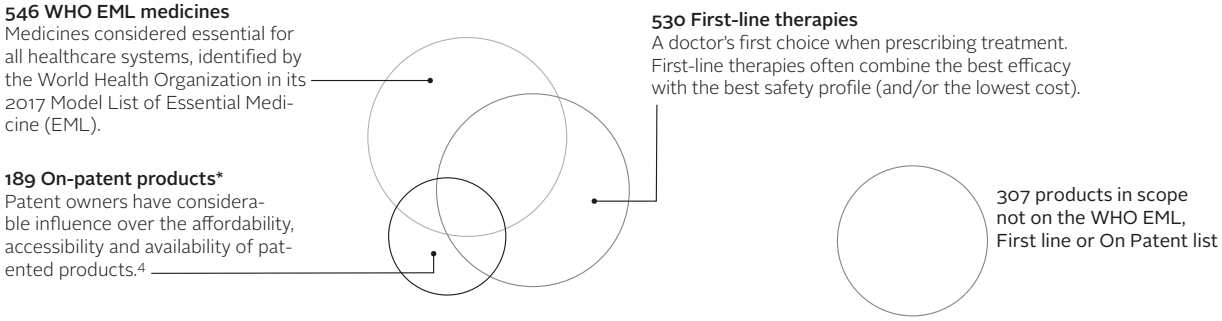
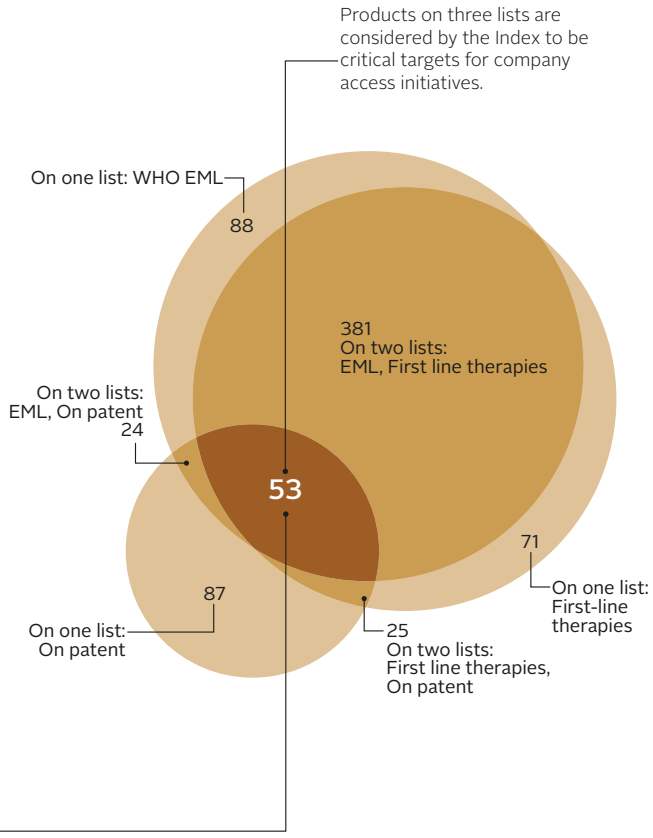


Table 3. No. of on-patented products that are...

Company	On the WHO EML	On the EML and first-line therapies
AbbVie	5	2
Astellas	1	1
AstraZeneca	3	2
Bayer	3	3
Boehringer Ingelheim	1	0
Bristol-Myers Squibb	3	2
Daiichi Sankyo	1	1
Eisai	0	0
Eli Lilly	1	1
Gilead	6	4
GSK	25	21
Johnson & Johnson	4	1
Merck & Co., Inc.	10	5
Merck KGaA	0	0
Novartis	3	1
Novo Nordisk	0	0
Pfizer	5	4
Roche	2	1
Sanofi	3	3
Takeda	1	1
Total		**53**



**The numbers used for this analysis include unique product counts. Patented products developed and marketed by multiple companies, were only counted once in this Venn diagram. When analysing the total number of access initiatives covered by products in the Index (1036), individual companies are evaluated for their respective access initiatives for a given product for which they have marketing rights. Patent status is determined based on data available from the US FDA and Health Canada. See Appendix IX.

Figure 46. First-line therapies on the WHO EML: more than half have access initiatives

The Index analyses 1,036 products for the diseases in scope, including 438 that are are first-line therapies on the WHO EML. Of these, just over half (55%, or 240) are supported by at least one company access initiative.

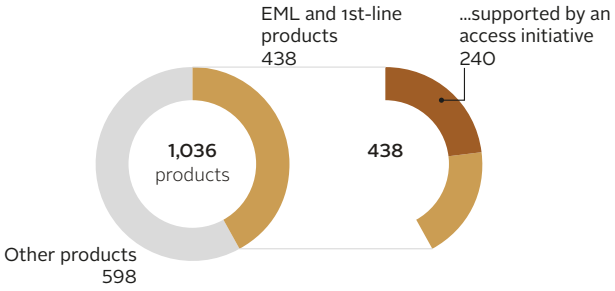
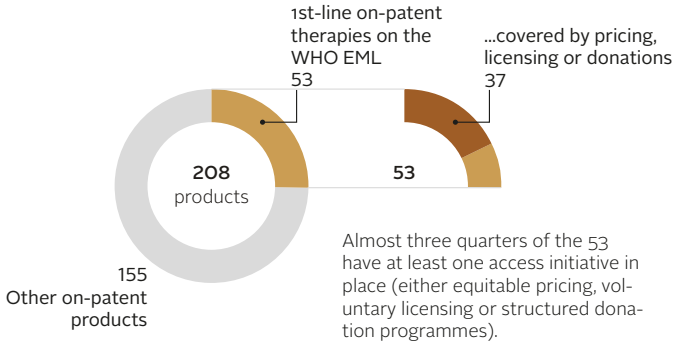


Figure 47. On-patent, first-line therapies on the WHO EML: 70% have access initiatives

Out of the 1,036 products evaluated by the Index, 208 are on patent. Of these, 53 are also first-line therapies on the WHO EML, making them critical targets for company access initiatives.

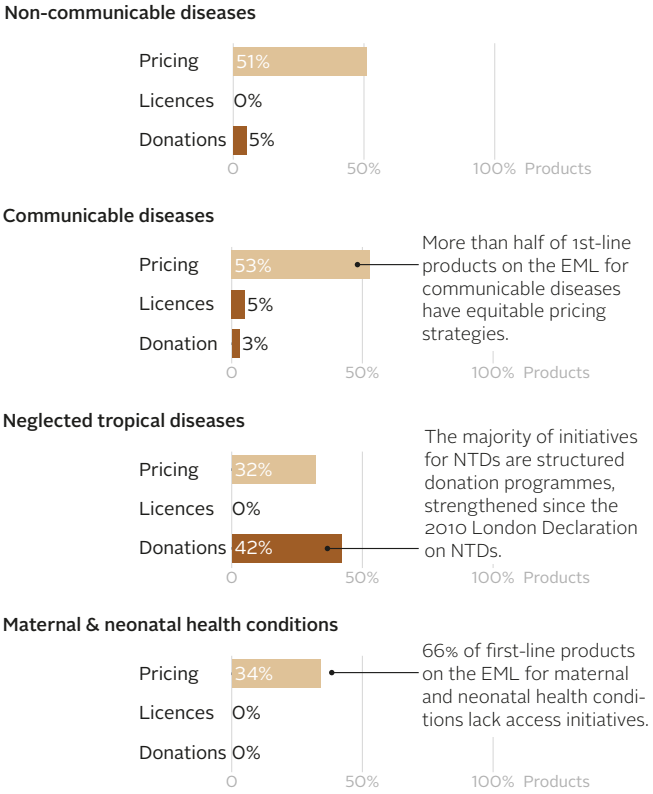


Almost three quarters of the 53 have at least one access initiative in place (either equitable pricing, voluntary licensing or structured donation programmes).

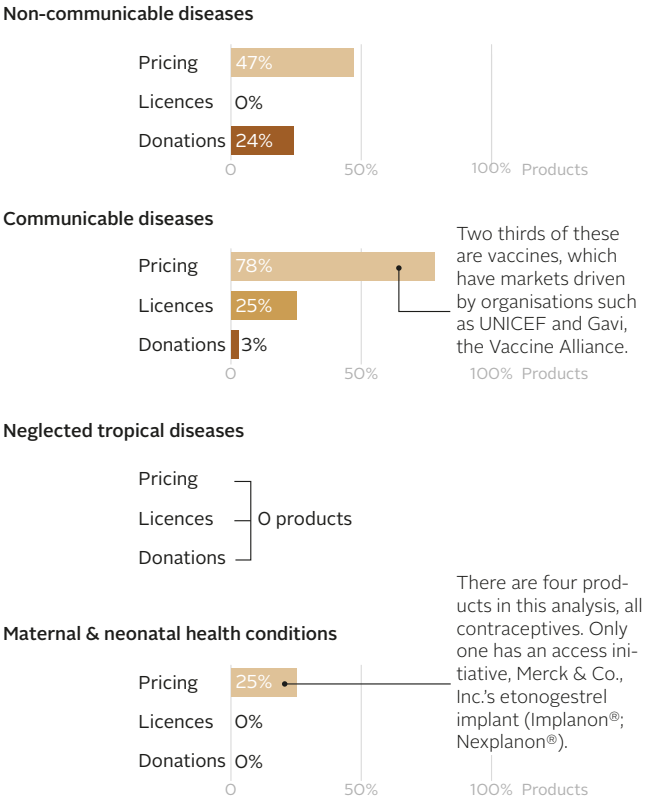
Figure 48. Pricing strategies are used most widely in all disease categories

The charts compare the coverage of different access initiatives across products for diseases in different categories. Equitable pricing strategies are used most widely in all categories. Non-exclusive voluntary licences have only been granted for communicable disease products (for HIV/AIDS or hepatitis C). Products for maternal & neonatal health conditions have the lowest coverage of access initiatives.

Coverage of first-line products on the EML (438)



Coverage of on-patent, first-line products on the EML (53)



▶Equitable pricing strategies
Companies take affordability into account when determining prices for different population segments.

▶Voluntary licensing agreements
Give generic manufacturers (non-exclusive) permission to develop and manufacture versions of on-patent products under transparent and access-friendly terms, which can support affordability.

▶Product donation programmes
Donations that align with international guidelines and respond to specific, local need for greater access.

During the period of analysis, no access initiatives were recorded for glecaprevir/pibrentasvir (Mavyret™). However, in November of 2018 AbbVie announced the application of a non-exclusive voluntary licence to support extended access to glecaprevir/pibrentasvir through the Medicines Patent Pool.

PRICING, MANUFACTURING & DISTRIBUTION

Best Practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations.

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness,
- Sustainability,
- Replicability,
- Alignment with external standards/ stakeholder expectations.

The 2018 Index identified three best practices in this area, from three companies. No innovative practices were identified.

ASTRAZENECA

Sophisticated pricing model tailors discounts to population groups

BRAZIL

Customised approach to assigning discounts to patients based on ability to pay (called Mosaic Segmentation).

In low- and middle-income countries, affordability remains a significant issue and barrier to people gaining access to medicine. Patients must often self-fund their healthcare from limited incomes, and many rely heavily on privately funded health services. Governments and insurance companies do not always cover the full cost of treatment, yet most people cannot afford out-of-pocket (non-reimbursed) expenses themselves.

How can companies improve price setting for countries in scope?

Pharmaceutical companies can help increase access to medicine for populations that could not otherwise afford them by using economic data and socioeconomic factors when setting prices. This information can be used to determine a variety of price points for different sub-groups that are intended to be affordable.

To address these issues, AstraZeneca is finding ways to accomodate people's unique ability to pay. It is using differential pricing via a customised approach called Mosaic Segmentation.

What makes this a best practice?

One key element of this approach is to use economic data to compile a set of profiles for different segments of the population. This enables the programme to assign each patient, on registration, a discount level that is more likely to match their ability to pay.

Since February 2016, AstraZeneca has worked with Experian, a data provider, to develop and implement its model in Brazil, helping to increase affordability for 150,000 patients in need of medicines for hypertensive heart disease. This model is a sophisticated intra-country equitable pricing strategy that applies to an in-scope country, for at least one in-scope disease, identified by the 2018 Access to Medicine Index.

The initiative was recognised as innovative by the 2016 Index. Back then, the project was in an early phase, and few details were publicly available. Since then, the initiative has been included in AstraZeneca's public Access to Healthcare report, with progress recorded. The Index recognises it as a highly refined intra-country equitable pricing model that now represents current best practice.

GILEAD

Strong transparency on where products are registered

GLOBAL

Only company to publish full details of the registration status of its products. A comprehensive list is available on the company's website.

Companies that provide detailed information about where their products are registered offer a key method of evaluating the scope of potential access to those products. Information can help others to determine whether products are likely to be available in specific countries and if new products are registered soon after first global market launch. It can also give generic medicine manufacturers and regulatory health authorities a better understanding of the geographic extent of a product's availability.

Only company to publish registration status of products

The Index examines whether pharmaceutical companies publicly disclose the registration status for most (and ideally all) of their products in scope. Even so, Gilead is the only company to publish full details of the registration status of the majority of its products in scope of the Index, including registration information for priority countries.

On its website, for example, it publishes a clear list of details for products corresponding to HIV/AIDS, hepatitis C and visceral leishmaniasis. This allows stakeholders to see which products are available in which countries. It shows whether products have been filed for registration or approved for market use by local health authorities or regulatory bodies.

What makes this a best practice?

The initiative first received credit in 2016 as a best practice. Two years on, Gilead is again the only company to provide this level of detailed information about registration status for the majority of its products in countries in scope. As the initiative places few strains on resources and capacity, it appears highly sustainable.

TAKEDA

Commits to registering new products in poorer countries within 12 months.

GLOBAL

Parallel dossier preparation to facilitate faster registration.

The registration of newly launched products typically occurs less commonly in lower-income countries than in higher-income countries with larger markets. Yet, without a product being registered for sale in a country, it cannot be made available to the people who live there. This can adversely affect the health of people who need new products the most. Conversely, if a company commits to filing to register new products as soon as possible, this can accelerate the rate at which people get the medicines they need.

How does Takeda's registration commitment compare to peers?

The Index examines whether companies commit to filing to register recently launched products in countries in scope of the Index within 12 months of the first global product launch. Companies including Johnson & Johnson and Pfizer are participating in the World Health Organization's collaborative procedure to help expedite the registration of some of their products in some countries in scope of the Index. However, Takeda's overall commitment to filing to register new products is the strongest of all companies examined. It commits to prioritising and expediting the registration filings of all future products in all countries in scope in parallel to the first global market launch.

Expedited registration in Takeda's case involves working proactively to prepare new product dossiers in parallel with dossiers for major markets. To enable this parallel filing strategy, Takeda has incorporated local and regional registration requirements for emerging markets into global development plans and works to address those requirements earlier in the development of new drugs.

What makes this a best practice?

Takeda is the only company to make an explicit commitment via the Index to partake in the parallel registration of new products. It strives to shorten the time taken to file to register its products, with the potential to achieve registration within 12 months or less, wherever possible. These products include a dengue vaccine, which is in Phase III, a norovirus vaccine for diarrhoeal diseases in Phase II and a Phase II antimalarial in collaboration with the Global Health Innovative Technology Fund (GHIT) and the Medicines for Malaria Venture (MMV).

The new initiative, launched in 2018, is part of Takeda's global strategy. Working with key partners such as local health authorities and WHO, it aims to achieve approval for all countries in parallel to receiving its first major regulatory approval (for example, from the FDA or the EMA) for a product. If implemented, Takeda's commitment would help populations in countries in scope to benefit from faster access.

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E Patents & Licensing

CONTEXT

How companies manage their intellectual property (IP) impacts the availability and affordability of medicines, most significantly when they facilitate generic medicine manufacturers in bringing cheaper versions into new markets. This impact has been demonstrated by the game-changing engagement between R&D-based manufacturers and generic medicine manufacturers in the global market for HIV/AIDS medicines.[1] Pharmaceutical companies have an obligation to manage their IP rights responsibly, to ensure they do not limit access to medicine for poor and vulnerable populations.

HOW WE MEASURE

The Index conducts an independent review of the patent status of medicines in scope, based on a methodology that includes a review of the FDA Orange Book and Health Canada registration data. The Index validates data submitted by companies against information that is publicly available about: patent filing/enforcement policies; patent status in low- and middle-income countries; and the quality and geographic scope of licences. The Index conducts an independent analysis of judgements and settlements reached for breaches of competition law, and any other instance where the fair entry of generic competition has been hindered.

WHAT WE MEASURE

The Index measures four central ways companies can manage IP responsibly:

1 **Responsible patenting policies:** do companies publicly pledge to waive or not enforce patent rights in low- and middle-income countries, including for products that have not yet reached the market?
2 **Patent transparency:** do companies publish the patent status of products in all countries in scope?
3 **Voluntary licensing:** do companies issue licences on terms that promote access, for example by granting licensees permission to source active ingredients from any supplier?
4 **Trade policy:** company approaches to internationally agreed flexibilities for intellectual property (IP) intended to safeguard public health.

TOP INSIGHTS

▶ The majority of companies improve in at least one area, particularly around the public disclosure of patent information.

▶ 15 companies make a public commitment not to enforce patents in Least Developed Countries and low-income countries, up from 13 companies in 2016.

▶ As in 2016, seven companies use non-exclusive voluntary licences or non-assert declarations to enable generic versions of their products.

▶ Public disclosure of patent status information has improved significantly since 2016, with 17 companies placing such information in the public domain.

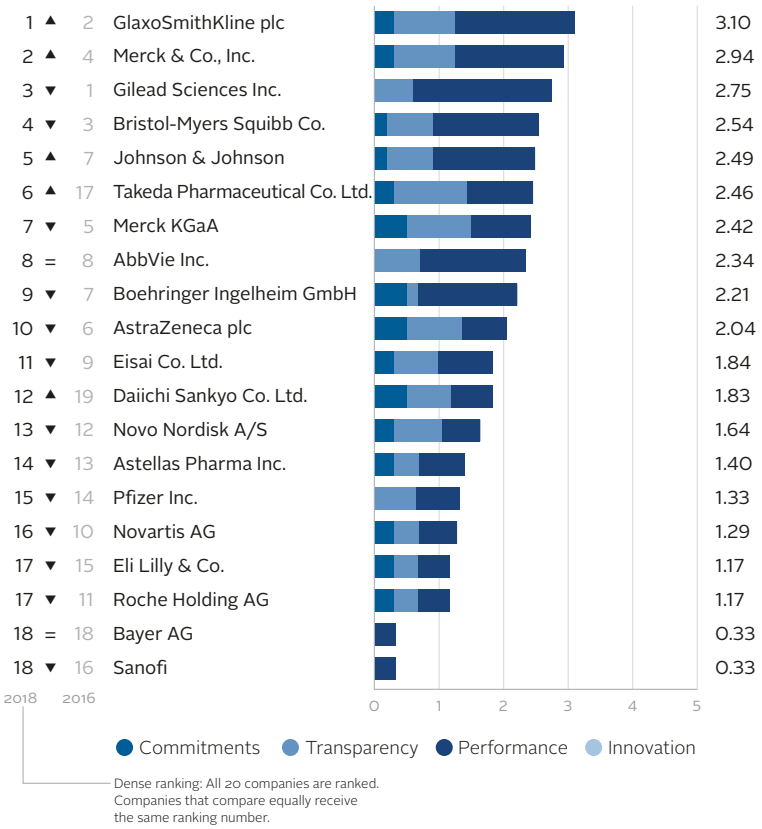
IN THIS CHAPTER

HOW COMPANIES COMPARE

Top four companies lead through broad licensing approaches

- GSK, Merck & Co., Inc. and Gilead take the top three ranks with marginal differences in score.
- The companies divide into five clusters: three clear leaders, followed by three clusters in the middle, and a lagging group of two.
- Companies that engage in licensing either through non-exclusive voluntary licensing or non-assert declarations continue to lead.
- The majority of companies improve in at least one area, particularly around the public disclosure of patent information.

Figure 49. Company ranking: Patents & Licensing



Leaders issue licences with wide geographic scope and pro-access terms

GSK, Merck & Co., Inc., Gilead and Bristol-Myers Squibb lead for different reasons, but all have broad licensing approaches. Merck & Co., Inc. moves into 2nd place.

Leaders issue non-exclusive voluntary licences with comparatively wide geographic coverage and more licence terms that promote access to the specific product. Agreements are disclosed publicly.

GSK (1st) licenses abacavir (Ziagen®) and dolutegravir (Tivicay®), both first-line treatments for HIV/AIDS on the WHO EML, through the Medicines Patent Pool (MPP).

Merck & Co., Inc. (2nd) licenses the paediatric formulation of raltegravir (Isentress®) a second-line treatment for HIV/AIDS on the 2017 WHO Model List of Essential Medicines (WHO EML), through the MPP.

GSK and Merck & Co., Inc. both have a public policy of not filing for or enforcing patents in Least Developed Countries, and both disclose patent information via Pat-INFORMED.

Gilead (3rd) licenses all its on-patent products for diseases in scope, both directly with generic manufacturers and via the MPP. However, unlike the two leaders, it has no public policy of not filing for or enforcing patents, and shares no public position regarding the TRIPS agreement.

Bristol-Myers Squibb (4th) has non-exclusive voluntary licensing agreements in place for two compounds for diseases in scope. Its broadest licence, for atazanavir sulfate (Reyataz®), encompasses 97 countries including 66 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

While licensing progresses slowly, patent transparency leaps forward

There have been few improvements in licensing since 2016. Two new compounds have been licensed, and licensing practices remain limited to HIV/AIDS and hepatitis C.* However, the majority of companies (16) newly disclose patent information

*In November of 2018 AbbVie announced the application of a non-exclusive voluntary licence to support extended access to two additional compounds, glecaprevir and pibrentasvir (MavyretTM) through the Medicines Patent Pool.

via the Pat-INFORMED database.

Takeda and Daiichi Sankyo have risen 11 and 7 places to 6th and 12th, respectively. This is based on a strong shift in transparency regarding their approach to filing for and enforcing patents. Further, both companies publish policy positions relating to such practices in Least Developed Countries, and both publish information about their patents via Pat-INFORMED. They are both engaged in intellectual property (IP) sharing and publicly acknowledge the Doha Declaration.

Roche and Novartis have both fallen six places to 17th and 16th respectively, mainly due to improvements in performance from peers since 2016.

Middle group delivers mixed results

Companies ranked 4th through 9th (Bristol-Myers Squibb to Boehringer Ingelheim) are tightly packed in terms of the scores achieved but exhibit diverse performances. Four of this pack license or issue non-assert declarations (AbbVie, Boehringer Ingelheim, Bristol-Myers Squibb and Johnson & Johnson). The remainder have variable strengths in terms of their public positions on not filing for or enforcing patents in Least Developed Countries, disclosure of patent statuses and whether they publish a position on the Doha Declaration.

Companies in the second cluster (ranks 10 to 13) do not engage in licensing (AstraZeneca, Eisai, Daiichi Sankyo and Novo Nordisk), but have strong public positions on not filing for or enforcing patents in Least Developed Countries, disclose patent statuses and publish their positions on the Doha Declaration.

The third cluster (Astellas, Pfizer and Novartis) have mixed approaches in terms of their public positioning, licensing and levels of patent disclosure.

The lowest ranked companies (Bayer and Sanofi, tied in 18th place) disclose very little information about their patents, licences or approaches to IP management; lack public policies on not filing for or enforcing patents; and have no patent transparency, and no public position regarding the World Trade Organization's (WTO) 2001 Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health.

INDUSTRY ACTIVITY PER TOPIC

Licensing plateaus, while patent transparency leaps forward

How companies manage their IP impacts the availability and affordability of medicines, particularly when they facilitate generic medicine manufacturers in bringing cheaper versions into new markets. This impact has been demonstrated by the game-changing role played by Indian generic medicine manufacturers in the global market for HIV/AIDS medicines.[1]

The Index measures three ways in which companies can manage IP responsibly: whether they are transparent about the patents they hold; whether they have responsible patenting policies; and whether they engage in non-exclusive voluntary licensing.

In 2018, the pharmaceutical industry continues to move slowly towards a more access-oriented approach to managing IP. In this context, 'access-oriented' refers to four issues: (1) whether a company voluntarily licenses its products on terms that facilitate access; (2) transparency about the patents a company holds; (3) a company's public positioning on IP policy; and (4) whether it pledges not to file for and/or enforce patents in a wide range of countries.

DISCLOSURE OF PATENT STATUS

What do we know about which patents companies hold and where?

Compared to 2016, there is a striking shift in the level of transparency about which patents companies hold. Such transparency supports the entry of generic medicines into markets, allowing procurers greater confidence in selecting generic alternatives to patented products. This in turn leads to a larger, more secure supply and more affordable prices. Companies are expected by the Index to disclose complete identifying information about patent status for all products, regardless of type, including information such as patent number, expiry date and jurisdiction.

Today, almost all companies (17; all except Bayer, Boehringer Ingelheim and Sanofi) disclose at least some information about their patents. This is a marked improvement. Only four companies went this far in 2016 (AstraZeneca, Gilead, Merck KGaA and Novo Nordisk).

Of these 17 companies, 15 disclose patent information through the Pat-INFORMED online database, an initiative of the World Intellectual Property Organization (WIPO). This database is intended to provide patent information to support health agencies responsible for medicine procurement.[2] The initial phase of the database, launched online in September 2018, discloses patent information for small molecule products within six therapeutic areas (cardiovascular disease, diabetes, hepatitis C, HIV/AIDS, oncology and respiratory diseases) as well as for products listed on the 2017 WHO Model List of Essential Medicines (WHO EML). In its second phase, the initiative will expand to cover all therapeutic areas, and potentially will include complex therapeutics such as vaccines and biologics.

The Pat-INFORMED database requires companies to meet transparency standards comparable with those set by the US Food and Drug Administration's (FDA) Approved Drug Product with Therapeutic Equivalence Evaluations (commonly known as the 'Orange Book'). This database will be periodically updated and includes a range of information about patents, including, for example, the filing date, grant number, grant date and jurisdiction. Companies are encouraged to provide the Pat-INFORMED platform with complete, current patent information. The Index welcomes Pat-INFORMED's stated intention to expand to further therapeutic areas and product types. Adding information about pending patent applications would further enable procurement agencies to make fully informed purchasing decisions.

Two companies that disclose patent data outside of the Pat-INFORMED database and are not members of Pat-INFORMED are AstraZeneca and Gilead. Gilead licenses its products both bilaterally

IN BRIEF

- The Index evaluates 3 main ways companies can manage IP responsibly, including patent transparency, where they enforce patents, and whether they license their products.
- Since 2016, 2 more companies have committed to waiving patent rights in the poorest countries (up from 13 in 2016).
- Since 2016, there are 2 more compounds* covered by voluntary licensing agreements, bringing the total to 20.
- Licensing remains confined to just 2 diseases: HIV/AIDS and hepatitis C. 7 companies have agreed voluntary licences.
- 17 companies, up from just 4, have now published details about their patents for at least some products relevant to the Index.

with generic medicine manufacturers and through the MPP, in both cases disclosing information about both granted and pending patents in the appendices of licensing agreements. The company includes jurisdiction and patent numbers but does not include expiry dates. AstraZeneca discloses patent status information in countries in scope on its own website, as does Merck KGaA and Novo Nordisk (both are members of Pat-INFORMED). Novo Nordisk is the most transparent of this group, publicly disclosing for all its products (including biologics): product information, country, patent status (granted and pending), patent number, patent type and expiry date. AstraZeneca and Merck KGaA do not disclose patent numbers.

PATENTING STRATEGY

Two more companies pledge not to enforce patent rights in poorer countries

15 companies (up from 13) now publicly pledge neither to file for or enforce patent rights in Least Developed Countries. These companies apply their pledges to all products for at least the diseases in the scope of the Index. Daiichi Sankyo and Takeda have newly published pledges since 2016, leaving only AbbVie, Bayer, Gilead, Pfizer and Sanofi to yet publish such pledges.

Four companies (AstraZeneca, Boehringer Ingelheim, Daiichi Sankyo and Merck KGaA) extend their commitments to include subsets of lower-middle income countries.

Of the five remaining companies, Bristol-Myers Squibb and Johnson & Johnson make similar pledges, but with much more limited scope. Bristol-Myers Squibb's pledge applies to didanosine (Videx®) and stavudine (Zerit®) in sub-Saharan Africa (SSA), both of which are now off-patent. Johnson & Johnson's pledge applies to darunavir (Prezista®), for HIV/AIDS, in SSA and in Least Developed Countries.

SHARING INTELLECTUAL PROPERTY

50% of companies agree new IP-sharing arrangements

The Index also examines whether companies share IP assets with other researchers under terms designed to improve access to medicine. By sharing assets such as compound libraries, proprietary processes or technologies, companies can speed up the development of much needed new products. Ten companies reported sharing IP assets with third-party researchers: Astellas, Eisai, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc, Merck KGaA, Novartis, Pfizer and Takeda. The IP assets being shared most commonly relate to neglected tropical diseases, malaria and tuberculosis (TB).

Takeda and Eisai perform best here as they engage in the largest number of IP-sharing agreements with academic institutions and product development partnerships (PDPs). The majority of their agreements focus on communicable diseases such as TB and malaria.

Companies share a range of different assets with research institutions, including compound libraries, unpublished data and techniques, among others.

LICENSING OF PATENTED PRODUCTS

Same seven companies active in licensing

The 2018 Index has identified 20 compounds – from seven companies – that are covered by voluntary licences (18 compounds) or non-assert declarations (2). Non-assert declarations are pledges not to enforce patents in certain territories or under certain conditions.

Compared to 2016, two more compounds have been added*: Gilead's bictegravir for HIV/AIDS and voxilaprevir, which forms part of a new fixed-dose combination for hepatitis C (sofosbuvir/velpatasvir/voxilaprevir [Vosevi®]). Gilead's bictegravir was licensed before market approval, making it available to manufacture by third parties. This combination is pangenotypic, with the associated benefit of removing the need for genotyping, a constraint particularly felt in low-income settings.

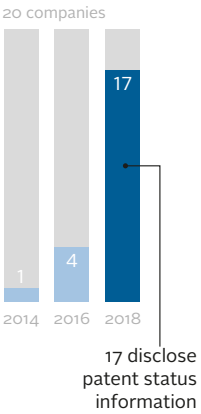
Six companies have issued licences (AbbVie, Bristol-Myers Squibb, Gilead, GSK, Johnson & Johnson and Merck & Co., Inc.), while two have issued non-assert declarations (Boehringer Ingelheim and Johnson & Johnson). The non-assert declarations relate to two compounds for HIV/AIDS: nevirapine (Viramune XR®) by Boehringer Ingelheim and darunavir (Prezista®) from Johnson & Johnson.

Opportunities for increased engagement from companies exist. The MPP, a key body driving access-oriented licensing, has refreshed its strategy, with an expanded mandate that includes patented medicines on the WHO EML in its patent pooling and voluntary licensing initiatives.

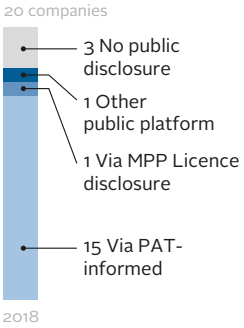
Licensing has not yet expanded beyond HIV/AIDS and hepatitis C

As in 2016, such licences and declarations are used only for HIV/AIDS (15 compounds) and hepatitis C medicines (5 compounds). One such example involves GSK's dolutegravir (Tivicay®). GSK's licence for dolutegravir has the widest reach of any non-exclusive voluntary licence agreed by any company in scope of the Index. It has been licensed to generic medicine manufacturers and developed into the fixed-dose combination tenofovir(TDF)/

13 new companies share patent info



Pat-INFORMED is the most used tool for sharing patent info



*In November of 2018 AbbVie announced the application of a non-exclusive voluntary licence to support extended access to two additional compounds, glecaprevir and pibrentasvir (Mavyret™) through the Medicines Patent Pool.

lamivudine(3TC)/dolutegravir(DTG), gaining market approval in August 2017. It became the preferred adult first-line treatment in July 2018, when WHO updated its HIV/AIDS treatment guidelines.

For hepatitis C, existing non-exclusive voluntary licences mean that all first-line WHO pangenotypic regimens except one can be made available in countries in scope through generic supply. The exception is AbbVie's glecaprevir/pibrentasvir (Mavyret™).* Voluntary licensing could have a significant positive impact on efforts to tackle hepatitis C, which is estimated to affect 71 million people globally.[3]

Licensing terms are generally transparent

The terms of non-exclusive voluntary licences are generally transparent. Where licences have been negotiated via the MPP, the terms are made public via the MPP's website.[4] Five companies have agreed such licences: AbbVie, Bristol-Myers Squibb, Gilead, GSK and Merck & Co., Inc. Terms are disclosed in full, including royalty rates and geographic scope, as well as whether licensees may develop fixed-dose combinations and/or manufacture the necessary active pharmaceutical ingredients (APIs) amongst others. The two companies that have agreed non-exclusive voluntary licences outside the MPP are Gilead and Johnson & Johnson. Johnson & Johnson discloses the terms (such as country scope, the ability to develop fixed-dose combinations, the ability to manufacture APIs and the inclusion of technology transfer) of its licence for rilpivirine (Edurant™) but does not publish the actual licence document. Gilead maintains its high transparency standards for its licences negotiated outside of the MPP by disclosing complete pro-forma licences.

The MPP continues to be the central independent driver of access-oriented licensing in the pharmaceutical industry. Licences agreed via the MPP include the majority of the access-oriented terms and conditions looked for by the Index. Non-exclusive licences agreed outside of the MPP include an average of five out of eight of such access-oriented terms. They most commonly do not include waivers on data exclusivity. Out of the 20 licensed compounds captured by the Index, 13 were negotiated via the MPP.

Middle-income countries (MICs) with large populations in need are often excluded from licence scopes. Since 2016, two companies have expanded the geographic scope of their licences to include such MICs. Bristol-Myers Squibb's licence for atazanavir (Reyataz®), indicated for HIV/AIDS, now includes 12 new countries, eight of which are MICs: Egypt, Equatorial Guinea, Indonesia, Morocco, Philippines, Tunisia, Ukraine and Vietnam. Gilead has announced the expansion of both its HIV/AIDS licences negotiated via the MPP and its bilaterally agreed HCV licences to include two additional MICs in scope: the Philippines and Ukraine.

TRADE POLICY

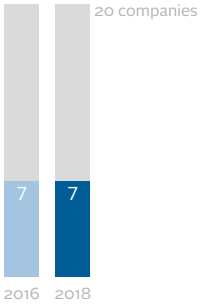
TRIPS flexibilities have limited support

The pharmaceutical industry remains hesitant to endorse the rights of national governments to deploy IP systems flexibly when there is a need to do so. This is shown in companies' limited public support for the flexibilities in the international IP system (as set out in the WTO's 2001 Doha Declaration on the TRIPS Agreement and Public Health). The TRIPS agreement includes flexibilities for WTO member states to (amongst other things) set aside patent rights to protect public health.[5]

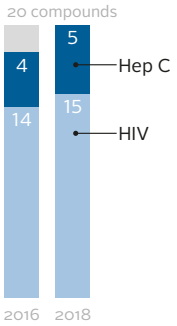
In 2018, half of the companies evaluated by the Index do not publicly support the Doha Declaration and the policy flexibilities intended to protect public health, although companies do give a limited degree of support to these flexibilities given specific restricted conditions. AstraZeneca sets itself apart from the pack, acknowledging that countries are free to determine what constitutes a 'public health emergency'. Merck KGaA also adopts a more constructive stance, acknowledging that it is the right of countries – provided criteria are fulfilled such as engagement with the rights-holder – to determine the grounds for issuing compulsory licences.

All 20 companies are members of trade associations that have taken positions not fully aligned with the international consensus on IP and public health. They were linked either to (1) lobbying for IP protections beyond the provisions set out in the original TRIPS agreement; or (2) attempts to influence legislation in order to prevent countries from taking advantage of TRIPS flexibilities. Following a systematic review of the available evidence during the period of analysis across companies, information published by the Colombian Government, in which Novartis discourages Colombian authorities from issuing a declaration of public interest concerning imatinib mesylate (Glivec®), was identified. GSK demonstrates that companies can take opposing positions to those adopted by the associations of which they are members. The company has described a procedure for ensuring those positions with which it disagrees do not form part of its regular public engagement activities.

No new companies using voluntary licences



Two more compounds covered by voluntary licences*



*In November of 2018 AbbVie announced the application of a non-exclusive voluntary licence to support extended access to two additional compounds, glecaprevir and pibrentasvir (Mavyret™) through the Medicines Patent Pool.

PATENTS AND LICENSING

Best Practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations.

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness,
- Sustainability,
- Replicability,
- Alignment with external standards/ stakeholder expectations.

The 2018 Index identified three best practices in this area, from three companies. No innovative practices were identified.

GILEAD

Widest use of non-exclusive voluntary licensing

GLOBAL

Gilead licenses its entire on-patent portfolio of products for diseases in scope to speed the entry of generics into market.

When rights-holding companies issue non-exclusive voluntary licences for patented medicines, they enable other manufacturers to develop generic versions of these medicines. This helps to foster competition, support supply, increase affordability and improve access.

What makes this a best practice?

Gilead's approach to licensing remains a best practice amongst companies evaluated by the Index, as in 2016. Gilead voluntarily licenses its entire in-scope portfolio of on-patent products. The company's proactive, supportive approach speeds the entry of generic medicines into markets within the countries it includes within agreed licences.

The licensed products are for the treatment of either HIV/AIDS or hepatitis C, and have a high public health value. In many cases the licensed products appear both on the WHO EML and are regarded as first-line treatments: emtricitabine, sofosbuvir, ledipasvir and velpatasvir. Its licences for products for HIV/AIDS are agreed via the Medicines Patent Pool (MPP), whereas Gilead has agreed the licences for products for hepatitis C, the first company to do so directly with generic manufacturers. In both cases, Gilead demonstrates that it plans for (and agrees) licensing terms prior to FDA or EMA approval. Further, it commits to filing new products for registration in as many low-income countries (LICs) and middle-income countries (MICs) as possible within 12 months of FDA and EMA approval, while publishing where they have filed and whether it was successful. These steps can all work together to support the efficient entry of generic medicines to market, potentially reducing the time before those in need within these countries can access the product.

Partnering for greater reach

Gilead has engaged with the MPP to negotiate licences since 2011 and was the first company to do so. It has signed licence agreements for the treatment of HIV/AIDS via the MPP for bictegravir, cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide and tenofovir disoproxil fumarate. Country coverage within these licences applies to countries that are home to 90% of people living with HIV/AIDS in low-and middle-income countries.[6] Working directly with generic manufacturers, Gilead licenses products for the treatment of hepatitis C, including sofosbuvir, ledipasvir, velpatasvir and voxilaprevir. The terms Gilead reaches in its bilateral licences are comparable (in transparency and geographic breadth) with the licences negotiated via the MPP. However, compared to its licences for HIV/AIDS products, Gilead's hepatitis C licences are a more limited tool for providing access to people living with hepatitis C. The regions that are most affected by hepatitis C are WHO Eastern Mediterranean and European Regions, which are typically not covered by Gilead's hepatitis C licences.

In 2017, Gilead further expanded the number and scope of HIV/AIDS licences it signed with the MPP. It newly licensed bictegravir to the MPP and added two new middle-income countries within the Index scope to the terms of the licence: Philippines and Ukraine.

GSK

Dolutegravir (Tivicay®) licence has widest geographic potential for improving access

GLOBAL

The non-exclusive voluntary licence for dolutegravir (Tivicay®) covers 95% of countries in scope.

Middle-income countries (MICs) are home to the majority of the world's poor and shoulder the greatest share of the global disease burden. Compared to low-income countries (LICs), they have greater purchasing power and thus represent more attractive commercial markets. MICs are thus more likely to be excluded from non-exclusive licensing agreements for medicines – preventing their populations from accessing the dual benefits of increased affordability and a more secure supply that such licensing agreements can provide.

When agreeing the terms of non-exclusive voluntary licences, rights-holding companies – in negotiation with generic medicine manufacturers, or parties such as the MPP – agree a geographic scope (or licence territory) within which generic manufacturers are permitted to supply the product.

What makes this a best practice?

GSK continues to represent best practice here. It sets the single largest geographic scope of any voluntarily licensed product. GSK was recognised for the same practice in 2014 and 2016.

GSK's non-exclusive voluntary licence for paediatric formulations of dolutegravir (Tivicay®) – negotiated via the MPP – achieves the widest reach of any non-exclusive voluntary licence agreed by any company within the scope of the Index, covering countries that are together home to 99% of children living with HIV in low- and middle-income countries.[7] The licence for the adult version has the widest reach, facilitating the possible entry of generic versions to countries that are home to more than 94% of adults living with HIV/AIDS in low- and middle- income countries.[7] Dolutegravir is a key product in HIV/AIDS treatment. It is a best-in-class integrase inhibitor, appears on the WHO EML and is recommended by WHO as an alternative first-line HIV/AIDS regimen.

Reaching countries in need

The paediatric licence covers 121 countries in total (compared to the paediatric licence with the lowest number of countries – Merck & Co., Inc.'s raltegravir (Isentress®) – at 92 countries) and includes all LICs, all Least Developed Countries (LDCs) and all sub-Saharan African (SSA) countries, in addition to several upper middle-income countries. The licence covers all MICs in scope of the Index except four: Brazil, China, Mexico and Suriname. Looking at disease burden per MIC, the licence includes seven of the ten countries within scope outside of SSA which bear the highest burden of HIV/AIDS.

Notably, GSK also permits the supply of dolutegravir (Tivicay®) outside of the agreed territory to wherever patents are not in force or where the sale of a generic version does not infringe on an existing patent. This further expands the potential reach of this licence to at least 131 countries.

TAKEDA

Extensive sharing of IP assets with third-party researchers

GLOBAL

Sharing IP assets with third-party researchers developing products for diseases in scope of the Index.

Much of the R&D into new medicines and vaccines undertaken is done in house. However, companies also have the option to share their intellectual property (IP) assets with third-party researchers. This underutilised approach can enable swifter development and adaptation of products and provide benefits for people living in low- and middle-income countries.

What makes this a best practice?

When it comes to sharing IP assets, Takeda represents best practice. Of all its peers, it has established the largest number of IP-sharing agreements with many research institutions and product development partnerships (PDPs).

Overall, Takeda shares 18 assets through nine different IP-sharing agreements. Research institution partners include the University of California, San Diego, and the University of California, San Francisco, with whom Takeda shares IP assets for neglected tropical diseases (NTDs) such as schistosomiasis. With the University of Melbourne and National Institutes of Health, Takeda shares assets for malaria. Through its agreement with the University of British Columbia, it shares assets relating to tuberculosis.

Takeda also shares IP assets with a range of PDPs, including the Drugs for Neglected Diseases initiative (DNDi), the MMV and the TB Alliance. Another partner is PATH, an NGO whose mission is to eliminate health inequalities and improve health globally.

Through these agreements, third-party researchers conducting R&D for neglected diseases are able to deploy Takeda's IP assets, which include molecule libraries, patented compounds, processes and technologies.

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F Capacity Building

CONTEXT

Some of the biggest barriers to access to medicine relate to gaps in local pharmaceutical and health systems. Companies can draw on their capabilities and expertise to increase the availability of quality-assured, safe and effective medicine and healthcare, while simultaneously helping to build and strengthen future markets. Company initiatives need to be held to high standards to ensure their activities are both responsible and impactful. In order to better assess the quality of company initiatives, the Index assessed a sample of initiatives (no more than five per area) against a set of stakeholder expectations referred to as the framework of good practice standards.

HOW WE MEASURE

The 2018 Index assesses company capacity building initiatives against a framework of six good practice standards:

1 Address local needs, priorities and/or skills gaps;
2 Work in partnership with appropriate stakeholders;
3 Have clear, measurable goals and objectives;
4 Aim to achieve long-term improvements and sustainability;
5 Measure progress, outcomes and/or impact; and
6 Have good governance structures in place between partners, including processes to mitigate risk of conflict of interest.

WHAT WE MEASURE

The Access to Medicine Index assesses pharmaceutical companies' efforts to engage in capacity building activities in five different areas:

1 **R&D capacity building:** partnering with local research institutions to build research capacity.
2 **Manufacturing capacity building:** working with local manufacturers to ensure GMP and improve local supply.
3 **Supply chain capacity building:** working with relevant local partners to strengthen local supply chains.
4 **Pharmacovigilance capacity building**: working with regulatory authorities to build local national capacity for pharmacovigilance.
5 **Health system strengthening**: working in partnership to better detect and treat diseases.

TOP INSIGHTS

▶ Leading companies perform well in all areas of capacity building.

▶ 5 companies show evidence of measuring the impact of their initiatives.

▶ Most activity centred around strengthening local health systems.

▶ Majority of initiatives are active in sub-Saharan Africa.

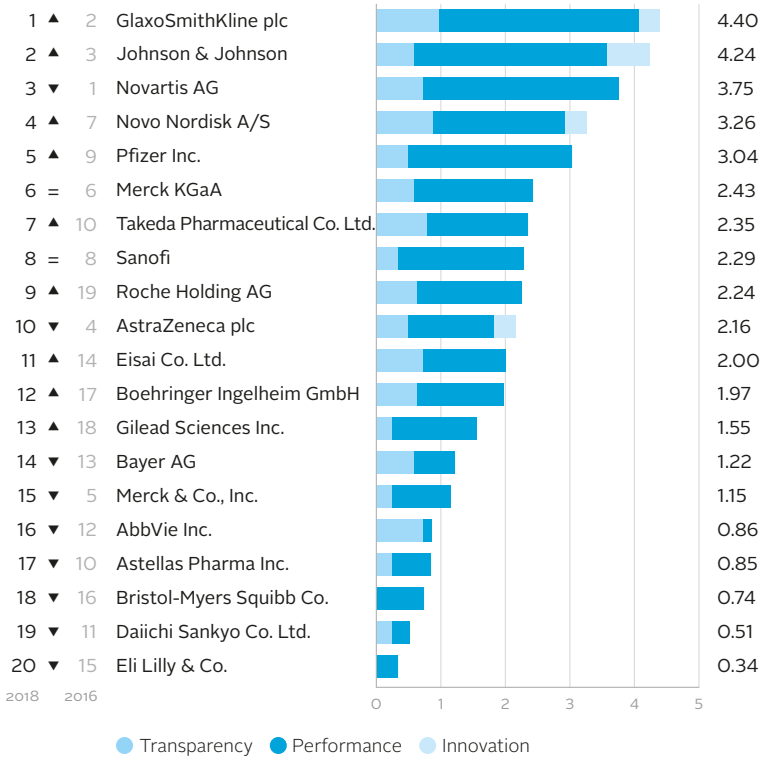
IN THIS CHAPTER

HOW COMPANIES COMPARE

Leaders build diverse capacities, with more initiatives in line with expected standards

- GSK and Johnson & Johnson overtake Novartis to gain the lead.
- Most top ten companies build diverse capacities around the world.
- Overall, the 20 companies are most active in health system strengthening in countries in scope and least active in pharmacovigilance.
- There are four groups: two leaders (GSK and Johnson & Johnson), three good performers (Novartis, Novo Nordisk and Pfizer) ahead of a middle group of seven (Merck KGaA to Boehringer Ingelheim) and a large group of laggards.
- Ranking in 2018 puts more emphasis on the quality of initiatives than in 2016.
- There is some movement up the ranks and a wider spread of scores than in 2016.

Figure 50. Company ranking: Capacity Building



Leaders innovate and measure impact

The two leaders are active in all five areas of capacity building examined. In all five, they have initiatives that meet all good practice standards.* They are among only five companies measuring the impact of at least one capacity building initiative.

GSK (1st) and **Johnson & Johnson** (2nd) both have 23 initiatives that meet basic criteria, including 18 and 11 initiatives respectively that meet all good practice standards.

They perform well in all areas, and both demonstrate innovative approaches to health systems strengthening. GSK works with partners to improve the health, wellbeing and productivity of garment workers in Bangladesh (see page 117). Johnson & Johnson is involved in the DREAMS partnership run by the President's Emergency Plan for AIDS Relief (PEPFAR) and an HIV resistance-mapping project (see page 118). This initiative operates in ten sub-Saharan African countries.

Movement up the rankings reflects quality of initiatives

There is movement up and down the ranking due to the 2018 Index's focus on the quality of a selection of capacity building initiatives (in previous years, the Index assessed the total number of initiatives companies run).

Companies move up or hold on to higher rankings by showing that initiatives meet more good practice standards.

Roche rises 10 (to 9th), with multiple capacity building activities aimed at improving cancer control and improved transparency compared to 2016.

Gilead rises 5 (to 13th), with a strong philanthropic approach and initiatives in R&D capacity building and health system strengthening.

Pfizer rises 4 (to 5th), possibly as philanthropic

investment in global health is one of the pillars of its access-to-medicine strategy. It has multiple high-quality initiatives in manufacturing, supply chain and health system strengthening.

Daiichi Sankyo falls 8 (to 19th) as the Index puts greater emphasis on initiative quality. It has fewer initiatives in 2018 that meet the criteria for assessment (two initiatives, both in manufacturing capacity building).

Merck & Co., Inc. falls 10 (to 15th). It is less transparent than in previous years, particularly regarding capacity building activities in R&D, manufacturing and pharmacovigilance.

Middle ranked companies shine in one or two areas

Novartis, Novo Nordisk and Pfizer are the three good performers chasing the leaders. They all perform well in four out of five areas examined.

Novo Nordisk also has an innovative new initiative to provide basic care and treatment to people with hypertension and diabetes during humanitarian crises.

The seven companies in the middle group (Merck KGaA in 6th to Boehringer Ingelheim in 12th) typically perform well in one or two areas of capacity building. For example, Merck KGaA (6th) does well in manufacturing capacity building while AstraZeneca (10th) and Boehringer Ingelheim (12th) excel in health systems strengthening.

The nine laggards (Gilead in 13th to Eli Lilly in 20th) each have between one and eight initiatives that met inclusion criteria, including a few that meet several good practice standards.

Several companies are considerably less transparent than peers across several areas of measurement, namely Merck & Co., Inc. (15th), AbbVie (16th) and Eli Lilly (20th).

In Bangladesh, GSK works with partners to support community health workers providing care for garment workers and their families.

Novartis leverages mobile technology in capacity building initiatives such as telemedicine to improve care.

Through the DREAMS partnership, Johnson & Johnson aims to reduce HIV infections by supporting and empowering young women in sub-Saharan Africa.

*Companies were scored only on the basis of initiatives that met the basic standards set in the framework. The framework is tailored to each area of capacity building analysed (R&D, manufacturing, supply chain, pharmacovigilance and health systems strengthening). See Appendix XIII for more details.

INDUSTRY ACTIVITY PER TOPIC

Around one third of initiatives evaluated meet all good practice standards

Pharmaceutical companies are engaged in diverse initiatives to build capacity in low- and middle-income countries. The diversity lies in the types of activities covered by the initiatives as well as the quality of initiatives. In 2018, the Index used a framework of good practice standards* to assess the quality of each initiative. Within the scope of this framework, the industry performs best when building capacities to strengthen health systems. By contrast, pharmacovigilance is the area of weakest performance. The companies submitted 383 initiatives for evaluation; more than half (213) meet the inclusion criteria set out in the good practice framework, and just over one third (82) meet all standards set. Leading companies forge strong partnerships with local organisations and embed initiatives within defined access to medicine or global health units. For example, GSK runs initiatives through its Reinvestment Initiative to Improve Healthcare Infrastructure in the Least Developed Countries (LDCs) and ViiV Healthcare; Novartis through its Social Business Unit and its philanthropic foundation; and Johnson & Johnson through its Global Public Health (GPH) and Global Community Impact (GCI) units.

Capturing the quality of capacity building initiatives

Each successive Index has reported expansions in capacity building activities to improve access to medicine in countries in scope of the Index. Companies have engaged in new areas of capacity building, new initiatives have been launched and existing initiatives have been built upon.

Since it is clear that companies are consistently engaging in capacity building, for the 2018 Index the Foundation's analysis has shifted to checking each initiative for whether it aligns with stakeholder expectations of good practice. Based on findings from the 2016 Index and engagement with external stakeholders, the 2018 Index identified a set of six good practice standards. Meeting these standards is thought – in the absence of understanding the real impact of these programmes – to increase the likelihood of initiative success, through alignment with local needs, appropriate governance and close monitoring of progress. This framework has been tailored based on stakeholder expectations for each subtheme in the Capacity Building Technical Area.

The framework of good practice standards checks whether each initiative: (1) addresses local needs, priorities and/or skills gap; (2) is carried out in partnership with appropriate stakeholders; (3) is guided by clear, measurable goals or objectives; (4) aims to achieve long-term impact and sustainability; (5) measures progress, outcomes and/or impact (and shares results publicly); and (6) has good governance structures in place, including for mitigating or preventing conflicts of interest.

There are three basic criteria that all initiatives must meet: (1) initiatives must be active during the period of analysis; (2) take place in a country/countries in scope; and (3) address a clearly defined local need. Initiatives in all subareas, except manufacturing, are expected to be done in partnership, while health system strengthening initiatives must also have processes in place to prevent conflict of interest in order to be eligible for analysis. See Appendix XIII for further details.

Steps being made to measure outcomes and impact

Performance in meeting the standards was highly varied per initiative. Yet, initiatives commonly fell short on measuring progress and outcomes. This aligns with findings from a 2017 study conducted by Boston University which found that across 120 different access-to-medicine initiatives only seven initiatives (6%) had so far published evaluations.[1] Nevertheless, there is evidence of some companies beginning to acknowledge the importance of monitoring and evaluating their initiatives, with some already taking steps. Examples of good practice in this area include: Merck & Co., Inc., Novartis and Novo Nordisk who work with partners to

IN BRIEF

- The Index assesses capacity building initiatives against a framework of 6 good practice standards, e.g., addressing local needs and having clear measurable goals and objectives.
- The companies submitted 383 initiatives for evaluation. More than half meet the basic criteria, and just over one third meet all standards set.*
- Impact measurement remains limited. 5 companies are taking steps to assess the impact of at least one capacity building initiative and to track progress.
- Capacity building initiatives are mostly concentrated in sub-Saharan Africa, particularly in Kenya, and particularly where health system strengthening is involved.
- Reporting of substandard and falsified medicines is expanding, albeit from a low base, with 7 companies now reporting policies in this area, up from 2.

measure and evaluate their initiatives, publishing results either through peer-reviewed journals or partners' websites.

The Index also identified examples of companies that go one step further, measuring beyond outcomes, and looking at the impact of their initiatives. Three companies (GSK, Johnson & Johnson and Novartis) have developed frameworks or 'logic models' to guide impact assessments for health system strengthening initiatives. Novo Nordisk and Merck & Co., Inc. have also conducted impact assessments for their supply chain capacity building initiatives, working with academic partners and making final reports publicly available. Furthermore, 15 companies in scope of the Index are members of Access Accelerated (AA), a multi-sector initiative that has partnered with Boston University to develop a framework for measuring the impact of companies' initiatives within AA. Through AA, these companies commit to evaluate the real-world impact of their efforts and to share their findings via the Access Observatory, a public platform for reporting on access to medicines programmes.

There is an opportunity for companies to engage even more deeply in monitoring and evaluating the outcome and impact of their initiatives. Conducting these measurements requires time and financial investment, but this is important in order to generate evidence that company engagement in capacity building has an important impact on health and access to medicines. This will allow companies and partners to identify success – and failures – and to ensure that successful practice can be more widely adopted and scaled up.

Company performance varies by area of capacity building

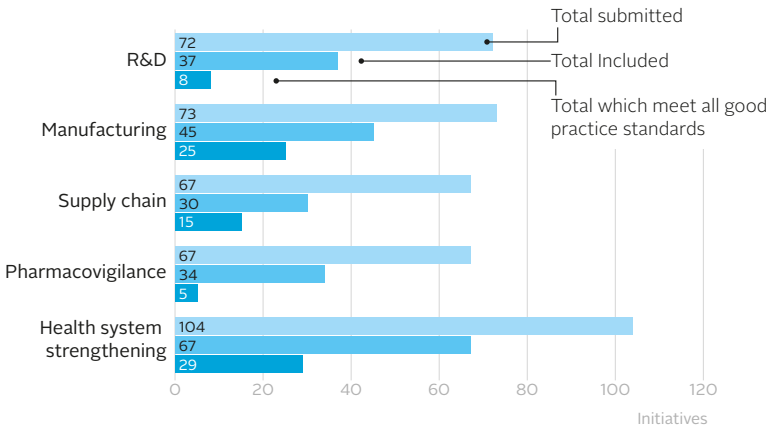
Looking at those initiatives that meet inclusion criteria (213 initiatives), approximately one third fall under health system strengthening (67 initiatives). This is followed by capacity building for manufacturing (45 initiatives) and R&D (37). This list is similar when looking at initiatives that meet all of the good practice standards set (82 initiatives): 29 initiatives for health system strengthening, followed by 25 for manufacturing and 15 for supply chain strengthening (see figure 51).

Initiatives concentrated in sub-Saharan Africa

The Index finds that where companies build capacity to support local manufacturing, they generally do so in emerging markets with higher levels of infrastructure. Manufacturing initiatives are located in 21 countries, most of which have established pharmaceutical manufacturing capabilities,

Figure 51. Breakdown: Capacity Building initiatives by area

213 initiatives meet inclusion criteria set out in the good practice framework developed by the Index. Almost one third fall under health system strengthening.



such as India (13), China (11 initiatives) and Brazil (9). These countries are also a focus for R&D capacity building, as are South Africa, Kenya and Uganda.

The widest spread of initiatives is for health systems strengthening, covering 80 countries. Overall, the majority of initiatives are in sub-Saharan Africa (covering 46 countries across the region). Kenya has the most initiatives in sub-Saharan Africa (54) and is likely a favourite for such initiatives due to the prioritisation of healthcare from the Kenyan government and high activity from NGOs and other partners. It is also a rapidly growing healthcare market.

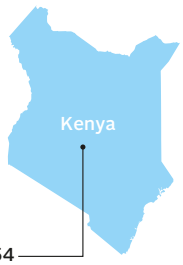
R&D CAPACITY BUILDING

R&D initiatives focus on communicable diseases

Companies have the expertise and ability to support the development of a skilled R&D sector in low- and middle-income countries. Engagement efforts aimed at building local R&D capacity support the development of research skills that can enable local researchers to address relevant health needs and priorities. The skills and capacities companies can support are not limited to pharmaceutical R&D, but also epidemiology and other health science related research. Companies are expected to collaborate with local universities or public sector research organisations to identify and address local skills gaps or infrastructure needs relating to R&D. When local researchers have the capacity to conduct their own studies, they can focus on relevant health issues in the context of their own country or region, rather than applying findings from studies in Western populations.

The Index examined 37 initiatives from 13 companies that meet the inclusion criteria for R&D

Most activity in sub-Saharan Africa



54
Greatest number of initiatives across all areas

capacity building: they address a local need for the development of research skills and are in collaboration with a local university or public research institution. Of these, eight initiatives meet all good practice standards. These eight initiatives are being run by four companies who lead in this area – GSK, Johnson & Johnson, Novartis and Takeda. Three of these initiatives have been highlighted as best practices for R&D capacity building as well: GSK's Africa NCD Open Lab, Johnson & Johnson's work in the establishment of the Ugandan Academy for Health Innovation and Impact and Takeda's R&D Access to Medicines Employee Fellowship Program (for more details, see page 110). These initiatives stand out for their approach to identifying local needs through engagement with local stakeholders; they also ensure that they empower local researchers to conduct their own research and diffuse learned skills to more researchers.

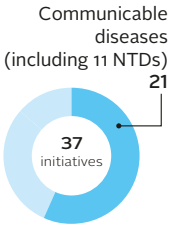
R&D initiatives are mostly focused on communicable diseases (e.g., HIV/AIDS, malaria and tuberculosis), with only ten focused on a non-communicable disease (NCD). Initiatives are most concentrated in sub-Saharan Africa, with the majority in four countries with established research universities: Kenya, South Africa, Tanzania and Uganda. R&D capacity building initiatives take a range of forms, namely grants for local researchers, research collaborations with local universities, training for clinical trials (which meet Good Clinical Practice) and R&D fellowship programmes.

Fellowship programmes frequently link company employees with a local NGO or research institution in order to transfer knowledge and expertise. Four companies are running employee fellowship programmes that meet inclusion criteria: Johnson & Johnson, Novartis, Roche and Takeda. Fellowship programmes can also include those that bring researchers or PhD students from low- and middle-income countries to work in the research facilities of the pharmaceutical company in order to transfer knowledge and foster experience they can take back to their home country. Both types of fellowship programmes provide value by exchanging knowledge and expertise directly between researchers from different countries.

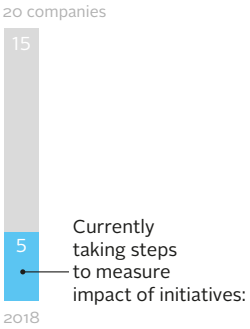
Another example of R&D capacity building is the provision of lab equipment paired with training and ongoing support for researchers receiving the equipment. Takeda, Eisai and Merck KGaA are part of the Instrumental Access Program, run by the Boston-based NGO, Seeding Labs. Seeding Labs aims to remove barriers to scientific discovery for researchers in the developing world. They respond to requests for lab equipment from reputable universities and research institutes in low- and middle-income countries by providing them with equipment from donors, such as pharmaceutical companies. Seeding Labs also make sure those scientists have the infrastructure, training, resources and available answers to get the highest and best use of the equipment. Takeda reports that they also work with the recipients of the equipment by providing training, resources and tools for these researchers.

Overall, the majority of company initiatives involve short-term fellowship programmes or providing grants to local researchers for specific projects. Companies can do more by extending support beyond individual researchers and build capacity of local public research institutes and universities, addressing gaps identified by the institutes and universities themselves. By ensuring these research institutes and universities in low- and middle-income countries are well-equipped and capable of conducting reputable research, they can in turn support and cultivate more researchers within their countries. More reputable institutes will begin to emerge which can conduct research on health issues specific to their populations.

R&D initiatives mostly focus on:



Small number of companies measure impact:



- GSK
- Johnson & Johnson
- Merck & Co., Inc.
- Novartis
- Novo Nordisk

MANUFACTURING CAPACITY BUILDING

Most companies use technology transfers to enhance local manufacturing

Manufacturing medicines locally can lead to reduced costs and improved supply, but quality must be guaranteed. When companies work with third-party manufacturers in low- and middle-income countries, they are expected to ensure local staff have the skills and technology necessary to meet the requirements of good manufacturing practices (GMP). Companies are also encouraged to engage with other manufacturers and universities to build capacity in quality manufacturing beyond their own products. This can lead to more sustainable improvements to manufacturing capacity, and the stable local supply of quality medicines and vaccines in the long-term.

The Index examined 45 initiatives from 15 companies that meet the inclusion criteria for manufacturing capacity building: they address local needs and/or skills gaps with third-party or unaffiliated manufacturers, or work with external partners such as local universities. Of these, 25 initiatives meet all good practice standards. The good practice standards were tailored based on stakeholder expectations for manufacturing capacity building, which resulted in four standards rather than six (see Appendix XIII). Companies were expected to meet local manufacturing needs and skills gaps, aim for long-term and sustainable

improvements that are guided by clear goals and measure progress.

The majority of manufacturing capacity building initiatives comprise technology transfers (23 initiatives). This involves the transfer of expertise and processes for manufacturing a specific product to a contracted manufacturer; most transfers take place over a period of several years where ongoing support and training is provided to the local manufacturer. Often skills are built in areas that can be applied broadly to the manufacturer beyond the product being transferred, for example, processes for ensuring GMP and safety. This builds the capacity of that manufacturer for improved local manufacturing of all products they produce. Companies with high performances through technology transfers, such as Gilead, Johnson & Johnson and Sanofi, considered the local capacity gaps and needs of the manufacturer in question, set clear goals and objectives for the transfer and planned for sustainable, long-term manufacture of the product, all while monitoring the progress of the transfer. Progress and results are rarely shared, and only internally among the partners/manufacturers. Other types of initiatives include training for staff from third-party manufacturers on GMP or the company's own manufacturing standards (11 initiatives), or training for students of pharmaceutical manufacturing at local universities (two initiatives).

Companies can do more to support the development of manufacturing skills within countries beyond their own Contract Manufacturing Organisations. This would increase the pool of potential manufacturers meeting GMP to work with. This could create incentives for more manufacturers to ensure they meet GMP in order to get more business, thus improving quality of medicines produced locally (in low- and middle-income countries). The majority of manufacturing activities take place in three countries: China, Brazil and India. Companies can engage in building capacity for local manufacturing in more countries, particularly in sub-Saharan Africa. Companies only provided evidence of manufacturing capacity building activities that meet inclusion criteria in three sub-Saharan African countries (Ghana, Nigeria and South Africa).

SUPPLY CHAIN CAPACITY BUILDING

New technologies being used to overcome supply barriers

Inefficiencies and weaknesses along supply chains – whether in the procurement process, delivery logistics, storage or other stages – can impact the accessibility, availability and quality of medicines. Companies are expected to engage with relevant, local partners to identify bottlenecks and improve capacity for good supply chain management within countries in the scope of the Index.

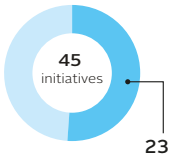
The Index examined 30 initiatives from 12 companies that meet the inclusion criteria for supply chain capacity building: they address a specific local need for supply chain capacity and are being run with a relevant, local partner. Of these, 15 initiatives meet all good practice standards. These initiatives are being run by eight different companies: GSK, Johnson & Johnson, Merck & Co., Inc., Novartis, Novo Nordisk, Pfizer, Roche and Sanofi.

Four of these companies, GSK, Merck & Co., Inc., Novartis and Novo Nordisk, are recognised for best practice in supply chain capacity building. These initiatives each focus (or initially focused) on a specific disease area or product type, such as Novo Nordisk's Base of the Pyramid programme for the supply of insulin or GSK's mVacciNation programme to increase vaccine immunisation. Each of these programmes began with an innovative solution that was piloted in one country for a specific product or type of product. The companies and their partners monitored these pilots and when they proved to be effective, the solutions were scaled up to more countries or more products or both.

Initiatives in this area range from trainings on good distribution practices, proper warehousing, forecasting and cold chain requirements, to projects that use technology to track stock and prevent stock outs. Companies using mobile technology to track stock are among those counted as best practices (GSK's mVacciNation and Novartis' SMS for Life 2.0, see pages 110, 114). Other forms of innovative technology solutions are being used to address last-mile supply chain challenges as well. For example, two companies are collaborating on programmes using drone technology to make last-mile deliveries: Pfizer has partnered with logistics company Zipline to deliver medicines to remote communities; and Sanofi works with Eureka to deliver malaria diagnostics and medicines to remote areas in the Greater Mekong international region of Southeast Asia.

Most supply chain capacity building initiatives assessed by the Index are active in sub-Saharan Africa. There are very few initiatives in the regions of South Asia or East Asia & the Pacific. Companies can apply lessons learned from best practices in supply chain capacity building to these regions, while adapting them to meet specific gaps and needs. Further, while there are several examples of strong initiatives for building supply chain capacity, these are run by only a handful of

Half of manufacturing initiatives use technology transfers



23
Involve technology transfer

companies. More companies can engage in activities that test innovative solutions, while also working with ministries of health and ensuring improvements can be transitioned and locally owned after the initiative ends.

Improved reporting of substandard and falsified medicines

The Index also examines whether companies systematically report cases of substandard or falsified (SF) medicines to national authorities and/or WHO Rapid Alert. SF medicines pose a serious threat to the health of patients.[2] When cases of SF medicines (products that deliberately misrepresent their identity or fail to meet quality standards or specifications) are detected, action must be taken quickly in order to prevent further harm to patients who may have received the product. Companies should prioritise fast confirmations of suspected cases and then in turn report them within seven days to either the local regulatory authority or WHO Rapid Alert to put in motion a public health response.

As in 2016, the overall level of performance in this area is low. There are, however, signs of improvement. Seven companies (up from two in 2016) now show evidence of policies for reporting cases within the recommended time frame of seven days of the case being confirmed. Leading practice in this area comes from AbbVie, Eisai and GSK. All three companies provided evidence that they, as a policy, confirm suspected cases of SF medicines within seven days of discovery and subsequently report confirmed cases to WHO Rapid Alert and/or relevant local regulatory authorities within the stakeholder recommended time frame of seven days.

PHARMACOVIGILANCE CAPACITY BUILDING

Pharmacovigilance initiatives usually short-term in nature

Many countries lack efficient systems for detecting, evaluating and responding to safety issues regarding medicines and vaccines. Companies are encouraged to engage with third-party partners to strengthen national pharmacovigilance systems through training, secondments or consulting, while managing conflicts of interest.

The Index examined 34 initiatives from 11 companies that meet the inclusion criteria for pharmacovigilance capacity building: they respond to a specific local need for improved pharmacovigilance and are being run with relevant partners (working via a third party with regulatory authorities). Of these, five initiatives meet all good practice standards. These initiatives are run by four leading companies in this area: AstraZeneca, GSK, Johnson & Johnson and Pfizer. For example, AstraZeneca has incorporated training for healthcare workers on adverse events and pharmacovigilance reporting into the Healthy Heart Africa programme in Kenya. Another example, GSK in partnership with PATH and country ministries of health and regulatory authorities, is running the Pharmacovigilance Enhancement Project in sub-Saharan Africa. The project, which aims to improve adverse event reporting to better monitor vaccines and medicines, is currently running in Côte d'Ivoire, the Democratic Republic of Congo and Malawi.

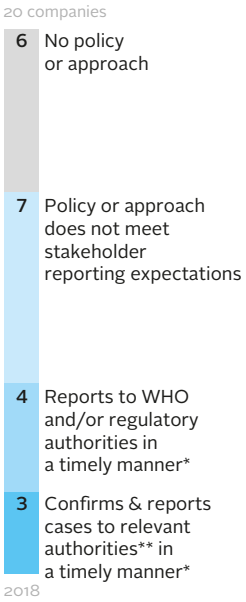
This is the weakest area of capacity building. Most company activity in this area consists of short-term trainings and workshops. While this is valuable, there are no stand-out practices in this area. It is also the area where the role of pharmaceutical companies can be less clear. Responsive pharmacovigilance systems require good governance from regulatory and health authorities, and national governments hold the primary responsibility for establishing and maintaining pharmacovigilance systems. Such agencies are expected to be independent in order to regulate companies' products. For this reason, a partnership with a company could raise concerns of conflicts of interest. Therefore, companies should have processes for mitigating these risks and involve third parties when working directly with regulatory authorities. Out of the 34 submitted initiatives, only one third (11) of the initiatives demonstrate good governance structures in place, that are supported by processes, to mitigate potential conflicts of interest.

Companies can continue to work with NGOs and organisations such as WHO on short-term projects to build pharmacovigilance capacity in countries, ensuring that governance structures and processes for mitigating conflicts of interest are in place. They can also incorporate training on pharmacovigilance reporting into their other capacity building programmes, especially those focused on specific products.

More than half of companies share safety data

In this area, the Index also examines whether companies share data on the safety of their medicines (e.g., Periodic Safety Update Reports (PSURs) and post-marketing surveillance safety data) with national authorities. Slightly more than half of companies (12) share safety data either voluntarily (8) or by request (4) with relevant authorities in countries in scope. Most (14) companies also provide evidence that they update safety and efficacy labels of their products, regardless of patent

How do companies report substandard and falsified medicines?



*Stakeholders expect confirmation to occur within 7 days of discovery and reporting to authorities to occur within 7 days of confirmation.
**WHO Rapid Alert and/or local regulatory authorities.

status, in countries in scope. Some (8) companies provided evidence of policies for both sharing safety data with national authorities and updating safety and efficacy labels.

HEALTH SYSTEM STRENGTHENING

Companies use expertise to strengthen local health systems

Robust health systems must be in place in order for products to be deployed, prescribed and administered efficiently. Activities that strengthen local health systems can both improve access to medicines and improve health outcomes for patients. Health system strengthening activities from pharmaceutical companies include efforts that build capacity outside the pharmaceutical value chain, with a focus on prevention, education, diagnosis and/or treatment in countries in scope.

The Index examined 67 initiatives from 18 companies that meet the inclusion criteria for health system strengthening: they respond to a specific local need for greater capacity, are being run with relevant partners and include processes to mitigate or prevent conflict of interest. Of these, 29 initiatives meet all good practice standards, making this the best performing area in capacity building.

This finding is of interest because out of the five areas of capacity building, this is the only one that falls outside of the pharmaceutical value chain, thus arguably companies have the least role to play. This activity could be attributed to an increasing acknowledgement by companies that strong, responsive health systems are needed in order to improve access to their medicines. The motivation to build health systems in low- and middle-income countries can also be linked to the potential for building strong, established markets for their products. When health systems are strong, healthcare professionals can more appropriately detect and treat conditions, ultimately leading to an increase in demand. Health system strengthening initiatives can, therefore, be a potential win-win investment in the longer term – though this commercial interest is also precisely the reason why conflicts of interest need to be managed appropriately.

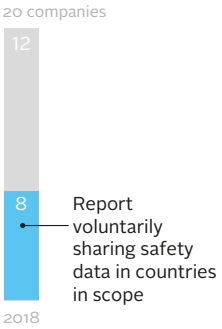
As companies grow increasingly active in this area, it is important that priorities are set to guide where and how they engage in such activities. Kenya is the country with the greatest number (27) of health system strengthening initiatives, but other countries in the region receive less attention and also have needs for health system strengthening. Companies can be guided by a prioritisation or overview of countries with high need for health system strengthening activities and what those needs are.

Companies have the capacity, expertise and resources to contribute towards health system strengthening through training for healthcare professionals, awareness raising, patient education, building infrastructure and implementing digital solutions (e.g., mobile health and data-management systems). Companies typically engage in this area via a Corporate Social Responsibility (CSR) division or through a company-run non-profit foundation.

Most initiatives take a disease specific approach, focusing activities on a predetermined set of diseases which that company has products and expertise in. Almost two thirds of the initiatives that meet the inclusion criteria (40 out of 67) focus on non-communicable diseases (communicable diseases are the focus of 14 initiatives). Of these, 16 initiatives are focused on improving access to cancer care. Cancer incidence and mortality is on the rise in low- and middle-income countries. Over half of all new cancer cases (57%) and cancer deaths (65%) in 2012 occurred in low- and middle-income countries.[3] There is growing demand for cancer products in low and middle-income countries, and yet cancer screening, diagnosis, treatment and palliative care are lacking in many of these countries. Most cancer products (including screening, diagnostic and treatment products) require advanced facilities for administration, meaning that the knowledge and expertise held by pharmaceutical companies is particularly in demand. Robust initiatives which meet good practice standards can improve capacity for cancer care in these settings. Two examples of companies with such initiatives are AstraZeneca and Takeda. AstraZeneca's Phakamisa programme focuses on raising awareness and empowering healthcare professionals by promoting early detection and diagnosis of breast and prostate cancer in South Africa. The programme aims to screen 5 million men and women for these two cancers by 2025. Takeda is working to transform cancer care in sub-Saharan Africa through their Accelerating Cancer Care in Sub-Saharan Africa programme. Working with a wide range of partners across ten sub-Saharan African countries, the programme aims to improve the provision of cancer services from primary prevention to treatment and aftercare services.

Mental health disorders such as depression, anxiety and schizophrenia have a high level of disease burden in low- and middle-income countries as well. It is estimated that globally over a billion people are likely to experience a mental disorder in their lifetime, with 80% from low- and middle-income countries.[4] Yet many people living in these countries go undiagnosed and untreated due to a

Voluntary data sharing improves



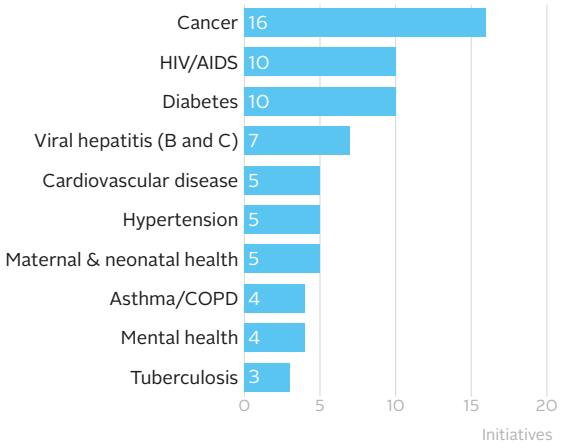
lack of mental health services.[5] Some companies have recognised the need for mental health initiatives in these countries and are working with partners to address it. Three initiatives with a primary focus on mental health conditions were submitted by three companies: Johnson & Johnson, Sanofi and Takeda. In 2018, Johnson & Johnson, in partnership with the Ministry of Health, launched a pilot project in Rwanda that aims to strengthen and expand access to quality mental health treatment, with an initial focus on schizophrenia treatment.

Sanofi set up the Fight Against Stigma (FAST) programme with the World Association of Social Psychiatry (WASP) and the Institute of Epidemiology and Tropical Neurology (IENT) in 2008. This programme aims to improve access to care for mental health and epilepsy, with a focus on fighting the social stigma associated with mental health which can be a barrier to access. Takeda, through its R&D Access to Medicines Employee Fellowship Program, has helped to implement the Access to Health Project in Haiti which aims to establish the integration of community-based mental health services and ultimately achieve a nationally-scaled mental health model in Haiti.

In Sanofi's FAST programme, educational tools are used to raise awareness of mental health conditions.

Figure 52. Health system strengthening initiatives target many different diseases

Company initiatives in health system strengthening are largely focused on building capacity for non-communicable diseases such as cancer, diabetes, hypertension and mental health. Other disease areas with a strong focus include HIV/AIDS and viral hepatitis (B and C). Only five of the included initiatives focus on maternal & neonatal health.



*Companies were scored only on the basis of initiatives that met the basic standards set in the framework. The framework is tailored to each area of capacity building analysed (R&D, manufacturing, supply chain, pharmacovigilance and health systems strengthening). See Appendix XIII for more details.

CAPACITY BUILDING

Best Practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations (see page 117).

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness,
- Sustainability,
- Replicability,
- Alignment with external standards/ stakeholder expectations.

The 2018 Index identified 12 best practices in this area, from six companies.

GSK

The Africa Non-Communicable Disease (NCD) Open Lab advances NCD research

AFRICA

A notable number of collaborations with African institutions to assess, support and improve NCD research.

In 2014, GSK established the Africa NCD Open Lab to support and build the capacity of African scientists to conduct research on non-communicable diseases (NCDs).

In the 2016 Index, GSK received innovation credit for its work with the Clinical Research Unit at Liverpool School of Tropical Medicine to independently assess NCD research capacity in African institutions and identify opportunities to build capacity. This work has allowed GSK to target and address gaps in NCD research in Africa.

How does this initiative build capacity for NCD research?

Currently, the Africa NCD Open Lab works in various ways to respond to local needs to build capacity for research in African universities and public research institutions. It supports scientists, for example, by funding research proposals selected by an independent scientific advisory board, the majority of whose members are African scientists. GSK plans to make further calls for research proposals. To support the next wave of African scientists, it even has a dedicated stream for early career researchers.

The Africa NCD Open lab is also building biostatistics capability, which was identified as a key research gap. It collaborates with the University of the Witwatersrand in South Africa on pharmacogenomics research.

What makes this a best practice?

This initiative has been recognised for best practice for two key reasons. First, it meets all good practice standards: it has good governance structures, it aligns with research institute goals, it has the aim of long-term improvement in research and science in Africa, and it has developed a framework to monitor, track and evaluate the progress of activities. Second, the approach to assessing and targeting local needs credited in 2016 is evident in GSK's collaborations with African institutions and is a strong example of how companies should ensure they meet local needs. Second, the novel approach it takes to identifying local needs (an approach credited in 2016) is now established and is evident in the lab's collaborations with African institutions.

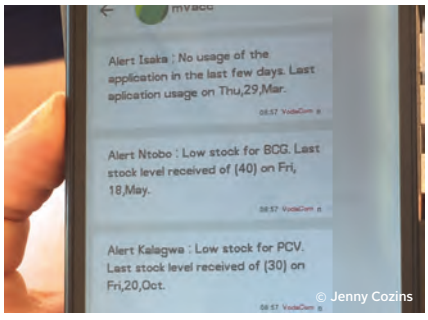
In the breadth and number of its collaborations with universities and institutions to build capacity, within a specific area of need (NCDs), GSK's notable example stands out among its peers.

GSK

mVacciNation improves vaccine stock issues

MOZAMBIQUE, NIGERIA AND TANZANIA

A successfully scaled-up mobile technology platform that tracks vaccine stock data in remote locations.



GSK's mVacciNation platform uses mobile phones to track vaccine stock.

It's estimated that up to a fifth of children worldwide do not receive basic vaccines, despite advances in funding and availability.

GSK's mVacciNation programme uses the proliferation of mobile phones in Africa to establish innovative ways to increase vaccination and improve supply. The programme operates a health intervention to record newborn and childhood vaccinations electronically and addresses needs in the supply chain, specifically in demand forecasting and real-time stock visibility.

Through mVaccinNation, mobile phones are used for three purposes: to improve stock management through a stock visibility system; to establish an electronic medical record of vaccinations and improve data efficiency; and to remind caregivers when children are due for vaccination, and encourage them to complete a regimen.

How does this initiative improve child vaccination?

Initially, GSK and its partners, including Vodafone, ran a one-year pilot in Mozambique, in collaboration with the country's ministry of health, combining expertise in healthcare, vaccines and technology. Through mobile technology, it aimed to increase the proportion of children covered by vaccination by up to 10%. In 2014, the Index recognised the pilot in Mozambique as an innovation. Then in 2016, the programme earned Index scale-up credit through its expansion in Mozambique. More than 100,000 children in Mozambique have been reached and over 400,000 vaccinations have been provided.

The partners have rolled out mVacciNation in two more countries, Tanzania and Nigeria, in 2015 and 2017, respectively, with funding from the Human Development Innovation Fund (HDIF), Gavi and USAID.

What makes this a best practice?

The scale-ups have begun to show success as well, with evidence of mothers returning to healthcare facilities for vaccinations due to SMS reminders from the mVacciNation system. By replicating the programme and showing it can scale successfully, GSK has created an example of best practice in supply chain capacity building.

This initiative meets all good practice standards applicable to supply chain initiatives. It addresses local needs, works in partnership, is guided by clear goals and objectives, aims to make long-term and sustainable improvements and measures progress and outcomes. For example, it uses clearly defined key performance indicators and deliverables to measure the progress its implementation partners are making.

Before pilots began in Tanzania and Nigeria, GSK commissioned independent parties to conduct a comprehensive baseline study in each country. When these pilots end, GSK plans to carry out end line assessments to demonstrate proof of concept.

GSK

Extensive initiative to improve child healthcare

GLOBAL

A wide range of projects through a global partnership with Save the Children, to help one million children access needed medicine and vaccines.

The GSK-Save the Children partnership trains healthcare workers to improve child vaccination.

Worldwide, nearly six million children under five die each year from treatable causes. In 2013, GSK partnered with Save the Children in a long-term, strategic initiative aiming to help save one million children's lives. By combining their expertise and experience, the partners aim to reduce the number of deaths from treatable diseases in the world's poorest countries.

Initially, GSK and Save the Children committed to collaborate for five years. They have now agreed to continue the initiative for a further five years, until the end of 2023.

How does the initiative improve child healthcare?

The initiative consists of a wide range of projects, with GSK contributing by developing medicines and vaccines among other activities. Beyond the value chain (the range of activities bringing a product from conception to consumer), the partnership is also involved in numerous projects to strengthen health systems. Many of these focus on training healthcare workers and improving coverage for vaccines.

What makes this a best practice?

This initiative represents best practice in strengthening health systems. It meets all good practice standards, and is also making efforts to measure and understand the impact of the partnership's activities toward reaching their goal of reducing preventable childhood deaths.

As they implement projects, GSK and Save the Children work with local health systems to ensure they align their efforts with local needs and national priorities. For many projects, the main partners use local partners to conduct baseline assessments and surveys. This enables them to identify gaps and see opportunities to build capacity.

The partnership operates through five different work streams and is governed by a steering committee. The partnership takes risk of conflict of interest seriously and includes it as a standing item of steering committee meetings. There is also strong contractual language aimed at further reducing the risks of conflict of interest with GSK's commercial business.

The partnership strives to make long-term impacts and create solutions that are sustainable. One approach is to advocate for change in tandem with projects that create change. Other projects include training health workers and developing programmes in collaboration with local government.

The activities of the partnership are

guided by the clear goal to help save the lives of one million children. This is further supported by core objectives and five key hoped-for impacts.

Stands out for efforts to measure impact

Notably, the impact is measured through a logical framework matrix ('log frame') based on a theory of change developed for the purpose. Save the Children's in-house team supports the initiative's monitoring and evaluation. It is not yet clear how GSK plans to publicly disseminate results from its measurement of impact.

JOHNSON & JOHNSON

Academy supports local scientists in Uganda

UGANDA

A public institute that supports the development of scientists in Africa and conducts its own research.

The Ugandan Academy is training local scientists to develop innovative health solutions.

Through its pharmaceutical company arm (Janssen) and its Corporate Citizen Trust, Johnson & Johnson founded the Uganda Academy for Health Innovation and Impact (UA) in 2015 in partnership with the Ugandan Ministry of Health and the Infectious Diseases Institute (IDI) of Makerere University. The Academy is the first flagship implementation of Johnson & Johnson's Connect for Life™ programme.

How does the initiative build research capacity in Uganda?

The academy's aim is to improve health outcomes through innovations in clinical care, capacity building, systems strengthening and research. The academy's work focuses on, but is not limited to, HIV and TB.

Part of the planning for the UA involved commissioning local experts from IDI to conduct a landscape assessment to identify gaps in areas such as clinical care, capacity building, health systems and research relating to HIV and TB. The partnership used these gaps to define high-level objectives: driving innovation for impact in the health sector; leveraging partnerships, collaborations and advocacy; and ensuring sustainability.

What makes this a best practice?

The UA now runs its own projects, combining research with training and support. It builds capacity by developing open-access e-learning materials, and supporting postgraduate research. Overall, the vision is to increase availability and accessibility of sustainable healthcare in Uganda.

In the UA, Johnson & Johnson has led the way in contributing to the creation of a public institute that supports the development of scientists in Africa and conducts its own research. This initiative meets all good practice standards and represents best practice in R&D capacity building.

The partnership defines and addresses gaps in research capacity, and has clear strategic objectives, including sustainability. Janssen provided initial funding for the academy (through 2020) and is helping it develop a model for sustainable fundraising and to improve internal systems and processes.

The UA is governed by a memorandum of understanding (MOU), overseen by a secretariat that runs the institute day-to-day, monthly check-ins with Janssen's project leader and quarterly meetings of an advisory board. Tracking happens quarterly, supplemented by an annual report that summarises the UA's achievements. This is available publicly as part of the IDI's annual report.

JOHNSON & JOHNSON

New Horizons addresses unmet needs in paediatric HIV care

SUB-SAHARAN AFRICA

Collaborative initiative aimed at advancing paediatric HIV care, particularly for those failing treatment.

In 2014, Johnson & Johnson's pharmaceutical arm Janssen and their partners launched a collaborative initiative, New Horizons. Globally 1.8 million children under the age of 15 live with HIV. In sub-Saharan African, paediatric coverage of antiretroviral therapy (ART) is at approximately 49%, and at the same time treatment failure is increasingly being identified.[6]

How does this initiative improve paediatric HIV care?

Working in sub-Saharan countries with the highest burden of paediatric HIV, New Horizons aims to catalyse a collective effort to enhance access to high-quality, appropriate and sustainable treatment and care. With an integrated approach that involves donating medicines, strengthening health systems and sharing knowledge, it addresses specific needs for third-line antiretroviral treatment for children and adolescents with HIV, who are failing other treatments.

Early partners in the initiative were the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), the Partnership for Supply Chain Management (PFSCM) and Imperial Health Sciences. Others joining since 2014 include the Collaborative Initiative for Paediatric HIV Education and Research (CIPHER), The Relevance Network and Right to Care.

What makes this a best practice?

New Horizons' activities to strengthen health systems include training and education for health workers, focusing on third-line treatment and psychosocial support. It addresses an unmet need for children and adolescents who are failing HIV treatment. It also addresses country-specific needs, creating tools such

as dosing cards and launching an electronic education programme on paediatric HIV/AIDS for healthcare workers in resource-limited settings.

Stands out for efforts to measure impact

New Horizons is recognised as a best practice because it meets all good practice standards and is also measuring its impact. EGPAF, one of its partners, is using a monitoring and evaluation (M&E) framework and logic model ('log frame') to guide measurements of impact.

In addition, the initiative is guided by clear goals and objectives, linked to clear measures in its M&E framework. The partnership has a governance structure with defined roles and responsibilities, and there is regular communication. Procedures are in place to mitigate risks of conflict of interest.

MERCK & CO., INC.

Informed Push Model strengthens supply chain for contraceptives

SENEGAL

Model removes the burden of tracking and ordering inventory from pharmacies by using logistics operators to regularly deliver and track supplies to ensure sufficient stock.

In 2018, Merck & Co., Inc.'s continued work on the Informed Push Model in Senegal, through its initiative Merck for Mothers, once more represents best practice in supply chain capacity building. The initiative began in 2013 and was given best practice credit in 2014 and 2016.

Senegal's government, recognising that contraception is one of the most efficient methods to save the lives of women and children, committed itself to increase access to family planning. Creating improvements in the public health supply chain were central to achieving this goal.

How does this initiative improve the supply of contraceptives?

Merck & Co., Inc. began working in partnership with IntraHealth, the Bill & Melinda Gates Foundation, Dimagi and Senegal's Ministry of Health and national pharmacy to develop the Informed Push Model with third-party logistics providers (IPM-3PL). Launched in 2013 with a pilot in two health centres, the model is now known as Yeksi Naa ('I have arrived'). Across Senegal, it provides reliable last-mile access to contraceptives and essential medicines.

The model has strengthened the flow of commodities, data and financial information throughout the public health supply chain. It removes the burden of tracking and ordering inventory from pharmacies and clinics, using trained logistics operators to deliver supplies on a regular schedule and to collect data to ensure each site has sufficient stock. Now scaled up, Yeksi Naa delivers around 90 essential commodities to Senegal's public health facilities, including contraceptives and medicines for HIV, malaria and tuberculosis.

What makes this a best practice?

As well as expanding the range, Merck & Co., Inc. and partners created a robust roadmap to enable the Senegalese government to take over management, a transition completed at the end of 2017. Merck for Mothers and the Bill & Melinda Gates Foundation have now joined with the Global Financing Facility and the UPS Foundation to create a new public-private partnership. They aim to build on the Informed Push Model to help countries similar to Senegal to improve public access to essential medicines and health commodities.

The initiative meets all good practice standards measured by the Index, and it has even included an evaluation of impact. It commissioned the London School of Hygiene and Tropical Medicine to conduct the evaluation with data collected since 2013; this was published in October 2017 and is publicly available. The model reaches every standard for best practice in a supply chain intervention: established, scalable, sustainable and able to show evidence of impact.

MERCK & CO., INC.

Merck for Mothers invests $500 million to improve maternal health

GLOBAL

A $500 million, 10-year initiative, to design scalable solutions to help end preventable maternal deaths.

Merck for Mothers (known outside of the US and Canada as MSD for Mothers) is a $500 million 10-year initiative, created by Merck & Co., Inc., to improve the health and wellbeing of mothers before, during and after pregnancy and childbirth.

Beginning in 2011 and set to continue until 2021, the initiative is working with around 100 partners to implement 50+ programmes in more than 30 countries. It has a particularly strong focus on several countries in scope of the Index, such as India, Senegal, Uganda and Zambia.

How does this initiative improve maternal health?

To improve maternal health and help prevent maternal death, Merck for Mothers/MSD for Mothers designs and implements innovative, scalable solutions that empower women, equip healthcare providers and strengthen local health systems. One example is the acclaimed Informed Push Model in Senegal, recognised individually by the 2018 Index as a best practice in supply chain capacity building.

Another focus has been the development of the Mothers' Shelters Alliance in Zambia. Half of all women who give birth in Zambia live more than 15 miles from a facility with basic emergency services. The alliance, founded in 2015, has helped build or revamp 24 shelters, giving women the ability to stay near a health facility before and after giving birth. The initiative also works to strengthen the capacity of private-sector maternity providers.

What makes this a best practice?

Overall, Merck for Mothers/MSD for Mothers represents best practice, meeting every good practice standard.

The initiative is governed by a group of experts from many of its partner organizations which forms its advisory board. Merck & Co., Inc. has an internal policy to mitigate the risk of conflicts of interest. Each model or activity within the initiative has its own set of goals and objectives, and all of the many different models aim to be scalable and sustainable.

While there is no comprehensive plan to measure cumulative impact through the decade, Merck for Mothers/MSD for Mothers does evaluate individual activities in partnership with the London School of Hygiene and Tropical Medicine (LSHTM). LSHTM undertook and published one such evaluation for the Informed Push Model.

NOVARTIS

SMS for Life 2.0 expands to further prevent stock-outs of medicines

NIGERIA, TANZANIA, ZAMBIA, CAMEROON AND PAKISTAN

Enhanced mobile technology supply chain management system now utilising new technologies and expanding to countries and a wider range of products

Novartis' enhanced SMS for Life 2.0 uses tablets to improve stock management for medicines.

In countries where resources are constrained, and problems exist in supply chains, patients can find it difficult to get essential medicines and commodities, especially if they live in remote areas. Local health facilities will often experience stock-outs of essential medicines, meaning it is unavailable for the patient when they need it.

How does this initiative prevent stock-outs?

In 2009, supported by public and private partners, Novartis launched SMS for Life, aiming to improve the management of drug inventories in sub-Saharan African countries. Using basic SMS mobile technology, the initiative worked initially in Tanzania to improve stock visibility and prevent public health facilities from running out of antimalarial medications.

Over the years, SMS for Life has demonstrated considerable success in reducing stock-outs, using technologies that are simple, affordable and widely available. By making information visible to district medical officers responsible for treatment, and providing opportunities to monitor and support operations in health facilities, the initiative helps individuals make fact-based decisions in assessing the adequacy of resource allocation, against actual needs. It was rolled out to more than 10,000 public health facilities in Cameroon, the Democratic Republic of Congo, Ghana and Kenya, and was recognised by the Index in 2016 as a best practice in supply chain capacity building.

What is new in the updated version?

Novartis launched SMS for Life 2.0 late in 2016, and is now implementing this enhanced version in Nigeria, Tanzania and Zambia, with the aim of monitoring a wider range of products at peripheral healthcare facilities.

SMS for Life 2.0 uses updated technology including smartphones and tablets, and has expanded its range to include vaccines and medicines for HIV, tuberculosis and leprosy, with potential to include treatments for non-communicable diseases. The new version runs on tablets also allows for disease monitoring in line with the country's needs, and also delivers high-quality training to healthcare workers through eLearning modules, available on demand.

What makes this a best practice?

Scaled up and enhanced, this improved version of SMS for Life has the benefit of being established and proven as a model. It continues to represent a best practice in supply chain capacity building, meeting all good practice standards.

To ensure it addresses local need, Novartis deploys SMS for Life 2.0 only in countries where local authorities specifically request assistance, and where a country's ministry of health defines the need. It designs and implements activities in partnership with governments and Vodacom, an African mobile communications group. To ensure activities are sustainable, SMS for Life 2.0 works closely with ministries of health, putting management into local hands from the start. Novartis funds the first two years including all start-up costs with expectations for the government to take over costs afterwards. Novartis supports the ministries of health in either budgeting to keep the system running or in finding innovative means to support the government to maintain the system.

SMS for Life 2.0 has clear goals and objectives. Novartis works with university and other third parties to conduct evaluations of the initiative, specifically Boston University School of Public Health (in Zambia) and the Swiss Tropical Public Health Institute (in Tanzania). Previous studies of the original SMS for Life initiative have been published in peer-reviewed journals.

NOVARTIS

Going beyond philanthropy: strengthening care at community level

CAMEROON, CHINA, INDIA, KENYA AND VIETNAM

Over 10 years, it has run initiatives alongside government health ministries and local NGOs to ensure it tailors healthcare activities to local needs.

Novartis represents best practice in its approaches to strengthening health systems at the community level. Rural and impoverished communities often lack access to affordable primary healthcare. For more than a decade, it has run initiatives to improve community-level

healthcare and health education with a focus on non-communicable diseases (NCDs).

Novartis' Healthy Family initiative has reached over 4 million people in Vietnam alone thus far.

How does this initiative strengthen community-level care?

Novartis Social Business oversees three community-level initiatives: Healthy Family in India, Kenya, Vietnam and Cameroon; the Community Health Educator Replication (CHER II) programme in Kenya; and a separate initiative, Health Express – 'Jian Kang Kuai Che' (JKKC) – which operates in China, Kenya and Cameroon.

All are based on the belief that to strengthen health systems in a sustainable way, efforts must go beyond philanthropy. This is why initiatives in Novartis Social Business offer commercial solutions to support public health needs and increase patient reach. Each initiative aims to expand public access to health education and affordable healthcare, increase the capabilities of healthcare workers and raise awareness about health within communities, while providing jobs, income and development opportunities for those in the community working on projects.

What makes this a best practice?

Novartis' approach to strengthening care at the community level represents a best practice. Its initiatives meet good practice standards, and each engages with government health ministries and local NGOs to ensure it tailors activities to local needs. All initiatives work with local partners, and are underpinned by a governance structure that clearly defines partner roles and processes for communication and to mitigate conflicts of interest.

Stands out for efforts to measure impact

Novartis Social Business is working with Boston University to evaluate the impact of its programmes and plans to report the results publicly. Activities are designed to deliver long-term, sustainable improvements, guided by clear goals and objectives laid out in the evaluation framework. Novartis has piloted and expanded its initiatives over several years, and this process has helped to establish them as best practices in health system strengthening.

NOVO NORDISK

No Empty Shelves joins forces to strengthen supply chains

KENYA AND SENEGAL

Partnership to assess supply chain strengths and bottlenecks, as well as availability and affordability of essential medicines and technologies (EMTs).

Data was collected in health facilities and pharmacies in Senegal to identify access barriers.

With PATH (a global health NGO), Novo Nordisk implemented its No Empty Shelves project in 2014. It aims to improve understanding about issues that limit access to essential medicines and technologies for diabetes in low- and middle-income countries, for stakeholders to use to develop solutions. This project has now led to the creation of a global network of organisations that are committed to making such medicines and technologies available and affordable.

How is this initiative working to strengthen supply chains?

No Empty Shelves' main objective has been to strengthen the global evidence base on affordability and availability of essential medicines and technologies (EMTs) for diabetes in low- and middle-income countries. It conducted comprehensive studies in two countries, Kenya and Senegal, to assess supply chain strengths and bottlenecks in these countries and to evaluate levels of availability and affordability for essential supplies. In both countries, Novo Nordisk and PATH presented the results to key national stakeholders, for use in addressing barriers to access and developing solutions.

The partners met their objective by generating a global landscape report titled, 'Diabetes Supplies: Are they there when needed?' The results are available online via PATH's website. Findings confirmed insufficient availability of technologies and equipment such as blood glucose monitoring and syringes, especially at the primary care level. A variety of causes, from lack of financing to inadequate forecasting and supply planning, were identified as barriers to availability.[7]

The main outcome of No Empty Shelves has been the Coalition for Access to NCD Medicines and Products, launched in 2017. This global, multi-sector coalition, led by PATH, aims to increase access to essential medicines and products for NCDs. The Coalition works closely with governments and the World Health Organization to build on existing initiatives, helping to improve supply chains for NCD products.

What makes this a best practice?

No Empty Shelves represents a best practice in supply chain capacity building. It meets all good practice standards. It has a particular strength in identifying local needs and weaknesses in supply chains.

NOVO NORDISK

Base of the Pyramid (BoP) scales up

GHANA, KENYA, NIGERIA AND SENEGAL

Initiative to improve access to diabetes care reaches three new countries.

How does the initiative improve supply of insulin?

The BoP initiative works to provide a stable, affordable supply of insulin by working with national and faith-based distributors to regulate cost structures and coordinate supply. It aims to create value for both communities and for Novo Nordisk itself by developing scalable, sustainable and profitable solutions that increase access to diabetes care for the working poor at the base of the economic pyramid. For this reason, BoP was recognised as an innovative business model in General Access to Medicine Management in the 2014 Index. It has since been scaled up and is seen as best practice in supply chain capacity building.

Activities include providing access to quality care by trained healthcare professionals, to a stable and affordable supply of insulin and to patient education to improve self-management. Novo Nordisk works with local partners including Kenya's Ministry of Health and a faith-based supply chain distributor, Mission for Essential Drugs and Supplies. Together, the partners work to regulate the cost structures of insulin, decrease mark-ups along the supply chain and coordinate supply.

BoP has built capacity in Kenya by transferring skills, knowledge and information about diabetes care, and setting up two centres of excellence at large public hospitals. Now Novo Nordisk is scaling up the initiative and has rolled it out to countries including Ghana, Nigeria and Senegal.

What makes this a best practice?

As an established and scaled-up initiative, BoP represents a best practice in supply chain capacity building. Guided by clear goals and objectives, it meets all good practice standards, and in some cases exceeds them. For example, while the Index does not currently expect companies to measure the impact of their activities relating to supply chain capacity building, Novo Nordisk has worked with University College London (UCL) to evaluate BoP's impact. It published the results and made them publicly available.

The evaluation showed where the initiative was successful and highlighted areas where work is needed (for example, in raising awareness). BoP aims to make improvements that are sustainable in each of the countries where it operates.

TAKEDA

R&D Employee Fellowship Program engages in longer-term projects

HAITI, KENYA AND TANZANIA

Employee fellowship programme that enters long-term engagements with selected NGOs.

Takeda employees engage with local partners on a project to improve mental healthcare in Haiti.

Takeda launched its R&D Access to Medicines (AtM) Employee Fellowship Program in late 2016. Several other companies evaluated by the Index have employee fellowship programmes. Most of these programmes will second individual employees to projects for a period of between three and six months, to work toward a specific deliverable.

What makes Takeda's fellowship programme unique?

Takeda's programme stands out for its design and longer-term engagement. The Takeda R&D AtM Employee Fellowship Program enters into two- to three-year agreements with selected NGO partners which have experience working with the medical and scientific communities in low- and middle-income countries. The fellows join a 'project team' which consists of multiple fellows and partners from the NGO. The fellows work within these teams on specific projects to address local gaps or needs. The purpose of the long-term engagement is to give fellows the opportunity to work towards sustainable solutions.

For example, the company's NGO partners can identify needs for research capacity in local universities. With secondments that last longer, Takeda fellows can contribute to sustainable improvements.

The design of the fellowship programme allows Takeda's employees to share their skills, experience and technical expertise to support and build healthcare capacity in areas such as clinical care, epidemiology, training, R&D project management and supply chain. It also enables them to enhance Takeda's own understanding of access to medicine. Currently, Takeda has fellowship projects operating in Haiti, Kenya and Tanzania.

What makes this a best practice?

Takeda's R&D AtM employee fellowship programme represents a best practice in R&D capacity building, meeting all applicable good practice standards. Through its partners, Takeda is linked with local universities where they can contribute knowledge and expertise in different areas of research. Takeda's partnerships with NGOs operate under project-specific governance structures, and each project has its own goals, objectives and deliverables. Progress towards these is measured in agreement with Takeda's NGO partners.

CAPACITY BUILDING

Innovative Practices

ABOUT INNOVATIVE PRACTICES

Many challenges exist for healthcare systems in low- and middle-income countries such as patchy healthcare services, poor infrastructure and lack of resources.

The Access to Medicine Index recognises those companies that are trialing unique approaches to overcome some of these barriers. These practices are classified as innovative. The Index also highlights previously identified innovations that have been scaled-up or expanded.

The 2018 Index identified five innovations in this area, from four companies.

ASTRAZENECA

New pilot programme considers more than just health

KENYA

Dunga Beach Biogas Project, that aims to reduce air pollution and improve respiratory health, also contributes to local economic and employment development.

AstraZeneca's Dunga Beach Biogas Project is a pilot programme that aims to reduce exposure to air pollution and improve the respiratory health of those living in Kisumu, Western Kenya. The programme came out of a partnership with the Cambridge Institute of Sustainability Leadership (CISL) and involves a local firm, Biogas International Ltd (BIL).

What makes this initiative innovative?

The programme takes an innovative multi-pronged approach, aiming to improve or mitigate impacts not only on health, but also on the local environment and economy. Specifically, the pilot will launch biogas plants in Dunga Beach to convert organic waste into clean energy.

How does the initiative perform against the good practice standards?

Measured against the good practice standards, this initiative meets all but one: AstraZeneca does not yet measure outcomes or impact. However, the programme has clear and measurable objectives, and AstraZeneca reports to the Index that, with its partners, it is finalising measurement plans.

CISL, AstraZeneca's partner, developed the programme after identifying local needs and environmental challenges. It then approached AstraZeneca to partner in the programme's health component. The partnership is governed through regular meetings between partners, including the Ministry of Health, and detailed governance processes are laid out in the services agreement. Conflicts of interest are mitigated through letters of assurance and as part of training for implementation partners.

CISL and AstraZeneca's partnership with the Ministry of Health and local biogas company helps to increase the likelihood that this pilot programme will be sustainable and will provide long-lasting improvements to health, the environment and the local economy.

GSK

HALOW partnership to improve workers' health

BANGLADESH

Cross-sector partnership to address the health and wellbeing of workers in the textile industry.

HALOW works to improve access to healthcare services for garment workers in Bangladesh.

GSK has partnered with Marks & Spencer, PricewaterhouseCoopers (PWC) and CARE (an NGO) to create a programme to improve the health and wellbeing of those working in the ready-made garment (RMG) industry in Bangladesh.

Among GSK's peers, this kind of cross-sector partnership – one that aims to achieve both economic and health gains for a specific,

disadvantaged population – is a new development, offering a fresh model.

How does the initiative help RMG workers?
Bangladesh has 6,000 RMG factories, employing approximately 4.5 million workers. Most RMG workers are women who migrated from rural areas and are now living in slums near the factories. Their gender and social status make it challenging to request services for health and improved working conditions. Together with Marks & Spencer and CARE International, GSK set up the HALOW partnership with the overall goal to improve the lives of 50,000 workers by enhancing their health, and facilitating dignified work. The partnership also aims to demonstrate the business and ethical case for RMG factories to invest in their workers.

A pilot programme, which began in 2015 and lasted for one year, focused on two garment supplier factories that supply Marks & Spencer. The full programme is now being rolled out to further factories throughout Bangladesh.

Frequently, RMG workers live in poor conditions and have a low social status. These factors and others may prevent them from advocating for their own health and social needs, or requesting improved services at work or in their communities. The HALOW programme aims to help these workers by providing health education, raising awareness of health issues and empowering them to access services. The programme also includes the families and communities of the RMG workers.

How does the initiative perform against the good practice standards?
GSK and its partners recognise the need to measure the progress of their interventions and any social or health outcomes. One partner, PWC, is contracted to conduct a business-focused 'return on investment' survey. Additionally, the partners have formed a working group and created a framework to monitor and evaluate the programme, including key performance indicators.

The programme meets all good practice standards. In addition to meeting standards for partnership, addressing local needs and measuring outcomes, the HALOW partnership has created clear objectives, defined governance structures and developed processes to mitigate any conflicts of interest. The initiative is designed with the aim of bringing long-term improvements, and to be sustainable.

JOHNSON & JOHNSON

DREAMS learns from local young women to reduce HIV

SUB-SAHARAN AFRICA

The collaborative partnership, to reduce new HIV infections among young women, uniquely engages directly with local young people through workshops to design learning activities.

In DREAMS, Johnson & Johnson engages with young women to develop capacity building activities that meet their specific needs.

Johnson & Johnson is a partner in DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe), a public-private partnership led by PEPFAR (the US President's Emergency Plan For AIDS Relief). Beginning in 2014, the initiative operates in ten sub-Saharan African countries, aiming to reduce new HIV infections by 40 percent among young women aged 15-24 years. Johnson & Johnson became a formal partner in 2016. This age group of girls and young women account for 74 percent of new HIV infections among adolescents in sub-Saharan Africa.

What makes Johnson & Johnson's role innovative?
In addition to PEPFAR and Johnson and Johnson, DREAMS partners include the Bill & Melinda Gates Foundation, Gilead Sciences, Girl Effect and ViiV Healthcare. Johnson & Johnson is not the only pharmaceutical company involved in the initiative, but it has played a unique and innovative role in generating insight and driving engagement. Notably, Johnson & Johnson has worked to generate insights on behavioural change in target countries, using expertise and strategies from its consumer business, and segmentation analyses of more than 2,500 adolescent girls and young women (AGYW).

How does DREAMS reach young women?
By engaging local stakeholders at all levels, including directly engaging local young people through workshops, the company has been instrumental in shaping the technical design of DREAMS programmes. Input from target groups guided the development of activities, such as the formation of the DREAMS Amplification Leadership Team which is a new Peer to Peer programme. The input from the AGYW also led to the creation of the programme's motto: 'Nothing For Us Without Us.'

By drawing on its own resources from both within its consumer business and its Global Public Health unit in an innovative way, Johnson & Johnson has made a significant contribution to DREAMS' development and implementation.

How does the initiative perform against the good practice standards?
The initiative meets every good practice standard expected by stakeholders. It works to meet local needs in a specific target population and has clear, measurable goals. It has strong governance structures and processes to mitigate conflicts of interest. Seeking contributions from the target population (AGYW) and local stakeholders, it designs activities to be sustainable and able to make long-term improvements by reducing the number of new HIV infections.

The partnership is also measuring outputs and outcomes, using a monitoring and evaluation framework co-developed by the Bill and Melinda Gates Foundation. Data collected thus far is showing a decline in new HIV diagnoses among young women in DREAMS intervention districts. Johnson & Johnson is conducting its own social 'return on investment' analysis of DREAMS, and plans to make the results publicly available through conferences and peer-reviewed journals.

JOHNSON & JOHNSON

Combining data sources to map HIV resistance

DEMOCRATIC REPUBLIC OF CONGO AND UGANDA

A modelling tool that blends multiple types of data to map HIV resistance.

HIV drugs have increasingly become available for people living in resource-limited settings. However, with these treatment scale-ups, HIV drug resistance has started to emerge. The consequences of HIV drug resistance include less effective or even failed treatments and further spread of drug-resistant HIV.

Drug-resistant HIV poses a serious threat to achieving the UNAIDS 90-90-90 targets. Issues such as stock-outs, poor monitoring and lack of adherence increase the risk of drug-resistant HIV. Tackling HIV drug resistance effectively requires building an understanding of where resistance is emerging, tracking its extent and distribution, and monitoring this over time.

How does the initiative address HIV drug resistance?

Johnson & Johnson Global Public Health (GPH), in partnership with the data technology company BlueSquare HUB, is innovating by using multiple data sources to map HIV drug resistance. This initiative to map resistance will result in a dynamic tool to help the countries' policymakers decide on interventions and plan for the provision of second- and third-line HIV therapies. The tool could also be used for advocacy, to develop HIV prevention strategies and to train health workers.

The initiative, which began in early 2018, is initially focusing on Uganda and the Democratic Republic of Congo (DRC). Here, the partners are combining population density maps with multiple sources of data, including epidemiological data collected by the country's health data management system (DHS and DHIS2) and non-epidemiological data (spending on healthcare, and data about political stability, environmental conditions, movement of people and supply chain factors).

What is innovative about this mapping exercise?

The initiative innovates in blending statistics with data analysis and predictive modelling techniques – combining data sources with other tools to map resistance. The first stage will provide proof of concept, with updates for ongoing monitoring. After the completion of the initial mappings in mid-2019, the partners plan to extend the initiative to other regions and countries. In addition to the mapping exercise, Johnson & Johnson GPH will host a hackathon in late 2018 to solve challenges in modelling and addressing HIV resistance. The hackathon will bring together a diverse group of talent and skills, including from local stakeholders.

How does the initiative perform against the good practice standards?

The initiative meets all good practice standards. It is guided by clear objectives and addresses the local need to understand emerging patterns of HIV drug resistance. Johnson & Johnson's partnership with BlueSquare is governed by a contract that sets out partners' roles and responsibilities, overseen by a steering committee. Measuring progress is inherent to the nature of the initiative.

By creating a modelling tool that can continuously monitor resistance, and inform policy decisions and future initiatives, Johnson & Johnson is demonstrating the potential to bring sustainable, long-term value in this area.

NOVO NORDISK

New approach to address chronic care in crisis situations

GLOBAL

The Partnering for Change initiative addresses an unmet need for chronic care for people in crises, with partners appropriate for humanitarian settings.

Novo Nordisk's Partnering for Change offers care for conditions often neglected in crisis settings.

Novo Nordisk is one of the central partners in a new initiative to address an unmet need for chronic care for people in humanitarian settings.

In crisis situations, the focus is often on acute health threats, such as infectious disease or injury. In such circumstances non-communicable diseases (NCDs) can be less of a priority, and may be left untreated. Early in 2018, Novo Nordisk and its partners, the International Committee of the Red Cross (ICRC), the Danish Red Cross (DRC) and others, launched an initiative to address this.

How does the initiative aim to address care in humanitarian settings?

The main aims of Partnering for Change are to ensure an efficient supply of low-cost human insulin and to increase capacity for primary healthcare in humanitarian settings. Novo Nordisk will provide human insulin to its humanitarian partner organisations at a low cost, ensuring access for diabetics in crisis situations. It will also support partners' health programmes, helping to improve NCD prevention and care.

Specifically, at a primary healthcare level in humanitarian settings, partners will test different models of providing basic care and treatment to patients with hypertension or diabetes.

They will be starting with two or three field projects and will draw lessons from these initial projects in order to find the most sustainable solutions to providing chronic care.

What makes this initiative innovative? The initiative's focus on chronic care for NCDs such as diabetes and hypertension in humanitarian settings is innovative. The Index knows of no other capacity building approach that targets healthcare capacity in humanitarian crises.

How does the initiative perform against the good practice standards? Partnering for Change meets all good practice standards. It addresses an unmet need, with partners appropriate for humanitarian settings. It aims to identify a sustainable solution for care in these settings, with activities guided by clear objectives.

The partners are developing governance structures, using input from an external party to ensure a solid framework. Novo Nordisk is also considering how to mitigate any potential conflicts of interest from its participation. One way in which it is doing this is by creating separate agreements with the partners for the provision of insulin and another for its engagement in the capacity building projects.

Plans are also being made to measure the initiative's impact. The London School of Hygiene and Tropical Medicine (LSHTM) has been selected as the external, academic partner, conducting needs assessments and monitoring and evaluation, and assessing impact. The partners will share publicly the needs assessments, preliminary findings and a final evaluation of the initiative.

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G Product Donations

CONTEXT
Donations of medicines and other products are an important tool for improving access to medicine in specific circumstances: for the control, elimination or eradication of diseases impacting the poorest populations in the world; for supporting governments with severely constrained budgets; and as a bridging solution until longer-term, more sustainable routes to ensuring access to medicine are established. There is a growing consensus that sustainable access is better guaranteed through models such as equitable pricing or licensing. To better guarantee sustainability, companies can commit to remaining engaged until elimination or eradication targets are achieved, and/or work with governments on transition plans once the donation programme reaches an end.

HOW WE MEASURE
The Index reviews data submitted by companies about the donations programmes and reviews and uses public sources of information about donation programmes, including for example information published by implementation partners and the organisation Uniting to Combat NTDs.

WHAT WE MEASURE
Scale and reach: The Index looks at the scale of donation programmes in terms of the number of people reached, the financial value, and the number of disease-endemic countries in which the donation programme is active.
Quality and sustainability: whether companies monitor the outcomes and impact of donation programmes, and incorporate elements such as training and diagnosis to maximise its effectiveness. The Index also looks at how companies ensure longer-term access to donated products, for example, by assessing any transition plans.
Ad hoc donations: the processes companies have in place to ensure they can respond rapidly to emergency situations or humanitarian crises.

TOP INSIGHTS

▶ Half of donation programmes for neglected tropical diseases are explicitly committed to continuing until the disease in question is eliminated or eradicated.

▶ Donation programmes for cancer address narrower patient populations than other programmes.

▶ Seven donation programmes for non-communicable diseases apply a range of transition planning approaches for diseases which require long-term or ongoing treatment.

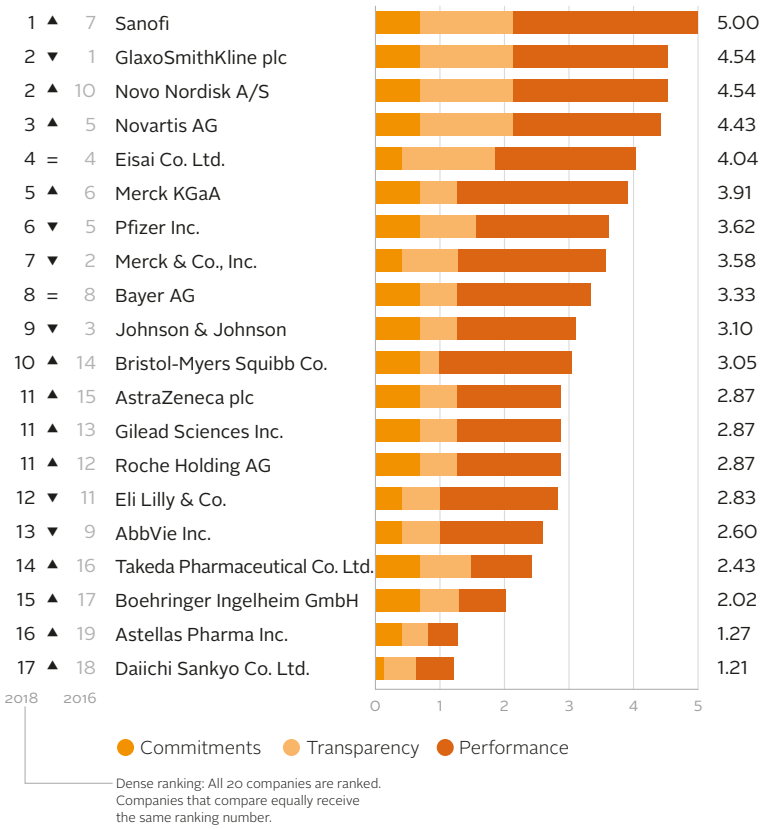
IN THIS CHAPTER

HOW COMPANIES COMPARE

A focus on coverage and sustainability brings newcomers to the leading group

- Sanofi takes the lead with its donation programme for human African trypanosomiasis achieving a wide geographic coverage of countries in which the disease is endemic.
- The pack is split into four distinct clusters: 4 leaders (Sanofi to Novartis), followed by a more widely spread group of 5 (Eisai to Bayer), a tightly packed group of 7 (Johnson & Johnson to AbbVie) that donate mainly for non-communicable diseases, and then 4 companies that do not run donation programmes.
- Just under half of all programmes (16 of 38) address neglected tropical diseases.
- Companies with one or more structured donation programmes take higher positions in the ranking. All companies ranked in the top ten have at least one structured donation programme.

Figure 53. Company ranking: Product Donations



Leaders stand out for their wide geographic coverage

The leaders in product donations are Sanofi (1st), GSK and Novo Nordisk (joint 2nd), and Novartis (3rd). In general, these companies run donation programmes that cover a wide range of endemic countries and meet the majority of criteria looked for by the Index. This includes taking sustainability into account and transparency around programme scale and impact.

Sanofi (1st) leads with its donation programme supplying eflornithine (Ornidyl®), melarsoprol (Arsobal®) and pentamidine (Pentacarinat®) that aims to eliminate human African trypanosomiasis in 17 endemic countries.

GSK (2nd) donates albendazole (Zentel®) to eliminate lymphatic filariasis in 39 countries, and to control soil-transmitted helminthiases (STH) in 50 countries.

Novo Nordisk (2nd) supplies human insulin in 14 countries through its Changing Diabetes in Children (CDiC) programme.

Novartis (3rd) donates the multi-drug combination therapy rifampicin, dapsone and clofazimine to treat leprosy in 49 countries, as well as imatinib (Glivec®) and nilotinib (Tasigna®) to treat chronic myeloid leukaemia (CML) in 57 countries.

Sustainability drives change

Rankings in 2018 include an assessment of how companies either plan to ensure access once a programme has concluded, or commit to stay until eradication or elimination goals are achieved. Of the 16 companies with a structured donation programme, 11 take sustainability into account for at least one programme.

In order to fairly compare the size of companies' donation programmes, companies were assessed in two categories, based on whether their donation

programmes covered (a) short-term treatment or (b) long-term treatment (on-going treatment). They were then benchmarked for programme size against group peers. These shifts have contributed to changes in position.

Novo Nordisk rises 8 (to 2nd) with a high quality donation programme for paediatric diabetes. The company shows that it considers whether access to the medicine can continue once the programme ends.

Bristol-Myers Squibb rises 4 (to 10th) with a newly included donation programme for CML, in partnership with the Max Foundation (cancer is newly in scope in 2018).

AbbVie falls 4 (to 13th), despite having four structured programmes, these programmes reaching a comparatively small number of countries.

Eli Lilly falls 1 (to 12th). Although the company donates medicines for diabetes, cancer and mental health, it falls back against measures that assess whether programmes include plans for ensuring access to the medicine can continue once the programme ends.

Middle group less involved in large-scale activities

The two groups of mid-ranking companies generally run programmes with a narrower geographic reach (measured by number of endemic countries, and benchmarked within peer groups).

The first group, of five companies (Eisai in 4th to Bayer in 8th) run donation programmes that mainly target neglected tropical diseases (NTDs) in multiple endemic countries.

The second group, of seven companies (Johnson & Johnson in 9th to AbbVie in 13th), run programmes mainly for non-communicable diseases (NCDs) generally with a smaller geographic scale.

The four companies ranked lowest (Takeda, Boehringer Ingelheim, Astellas and Daiichi Sankyo) do not run structured product donation programmes for products within the scope of the Index.

Novo Nordisk's CDiC provides insulin and blood sugar testing supplies for a young patient in Myanmar.

Blood samples are tested in a mobile clinic as part of Bayer's donation programme which provides free treatment for patients infected with human African trypanosomiasis.

INDUSTRY ACTIVITY PER TOPIC

Companies take a range of approaches to sustainability planning for donation programmes for non-communicable diseases

Donations of medicines and other products are an important tool for improving access to medicine in specific circumstances: for the control, elimination or eradication of diseases impacting the poorest populations in the world; for supporting governments with severely constrained budgets; and as a bridging solution until longer-term, more sustainable routes to ensuring access to medicine are established.

The Index looks at two types of donation: *ad hoc* donation programmes, which are made in response to humanitarian crises; and structured donation programmes, which the Index defines as 'gifts of, e.g., medicines or vaccines that are set up strategically to target local health priorities with the aim of treating, controlling, eliminating or eradicating diseases within scope'. To categorise the programme as structured, the Index also uses its planned duration, with 5 years or more being the basic expectation.

There is a growing consensus that sustainable access is better guaranteed through models such as equitable pricing or licensing. To better guarantee sustainability, companies can commit to remaining engaged until elimination or eradication targets are achieved, and/or work with governments on transition plans once the donation programme reaches an end.

SCALE AND REACH

Donation programmes for NTDs have the widest reach

Overall, the Index identified 38 structured donation programmes that address one or more of the 55 diseases in scope. Of these, most relate to communicable diseases (21 programmes), compared to 17 NCD programmes. Of the 20 companies in scope, 16 are running one or more structured donation programmes.

Some programmes for NCDs (including cancer) are based on the concept of providing patients with ways of financing their care. Patient assistance programmes (PAPs) use a variety of means to offer financial assistance with purchasing medicines like free or discounted product coupons, and co-pay schemes for those with limited financial resources. Typically, companies administer these programmes through their own foundations or independent charitable organisations.

The Index examines the number of countries and beneficiaries that companies reach through their structured donation programmes. Companies are expected to expand the coverage of good-quality donation programmes to include more people who have no other means to access products they need.

The Index finds a clear difference between the scale and geographic reach of donation programmes for NTDs, versus programmes for diseases such as HIV/AIDS, and many NCDs. This is likely because NTDs can be eliminated or eradicated, whereas NCDs cannot, with patients needing ongoing, long-term, and often life-long treatment. In this analysis, programmes for diseases that can be eliminated or eradicated such as NTDs typically target a larger number of low- and middle-income countries, in which those diseases are endemic. On average, the Index finds that donation programmes for NTDs target 48% of countries where NTDs are endemic compared to 16% for diseases such as HIV/AIDS, and many NCDs.

Impact of the 2012 London Declaration

External factors such as the London Declaration on Neglected Tropical Diseases (London Declaration) of 2012, and WHO's 2020 Roadmap for NTDs have specifically accelerated efforts to address NTDs that can be eliminated or eradicated.[1]

In 2012, the London Declaration was launched to coordinate efforts to combat NTDs. Together with the WHO Roadmap for NTDs, which followed on from the London Declaration, this marked a turning point for millions of people who suffer from these diseases.[2]

Companies signing the declaration in 2012 were AbbVie, Bayer, Bristol-Myers Squibb, Eisai, Gilead,

IN BRIEF

- Donations are an important tool for improving access to medicine in specific circumstances, particularly for the poorest populations.
- Donation programmes for communicable diseases continue to outnumber those for non-communicable diseases (21 vs 17).
- The broadest donation programmes are for neglected tropical diseases, which reach more patients than other programmes.
- Sustainability planning for donation programmes takes different forms depending on whether communicable diseases or non-communicable diseases are the focus.
- For half of the 16 programmes targeting NTDs, companies commit to donating until the disease is eradicated or eliminated.

GSK, Johnson & Johnson, Merck KGaA, Merck & Co., Inc., Novartis, Pfizer and Sanofi. Ten of these companies, with the exception of AbbVie and Bristol-Myers Squibb, now run at least one NTD structured donation programme. Together, these target a range of diseases: leprosy, trachoma, lymphatic filariasis (elephantiasis), soil-transmitted helminthiasis, onchocerciasis (river blindness), schistosomiasis (bilharzia, or snail fever), leishmaniasis (painful condition that causes skin ulcers), Chagas disease and human African trypanosomiasis (parasitic diseases that can lead to heart failure and neurological problems) and food-borne trematodiasis (which can cause a range of health problems including cancer of the bile duct). These programmes can take the form of mass drug administration programmes, where whole populations regardless of disease status have the medicines administered.

Of the 12 companies that signed the London Declaration, ten companies are responsible for all 16 NTD donation programmes in scope. For eight out of the 16 NTD structured donation programmes, the companies responsible commit to donating until elimination of the diseases targeted or as long as needed. These programmes include Bayer's human African trypanosomiasis (*T.b. gambiense* and *T.b. rhodesiense*) and Chagas donation programmes. Three lymphatic filariasis structured donation programmes carried out by Eisai, GSK, Merck & Co., Inc. One onchocerciasis donation programme is carried out by Merck & Co., Inc, and one schistosomiasis donation programme is carried out by Merck KGaA. The longest running programmes are Merck & Co., Inc.'s lymphatic filariasis and onchocerciasis programmes, which started in 1987, followed by GSK's programme for lymphatic filariasis, which began in 1999. Pfizer has recently refreshed the company's commitment to elimination of trachoma, extending its engagement in the donation of azithromycin (Zithromax®) in partnership with the International Trachoma Initiative until 2025.

Collaboration to tackle NTDs

Due to their large size and scope, these NTD donation programmes benefit from a collaborative approach to ensure that products reach patients. The United to Combat NTDs consortium coordinates and implements donations, and stakeholders provide accountability through a working group, which monitors progress through scorecards and milestone tables.

Donation programmes that address NTDs not only have greater geographic reach, but also offer the highest levels of disclosure around scale and outcome. In part, this may arise from the high level of political commitment to eliminating these diseases. NGO implementation partners and WHO often report on activities and achievements to eliminate or eradicate NTDs.

Of the 16 structured donation programmes for NTDs, 13 disclose the programme's financial value, together with the number of units (of product) donated and the number of beneficiaries reached.

PROGRAMMES TARGETING CANCER

Five companies help improve access to cancer care

For the first time in 2018, the Index has evaluated companies' access-to-medicine policies and practices as they relate to cancer medicines, including their donation programmes.

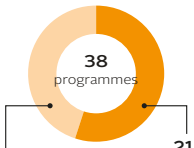
For 2018, the Index identified five companies which, between them, have seven structured donation programmes for medicines to treat cancer: AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Novartis and Roche. These donation programmes cover a range of components along the 'cancer continuum of care', encompassing aspects from awareness raising and prevention through to palliative care. Compared with programmes for NTDs, these seven donation programmes for cancer care have a narrower geographic scope and reach smaller numbers of beneficiaries (with five programmes included for analysis each covering only one country in scope of the Index). These programmes often take the form of patient assistance programmes (offered by pharmaceutical companies to provide free or low-cost prescription drugs to qualifying individuals).

Two programmes achieve the greatest coverage. Novartis leads the way with its programme donating imatinib (Glivec®) and nilotinib (Tasigna®) to treat CML in 57 countries out of 106 in the scope of the Index.

Bristol-Myers Squibb's programme for dasatinib (Sprycel®), also treating CML and operating in partnership with The Max Foundation, operates in 15 countries in scope. The company launched this in 2016 as a pilot, initially intending it to last 12 months, but has extended it for a further year. It will review the programme annually to determine how many patients it will treat. Bristol-Myers Squibb estimates that nearly 400 patients have received treatment since the inception of the programme.

Five programmes targeting cancer each cover one country in scope of the Index. AstraZeneca's Cambodia Breast Cancer Initiative involves the donation of anastrozole (Arimidex®) through an ongoing partnership with Americares based in Phnom Penh, Cambodia. This provides free medicine to postmenopausal breast cancer patients,

55 diseases targeted by structured donation programmes



21
Target communicable diseases, of which 16 target neglected tropical diseases.

17
Target non-communicable diseases

Diseases eliminated since 2016:

Togo
In 2017, after 3 centuries, Togo eliminated lymphatic filariasis as a public health problem.

Ghana
In June 2018, Ghana eliminated trachoma, saving millions from blindness.

5 companies have donation programmes to treat cancer:

- AstraZeneca
- Bristol-Myers Squibb
- Eli Lilly
- Novartis
- Roche

and supports education about the importance of early detection and prompt seeking of care. It aims to identify breast cancer at earlier stages and begin treatment before disease becomes advanced. The programme started in 2008 and is set to continue until at least 2028. Since the start of the programme, AstraZeneca reports reaching more than 800 patients with anastrozole (Arimidex®).

Eli Lilly has a donation programme for Gemzar® (gemcitabine), used to treat breast, lung, pancreatic and biliary tract cancer. This aims to reach 193 patients over the next five years in Kenya in partnership with AMPATH.

Roche runs three separate patient assistance programmes (with partners) in China, Pakistan and the Philippines to supply medicine for breast cancer (trastuzumab [Herceptin®]). These began in 2011, 2012 and 2017. The programmes group patients according to their ability to pay, enabling those on low incomes to afford the medicines. As part of this, Roche provides some treatments for free, for example, in Pakistan where Roche splits 50% of the cost with the federal government for patients in need. In China alone, Roche reports that 20,000 breast cancer patients have benefited from this programme.

PROGRAMMES TARGETING OTHER NCDS

Some attention for diabetes and mental health

Among companies that run structured donation programmes for other NCDs, Novo Nordisk's programme Changing Diabetes in Children (CDiC) achieves significant reach through its operations in 14 countries with nearly 17, 000 children enrolled since the start of the programme. This programme offers a high level of public disclosure relating to scale and impact assessments. Between 2009 and 2017, it donated more than 1.5 million vials of human insulin. It also discloses the financial level at which it funds the programme.

Eli Lilly donates also medicines for diabetes (insulin lispro [Humalog®]) through its Life for a Child programme. This is active in 23 countries within scope of the index, and by 2017 had donated 1.4 million insulin vials through the International Diabetes Foundation.

When considering health funding in low-income countries, policy-makers and donor agencies are guided by epidemiological evidence that indicates the burden of disease on these populations. For various reasons such as social pressures and stigma, mental health does not receive sufficient attention in low-and middle-income settings. Three companies operate four programmes that donate products to treat mental health conditions. AbbVie donates divalproex sodium (Depakote®) for bipolar affective disorder in Cambodia and Kosovo. Eli Lilly donates Olanzapine (Zyprexa®) and fluoxetine hydrochloride (Prozac®) to treat patients in Kenya. Eli Lilly's implementation partner, AMPATH holds a special clinic weekly to meet the mental health needs of patients. A mental health nurse provides onsite counselling at rural clinics. Johnson & Johnson donates haloperidol (Haldol Decanoas®) and risperidone (Risperdal®) to treat schizophrenia, with the programme active in six countries in scope of the Index. Beyond product donations, the company's support covers capacity building activities including family engagement programs.

3 companies have structured donation programmes for mental health:

- AbbVie
- Eli Lilly
- Novo Nordisk

One company donates for maternal & neonatal health: AbbVie

In maternal and neonatal health, AbbVie is the only company to donate any products in this area, operating two structured programmes for beractant (Survanta®), which addresses respiratory distress in newborns. The programmes operate in Honduras, India, Jamaica, Kosovo and Paraguay. In Kosovo, AbbVie's partner Americares estimates that more than 2,000 babies received treatment. AbbVie publicly discloses information about this programme, including financial value, units donated and number of beneficiaries. Donating to the neonatology unit at the University Clinical Center of Kosovo since 2009, it gave 204 units in 2017.

QUALITY & SUSTAINABILITY OF PROGRAMMES

Sustainability of access addressed through long-term planning

Companies have a responsibility to ensure that donation programmes lead to sustainable improvements in access to medicine. This means ensuring populations can continue to access donated products for as long as they are needed. This may involve companies making a firm commitment to donate until a disease is eliminated or eradicated. For programmes where this is not possible (for example, those that target NCDs), it may entail establishing transition plans for patients to access the product once the programme ends.

To help ensure that programmes are sustained and continue to provide quality donations, companies may incorporate capacity building activities, for example by helping to improve local screening and diagnosis capabilities. The Index also expects companies and their partners to monitor the outcomes and impacts of donation programmes, and to disclose the results publicly.

Of the 38 structured donation programmes the Index assessed, 15 take the sustainability of access improvements into account.

Out of 16 NTD donation programmes, half (8) have considered the need for ongoing access. The companies responsible for these eight programmes have made clear and public commitments to donate products until the disease is eliminated. The other eight make time-bound public commitments.

The remaining seven programmes that consider sustainability all address NCDs. In these programmes, practices for considering sustainability vary. Where donations are deemed appropriate, the consensus view is that programmes must include assessments of how access can be sustainable in the long-term. This means companies working with governments to establish plans to ensure recipient populations can continue to access treatments for as long as they are needed, even after donation programmes end. Once again, sustainable approaches are especially pressing where patients suffer from chronic diseases.

Bristol-Myers Squibb operates a donation programme to supply dasatinib (Sprycel®) to treat CML in 15 countries. The company contractually agrees to provide products to patients for as long as doctors recommend continuation of treatment, and no other means of accessing the product is available.

Roche has transition plans in place for its trastuzumab (Herceptin®) donation programme. For example, in China and the Philippines, it is working with national and local government units, health institutions and other stakeholders to ensure or increase public reimbursement for trastuzumab (Herceptin®), enabling patients to access their medicine through public healthcare systems. To ensure access will continue once the donation programme ends, the plan includes the mobilisation of alternative sources of funding, such as the development of private health insurance for cancer.

Novo Nordisk has put in place transition plans for its CDiC programme. With a process designed to be gradual, the company will continue to supply insulin to children enrolled at the planned end date in 2020, and will work with local stakeholders until they can operate the donations alone. For example, the company's local partners in Cameroon have secured an agreement with the government to cover blood sugar level tests (aprox. 10 USD per test) every third month and the purchasing of human insulin and syringes at a subsidised price.

Johnson & Johnson takes a different approach to sustainability. It runs two structured programmes for children to access the paediatric HIV/AIDS medications darunavir (Prezista®) and etravirine (Intelence®). The company commits to ensuring that treatment is not interrupted for enrolled children as they reach adolescence and transition into adult care. Johnson & Johnson is also working with the Paediatric HIV Treatment Initiative (PHTI), to develop a specific generic version of fixed dose darunavir/ritonavir that will help to ensure patients can afford medication longer term. That being said, the company's bedaquiline (Sirturo®) donation programme for tuberculosis in partnership with USAID is in the process of developing a transition plan in preparation for the planned end date in April 2019.

OUTCOMES AND IMPACT

How do companies ensure the effectiveness of programmes?

The Index looks for evidence that companies monitor outcomes and impact of structured donation programmes and engages in capacity building activities to support the quality of the initiative (through activities such as training, for example). Monitoring outcomes and impact enables companies to evaluate and improve ongoing programmes. Capacity building elements (e.g., training, diagnosis) enhance the effectiveness of programmes.

With CDiC, Novo Nordisk fulfills all the criteria for quality that the Index considers, such as its efforts to build capacity. Aiming to make sure that children with type 1 diabetes receive continuing care, it takes a three-pronged approach: to train healthcare professionals to develop diagnostic skills and expertise to manage type 1 diabetes; to adapt patient education materials for children and their families for local contexts; and to share best practice and insights on developing healthcare interventions specific to minority populations (such as children with diabetes living in settings where resources are constrained). Since its start in 2009, the programme has trained more than 10,000 healthcare providers, established 138 clinics, and educated more than 16,000 children about diabetes. From 2016, the programme has expanded to five further countries in scope: Cambodia, Côte d'Ivoire, Myanmar, Senegal and Sudan.

With the Glivec International Patient Assistance Program (GIPAP) for CML, conducted via the Max Foundation, Novartis supplies imatinib (Glivec®) and nilotinib (Tasigna®) in all 57 countries where the programme is running. Through partners, the programme provides diagnostic and laboratory services, supply management, pharmacovigilance procedures and patient support. These are integral to the programme.

40% of programmes consider ongoing access

AD HOC DONATION PROGRAMMES

Most companies donate in response to humanitarian emergencies

Long-term structured donation programmes are critically important, but companies also donate medicines and other products *ad hoc*, in response to emergency situations such as natural disasters. Low- and middle-income countries now account for nearly three quarters of deaths pertaining to NDCs, resulting in 28 million deaths.[3] Relief agencies such as the International Committee of the Red Cross (ICRC) and Médecins Sans Frontières, (MSF) have adjusted their relief efforts to account for NCDs.[3] This is reinforced by the WHO's NCD Global Action Plan with calls to 'improve the availability of life-saving technologies and essential medicines for managing NCDs in the initial phase of emergency response.'[4]

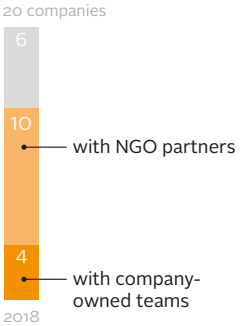
With *ad hoc* donations, companies need to position themselves to be able to move rapidly as they seek to respond to humanitarian emergencies. They must also make sure that any contribution corresponds to an expressed need, and aligns with WHO's international guidelines for medicine and vaccine donations.

The majority of companies the Index looked at (14 out of 20) have: 1) policies to ensure that donations align with international guidelines; 2) processes to make sure they can respond rapidly to requests, and 3) procedures to monitor delivery until the end user takes receipt of a donation.

Of the companies that do not meet all three of these criteria, five (AbbVie, Astellas, Eisai, Eli Lilly and Merck & Co., Inc.) fulfill two out of the three. Most commonly, these companies lack systematic processes to ensure it can respond rapidly to requests for *ad hoc* donations. Typically, a process to ensure rapid response to requests includes a company signing forward-looking agreements with established NGO partners to implement action on the ground. Rapid response processes ensure that the company can donate the medicine in a timely manner. Ten companies have such agreements in place, while four take different approaches including designating their own teams to deal with requests for *ad hoc* product donations. One example is Novo Nordisk's central team for humanitarian product supply; another is Bristol-Myers Squibb's disaster task force.

Daiichi Sankyo's *ad hoc* product donation policy states that it aligns with local guidelines but it is not clear how it aligns with international guidelines. Neither does it have processes in place to ensure it can respond rapidly to requests for *ad hoc* donations.

14 companies respond rapidly to emergencies



Children receive Johnson & Johnson's donated mebendazole (Vermox™) as part of a deworming campaign in Peru.

PRODUCT DONATIONS

Best Practices

ABOUT BEST PRACTICES

The Access to Medicine Index seeks best practices in each of the areas it measures. Once identified, these are shared to accelerate their uptake by other pharmaceutical companies, to help raise the level of standard practice and to achieve greater access to medicine.

Where companies are trialing something unique, these may be classed as innovations.

Best practices are not new – they have already been conceived of, applied and shown to meet at least some of the following criteria:

- Proven effectiveness,
- Sustainability,
- Replicability,
- Alignment with external standards/ stakeholder expectations.

The 2018 Index identified one best practices in this area, from five companies. No innovative practices were identified.

BEST PRACTICES	Page
Bayer	130
Eisai	130
GSK	130
Merck & Co., Inc.	130
Merck KGaA	130

REFERENCES

1 London Declaration on Neglected Tropical Diseases. http://www.who.int/neglected_diseases/London_Declaration_NTDs.pdf. Accessed October 12, 2018.

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4 WHO | Global Action Plan for the Prevention and Control of NCDs 2013-2020. WHO. 2015. https://www.who.int/nmh/events/ncd_action_plan/en/. Accessed October 30, 2018.

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BAYER, EISAI, GSK, MERCK & CO., INC., MERCK KGaA

Continued commitment to combat NTDs

GLOBAL

Sixteen donation programmes in place to provide free medicines to treat NTDs.

Treatment for lymphatic filariasis is provided during an annual drug administration in Tanzania.

There is a clear difference between initiatives that address diseases where patients need lifelong treatment, and those that aim to eliminate or eradicate disease altogether. Certain types of diseases such as NTDs offer companies the opportunity to commit resources and work with partners to eliminate or even eradicate them permanently.

Why commit to elimination or eradication?

NTDs such as sleeping sickness, river blindness, guinea worm disease and blinding trachoma are estimated to affect more than a billion people in the world's poorest countries.[5] Though they are rarely fatal, they can cause blindness, fatigue, disfigurement and debilitation. Eliminating or eradicating them can significantly improve people's lives. The pharmaceutical industry can help achieve this global goal of combatting NTDs through sustained engagement with the global health community as well as continuing to commit resources. So far, NTD donation programmes have helped millions of people to receive free regular treatment for numerous NTDs.

In January 2012, WHO drew up a comprehensive roadmap for the control, elimination and eradication of 17 NTDs by 2020. At the end of that month, pharmaceutical companies joined other partners to sign the London Declaration on Neglected Tropical Diseases, committing to provide necessary resources to control, eliminate or eradicate 10 diseases by 2020.

Twelve companies in scope of the Index signed the London Declaration and have aligned their commitments with those of WHO and the London Declaration. Sixteen donation programmes are in place to provide free medicines to treat NTDs. In eight, there is no commitment to donate until the disease is eliminated. In some cases, elimination is not viable. As of 2018, however, five companies in scope, working with the WHO, have committed to donate medicines through their programmes until the nine remaining NTDs are eliminated or eradicated.

Which companies demonstrate this best practice?

Bayer runs two donation programmes to treat sleeping sickness transmitted by tsetse fly, affecting people in nearly 40 African countries (human African trypanosomiasis, *T.b. gambiense* and *T.b. rhodesiense*). Bayer also has one for Chagas disease, a form of trypanosomiasis that occurs mostly in Latin America.

Eisai, GSK and Merck & Co., Inc. each operate a structured donation programme for lymphatic filariasis (elephantiasis). Merck & Co., Inc. also runs a programme for onchocerciasis (river blindness), while Merck KGaA has one for schistosomiasis (bilharzia), which causes liver damage and kidney failure.

Company Report Cards

The 2018 Access to Medicine Index includes a set of 20 company report cards, that provide the most detailed overviews of each company's performance.

Companies are all different in the way they operate, where they operate, and in their portfolio of investigational and marketed products.

Each Report Card includes a summary of the company's strengths and weaknesses, drivers behind changes in its ranking, as well as any best and innovative practices. The report cards are divided into seven sections:

▶ Performance
Explanation of the company's position in the 2018 Index and a summary of its access-to-medicine performance. Performance is broken down into Technical Areas and it gives the key drivers behind the company's changes in ranking and the main areas where it scores well or poorly compared to peers.

▶ Changes since 2016
Update on where the company's access-to-medicine performance has changed most notably since the 2016 Index. It includes new or expanded commitments, strategies, activities and programmes.

▶ Opportunities
Tailored opportunities for the company to improve access to medicine, taking account of its R&D pipeline, product portfolio, current equitable pricing strategies and approach to IP management, among other factors.

▶ Portfolio & pipeline
Analysis of the company's portfolio of marketed products and pipeline of R&D projects that fall within the scope of the Index. This section looks at the size and focus of the company's portfolio and pipeline, whether the company has products that are considered first-line or are on the WHO Model List of Essential Medicines and whether it is conducting priority R&D and planning for access during development.

▶ Business context
General description of the company's operations, recent mergers & acquisitions, revenue per region and geographical reach.

▶ Performance by Technical Area
Overview of the company's performance in each Technical Area measured by the Index. The report card performance points have been structured to be comparable between companies, while still describing the company's individual programmes, initiatives and approach.

▶ Best & innovative practices
A summary of all best practices and/or innovative practices identified for the company in any of the Technical Areas for the 2018 Index.

RANK	SCORE
1=	4.01
1 (2016)	

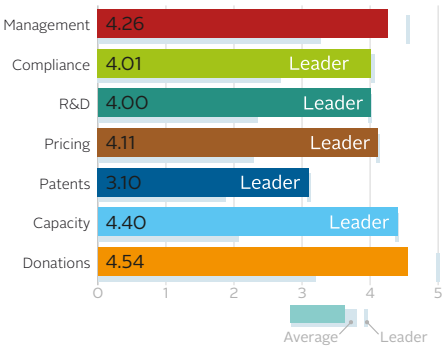
GlaxoSmithKline plc

Stock Exchange: XLON • Ticker: GSK • HQ: Brentford, United Kingdom • Employees: 98462

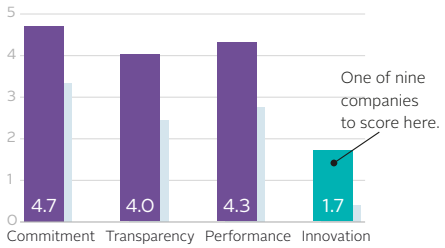
PERFORMANCE

Retains 1st place. It continues to outpace peers by building on a strong foundation of strategies that are applied to both R&D projects and products on the market. GSK leads in five out of seven Technical Areas.
Management: Retains third place. Access strategy is clearly linked to business rationale, with incentives for senior management aimed at long-term objectives.
Compliance: New to 1st place, it discloses all components of an internal control system looked for by the Index.
R&D: Retains top place, by creating an integrated Global Health R&D unit, and the largest number of projects targeting priority R&D gaps.
Pricing: Holds top place, with one of the highest proportions of equitable pricing strategies being applied to priority countries.
Patents: A new leader, with its voluntary licence for dolutegravir (Tivicay®) having the largest geographic spread.
Capacity: Leads for the first time with the highest number of initiatives meeting all good practice standards.
Donations: Falls to 2nd place. Maintains strong performance, but falls short compared to the leader in endemic country-coverage.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Ensure sustainability of established access systems while shifting to a distributor-led model. During the period of analysis, GSK reviewed and restructured its product deployment strategy for its pharmaceuticals business to a distributor-led approach in several countries within the scope of the Index, including sub-Saharan Africa. GSK should ensure that access to products is maintained and response to need and supply are addressed.

Continue to register key HIV products in countries in scope. GSK should work through ViiV Healthcare to register HIV/AIDS products in all priority countries, for example abacavir/dolutegravir/lamivudine (Triumeq®), dolutegravir/rilpivirine (Juluca®), and Dolutegravir (Tivicay®). Dolutegravir (Tivicay®) is GSK's most widely registered new product, registered in 50% of the possible priority countries. GSK can also file its paediatric formulation of dolutegravir (Tivicay®), for broad registration in priority countries. To help improve registration of HIV/AIDS medicines in priority countries, GSK can consider participating in the WHO Collaborative Registration Procedure.

Expand HIV voluntary licensing agreements. GSK can look to expand its non-exclusive voluntary licence for dolutegravir (Tivicay®) for HIV/AIDS, which currently covers 70% of middle-income countries in scope with the highest burden of HIV/AIDs. Middle-income countries with a high burden of HIV/AIDS excluded from the licence agreement are: Brazil, China, Mexico and Suriname.

Develop equitable pricing strategies prior to Phase III. GSK can work to ensure that all R&D projects have access plans during Phase II and continue to refine this process to allow for the earlier establishment of these provisions. In particular, it can work to establish equitable pricing strategies at Phase II of clinical development.

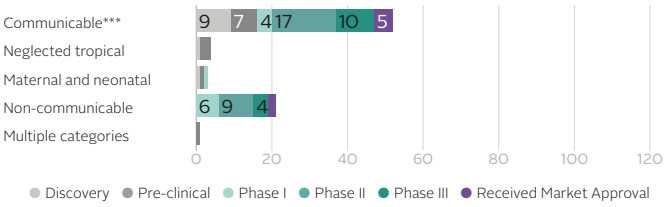
CHANGE SINCE 2016

- Partially reverses company ban on payments to healthcare professionals as of October 2018.
- Joined Access Accelerated with its Africa NCD Open Lab initiative. It has also committed to measure impact and share results publicly via Access Observatory for two of its projects.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Improved its access planning process to consider all R&D projects in scope, with access plans in place, after proof of concept, during Phase II of clinical development.
- Established a Global Health R&D Unit (part of the new Global Health Unit) that encompasses GSK's open innovation initiatives for maternal and neonatal health, non-communicable diseases in Africa and neglected tropical diseases while systematically incorporating access into these projects.
- Shifts to distributor-led model in key regions (e.g. Sub Saharan Africa, Southeast Asia) within the Index scope.

PIPELINE *for diseases and countries in scope*

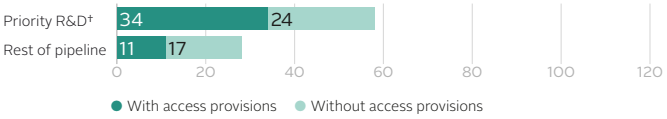
Comparatively large pipeline: 86* R&D projects for diseases in scope (59 medicines; 26 preventive vaccines; 1 diagnostic; 1 therapeutic vaccine; 1 vector control product).
Clinical candidates: 53, including tafenoquine for the treatment of *Plasmodium vivax* malaria in children and adults and a paediatric indication for dolutegravir/rilpivirine (Juluca®) for the treatment of HIV/AIDS.
Regulatory approvals: 7, including influenza H5N1 pre-pandemic vaccine (Prepandrix™) for paediatric usage.
R&D focus: communicable diseases (HIV/AIDS, malaria and lower respiratory infections) and non-communicable diseases (cancer, asthma and COPD).
Access provisions: for 45 projects, most commonly registration commitments.

Projects in the pipeline: 86**



Tafenoquine (Krintafel™) was approved by the FDA three weeks after the 2018 Index's period of analysis closed. It is the first treatment for *P. vivax* malaria in over 60 years, and GSK continues to develop the drug for paediatric usage.

Projects for R&D priority targets with access provisions: 34

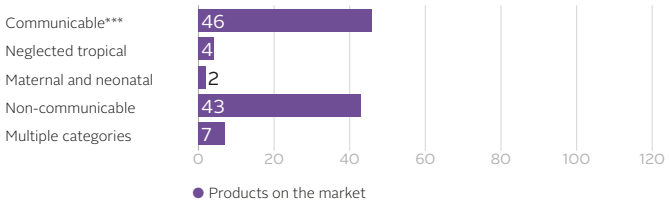


Of GSK's 86 R&D projects, 45 are supported by access provisions: e.g., the antimalarial tafenoquine includes not-for-profit pricing, patent waivers and a registration strategy. 32 of its 47 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

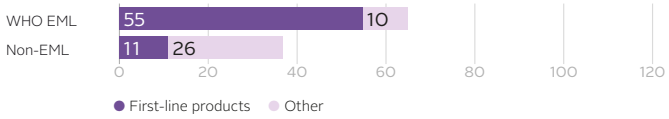
Comparatively large portfolio: 102 products for diseases in scope (77 medicines; 25 preventive vaccines).
Portfolio focus: communicable diseases (lower respiratory infections and HIV/AIDS) and non-communicable diseases (asthma and hypertensive heart disease).
Essential medicines: 64% of GSK's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 65% of GSK's medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 102



GSK's portfolio includes products such as dolutegravir/rilpivirine (Juluca®) and several preventive vaccines including an expanded indication for its Fluarix® quadrivalent influenza vaccine in children six months and older.

Essential medicines with first-line indications: 55



75% of GSK's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., the pneumonia and *H. influenzae* vaccine Synflorix®, the HPV vaccine Cervarix® and dolutegravir (Tivicay®).

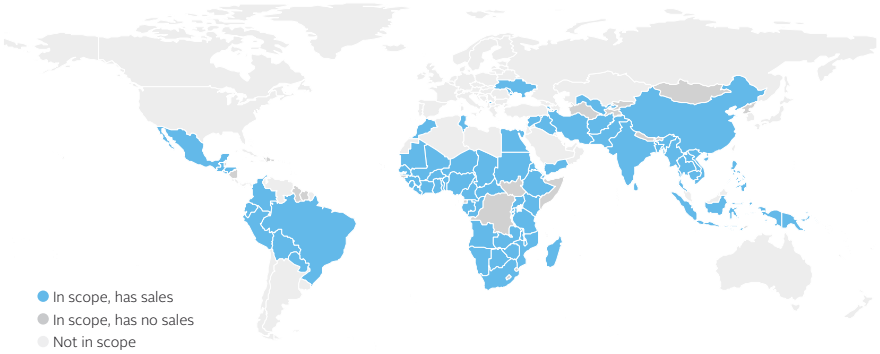
BUSINESS CONTEXT

Three business units: Pharmaceuticals; Vaccines; and Consumer Healthcare. Its pharmaceutical business segment has five therapeutic areas (respiratory; HIV/AIDS; oncology; rare diseases; and immuno-inflammation). Its vaccine portfolio focuses on traditional childhood vaccines (e.g., DTaP-containing combination vaccines) and newer vaccines with few other suppliers (e.g., HPV, pneumococcal disease and rotavirus). GSK holds a 78.3% equity share in ViiV Healthcare - a joint HIV/AIDS medicine venture with Pfizer and Shionogi.
M&A news: 2018 buyout of Novartis 36.5% stake in its Consumer Healthcare joint venture.
Presence in emerging markets: In 2018, GSK reports sales in 74 countries in scope; 18 less countries than in the 2016 Index. It reports that a large portion of its sales in 2017 came from regions outside of Europe and the USA.

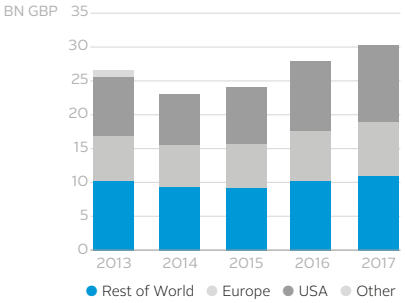
Turnover by segment (2017) - GBP

Pharmaceuticals	17,276 MN
Vaccines	5,160 MN
Consumer Healthcare	7,750MN
Total	30,186 MN

Sales in countries in scope



Turnover by geographic region



Statistics relate only to diseases and countries in scope.

*Projects that target multiple product types are counted more than once.
**Figure excludes 5 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.
***Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
†See Appendix IV for definition.

GlaxoSmithKline plc

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 3 SCORE 4.26

Has a strong access-to-medicine strategy with board-level responsibility. GSK is one of 14 companies that performs strongly with regards to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy centres around improving access to medicine and strengthening health systems in countries in scope by developing partnerships focused on access, such as ViiV Healthcare. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. GSK performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include a variable pay system linked to long-term results, bonuses and rewards. Senior management has a separate incentive that supports the company's long-term access oriented objectives.

One of the 16 companies working on impact measurement. GSK measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, targets and performance information. For example, for its partnerships with Amref Health Africa, CARE International and Save the Children, GSK reports reaching its goals on helping underserved people by training 65,000 frontline health workers. Furthermore, it is one of the companies that is measuring impact by reporting on the progress of its Save the Children partnership.

Clear stakeholder engagement approach that includes local stakeholders. GSK performs well when it comes to the disclosure of its stakeholder engagement. It publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with. It does incorporate local stakeholder perspectives into the development of access strategies. It has some policies covering responsible interactions with stakeholders, namely to operate with integrity and transparency with local stakeholders, following its standard for interacting with patient organisations.

MARKET INFLUENCE & COMPLIANCE

RANK 1 SCORE 4.01

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. GSK leads in the area of ethical marketing and anti-corruption governance. It has a code of conduct relating to ethical marketing and anti-corruption, and provides annual compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities such as technical knowledge and quality of service.

Internal control framework meets all Index criteria. GSK has all the components of an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It also has a monitoring system in place to track compliance in the workplace; it conducts audits involving both internal and external resources—that also applies to third parties. GSK also demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. GSK publicly discloses its policy positions on access-related topics. For example, it has a policy on intellectual property and access to medicine for developing countries. It is one of the few companies in scope to have a policy that prohibits political contributions. GSK discloses its membership of relevant institutions and whether it provides financial support. It discloses its policies for responsible engagement, including responsible lobbying. During the period of analysis, GSK was the only company to have a policy prohibiting payments to healthcare professionals to attend and speak at conferences.

RESEARCH & DEVELOPMENT

RANK 1 SCORE 4.00

PROJECTS: 86 IN CLINICAL DEVELOPMENT: 53

Publicly commits to R&D to meet public health needs. GSK has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale with each commitment developed in response to public health needs in these countries. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. GSK has one of the largest pipelines in the Index with 86 projects. For diseases in scope where priorities exist, GSK is active in 60 projects; 58 of these target priority R&D gaps.

Access provisions in place for 68% (32/47) of late-stage candidates. GSK has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope when possible. In general, GSK develops access plans for R&D projects in Phase II of clinical development, and it develops equitable pricing strategies in Phase III. To date, GSK has the highest number of project-specific access provisions, with 32 in place for its late-stage R&D projects. Of these, 19 are being conducted in partnership.

Public policy to ensure post-trial access; commits to registering trialed products. GSK has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, GSK commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 1 SCORE 4.11

PRODUCTS: 102

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY 61

Commits publicly to equitable pricing and reports a commitment to file to register new products in scope. GSK commits to filing its newest products for registration in countries in scope within one year of first market approval, where possible. It also publicly commits to implement inter-country equitable pricing strategies for the majority of its products for diseases in scope. However, this does not explicitly apply to future products. Its public commitments also apply to intra-country equitable pricing strategies.

Some new products in scope filed for registration in the majority of priority countries. Although GSK newly commits to filing its newest products for registration in countries in scope within one year of first market approval, it has

filed 10% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it publicly shares some registration information for the majority of its products.

60% of products have equitable pricing strategies targeting priority countries. GSK's overall performance is strong compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 60% of its products for diseases in scope. These strategies apply to an average of 35% of priority countries. The majority of these strategies apply both inter- and intra-country pricing; these take into account an average of four socioeconomic factors. GSK also applies equitable pricing strategies to 19 further products informed by a public health rationale.

Has both globally consistent recall guidelines for countries in scope and processes to track products. GSK has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 1 SCORE 3.10

Publicly discloses detailed information on patent statuses. Like most of its peers, GSK publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Uses licensing to enable generic supply. GSK performs strongly in this area. The company has non-exclusive voluntary licensing agreements in place for two compounds (for diseases in scope). Its broadest licence, for dolutegravir (Tivicay®), encompasses 102 countries including 71 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Shares some IP assets with 3rd-party researchers. Compared to its peers, GSK shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with UK research institutions such as the University of Keele and the University of Dundee. The assets shared include molecule libraries.

Public commitment not to enforce patents in countries in scope. GSK commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

CAPACITY BUILDING

RANK 1 SCORE 4.40

23 initiatives included for evaluation. GSK has 23 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; GSK submitted the maximum.

Strong focus on local manufacturing and strengthening health systems. GSK has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least two initiatives in each area which meet all good practice standards. GSK performs strongest in manufacturing capacity building and health system strengthening.

18 initiatives meet all applicable good practice standards:

- Water Scarcity in India and Bangladesh
- Academic Research Chair
- Comic Relief – GSK malaria partnership
- STEP (Strategic Training for Executives Programme)
- Positive Action programmes

A full list of GSK's capacity building initiatives which meet all good practice standards can be found online.

Out of GSK's five remaining included initiatives, three are in the area of pharmacovigilance. These initiatives typically fall short on having good governance structures in place and processes for mitigating conflicts of interest.

Timely approach to confirming and reporting substandard or falsified medicines. GSK provides evidence that it systematically confirms suspected cases of substandard or falsified medicines and then reports confirmed cases to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days for each, confirmation and reporting).

PRODUCT DONATIONS

RANK 2 SCORE 4.54

STRUCTURED DONATION PROGRAMMES: 2

Responds to emergencies and humanitarian crises and tracks delivery. GSK donated medicines on the request of relief agencies. For example, during the period of analysis, it donated various products such as amoxicillin/clavulanic acid (Augmentin™) in response to the 2016 hurricane in Haiti. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with Save the Children, Direct Relief, Americares and Map International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Two donation programmes covering diseases and countries in scope. GSK's programmes are focused on neglected tropical diseases (NTDs), namely lymphatic filariasis (LF) and soil-transmitted helminthiases (STH). Both programmes are carried out in partnership with WHO. Its programme for STH supplies albendazole (Zentel®) in 50 countries and has been ongoing since 2011. In 2017, GSK reported donating 123.7 million albendazole(Zentel®) tablets for STH and 770 million albendazole (Zentel®) tablets for LF.

Addresses long-term access by aiming to eliminate disease. GSK commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its albendazole (Zentel®) donation programme aims to eliminate lymphatic filariasis in 39 countries.

BEST PRACTICES

The Africa Non-Communicable Disease (NCD) Open Lab advances NCD research
A notable number of collaborations with African institutions to support and improve NCD research.
Extensive initiative to improve child healthcare
A wide range of projects through a global partnership with Save the Children.
mVacciNation improves vaccine stock issues
A successfully scaled-up mobile technology platform that tracks vaccine stock data.
Dolutegravir (Tivicay®) licence has widest geographic potential for improving access
The non-exclusive voluntary licence for dolutegravir (Tivicay®) covers 95% of low- and middle-income countries in scope.
Continued commitment to combat NTDs
One of five companies running donation programmes to eliminate or eradicate NTDs.
Largest proportion of pipeline dedicated to priority R&D projects
More than 60% of GSK's and Sanofi's pipelines focus on diseases for which products are urgently needed.
Plans ahead for largest proportion of pipeline
GSK leads in planning ahead to make future products accessible.
Three companies incorporate framework of strict guidelines to reduce non-compliance
Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks.

INNOVATIVE PRACTICES

HALOW partnership to improve worker's health
Cross-sector partnership to address the health and wellbeing of workers in the textile industry
Live Well social enterprise model builds and supports local distributor networks
Network of local outlets for health products run by community members.
Global Health R&D Unit to stimulate collaboration
Targeted open innovation incubators and research units with focus on R&D for conditions unique or endemic to low- and middle-income countries.

RANK	SCORE
2▲	3.21
3 (2016)	

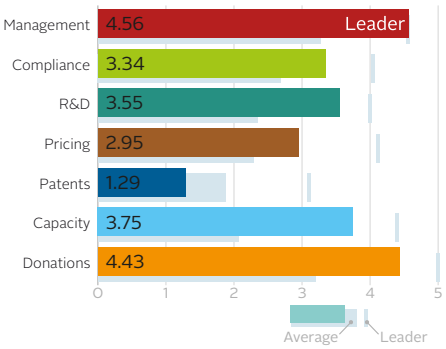
Novartis AG

Stock Exchange: SIX Swiss Exchange • Ticker: NOVN • HQ: Basel, Switzerland • Employees: 126,457

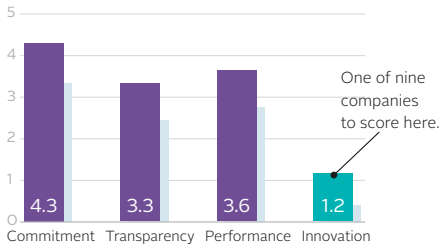
PERFORMANCE

Rises 1 place to 2nd position. The company has launched a new approach to access, embodied by the Novartis Access Principles, which aims to expand access planning across the company's pipeline.
Management: Holds 1st place. Refreshed access strategy underpinned by the Novartis Access Principles, with CEO remuneration linked to access performance.
Compliance: Rises 13 places to 2nd. Improved performance compared to peers in its internal controls and transparency, including financial support made to patient groups.
R&D: Rises to 3rd place for its new approach to considering access planning for all new medicines.
Pricing: Holds 3rd place, with an above-average performance across all pricing metrics but outperformed by leaders.
Patents: Falls 6 places to 16th. Despite a greater level of transparency around its patents, it falls due to an incident regarding the IP around imatinib (Glivec®) in Colombia.
Capacity: Falls 2 places to 3rd, but holds strong against new metrics for good practice, notably in health system strengthening.
Donations: Rises two places to 3rd, achieving a comparatively wide geographic coverage for its leprosy programmes which aim to eliminate the disease in 49 countries.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Apply Novartis Access Principles to increase access across its entire late-stage pipeline. Novartis can work to ensure that its Access Principles are successfully applied to establish access plans for all new medicines in late-stage development regardless of disease scope. As the Novartis Access Principles were recently implemented in 2018, early success is critical to proving that access can be considered across the pipeline and successfully executed.

Expand equitable pricing strategies to cover all priority countries. Novartis' nilotinib (Tasigna®) for the treatment of cancer (leukaemia), is an on-patent product on the 2017 WHO Model List of Essential Medicines (WHO EML) and a first-line treatment. While equitable pricing strategies apply in some priority countries, the company could expand its scope to include all countries where need is the highest, including Egypt, Arab Rep., Kosovo, Kiribati, Micronesia, Fed. Sts., São Tomé and Principe and Tonga. Novartis has developed a new tool, Potential Affordability by Decile, to determine price segmentation in countries in scope. Novartis could apply this tool to address the affordability of products including valsartan (Diovan®) for hypertensive heart disease and ischaemic heart disease in low- and middle-income countries.

Expand accesss to more manufacturers through voluntary licensing. Novartis can actively identify generic medicine manufacturing partners for the non-exclusive voluntary licensing of products for high-burden diseases. Possible products could include nilotinib (Tasigna®) listed on the WHO EML for imatinib-resistant chronic myeloid leukaemia.

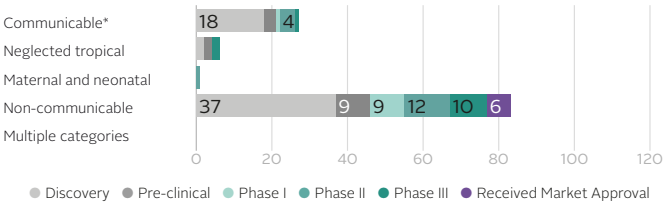
CHANGE SINCE 2016

- Established Novartis Access Principles to systematically integrate access strategies for all new products and Sandoz biosimilar launches beginning as early as Phase II.
- Reiterated its commitment to the control of non-communicable diseases with the Novartis Access Programme, expanding to new countries, such as Pakistan.
- Adapted the SMS for Life platform for stock management; the new, enhanced SMS for Life 2.0 has been launched in four countries since mid-2016.
- Launched the Better Hearts Better Cities initiative in May 2017 to improve cardiovascular health in low-income urban populations.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Published its expanded post-trial access policy to provide access to investigatory treatments for clinical trial participants that meet certain criteria after trials have concluded.
- Divests antibacterial and antiviral research.

PIPELINE *for diseases and countries in scope*

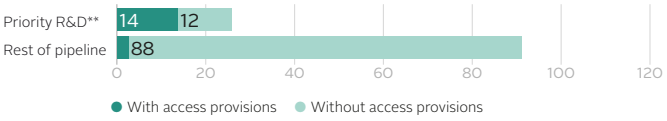
Comparatively large pipeline: 117 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 40, including three clinical candidates for the treatment of *Plasmodium falciparum* malaria.
Regulatory approvals: 6, erenumab (Aimovig™), a novel once-monthly self-injection for the prevention of migraines.
R&D focus: non-communicable diseases (cancer and COPD) and communicable diseases (malaria).
Access provisions: for 17 projects, most commonly registration and equitable pricing strategies.

Projects in the pipeline: 117



Triclabendazole (Egaten®) is approved in France for fascioliasis treatment, and Novartis is seeking approvals from additional health authorities. Novartis currently donates this product to WHO for use in endemic countries.

Projects for R&D priority targets with access provisions: 14

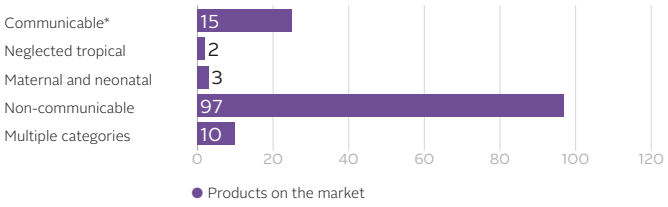


Of Novartis' 117 R&D projects, 17 are supported by access provisions: e.g., nilotinib (Tasigna®) has donation programmes available for chronic myeloid leukaemia patients in several countries in scope through the Max Foundation. Nine of its 36 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

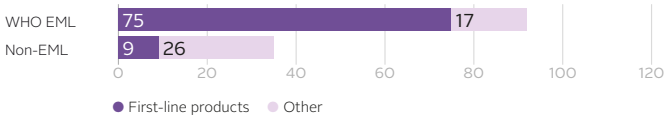
Largest portfolio: 127 products for diseases in scope (126 medicines; 1 contraceptive method).
Portfolio focus: non-communicable diseases (hypertensive heart disease and cancer) and communicable diseases (lower respiratory infections).
Essential medicines: 72% of Novartis' medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 66% of Novartis' medicines have first-line indications for diseases in scope.

Products on the market: 127



Novartis' portfolio includes products such as clofazimine/dapsone/rifampicin (MDT-Combi) for the treatment of multibacillary leprosy and sacubitril/valsartan (Entresto®) for the treatment of ischaemic heart disease.

Essential medicines with first-line indications: 75



80% of Novartis' medicines are listed on the WHO EML and/or as first-line treatments: e.g., the anticancer agents imatinib (Glivec®), anastrozole, tamoxifen and cisplatin.

BUSINESS CONTEXT

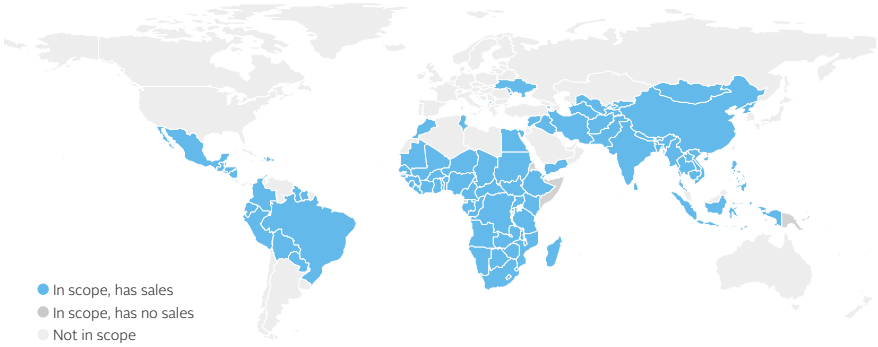
Three divisions: Innovative Medicines; Alcon; and Sandoz (generic medicines and biosimilars). Its Innovative Medicines division has two business units: Novartis Pharmaceuticals; and Novartis Oncology. Novartis Pharmaceuticals unit focuses on six therapeutic areas: ophthalmology; immunology; dermatology; neuroscience; respiratory; and cardiometabolic diseases. Novartis Oncology focuses on two therapeutic areas: cancers and rare diseases.

M&A news: 2018 sale of 36.5% stake in consumer healthcare joint venture to GSK. 2018 acquisition of cancer drugmaker Endocyte.
Presence in emerging markets: In 2018, Novartis reports sales in 95 countries in scope; 18 more countries than in the 2016 Index. It is the company with sales in the highest number of countries in scope. It reports that just over 20% of its sales in 2017 came from the Asia, Africa and Australia region.

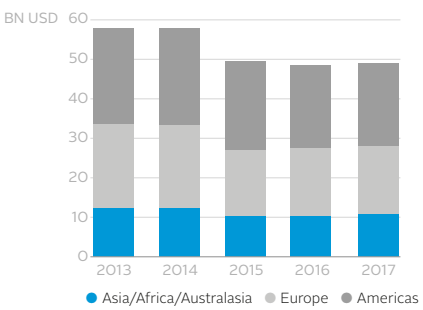
Net sales by segment (2017) - USD

Innovative Medicines	33,025 MN
Sandoz	10,060 MN
Alcon	6,024 MN
Total	49,109 MN

Sales in countries in scope



Net sales by geographic region



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
**See Appendix IV for definition.

Novartis AG

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 1 SCORE 4.56

Has a strong access-to-medicine strategy with board-level responsibility. Novartis is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy has three objectives focused on low-income markets: the control and elimination of disease; piloting new business approaches and engaging in R&D for unmet needs. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Novartis performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. Non-financial incentives include a global programme recognising associates making significant contributions towards corporate responsibility initiatives. Senior management achievement of access objectives is linked to compensation.

One of 16 companies working on impact measurement. Novartis measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives, targets and performance information. For example, for its Malaria Initiative, Novartis reports having provided more than 850 million treatments on a non-profit basis, to more than 60 countries since 2001, contributing to a significant reduction of malaria-related deaths. Furthermore, it is one of the companies that is measuring impact, with Boston University Metrics Framework, for at least one access initiative, e.g. Novartis Access.

Clear and transparent engagement approach that includes local stakeholders. Novartis publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by conducting a corporate responsibility materiality analysis, including research and surveys with internal and external stakeholders. Local stakeholder perspectives are incorporated into the development of its access strategies. It has some policies covering responsible interactions with stakeholders; namely on prioritising access to healthcare, innovation, patient health and safety, and ethical business practices.

MARKET INFLUENCE & COMPLIANCE

RANK 2 SCORE 3.34

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Novartis has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, Novartis newly rewards other aspects such as performance, innovation, collaboration, courage and integrity.

Internal control framework meets all Index criteria. Novartis has all the components looked for by the Index for an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It has a global risk assessment, and a monitoring system to track compliance. It also has an auditing and review mechanism in place, which apply to third parties. Novartis demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. Novartis publicly discloses its policy positions on access-related topics (e.g., its perspective on corporate responsibility including quality and safety of medicines, intellectual property, and its Access to Healthcare Perspective). The company discloses political contributions in countries in scope. It discloses its membership of relevant institutions and whether it provides financial support. Novartis discloses its policy for responsible engagement through its global policies for Responsible Lobbying and Anti-Bribery; its policies also include access perspective, intellectual property and quality and safety. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 3 SCORE 3.55

PROJECTS: 117 IN CLINICAL DEVELOPMENT: 40

Publicly commits to R&D to meet public health needs. Novartis has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Novartis has one of the largest pipelines in the Index with 117 projects. For diseases in scope where priorities exist, Novartis is active in 28 projects; 26 target priority R&D gaps.

Access provisions in place for 25% (9/36) of late-stage candidates. Novartis has a clear process in place to develop access plans during R&D through its Novartis Access Principles. This process considers all R&D projects for diseases in scope. In general, Novartis develops access plans for R&D projects in Phase II of clinical development. To date, Novartis has project-specific access provisions in place for nine of its late-stage R&D projects. Of these, four are being conducted in partnership.

Public policy to ensure post-trial access; commits to registering trialed products. Novartis has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Novartis commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 3 SCORE 2.95

PRODUCTS: 127

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 72

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Novartis does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implementing equitable pricing strategies for the majority of its products for diseases in scope.

Many new products in scope filed for registration in the majority of relevant priority countries. Novartis has filed 50% of its newest products for registration to date in more than half of

the priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

57% of products have equitable pricing strategies targeting priority countries. Novartis' overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 57% of its products for diseases in scope. These strategies apply to an average of 20% of priority countries. Almost all of these strategies apply inter- and intra-country pricing; these take into account an average of six and one socioeconomic factors, respectively. Novartis also applies equitable pricing strategies to three further products informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Novartis has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 16 SCORE 1.29

Publicly discloses detailed information on patent statuses. Like most of its peers, Novartis publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Novartis does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares few IP assets with 3rd-party researchers. Novartis shares one IP asset with third-party researchers developing products for diseases in scope. It shares this asset with the University of Cape Town. The assets shared include a molecule library.

Public commitment not to enforce patents in countries in scope. Novartis commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

CAPACITY BUILDING

RANK 3 SCORE 3.75

22 initiatives included for evaluation. Novartis has 22 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Novartis submitted the maximum.

Strong focus on strengthening capacity of local R&D, manufacturing and health systems. Novartis has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least one initiative in all areas which meet all good practice standards, except pharmacovigilance capacity building. Novartis performs strongest in manufacturing capacity building, R&D capacity building and health system strengthening.

12 initiatives meet all applicable good practice standards:

- Bangladesh alternative distributor project
- Novartis Malaria Initiative
- Better Hearts Better Cities
- Partnerships to develop capabilities in oncology
- Novartis Foundation Leprosy Initiative (LEARNS & LPEP)

A full list of Novartis's capacity building initiatives which meet all good practice standards can be found online.
Novartis's remaining included initiatives typically fall short on just one good practice standard. For example, two of its pharmacovigilance initiatives did not show evidence of good governance structures and process for mitigating conflicts of interest.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe.* Novartis has a policy of reporting cases of substandard or falsified medicines to relevant authorities and in some cases to WHO Rapid Alert. For example, Novartis reported a case of falsified arthemeter/lumefantrine (Coartem®) to WHO Rapid Alert in the period of analysis. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 3 SCORE 4.43
STRUCTURED DONATION PROGRAMMES: 3

Responds to emergencies and humanitarian crises and tracks delivery. Novartis donated medicines on the request of relief agencies. For example, during the period of analysis, it donated medicines in response to Hurricane Harvey in Haiti in 2017. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with the Swiss Red Cross and the International Committee of the Red Cross to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Novartis' programmes are focused on neglected tropical diseases (NTDs) and non-communicable diseases. All three programmes are carried out in collaboration with partners such as WHO and the Max Foundation. Its programme for chronic myeloid leukemia supplies imatinib (Glivec®) and nilotinib (Tasigna®) in 57 countries and has been ongoing since 2002. Novartis reports that almost 71,000 patients have been reached in Index Countries during the period of analysis.

Addresses long-term access by aiming to eliminate disease. Novartis commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its multi-drug therapy donation programme aims to eliminate leprosy in 49 countries.

BEST PRACTICES

Leading approach to measuring impact
A developed, tested and applied methodology for measuring impact on society in financial, environmental and social (FES) terms.
Three companies incorporate framework of strict guidelines to reduce non-compliance
Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks.
Makes detailed commitment to providing post-trial access, goes further than peers
Detailed policy for providing investigational products to all clinical trial participants until the product is commercially available.
R&D unit dedicated to adaptive R&D aims to improve efficacy, safety and access
Unique R&D unit dedicated to adapting existing medicines to meet the specific needs of people living in low- and middle-income countries.
SMS for Life 2.0 expands to further prevent stock-outs of medicines
Enhanced mobile technology supply chain management system, now utilising new technologies and expanding to more countries and products.
Going beyond philanthropy: strengthening care at community level
Over 10 years, it has run initiatives alongside government health ministries and local NGOs to tailor healthcare activities to local needs.

INNOVATIVE PRACTICES

Novartis Access Principles to establish access provisions during development
A systematic approach to developing access strategies for each new medicine during development.
Novartis Access uses portfolio approach to address affordability for NCD products
Portfolio of 15 products for non-communicable diseases marketed to national governments, NGOs and other stakeholders, for $1 per treatment per month, supported by capacity building.
ComHIP enables patients to access diagnosis and care at community level
Public-private partnership that embeds services for hypertension control and self-management in local communities

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
3▼	3.05
2 (2016)	

Johnson & Johnson

Stock Exchange: New York Stock Exchange • Ticker: JNJ • HQ: New Brunswick, New Jersey, United States • Employees: 134,000

PERFORMANCE

Falls 1 place to 3rd. Remains a leader in access through both its Global Public Health unit and its strong approach to Capacity Building. It slips in part as its access approach focuses on a narrower set of diseases in scope compared to other companies.

Management: Rises two places to 4th, with a robust internal structure for ensuring senior responsibility for access.

Compliance: Falls three places to 9th, against stronger performance of peers in internal controls for compliance.

R&D: Falls 1 place to 4th, in part due to a lower proportion of late-stage projects with access plans compared to the other leaders, despite a solid performance overall.

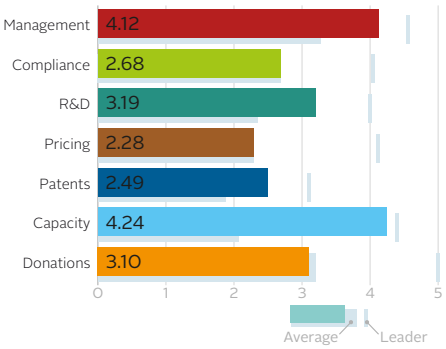
Pricing: Falls from 2nd to 10th place due to comparatively small proportion of portfolio that is covered by equitable pricing strategies.

Patents: Rises from 7th to 5th place, supported by the increased transparency of its patents held in low- and middle-income countries.

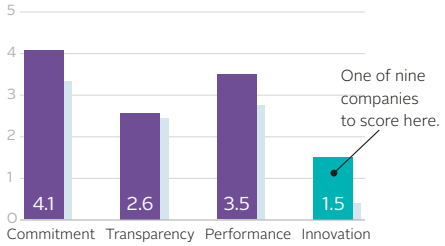
Capacity: Rises to 2nd place, with initiatives meeting all good practice standards in all areas of capacity building.

Donations: Falls from 3rd to 9th place associated in part due to poorer public transparency for some donation programmes.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Continue to expand its Global Public Health access approach. During the period of analysis, Johnson & Johnson successfully incorporated an additional disease area (mental health) into the ambit of its Global Public Health unit. The company can continue to review its portfolio and pipeline to consider additional priority areas for action, e.g., diabetes, cardiovascular disease, and cancer.

Establish access plans for all late-stage R&D projects. Johnson & Johnson can further apply the approach of its Global Public Health unit and establish access plans for all of its late-stage R&D projects, especially projects addressing a priority gap, to ensure broader access to more patients as soon as possible following market approval.

Focus on registering key products in countries in scope. The company's participation in the WHO's Collaborative Procedure for Accelerated Registration is a promising step towards faster registration of new products. The company can apply lessons from this pilot to help expedite registration of other recently launched products in more priority countries.

Extend pledge not to enforce patent rights, and its engagement in voluntary licensing. Johnson & Johnson can extend its pledge not to enforce IP rights to more high-need products beyond darunavir (Prezista®). Likewise, Johnson & Johnson can expand its use of non-exclusive voluntary licensing to ensure access to and supply of more of its on-patent products listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

Scale up well-structured initiatives. Johnson & Johnson's Born on Time initiative seeks to address the factors that can lead to preterm birth. It meets all good practice standards looked for by the Index. There is an opportunity for Johnson & Johnson to extend its commitment to this initiative, which is currently set to end in 2020, to support the expansion of activities to more countries which have expressed a need (the initiative is currently running in Bangladesh, Ethiopia, and Mali). Countries in scope with the highest burden of preterm birth are Nigeria, Pakistan and India.

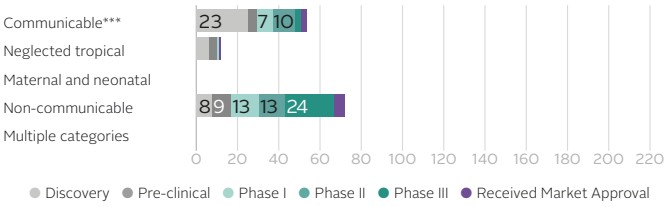
CHANGE SINCE 2016

- Joined Access Accelerated with multiple initiatives such as Helping Babies Breathe and Born on Time.
- Published Health for Humanity report with progress on access-to-medicine initiatives, and with such data independently verified.
- Launched a new pilot programme in Rwanda focused on improving access to mental healthcare.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Strengthened its process to develop access provisions during development using a Value, Access and Pricing (VAP) framework to assess affordability of all R&D projects, with access plans being established from Phase II onwards.
- Expanded Johnson & Johnson Innovation for global public health to accelerate R&D for HIV/AIDS, tuberculosis, maternal and child health and other diseases through unique inter-sector partnerships.

PIPELINE *for diseases and countries in scope*

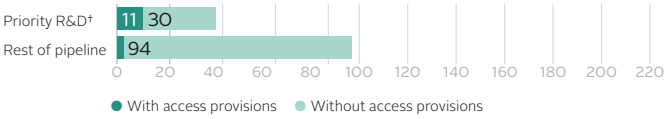
Comparatively large pipeline: 138* R&D projects for diseases in scope (111 medicines; 17 preventive vaccines; 6 diagnostics; 4 therapeutic vaccines).
Clinical candidates: 70, including a mosaic HIV-1 preventive vaccine candidate and pimodivir for the treatment of influenza type A, both in Phase II.
Regulatory approvals: 9, including mebendazole (Vermox™ Chewable) for the treatment of soil-transmitted helminthiasis in children and adults.
R&D focus: non-communicable diseases (cancer and diabetes mellitus), communicable diseases (lower respiratory infections and HIV/AIDS) and neglected tropical diseases (dengue).
Access provisions: for 14 projects, most commonly registration commitments.

Projects in the pipeline: 138**



Johnson & Johnson's pipeline contains a Phase III preventive vaccine for Ebola and the only leprosy project in the collective company pipeline: a new indication for multibacillary leprosy for bedaquiline.

Projects for R&D priority targets with access provisions : 11

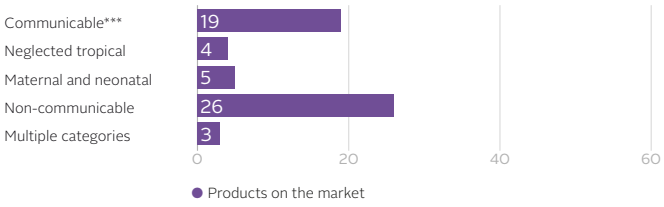


Of Johnson & Johnson's 138 R&D projects, 14 are supported by access provisions: e.g., bedaquiline (Sirturo®) for the treatment of multidrug-resistant TB in children involves a commitment to register in high-burden countries in scope. Eight of its 58 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

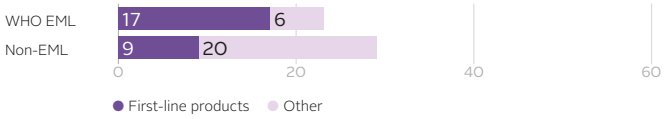
Mid-sized portfolio: 57 products for diseases in scope (45 medicines; 5 contraceptive methods; 5 diagnostics; 2 preventive vaccines).
Portfolio focus: non-communicable diseases (diabetes mellitus and schizophrenia), communicable diseases (HIV/AIDS) and maternal & neonatal health conditions (contraceptive methods).
Essential medicines: 44% of Johnson & Johnson's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 50% of Johnson & Johnson's medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 57



Johnson & Johnson's portfolio includes products such as bedaquiline (Sirturo®) for multidrug-resistant tuberculosis, fixed-dose dolutegravir/rilpivirine (Juluca®) and darunavir (Prezista®).

Essential medicines with first-line indications: 17



62% of Johnson & Johnson's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., mebendazole (Vermox®) and the long-acting antipsychotic haloperidol decanoate (Haldol® Decanoate).

BUSINESS CONTEXT

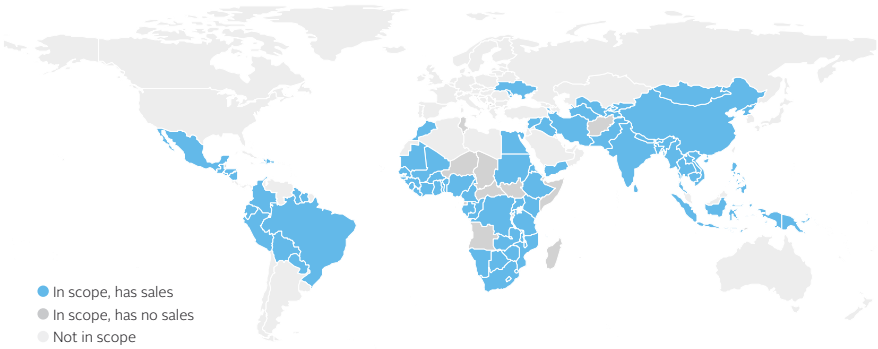
Three business units: Consumer Healthcare; Pharmaceuticals; and Medical Devices. The pharmaceutical segment has six therapeutic areas (immunology; infectious diseases and vaccines; neuroscience; oncology; cardiovascular diseases; and metabolism and pulmonary hypertension).
M&A news: 2017 acquisition of Actelion Pharmaceuticals, a biopharmaceutical company specialising in drugs for unmet high priority medical needs.

Presence in emerging markets: In the 2018 Index, Johnson & Johnson is one of the companies with sales in the highest number of countries in scope. It reports sales in 85 countries in scope; 16 more countries than in the 2016 Index. It reports that almost 20% of its sales in 2017 came from Asia-Pacific and Africa.

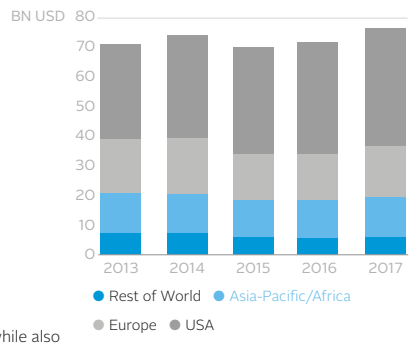
Sales by segment (2017) - USD

Consumer	13,600 MN
Pharmaceuticals	36,300 MN
Medical Device	26,600 MN
Total	76,500 MN

Sales in countries in scope



Sales by geographic region



Statistics relate only to diseases and countries in scope.
*Projects that target multiple product types are counted more than once.

**Figure excludes 6 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

***Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
†See Appendix IV for definition.

Johnson & Johnson

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 4 SCORE 4.12

Has a strong access-to-medicine strategy with executive-level responsibility. Johnson & Johnson is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy centres around promoting access to certain medicines within the company's portfolio, utilising strategies such as equity-based tiered pricing and partnerships with local organisations. The highest level of responsibility for access sits with the executive committee.

Financial and non-financial access-related incentives to reward employees. Johnson & Johnson performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include annual performance bonuses and long-term incentives based on individual performance. Senior management has a separate incentive that supports the company's long-term access oriented objectives.

One of 16 companies working on impact measurement. Johnson & Johnson measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives, targets and performance information. For example, it publicly shares its targets and independently verifies data in its Health for Humanity report. Furthermore, it is one of the companies that is measuring impact through a monitoring and evaluation framework that includes impact targets, for at least one access initiative, New Horizons.

Clear and transparent stakeholder engagement approach that includes local stakeholders. Johnson & Johnson publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by using different processes for each stakeholder group. Johnson & Johnson does not share a specific policy for responsible engagement but it has some policies covering responsible interactions with stakeholders, namely guiding its interactions with stakeholders for improving access.

MARKET INFLUENCE & COMPLIANCE

RANK 9 SCORE 2.68

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Johnson & Johnson has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets. The company reports that for some products it does not deploy sales and marketing representatives to facilitate sales.

Internal control framework meets some Index criteria. Johnson & Johnson's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place. It performs regular evaluations that also apply to third parties, and it has a monitoring system for compliance. However, Johnson & Johnson does not report conducting fraud-specific risk assessments, nor does it demonstrate having procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. Johnson & Johnson publicly discloses its policy positions on access-related topics (e.g., its position on universal health coverage, and intellectual property). Johnson & Johnson reports that outside the US, it only makes political contributions in Australia, Canada and Japan; and these contributions are tracked at the local level. It discloses its membership and financial contributions to relevant organisations. It also discloses its policies for responsible engagement with its charter for general oversight. Johnson & Johnson does not publicly disclose its policy approach for payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 4 SCORE 3.19

PROJECTS: 138 IN CLINICAL DEVELOPMENT: 70

Publicly commits to R&D to meet public health needs. Johnson & Johnson has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Johnson & Johnson has one of the largest pipelines in the Index with 138 projects. For diseases in scope where priorities exist, Johnson & Johnson is active in 58 projects; 41 of these target priority R&D gaps.

Access provisions in place for 14% (8/58) of late-stage candidates. Johnson & Johnson has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope using its Janssen Value, Access and Pricing (VAP) framework. In general, Johnson & Johnson begins to develop access plans for R&D projects in Phase II of clinical development. To date, Johnson & Johnson has project-specific access provisions in place for eight of its late-stage R&D projects. Of these, two are being conducted in partnership.

Policy to ensure post-trial access; commits to registering trialed products. Johnson & Johnson has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Johnson & Johnson commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 10 SCORE 2.28

PRODUCTS: 57

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 5

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Johnson & Johnson does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

No new products in scope filed for registration in the majority of priority countries. Johnson & Johnson has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-spe-

cific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for schizophrenia, is registered in five out of 12 possible priority countries. However, it publicly shares partial registration information for the majority of its products.

9% of products have equitable pricing strategies targeting priority countries. Johnson & Johnson's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 9% of its products for diseases in scope. These strategies apply to an average of 70% of priority countries. All of these strategies apply inter-country pricing; these take into account an average of two socioeconomic factors.

Globally consistent recall guidelines for countries in scope but no processes to track products. Johnson & Johnson has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 5 SCORE 2.49

Publicly discloses detailed information on patent statuses. Like most of its peers, Johnson & Johnson publicly discloses the patent statuses for small molecules in scope via the Pa-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Uses licensing and non-assert declarations to enable generic supply. Johnson & Johnson has a non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence, for rilpivirine (Edurant®), encompasses 88 countries, including 58 middle-income countries in scope. It has also issued a non-assert declaration for one patented compound in scope, darunavir (Prezista®).

Shares some IP assets with 3rd-party researchers. Compared to its peers, Johnson & Johnson shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with research institutions, such as the University of Toronto and the Walter and Eliza Hall Institute of Medical Research. The assets shared include molecule libraries.

Public commitment not to enforce patents in countries in scope. Johnson & Johnson commits publicly not to enforce certain patents related to diseases within the scope of the Index. This commitment is limited to darunavir (Prezista®), for the treatment of HIV/AIDS, in sub-Saharan Africa and in Least Developed Countries.

CAPACITY BUILDING

RANK 2 SCORE 4.24

23 initiatives included for evaluation. Johnson & Johnson has 23 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Johnson & Johnson submitted the maximum.

Strong focus on strengthening capacity of local R&D, manufacturing and health systems. Johnson & Johnson has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least one initiative in each area which meets all good practice standards. Johnson & Johnson performs strongest in manufacturing capacity building, R&D capacity building and health system strengthening.

11 initiatives meet all applicable good practice standards:

- GPH R&D Training Fellowship Program
- Asia Regional Pharmacovigilance Workshop
- Connect for Life™
- The Private Provider Interface Agency
- Born on Time

A full list of Johnson & Johnson's capacity building initiatives that meet all good practice standards can be found online.
Its remaining included initiatives typically have goals & objectives and good governance structures in place. However, it commonly falls short on measuring progress and outcomes in areas outside of health system strengthening.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Johnson & Johnson has a policy of reporting cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 9 SCORE 3.10
STRUCTURED DONATION PROGRAMMES: 4

Responds to emergencies and humanitarian crises and tracks delivery. Johnson & Johnson donated medicines on the request of relief agencies. For example, during the period of analysis, it donated various products in response to the 2016 hurricane in Haiti. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works with various organisations to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Four donation programmes covering diseases and countries in scope. Johnson & Johnson's programmes are focused on neglected tropical diseases (NTDs), communicable and non-communicable diseases. All four programmes are carried out in collaboration with partners such as WHO, Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Fracarita International and USAID. Its programme for soil-transmitted helminthiases supplies mebendazole (Vermox®) in 26 countries and has been ongoing since 2006. In 2017, Johnson & Johnson reports that 202 million doses of mebendazole (Vermox®) were donated.

Ensures longer-term access through transition planning. Johnson & Johnson has transition plans in place for two programmes to ensure ongoing access for patients once the programmes end. For example, its paediatric HIV donation programmes for darunavir (Prezista®) and etravirine (Intelence®), ensure that patients who are about to age out of the programme are able to transit into adult care without interruption of treatment. In addition to this, the company is working with the Paediatric HIV Treatment Initiative, to develop a generic fixed-dose combination of darunavir/ritonavir (120/20mg), to ensure affordability in the long term.

BEST PRACTICES

Leading platform to track access activities
A system that enables it to track how local access strategies are implemented, and how activities progress.
Global Public Health expands for better and wider access to healthcare
A multidisciplinary unit with a strong business rationale for its access-to-medicine strategy.
New Horizons addresses unmet needs in paediatric HIV care
Collaborative initiative aimed at advancing paediatric HIV care, particularly for those failing treatment.
Academy supports local scientists in Uganda
A public institute that supports the development of scientists in Africa and conducts its own research.

INNOVATIVE PRACTICES

DREAMS learns from local young women to reduce HIV
The collaborative partnership, to reduce new HIV infections among young women, uniquely engages directly with local young people to design learning activities.
Combining data sources to map HIV resistance
A modelling tool that blends multiple types of data to map HIV resistance.
Cross-sector partnership drives early-stage R&D
Extensive financial and on-site resources to enable groups behind early-stage projects to overcome limitations associated with development

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
4=	2.90
4 (2016)	

Merck KGaA

Stock Exchange: Frankfurt Stock Exchange • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 50,000

PERFORMANCE

Merck KGaA turns in a strong performance and holds fourth place. It is innovative with its Merck Global Health Institute, and shows particular strength in targeting R&D priorities and in minimising the risk of corruption and unethical marketing.

Management: Rises 2 places to 8th establishing a new sustainable business model: Curafa™, targeting populations in remote areas in Kenya.

Compliance: Rises 9 places to 2nd. One of the largest risers, it applies its code of conduct to third parties and non-sales-based incentives are in place for sales agents.

R&D: Holds 2nd place, newly creating the Merck Global Health Institute. A comparatively large proportion of its pipeline aims to address R&D priorities.

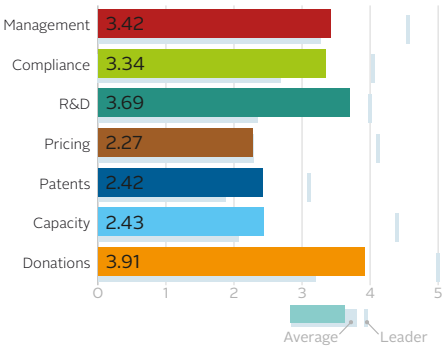
Pricing: Falls 5 places to 11th, overtaken by stronger performers, with comparatively weak registration commitments.

Patents: Falls 2 places to 7th, performing marginally poorer in new IP agreements reached over the period of analysis.

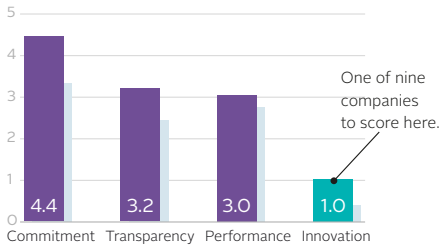
Capacity: Maintains 6th place, with a strong focus on local manufacturing, including technology transfer.

Donations: Rises from 6th to 5th place with a long-term commitment to eliminate schistosomiasis in 37 countries.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Refine access plans for all current and future Merck Global Health Institute projects. Merck KGaA can further develop its access plans for R&D projects conducted through the Merck Global Health Institute. Currently, Merck KGaA commits to address affordability by minimising development and manufacturing costs to lower the final cost of products. It can build on this commitment by also committing to apply pricing strategies that consider ability to pay, and committing to register products in all endemic countries (for schistosomiasis and malaria) and in all countries in scope (for antimicrobial resistance).

Expand availability and affordability of avelumab (Bavencio®). Merck KGaA can work to develop additional access plans for its current and future indications of avelumab (Bavencio®), an anti-cancer drug that is FDA-approved for a number of cancer types within the scope of the Index. By making this treatment available in countries in scope that have the capacity to administer this drug (including Brazil, India and China) Merck KGaA can help reduce inequity in access to cancer treatment.

Register broad spectrum antibiotics in countries in need. Currently, Merck KGaA does not register cefixime (Denvar®) in any priority countries for diseases for which the antibiotic is indicated (kidney diseases, lower respiratory infections, meningitis, or gonorrhoea). It is both on the 2017 WHO Model List of Essential Medicines (WHO EML) and is a first-line treatment. While antibiotic resistance must be considered, many priority countries currently lack access to essential products to treat these infections. Merck KGaA can file cefixime for registration in priority countries.

Consider equitable pricing strategies for additional first-line, WHO EML products. Merck KGaA's gentamicin (Refobacin®) for kidney diseases; lower respiratory infections; maternal sepsis; meningitis; and neonatal sepsis and infections is an-off patent first-line product on the WHO EML with no access plans in place. The company could provide equitable pricing strategies for corresponding priority countries. Similarly, Merck KGaA's itraconazole (Candistat) for meningitis is an off-patent, first-line product on the WHO EML with no access plans in place. The company could apply equitable pricing strategies to these products in priority countries including, Angola, Chad, Congo, Dem. Rep., Ethiopia, India, Nigeria and Uganda.

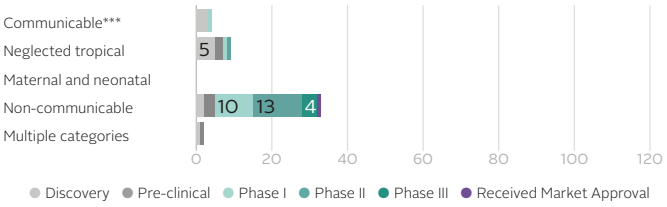
CHANGE SINCE 2016

- Joined the Drugs for Neglected Diseases initiative's NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis.
- Signed a Memorandum of Understanding in December 2017 to support the development of a new vaccine manufacturing plant in Ghana.
- Joined Access Accelerated with multiple initiatives including the Merck Capacity Advancement Program. It has committed to measure impact and share results publicly via the Access Observatory.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Established the Merck Global Health Institute to accelerate R&D, incorporate access provisions and build capacity for projects and initiatives targeting schistosomiasis, malaria and bacterial infections.

PIPELINE *for diseases and countries in scope*

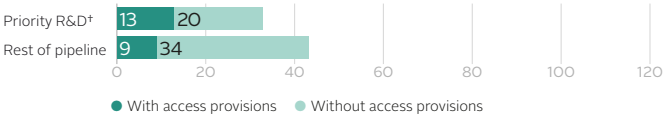
Mid-sized pipeline: 74* R&D projects for diseases in scope (59 medicines; 7 diagnostics; 6 platform technologies; 2 vector control products; 1 therapeutic vaccine).
Clinical candidates: 30, including praziquantel for the treatment of schistosomiasis in children and atacicept for the treatment of kidney diseases.
Regulatory approvals: 1, avelumab (Bavencio®) for the treatment of bladder cancer.
R&D focus: non-communicable diseases (cancer, diabetes, hypertensive heart disease and kidney diseases), communicable diseases (malaria) and neglected tropical diseases (schistosomiasis).
Access provisions: for 22 projects, most commonly registration commitments.

Projects in the pipeline: 74**



Merck KGaA is the lead of the Pediatric Praziquantel Consortium. It is responsible for the clinical development programme and acts as sponsor of clinical trials for a paediatric formulation of praziquantel to treat schistosomiasis.

Projects for R&D priority targets with access provisions: 13

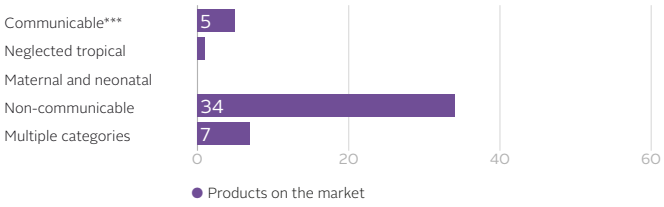


Of Merck KGaA's 74 R&D projects, 22 are supported by access provisions: e.g., avelumab (Bavencio®), in development for many cancer types, includes registration commitments for each indication developed in-house. Six of its 19 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

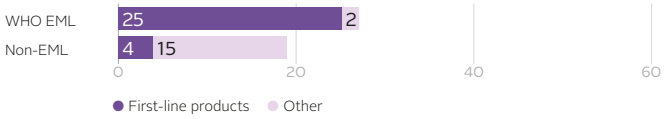
Mid-sized portfolio: 47 products for diseases in scope (46 medicines; 1 diagnostic).
Portfolio focus: non-communicable diseases (hypertensive heart disease, ischaemic heart disease and diabetes mellitus) and communicable diseases (lower respiratory infections).
Essential medicines: 59% of Merck KGaA's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 63% of Merck KGaA's medicines have first-line indications for diseases in scope.

Products on the market: 47



Merck KGaA's portfolio includes products such as the oral fixed-dose combination metformin/glibenclamide (Glucovance®) for the treatment of type 2 diabetes mellitus and the antifungal drug itraconazole (Candistat™).

Essential medicines with first-line indications: 25



67% of Merck KGaA's medicines are listed on the WHO EML and/or as first-line treatments: e.g., the antihelminthic agent praziquantel (Cestox®) and the antibiotic ofloxacin (Harpoon®).

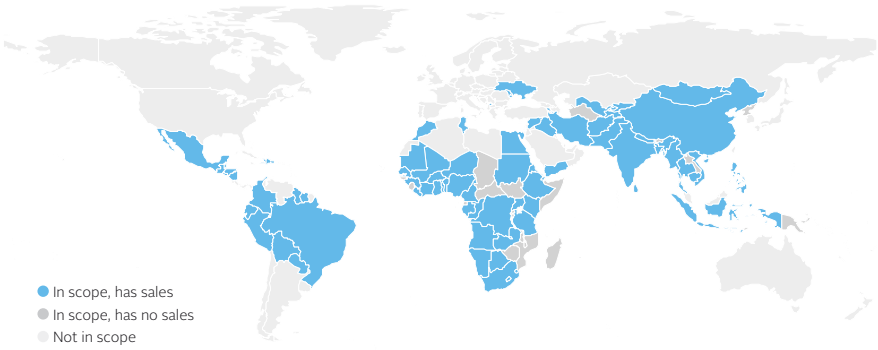
BUSINESS CONTEXT

Three business units: Healthcare; Life Science; and Performance Materials. Its Healthcare business has seven therapeutic areas (allergen immunotherapy; consumer health; endocrinology; general medicine; fertility; neurology and immunology; and oncology).
M&A news: 2017 divestment of biosimilar business, focused on oncology and autoimmune diseases, to Fresenius Kabi. 2018 ongoing divestment (expected to conclude fourth quarter 2018) of global Consumer Health business to Procter & Gamble.
Presence in emerging markets: In 2018, Merck KGaA reports sales in 76 countries in scope; similar to reported sales in the 2016 Index. It reports that around 40% of its sales in 2017 came from Middle East, Africa, Asia-Pacific and Latin America.

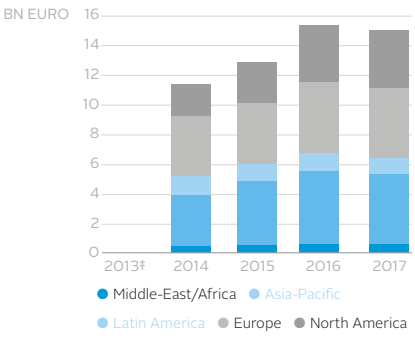
Net sales by segment (2017) - EUR

Healthcare	6,999 MN
Life Science	5,881 MN
Performance Materials	2,446 MN
Total	15,326 MN

Sales in countries in scope



Net sales by geographic region



Statistics relate only to diseases and countries in scope.
*Projects that target multiple product types are counted more than once.

**Figure excludes 26 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

***Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
†See Appendix IV for definition.
‡2013 data not comparable due to changes in company reporting practices

Merck KGaA

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 8 SCORE 3.42

Has a strong access-to-medicine strategy with executive-level responsibility. Merck KGaA is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy centres around ensuring its products are accessible through four approaches: availability; affordability; awareness; and accessibility. The highest level of responsibility for access sits with an executive manager.

Financial and non-financial access-related incentives to reward employees. Merck KGaA performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include grants and *ad hoc* awards.

One of 16 companies working on impact measurement. Merck KGaA measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its charter on access to health in developing countries, Merck KGaA reports on its activities to achieve targets aligned with United Nations Sustainable Development Goals (SDGs). Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Merck KGaA publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with in its 2017 Corporate Responsibility Report; e.g., it adopts a needs-based approach to establish partnerships which can promote access. It does not publicly share its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 2 SCORE 3.34

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Merck KGaA has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training via online classes for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities such as ethical behaviour in the workplace.

Internal control framework meets some Index criteria. Merck KGaA's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving internal resources, applying to all third parties and all countries where they operate. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Above average transparency regarding access-related practices. Merck KGaA publicly discloses its policy positions on access-related topics. For example, it publishes its position on drug shortages, ethical business practices, intellectual property rights, and it publicly supports the Doha Declaration. It is one of the few companies in scope to have a policy that prohibits political financial contributions, and it shares its position on responsible engagement in its code of conduct. It publicly discloses its membership and financial support of relevant organisations to access. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 2 SCORE 3.69

PROJECTS: 74 IN CLINICAL DEVELOPMENT: 30

Publicly commits to R&D to meet public health needs. Merck KGaA has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Merck KGaA has a mid-sized pipeline in the Index with 74 projects. For diseases in scope where priorities exist, Merck KGaA is active in 32 projects; all 32 of these target priority R&D gaps.

Access provisions in place for 26% (5/19) of late-stage candidates. Merck KGaA has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope. In general, Merck KGaA develops access plans for R&D projects when entering clinical development. To date, Merck KGaA has project-specific access provisions in place for six of its late-stage R&D projects. Five are being conducted in partnership.

Policy to ensure post-trial access; commits to registering trialed products. Merck KGaA has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Merck KGaA commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 11 SCORE 2.27

PRODUCTS: 47

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 14

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Merck KGaA does not commit to filing its newest products for registration in countries in scope within one year of first market approval. It publicly commits to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. Its public commitments also apply to intra-country equitable pricing strategies, albeit to only some of its products.

No new products in scope filed for registration in the majority of priority countries. Merck KGaA has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for diabetes mellitus, is registered in four out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

30% of products have equitable pricing strategies targeting priority countries. Merck KGaA's overall performance is average compared to

peers in equitable pricing. It demonstrates evidence of equitable pricing strategies for 30% of its products for diseases in scope. These strategies apply to an average of 23% of priority countries. Some of these strategies apply inter-country pricing; these take into account an average of four socioeconomic factors. However, all of its equitable pricing strategies apply intra-country pricing; these take an average of three socioeconomic factors into account. Merck KGaA also applies equitable pricing strategies to 9 further products informed by a public health rationale.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Merck KGaA has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 7 SCORE 2.42

Publicly discloses detailed information on patent statuses. Like most of its peers, Merck KGaA publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Merck KGaA does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares some IP assets with 3rd-party researchers. Compared to its peers, Merck KGaA shares some IP assets with third-party researchers developing products for diseases in scope. It shares four in total with research institutions and neglected disease drug discovery initiatives, such as the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases initiative (DNDi). The assets shared include molecule libraries and performing assays for drug discovery.

Public commitment not to enforce patents in countries in scope. Merck KGaA commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies to most Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

CAPACITY BUILDING

RANK 6 SCORE 2.43

14 initiatives included for evaluation. Merck KGaA has 14 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Merck KGaA submitted the maximum.

Strong focus on enhancing local manufacturing. Merck KGaA has initiatives which meet inclusion criteria in all five areas of capacity building. It performs strongest in manufacturing capacity building, including initiatives for training third-party manufacturers and technology transfers.

Two initiatives meet all applicable good practice standards:
-Virtual plant teams
-Product Development Partnerships in Brazil
Merck KGaA's remaining included initiatives typically have goals in place, but fall short on monitoring their progress and outcomes.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Merck KGaA has a policy for reporting cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 5 SCORE 3.91
STRUCTURED DONATION PROGRAMMES: 1

Responds to emergencies and humanitarian crises and tracks delivery. Merck KGaA donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in Yemen. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with the German Red Cross to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Merck KGaA's programmes are focused on neglected tropical diseases (NTDs). The programme is carried out in collaboration with WHO. Its programme for schistosomiasis supplies praziquantel (Cesol®) in 37 countries and has been ongoing since 2007. In 2016, Merck KGaA reported donating more than 200 million praziquantel (Cesol®) tablets to WHO.

Addresses long-term access by aiming to eliminate disease. Merck KGaA commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its praziquantel (Cesol®) programme aims to eliminate schistosomiasis in 37 countries.

BEST PRACTICES

Continued commitment to combat NTDs.
GLOBAL
One of five companies running donation programmes to eliminate or eradicate NTDs.

INNOVATIVE PRACTICES

Curafa™ programme establishes primary healthcare centres in Kenya
KENYA
Local primary healthcare facilities that provide pharmacy and nursing services, prescription and over-the-counter medications, and access to insurance schemes and healthcare financing.

Merck Global Health Institute partners up to accelerate R&D for bacterial infections, schistosomiasis and malaria
GLOBAL
Institute setting up R&D partnerships to develop projects to target bacterial infections, schistosomiasis and malaria present in low- and middle-income countries.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
5▲	2.75
15 (2016)	

Takeda Pharmaceutical Co. Ltd.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4502 • HQ: Tokyo, Japan • Employees: 32.691

PERFORMANCE

Rises further than all other companies, moving 10 places to 5th. Takeda has newly assigned responsibility for access to its CEO, with a raft of new policies, deepening its approach to equitable pricing, with a solid approach to Capacity Building.

Management: Rises 10 places, to 6th place with responsibility for the company's access-to-health strategy newly assigned to the CEO. It demonstrates innovation with the development of the Cancer Alliance.

Compliance: Rises 7 places to 6th place as its code of conduct applies to third parties, rewards for sales agents are not solely based on sales.

R&D: Rises 1 place to 6th with a solid performance, but displaced by peers due to lagging slightly behind in priority R&D and access planning.

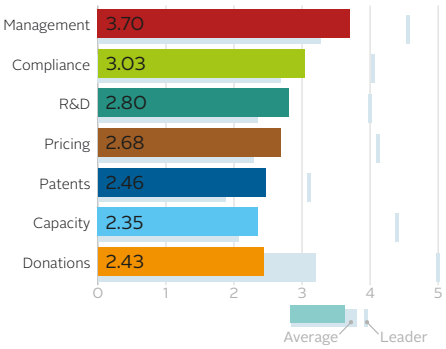
Pricing: Rising 11 places to 5th; it has a large increase of products with equitable pricing strategies.

Patents: Rises 11 places to 6th, a leading company in IP-sharing, along with a new public commitment not to enforce patents in LDCs and new levels of patent disclosure.

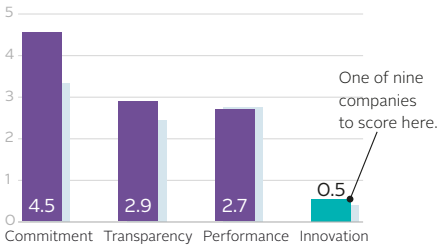
Capacity: Rises 3 places to 7th. Deepened approach to capacity building with a focus on strengthening health systems.

Donations: Rises 2 places to 14th, with no structured donation programmes, but working with partners to ensure rapid delivery of products in emergencies and humanitarian crises.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand price segmentation approach. Takeda developed a sophisticated Patient Assistance Tool to define intra-country pricing segmentation for some countries in scope. The company could apply this tool to more of its marketed products, for example, leuprorelin acetate (Enantone®) and leuprorelin (Lupron), both 2017 WHO Model List of Essential Medicines (WHO EML) listed cancer products in the scope of the Index, in countries where the tool is already being applied for other products, and to more countries in scope.

Establish project-specific access plans for late-stage projects, particularly for non-communicable diseases. Takeda can establish project-specific access plans for all late-stage projects with a focus on its non-communicable disease projects, such as those targeting cancer. By ensuring that access plans are not only considered but established, it can address key barriers to access that normally restrict access in low- and middle-income countries.

Strengthen registration approach. Takeda has registered aloglitpin (Nesina®) for diabetes mellitus in five out of twelve possible priority countries. The company could file to register the product in more priority countries, for example, Afghanistan, Dem. Rep. Congo, Ethiopia, Tanzania and Uganda.

Strengthen commitments through transparency to public. Takeda has strong, clear commitments to conduct R&D for diseases and countries in scope and for providing post-trial access to clinical trial participants. However, these policies are not readily available. Takeda can publish these commitments, reinforcing its values to advance access to medicine through R&D.

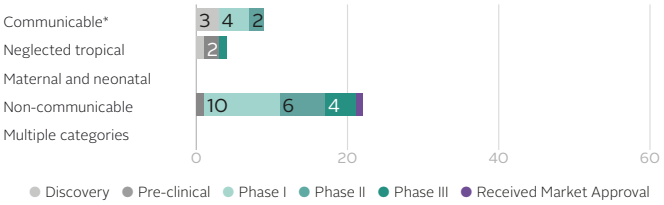
CHANGE SINCE 2016

- Established a structured process to develop access provisions for R&D projects, with execution carried out by a designated R&D Access to Medicine Office.
- Joined Access Accelerated with multiple initiatives, most focused on cancer care. It has also committed to measure impact and share results publicly via Access Observatory.
- Launched its Chronic Care Program (CCP) in late 2016, focused on improving public awareness and equipping community and primary healthcare workers for detecting diseases such as diabetes and hypertension.
- Launched the Strengthening Health Systems through Technology in 2017 which focuses on introducing and adopting digital platforms to strengthen healthcare delivery and management in low- and middle-income countries.
- Publicly discloses its new commitments to either not file or not enforce patents for its medicines in Least Developed Countries.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.

PIPELINE *for diseases and countries in scope*

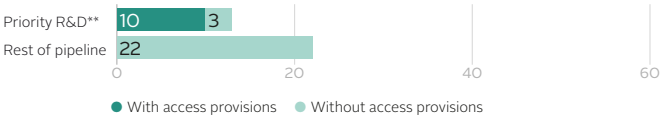
Mid-sized pipeline: 35 R&D projects for diseases in scope (30 medicines; 5 preventive vaccines).
Clinical candidates: 27, including preventive vaccines for Zika virus, norovirus and dengue.
Regulatory approvals: 1, brigatinib (Alunbrig™) for the treatment of metastatic lung cancer.
R&D focus: non-communicable diseases (cancer and schizophrenia) and communicable diseases (malaria).
Access provisions: for 10 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 35



Takeda's dengue vaccine for children and adolescents, TAK-003, has progressed from Phase II to Phase III and has demonstrated immunogenicity against all four types of dengue virus.

Projects for R&D priority targets with access provisions : 10

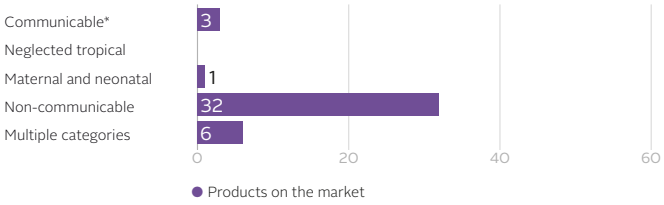


Of Takeda's 35 R&D projects, ten are supported by access provisions: e.g., Takeda's Phase III dengue vaccine will include a WHO prequalification application and registration, equitable pricing and supply strategies. Three of its 14 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

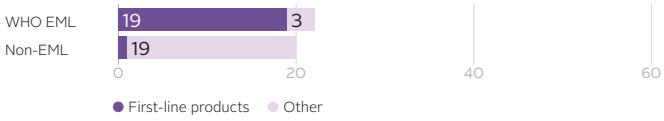
Mid-sized portfolio: 42 products for diseases in scope (all medicines).
Portfolio focus: non-communicable diseases (hypertensive heart disease and diabetes mellitus) and communicable diseases (lower respiratory infections).
Essential medicines: 52% of Takeda's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 48% of Takeda's medicines have first-line indications for diseases in scope.

Products on the market: 42



Takeda's portfolio includes products such as hexoprenaline (Gynipral®) to delay premature labour and delivery and Luivac®, an oral vaccine that confers protection against several lower respiratory infection-causing pathogens.

Essential medicines with first-line indications: 19



55% of Takeda's medicines are listed on the WHO EML and/or as first-line treatments: e.g., sumatriptan (Sitran®) for treatment of migraine and the antihypertensives azilsartan (Azilva®) and candesartan.

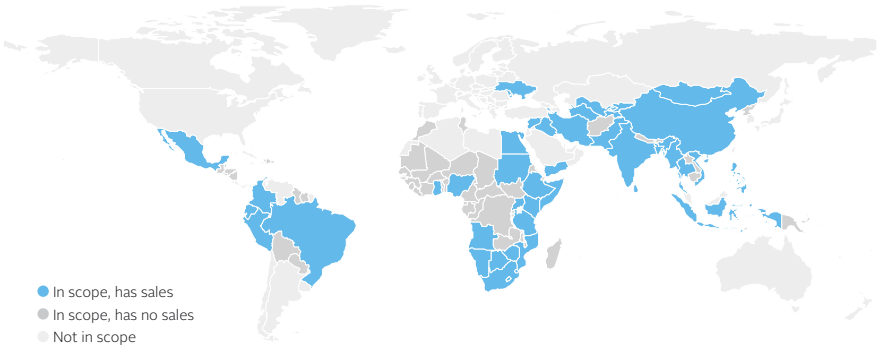
BUSINESS CONTEXT

Six business units: Four geographic business units - Emerging Markets, Europe & Canada, Japan, and the US; two therapeutic area business units - Oncology and Vaccines. Its portfolio of prescription drugs focus on: oncology; gastroenterology; neuroscience disorders; and vaccines.
M&A news: 2017 divestment of respiratory business to AstraZeneca; acquisition of oncology company ARIAD Pharmaceuticals. 2018 ongoing acquisition (expected to conclude mid-2019) of Shire, a biotechnology company specialising in rare diseases.
Presence in emerging markets: In 2018, Takeda reports sales in 44 countries in scope; five more than in the 2016 Index.

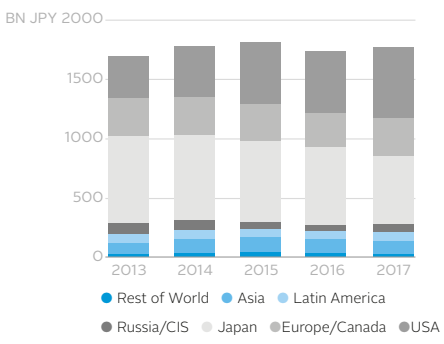
Revenue by segment (2017) - JPY

Prescription Drugs and Vaccines	1,691,500 MN
Consumer Healthcare and others	79,000 MN
Total	1,770,500 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

*Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
**See Appendix IV for definition.

Takeda Pharmaceutical Co. Ltd.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 6 SCORE 3.70

Has a strong access-to-medicine strategy with board-level responsibility. Takeda is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The strategy capitalises on partnerships, and focuses on addressing unmet needs, through R&D, IP management, patient assistance programmes and capacity building. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Takeda performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include financial bonuses and fellowship opportunities.

One of 16 companies working on impact measurement. Takeda measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments and performance information. For example, Takeda publicly committed to supply vaccines for infectious diseases such as dengue, Zika, norovirus and polio. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Takeda publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 6 SCORE 3.03

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Takeda has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees upon hire and on an annual basis. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities relating to accountability and integrity in the workplace.

Internal control framework meets some Index criteria. Takeda's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has some processes aimed at mitigating non-compliance, addressed in its global monitoring policy. It has an auditing and review mechanism in place, and performs regular evaluations, that also apply to third parties. It does not demonstrate evidence of having fraud-specific risk assessment. It does, however, have a monitoring system to track compliance in the workplace, and procedures to segregate duties, so that decisions are checked by another party.

Below average transparency regarding access-related practices. Takeda publicly discloses its policy positions on access-related topics (e.g., it publicly supports TRIPS and the Doha Declaration). It does not have a policy prohibiting political contributions in countries in scope, but reports that it did not make such contributions during the period of analysis. It does not publicly disclose its financial support and membership of relevant organisations, nor its policies for responsible engagement. Further, Takeda does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 6 SCORE 2.80

PROJECTS: 35 IN CLINICAL DEVELOPMENT: 27

Publicly commits to R&D to meet public health needs. Takeda has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on internal targets and data from external sources related to global health needs. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Takeda has a mid-sized pipeline in the Index with 35 projects. For diseases in scope where priorities exist, Takeda is active in 13 projects; all 13 of these target priority R&D gaps.

Access provisions in place for 21% (3/14) of late-stage candidates. Takeda has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope. In general, Takeda begins considering and developing access plans for R&D projects from the discovery phase onward. To date, Takeda has project-specific access provisions in place for three of its late-stage R&D projects. Of these, one is being conducted in partnership with the Medicines for Malaria Venture (MMV).

Policy to ensure post-trial access; commits to registering trialed products. Takeda has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Takeda commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 5 SCORE 2.68

PRODUCTS: 42

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 4

Commits publicly to equitable pricing and reports a commitment to file to register new products in scope. Takeda commits to filing its newest products for registration in countries in scope within one year of first market approval, where possible. It publicly commits to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope. This does not explicitly apply to future products. It also commits to implementing intra-country pricing strategies, albeit to only some of its products.

No new products in scope filed for registration in the majority of priority countries. Although Takeda newly commits to filing its newest products for registration in countries in scope within one year of first market approval, it has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). It publicly shares some registration information for the minority of its products.

10% of products have equitable pricing strategies targeting priority countries. Takeda's over-

all performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 10% of its products for diseases in scope. These strategies apply to an average of 22% of priority countries. All of these strategies apply inter-country pricing; these take into account an average of five socioeconomic factors. Takeda also applies equitable pricing strategies to one further product informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Takeda has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 6 SCORE 2.46

Publicly discloses detailed information on patent statuses. Like most of its peers, Takeda publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Takeda does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares many IP assets with 3rd-party researchers. Compared to its peers, Takeda shares many IP assets with third-party researchers developing products for diseases in scope. This includes 18 shared with research institutions and neglected disease drug discovery initiatives, such as MMV and the Drugs for Neglected Diseases initiative (DNDi). The assets shared include molecule libraries, patented compounds, processes and technologies.

Public commitment not to enforce patents in countries in scope. Takeda commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries.

CAPACITY BUILDING

RANK 7 SCORE 2.35

12 initiatives included for evaluation. Takeda has 12 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Takeda submitted 20.

Strong focus on strengthening health systems. Takeda has initiatives which meet inclusion criteria in all areas of capacity building, except manufacturing. It performs strongest in health system strengthening with most initiatives focused on non-communicable diseases such as cancer.

Four initiatives meet all applicable good practice standards:

- R&D Access to Medicines Employee Fellowship Program
- Accelerating Cancer Care in Sub-Saharan Africa
- Global Accelerating Cancer Care
- Chronic Care Program

Takeda's remaining included initiatives typically have goals in place, but fall short on monitoring progress and outcomes.

Timely approach to reporting substandard or falsified medicines to relevant authorities. Takeda provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to local regulatory authorities within the period recommended by stakeholders (maximum seven days).

PRODUCT DONATIONS

RANK 14 SCORE 2.43

STRUCTURED DONATIONS PROGRAMMES: 0

Responds to emergencies and humanitarian crises and tracks delivery. Takeda donated medicines on the request of relief agencies. For example, during the period of analysis, it donated pioglitazone/metformin (Actosmet®) and pioglitazone (Actos), both used for the treatment of diabetes, through the Pharmaceutical and Healthcare Association of the Philippines (PHAP) Cares Foundation. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americares and Direct Relief to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

No donation programmes covering diseases and countries in scope for products in scope. Takeda does not have any structured donation programmes that were active during the period of analysis in any countries in scope for products in scope.

BEST PRACTICES

R&D Employee Fellowship Program engages in longer-term projects

HAITI, KENYA, AND TANZANIA

Employee fellowship programme that enters long-term engagements with selected NGOs to support and build healthcare capacity in areas such as clinical care, epidemiology, training, R&D project management and supply chain.

Extensive sharing of IP assets with third-party researchers

GLOBAL

Sharing IP assets with third-party researchers developing products for diseases in scope of the Index.

Commits to registering new products in poorer countries in 12 months.

GLOBAL

Parallel dossier preparation to facilitate faster registration.

INNOVATIVE PRACTICES

Diverse stakeholders come together for The Cancer Alliance

SUB-SAHARAN AFRICA

Cross-sector partnership with local stakeholders – represents a new, regionally focused approach to integrate and improve the provision of cancer services.

RANK	SCORE
6▲	2.68
10 (2016)	

Novo Nordisk A/S

Stock Exchange: Copenhagen Stock Exchange • Ticker: NOVO B • HQ: Bagsværd, Denmark • Employees: 42,682

PERFORMANCE

Rises 4 places to 6th. Novo Nordisk focuses on one disease covered by the Index: diabetes. It has strong management structures for access and exhibits robust performance in the application of good practice in both capacity building initiatives and donation programmes.

Management: Falls 3 places to 5th, but remains in the first quartile, due to the reassignment of board-level responsibility for its access-to-medicine approach.

Compliance: Falls 4 places to 6th, as its internal control framework does not meet the same criteria as leading peers.

R&D: Rises 6 places to 9th with a new publicly available policy for post-trial access.

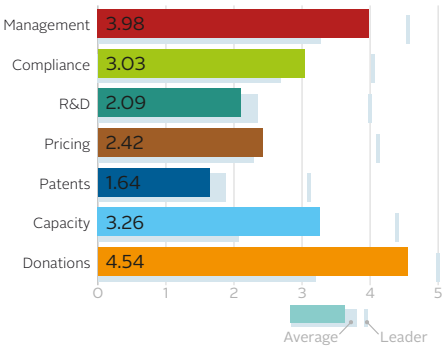
Pricing: Falls 2 places to 7th. Solid registration performance, but outperformed in the degree to which socioeconomic factors are used to determine affordable prices.

Patents: Falls 1 place to 13th. Static performance compared to 2016, as it reports no instances of sharing IP during the period of analysis.

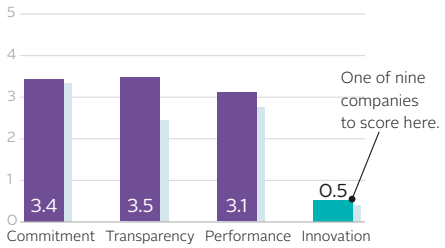
Capacity: Rises 3 places to 4th. Strong performance in capacity building with 11/13 initiatives meeting all good practice standards.

Donations: Rises 8 places to 2nd with a high-quality programme for paediatric diabetes, that considers longer-term access once the programme ends.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand access to insulin by supporting local manufacture. Novo Nordisk reports manufacturing capacity building initiatives in Bangladesh, India, Iran, and Egypt. The company can leverage this expertise and look to work with other insulin manufacturers (e.g., on the African continent, and in Latin America) to build capacity to produce high-quality insulin and help to stabilise local supply.

Expand Base of the Pyramid to more countries in scope. An evaluation from University College London demonstrated that Novo Nordisk's Base of the Pyramid has been successful in sustainably increasing access to care and diagnosis, raising awareness and providing a stable supply of insulin in Kenya. The programme currently reaches Ghana, Kenya, Nigeria and Senegal. The positive evaluation shows that shared value can be achieved and scalability is possible. Additional countries in need of access to diabetes care can be brought within the ambit of this programme.

Establish access plans during development that go beyond registration. Novo Nordisk currently focuses on registration strategies for its pipeline. It can also plan for equitable pricing strategies and (where possible) WHO prequalification. By addressing multiple barriers to access, it can help make critical therapies not only available for purchase but also at an affordable price in low- and middle-income countries. This is especially true of its oral GLP-1 agonist semaglutide (Ozempic®), which is currently in Phase III of clinical development and could address the heat-stability issues that have reduced the utility of other GLP-1 agonists in low- and middle-income countries in the past.

Expand access to more diabetic children with no access to insulin. Over the period of analysis, Novo Nordisk reported that the Changing Diabetes in Children (CDiC) Programme reached over 2,000 additional children. Programmes such as these fill an important gap, especially where diagnosis and treatment of type 1 diabetes in children is not yet achieved through Universal Health Coverage. CDiC continues to successfully expand, and should seek to include additional countries where children at risk live.

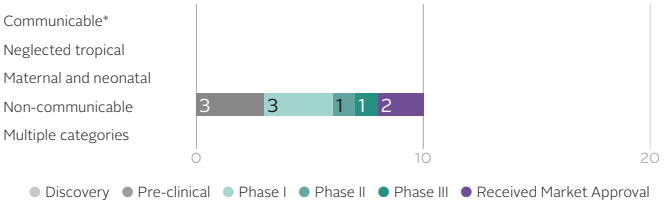
CHANGE SINCE 2016

- Improved its governance structure by anchoring its responsibility and accountability for its global access to diabetes care strategy at the highest level within Novo Nordisk in 2017.
- Founding member of the new global multi-stakeholder partnership, the Defeat-NCD Partnership, which was formally launched in September 2018. The initial focus will be on hypertension and diabetes.
- Launched the Partnering for Change - Chronic Care in Humanitarian Crises initiative in April 2018 which aims to ensure basic healthcare and improve supply of insulin in humanitarian settings.
- Novo Holdings launched the REPAIR Impact Fund in February 2018 with $165 million USD to invest in early-stage drug development projects targeting antimicrobial resistant microorganisms.
- Expanded its Changing Diabetes in Children programme in 2016, newly including Cambodia, Ivory Coast, Myanmar, Senegal and Sudan.
- Launched its Access to Insulin commitment in 2017, helping to ensure availability of low prices for insulin in the poorest parts of the world.

PIPELINE *for diseases and countries in scope*

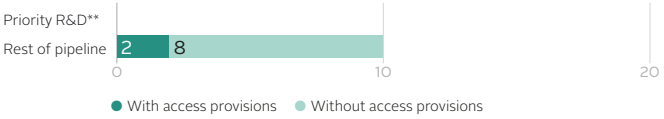
Smallest pipeline: 10 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 5, including a beta-cell preservation treatment for patients with newly diagnosed type I diabetes mellitus and oral semaglutide for type II diabetes mellitus.
Regulatory approvals: 2, including a faster-acting insulin aspart (Fiasp®) for the treatment of diabetes mellitus.
R&D focus: non-communicable diseases (diabetes mellitus).
Access provisions: for 2 projects, both of which have registration strategies.

Projects in the pipeline: 10



Novo Nordisk is developing a Phase III oral formulation of Ozempic® (semaglutide) which could make the use of GLP-1 agonists for diabetes mellitus more feasible in countries where the cold chain is difficult to maintain.

Projects for R&D priority targets with access provisions: 0

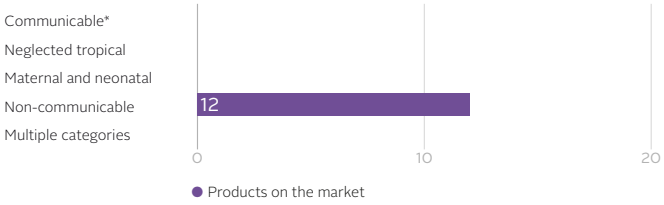


Of Novo Nordisk's ten R&D projects, two are supported by access provisions: e.g., the company plans to register both of its market-approved diabetes mellitus drugs, Fiasp® and Ozempic®, in several countries in scope. Two of its four late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

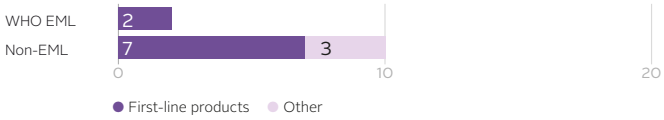
Smallest portfolio: 12 products for diseases in scope (all medicines).
Portfolio focus: non-communicable diseases (diabetes mellitus).
Essential medicines: 17% of Novo Nordisk's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 75% of Novo Nordisk's medicines have first-line indications for diseases in scope.

Products on the market: 12



Novo Nordisk's portfolio includes products such as the ultra long-acting insulin analogue insulin degludec (Tresiba®) and the injectable GLP-1 agonist liraglutide (Victoza®).

Essential medicines with first-line indications: 2



75% of Novo Nordisk's medicines are listed on the WHO EML and/or as first-line treatments: e.g., three human insulins and the long-acting insulin analogue insulin detemir (Levemir®).

BUSINESS CONTEXT

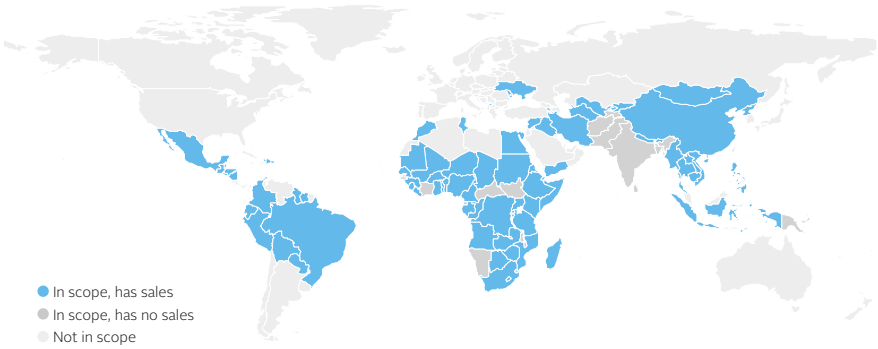
Two business units: Diabetes and Obesity Care; and Biopharmaceuticals. The company also operates in two other therapeutic areas (haemophilia; and growth disorders).
M&A news: 2018 acquisition of Ziylo Ltd, a biotechnology company with a glucose binding molecule platform. Parts of Ziylo's research were also spun out to a new company (Carbometrics).

Presence in emerging markets: In 2018, Novo Nordisk reports sale in 81 countries in scope; 2 more countries than in the 2016 Index.

Net sales by segment (2017) - DKK

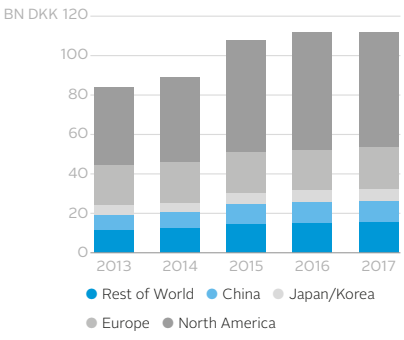
Diabetes and Obesity Care	92,877 MN
Biopharmaceuticals	18,819 MN
Total	111,696 MN

Sales in countries in scope



Statistics relate only to diseases and countries in scope.

Net sales by geographic region



* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
**See Appendix IV for definition.

Novo Nordisk A/S

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 5 SCORE 3.98

Has a strong access-to-medicine strategy with board-level responsibility. Novo Nordisk is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. For example, its strategy on improving access to diabetes care focuses on availability and affordability, building capacity in health systems and increasing access for the most vulnerable. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Novo Nordisk performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include bonuses for employees who perform remarkably and a long-term share-based incentive programme. Senior management has a separate incentive that supports the company's long-term access oriented objectives.

One of 16 companies working on impact measurement. Novo Nordisk measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments and performance information. For example, for its Changing Diabetes in Children initiative, the company reports on its performance, and its access to insulin commitments. Furthermore, it is one of the companies that is measuring impact by evaluation of its Base of the Pyramid initiative.

Discloses who it engages with, incorporates local perspectives into strategies. Novo Nordisk publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by following its stakeholder engagement plan prioritising stakeholders relevant for access to medicine, in close collaboration with relevant local offices. Local perspectives are incorporated into the development of access strategies. It has some policies covering responsible interactions with stakeholders, namely to comply with principles for stakeholder engagement to long-term business success, based on transparency and collaboration.

MARKET INFLUENCE & COMPLIANCE

RANK 6 SCORE 3.03

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Novo Nordisk has a code of conduct relating to ethical marketing and anti-corruption. It provides annual compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities such as technical knowledge and leadership competencies.

Internal control framework meets some Index criteria. Novo Nordisk's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving both internal and external resources, that also applies to third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Above average transparency regarding access-related practices. Novo Nordisk publicly discloses its policy positions on access-related topics (e.g., it publicly supports the WHO's Action Plan for Prevention and Control of NCDs). It is one of the few companies in scope to have a policy that forbids political contributions. It publicly discloses its membership and financial support of patient groups in countries in scope. It includes guidance for responsible interactions with stakeholders in its business ethics code of conduct. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 9 SCORE 2.09

PROJECTS: 10 IN CLINICAL DEVELOPMENT: 5

R&D commitment has limited public health rationale. Novo Nordisk has made a specific commitment to R&D for diabetes, a disease in scope, but this is not publicly available. Its R&D strategy for low- and middle-income countries lacks an evidence-based public health rationale including internal assessments and calls for action from external sources like WHO. It lacks time-bound strategies for completing R&D projects for diseases in scope. Novo Nordisk has the smallest pipeline in the Index with 10 projects. Novo Nordisk is active in R&D for diabetes, for which a globally accepted priority list does not exist.

Access provisions in place for 50% (2/4) of late-stage candidates. Novo Nordisk does not have a clear process in place to develop access plans during R&D. While Novo Nordisk considers access for all insulin products at some point, it is unclear whether or not this takes place during the clinical development stage. To date, Novo Nordisk has project-specific access provisions in place for two of its late-stage R&D projects, both of which have received market approval. Neither of these are being conducted in partnership.

Public policy to ensure post-trial access; commits to registering trialed products. Novo Nordisk has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Novo Nordisk commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 7 SCORE 2.42

PRODUCTS: 12

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 3

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Novo Nordisk does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. This does not explicitly apply to future products. It also commits to implementing intra-country pricing strategies.

Half of new products in scope filed for registration in the majority of relevant priority countries. Novo Nordisk has filed 50% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

25% of products have equitable pricing strategies targeting priority countries. Novo Nordisk's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 25% of its products for diseases in scope. These strategies apply to all priority countries. All of the strategies apply inter- and intra-country pricing; these take into account an average of one socioeconomic factor.

Globally consistent recall guidelines for countries in scope but no processes to track products. Novo Nordisk has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 13 SCORE 1.64

Publicly discloses detailed information on patent statuses. Novo Nordisk both publicly self-discloses the patent statuses for biologics in scope as well as via the Pat-INFORMED platform. Novo Nordisk's self-disclosure includes detailed information about patents, including expiry date, patent number and jurisdiction.

No use of non-assert or licensing arrangements. Novo Nordisk does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not share IP assets with 3rd-party researchers. Novo Nordisk reports no instances where it shares IP assets with third-party researchers developing products for diseases in scope, during the period of analysis.

Public commitment not to enforce patents in countries in scope. Novo Nordisk commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

CAPACITY BUILDING

RANK 4 SCORE 3.26

13 initiatives included for evaluation. Novo Nordisk has 13 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Novo Nordisk submitted 16.

Strong focus on local manufacturing and strengthening health systems. Novo Nordisk has initiatives that meet inclusion criteria in all areas of capacity building, except pharmacovigilance. It performs strongest in manufacturing capacity building and health system strengthening. Its initiatives are focused on diabetes care.

11 initiatives meet all applicable good practice standards:
- The Base of the Pyramid (BoP)
- No Empty Shelves
- The Defeat-NCD Partnership
- Changing Diabetes in Children (CDiC)
- Cities Changing Diabetes

A full list of Novo Nordisk's capacity building initiatives that meet all good practice standards can be found online.
Novo Nordisk has only two included initiatives which do not meet all good practice standards. These two fall short on measuring progress and outcomes.

Timely approach to reporting substandard or falsified medicines to relevant authorities. Novo Nordisk provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days).

PRODUCT DONATIONS

RANK 2 SCORE 4.54
STRUCTURED DONATION PROGRAMMES: 1

Responds to emergencies and humanitarian crises and tracks delivery. Novo Nordisk donated medicines on the request of relief agencies. For example, during the period of analysis, it donated insulin in response to the 2017 earthquake in Mexico. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with humanitarian organisations to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Novo Nordisk's programme is focused on non-communicable diseases, namely diabetes. The programme Changing Diabetes in Children (CDiC) is carried out in partnership with the World Diabetes Foundation (WDF), Roche and the International Society for Paediatric and Adolescent Diabetes (ISPAD), Ministries of Health, National Diabetes Associations as well as other local partners.
The programme supplies human insulin (rDNA) (Actrapid®), isophane human insulin (Insulatard®) and biphasic human insulin (Mixtard®) in 14 countries and has been ongoing since 2009. During the period of analysis, the company reports that more than 2000 additional children were enrolled in the programme.

Ensures long-term access through transition planning. Novo Nordisk has transition plans in place for its CDiC programme to ensure ongoing access for patients once a programme ends. The company will ensure that the completion of the programme will occur gradually over time as it continues to work with local stakeholders to ensure communities retain access to the medicine once a programme ends. The company will continue to supply insulin to children enrolled in the programme.

BEST PRACTICES

Base of the Pyramid (BoP) scales up.
GHANA, KENYA, NIGERIA AND SENEGAL
Initiative to improve access to diabetes care reaches three new countries.

No Empty Shelves joins forces to strengthen supply chains.
KENYA, SENEGAL
Partnership to assess supply chain strengths and bottlenecks, as well as availability and affordability of essential medicines and technologies (EMTs).

INNOVATIVE PRACTICES

New approach to address chronic care in crisis situations
GLOBAL
The Partnering for Change initiative addresses an unmet need for chronic care for people in crises, with partners appropriate for humanitarian settings.

RANK	SCORE
7▼	2.49
6 (2016)	

Sanofi

Stock Exchange: EURONEXT Paris • Ticker: SAN • HQ: Paris, France • Employees: 100,000

PERFORMANCE

Falls 1 place to 7th. While the company is a top performer in R&D, it slips compared to peers in its overall approach to pricing and is amongst the few companies not to disclose patent statuses and clarify filing/enforcement policies.

Management: Holds 7th place, with limited public disclosure of the company's approach to stakeholder engagement.

Compliance: Holds 5th place, with a solid performance on mitigating the risk of non-compliance, but with sales agents remaining solely incentivised by sales targets.

R&D: Falls 1 place to 5th. Amongst the top performers in R&D for its priority R&D and access plans. However, pipeline progression is comparatively average.

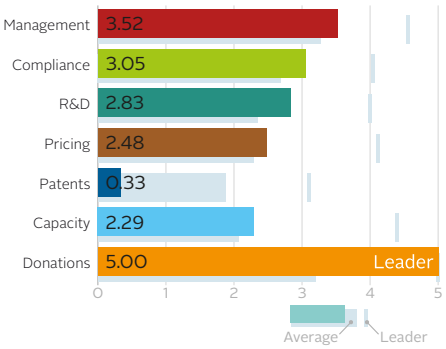
Pricing: Falls 2 places to 6th. Comparatively strong performance in registration, but pushed slightly down due to stronger performances from peers in both inter- and intra-country equitable pricing strategies.

Patents: Fall 2 places to 18th. Unlike many of its peers, it has no public position on patent filing and enforcement in low- and middle-income countries, or disclosure of patent status.

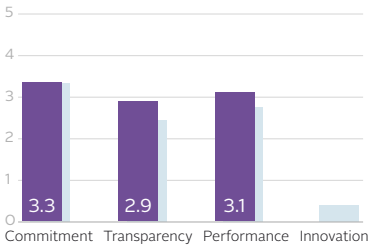
Capacity: Maintains 8th place with a strong focus on manufacturing and health systems strengthening.

Donations: Takes the lead, with a strong donation programme aiming to eliminate human African trypanosomiasis.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Review policies for access-oriented IP management. Sanofi is one of five companies that does not yet commit to not file for and/or not enforce patents in the poorest countries. Sanofi can look to adopt a general public stance to not filing for or enforcing patents related to diseases in scope in Least Developed Countries, low-income countries, and in a subset of middle income countries. Further, Sanofi can publicly disclose the status of its patents, clearly showing where products are on- and off-patent, and when patents are due to expire. Sixteen peers joined Pat-INFORMED, a platform to promote the accessibility of patent information for health agencies tasked with the procurement of medicines. Sanofi could disclose patent information via this platform, or also elect to self-disclose patent status.

Improve access plans for R&D projects during development. Although Sanofi has the third-highest proportion of late-stage R&D projects with access plans in place, its process to establish these provisions can be strengthened. For example, the company can go further than plans for WHO prequalification, and also implement equitable pricing strategies and registration targets. Sanofi can expand access planning to all R&D projects, regardless of product type and in-house or collaborative status, and implement a firmer timeline for developing these access provisions by Phase II of clinical development. Specific examples include developing access provisions for projects such as its Phase II clinical candidate preventive vaccine for respiratory syncytial virus (RSV) and its newly approved insulin lispro biosimilar, Admelog®.

Review sales incentive structures. Sanofi can work towards decoupling sales incentives from sales targets to better incentivise responsible practices. Removing an emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for e.g, rational prescribing. This can be critical for a company like Sanofi that produces antibiotics and other products which are often inappropriately used.

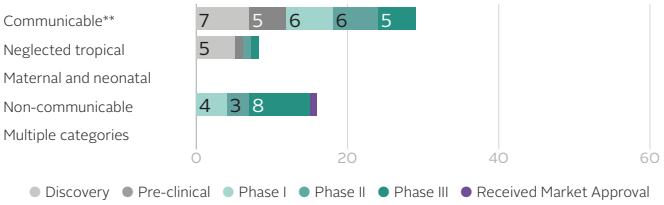
CHANGE SINCE 2016

- Entered into a technology transfer agreement with Moroccan manufacturer, Maphar, in 2017 to support the local production of Sanofi products and help improve supply in Africa.
- Joined Access Accelerated with multiple initiatives including its mental health programme, FAST (Fighting Against Stigma). It has also committed to measure impact and share results publicly via Access Observatory.
- Launched the Faster2Care drone delivery project to improve delivery of essential medicines in the Great Mekong Subregion to help control artemisinine resistance and contribute to malaria elimination in the region.
- Working since September 2016 with ACAME (Association des Centrales d'Achats Africaines de Médicaments Essentiels) to build supply chain capacity for central medical stores in the Western and Central African regions.
- Outsources research on antimicrobials to Evotec.

PIPELINE *for diseases and countries in scope*

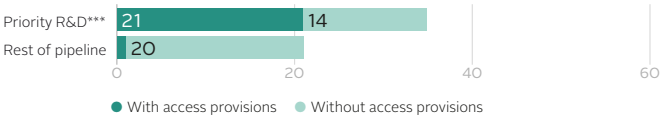
Mid-sized pipeline: 56 R&D projects for diseases in scope (36 medicines; 20 preventive vaccines).
Clinical candidates: 36, including fexinidazole for the treatment of human African trypanosomiasis and a preventive vaccine for rabies.
Regulatory approvals: 1, including a biosimilar for insulin lispro (Admelog®) for the treatment of diabetes mellitus.
R&D focus: communicable diseases (lower respiratory infections and TB) and non-communicable diseases (diabetes mellitus).
Access provisions: for 22 projects, most commonly plans to apply for WHO prequalification.

Projects in the pipeline: 56*



Over one-third of Sanofi's pipeline consists of preventive vaccine candidates including a paediatric vaccine for the prevention of diphtheria, hepatitis B, pertussis, poliomyelitis, tetanus and infections caused by *H. influenzae* (Hexaxim®).

Projects for R&D priority targets with access provisions: 21

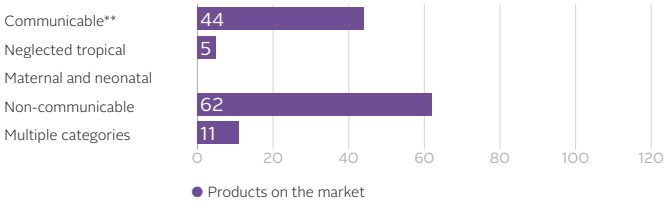


Of Sanofi's 56 R&D projects, 22 are supported by access provisions: e.g., Sanofi's oral cholera vaccine, Shanchol™, has received expanded WHO prequalification for storage at temperatures up to 40°C for up to 14 days before use. Ten of its 25 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

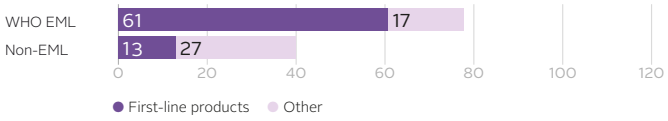
Comparatively large portfolio: 122 products for diseases in scope (102 medicines; 16 preventive vaccines; 4 platform technologies).
Portfolio focus: non-communicable diseases (diabetes mellitus and ischaemic heart disease) and communicable diseases (lower respiratory infections and diarrhoeal diseases).
Essential medicines: 66% of Sanofi's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 63% of Sanofi's medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 122



Sanofi's portfolio includes products such as the antibiotics teicoplanin (Targocid®) and cefpodoxime (Orelox®); and melarsoprol (Arsobal®) and eflornithine (Ornidyl®) for the treatment of human African trypanosomiasis.

Essential medicines with first-line indications: 61



77% of Sanofi's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., recombinant human insulin (Insuman®) and its meningococcal quadrivalent A, C, Y and W-135 vaccine (Menactra®).

BUSINESS CONTEXT

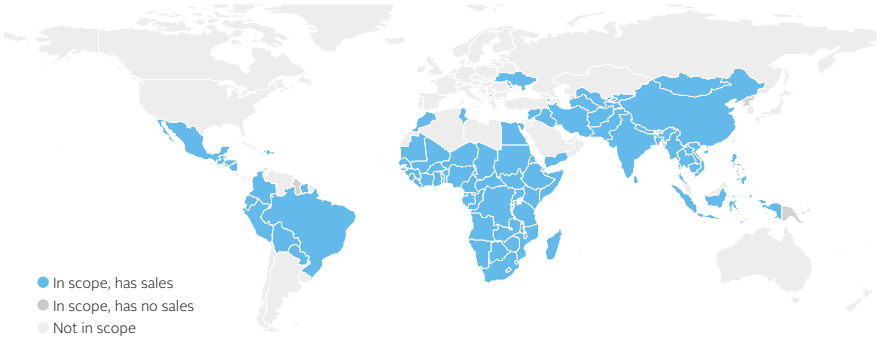
Five business units: Diabetes & Cardiovascular, Consumer Healthcare, Vaccines, Specialty Care (rare diseases, multiple sclerosis, oncology & immunology), General Medicines & Emerging Markets (established prescription products & generics). Its vaccines portfolio focuses on paediatric vaccines, influenza, adult and adolescent booster vaccines, meningitis, and travel and endemic vaccines.

M&A news: 2016 conclusion of joint vaccines venture with Merck & Co., Inc. in Europe to independently manage their product portfolios. 2018 acquisition of Ablynx, a biopharmaceutical company.
Presence in emerging markets: In 2018, Sanofi reports sales in 93 countries in scope; three less than in the 2016 Index. It is the company with the second highest number of countries in scope with sales. It reports that approximately 30% of its sales in 2017 came from emerging markets.

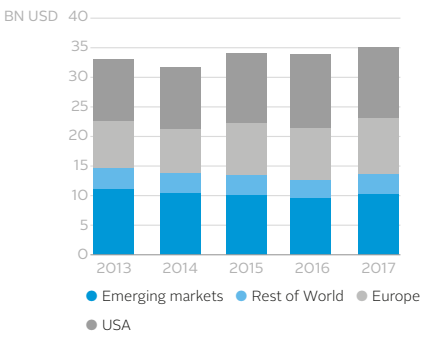
Net sales by segment (2017) - EUR

Pharmaceuticals	29,954 MN
Vaccines	5,101 MN
Total	35,055 MN

Sales in countries in scope



Net sales by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes 3 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
***See Appendix IV for definition.

Sanofi

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 7 SCORE 3.52

Has a strong access-to-medicine strategy with executive level responsibility. Sanofi is one of the 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The strategy centres around the development of new business models focused on developing medicines for unmet needs, affordability and strengthening healthcare systems. The highest level of responsibility for access sits with executive committee members.

Financial and non-financial access-related incentives to reward employees. Sanofi performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include salary increases, bonuses and awards.

One of 16 companies working on impact measurement. Sanofi measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its Global Polio Eradication initiative, the company is committed to adapt its production capacity based on needs, and to help provide vaccines to millions of children around the world, reporting a sustained reduction from 350,000 cases in 1988 to 22 in 2017. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Some transparency about stakeholder engagement approach. Sanofi publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 5 SCORE 3.05

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Sanofi has a code of conduct and policy relating to ethical marketing and anti-corruption. It provides regular compliance training for employees through e-learning tools. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Sanofi's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism, and performs regular evaluations that also apply to third parties. It reports that it regularly conducts fraud-specific risk assessments, and has procedures to segregate duties, so that decisions are checked by another party. It does not, however, demonstrate evidence of a monitoring system for compliance in place.

Above average transparency regarding access-related practices. Sanofi publicly discloses its policy positions on access-related topics (e.g., its global medicine protection strategy includes its position on counterfeit medicines). It is one of the few companies to have a global policy that prohibits political financial contributions. The company publicly discloses its financial support and membership of relevant organisations. It publicly discloses its policies for responsible engagement in its Code of Ethics. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 5 SCORE 2.83

PROJECTS: 56 IN CLINICAL DEVELOPMENT: 36

Publicly commits to R&D to meet public health needs. Sanofi has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Sanofi has a mid-sized pipeline in the Index with 56 projects. For diseases in scope where priorities exist, Sanofi is active in 38 projects; 35 of these target priority R&D gaps.

Access provisions in place for 40% (10/25) of late-stage candidates. Sanofi has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely vaccines. To date, Sanofi has project-specific access provisions in place for 10 of its late-stage R&D projects, eight of which are preventive vaccine candidates. Of these, four are being conducted in partnership with organisations including the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases initiative (DNDi).

Policy to ensure post-trial access; commits to conduct clinical trials only where it intends to make the product available. Sanofi has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Sanofi commits to only perform clinical studies in countries where it intends to make the product available.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 6 SCORE 2.48

PRODUCTS: 122

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 35

Does not publicly commit to equitable pricing or report a commitment to file to register products in scope. Sanofi does not commit to filing its newest products for registration in countries in scope within one year of first market approval. It also does not publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

Some new products in scope filed for registration in the majority of priority countries. Sanofi has filed 40% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). It also publicly shares some registration information for the minority of its products.

29% of products have equitable pricing strategies targeting priority countries. Sanofi's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 29% of its products for diseases in scope. These

strategies apply to an average of 35% of priority countries. Some of these strategies apply both inter- and intra-country pricing strategies; these take into account an average of one and two socioeconomic factors, respectively. Sanofi also applies equitable pricing strategies to six further products informed by a public health rationale.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Sanofi has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 18 SCORE 0.33

Does not publicly disclose patent statuses. Unlike most of its peers, Sanofi does not disclose the status of its products for diseases and countries in scope.

No use of non-assert or licensing arrangements. Sanofi does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing long term commitment agreements. Sanofi reported existing agreements with product development partnerships, including DNDi, MMV and TB Alliance. During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No public commitment not to enforce patents in countries in scope. Sanofi does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries. However, Sanofi shares information via the Index that it does not file or enforce patents in Least Developed Countries or low-income countries.

CAPACITY BUILDING

RANK 8 SCORE 2.29

18 initiatives included for evaluation. Sanofi has 18 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Sanofi submitted 23.

Strong focus on local manufacturing and strengthening health systems. Sanofi has initiatives which meet inclusion criteria in all five areas of capacity building. Most of these initiatives are focused on manufacturing and health system strengthening; it performs strongest in manufacturing capacity building with multiple technology transfers.

Six initiatives meet all applicable good practice standards:
- Technology transfer to Maphar (Morocco)
- Technology transfer to Abidi (Iran) for supplying Iranian market
- Vaccines manufacturing partnerships
- ACAME capacity building
- FAST (Fighting Against STigma)

A full list of Sanofi's capacity building initiatives which meet all good practice standards can be found at online.
Most of its other included initiatives have good governance structures in place, but it commonly falls short on setting clear, measurable goals & objectives and monitoring progress against them.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Sanofi has a policy for reporting cases of substandard or falsified medicines to relevant authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 1 SCORE 5.00
STRUCTURED DONATION PROGRAMMES: 1

Responds to emergencies and humanitarian crises and tracks delivery. Sanofi donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to floods and landslides in Peru and heavy rains in India. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with the NGOs such as Cruz Roja Peruana, Tulipe Association and Americares to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Sanofi's programme is focused on neglected tropical diseases (NTDs). The programme is carried out in partnership with WHO and has been ongoing since 2001. Its NTD programme for human african trypanosomiasis supplies eflornithine (Ornidyl®), melarsoprol (Arsobal®) and pentamidine (Pentacarinat®) reaches 17 countries, and Sanofi reported reaching more than 2000 patients in 2016.

Addresses long-term access by aiming to eliminate disease. Sanofi commits to long-term structured donation programmes by aiming to eliminate the diseases in question. Its eflornithine (Ornidyl®), melarsoprol (Arsobal®) and pentamidine (Pentacarinat®) donation programme aims to eliminate human african trypanosomiasis (HAT) in 17 countries by 2020.

BEST PRACTICES

Largest proportion of pipeline dedicated to priority R&D projects
More than 60% of GSK's and Sanofi's pipelines focus on diseases for which products are urgently needed.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
8▲	2.48
11 (2016)	

Eisai Co. Ltd.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4523 • HQ: Tokyo, Japan • Employees: 10,452

PERFORMANCE

Rises 3 places to 8th, taking a place amongst the top ten companies of the Index. Eisai demonstrates particular strength in R&D, engaging in partnerships to develop a comparatively high number of projects that address R&D priorities, and in Donations.

Management: Falls 4 places to 12th lacking board-level responsibility for access and a clear stakeholder engagement process to incorporate local perspectives.

Compliance: Holds 3rd place, extending ethical standards to third parties, and providing non-sales based incentives for sales agents.

R&D: Rises 2 places to 6th, with a clear strategy for engaging in R&D to meet public health needs and 17 projects targeting priority R&D gaps.

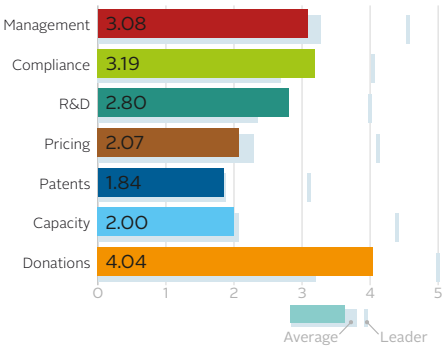
Pricing: Holds 14th place. Below average performance in both registration and pricing with weak outward-facing commitments.

Patents: Falls 2 places to 11th, showing strong performance in IP-sharing but peers have broader geographic commitments not to enforce patents.

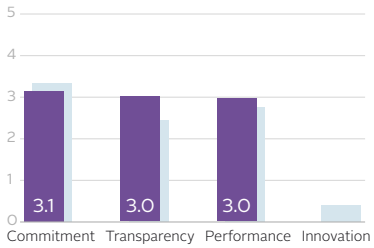
Capacity: Rises 3 places to 11th. Average performance with initiatives meeting most good practices standards but none meeting all.

Donations: Holds at 4th place. Maintains strong performance in donations with single strong programme committed to eliminate lymphatic filariasis.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand process to establish access plans for R&D projects during development. Eisai can improve its process to develop access plans by expanding this process to all projects for diseases in scope and consider the unique requirements needed for each project. It can also establish a firmer timeline for establishing access plans by Phase II of clinical development. This includes developing access plans for projects such as lenvatinib (Lenvima®), an oral medicine which was approved after the period of analysis for the treatment of liver cancer.

Expand registration for epilepsy medicines. Expand access by filing more epilepsy products for registration in countries in scope. Eisai's products for epilepsy, perampanel (Fycompa®), rufinamide (Inovelon) and zonisamide (Zonegran®), have been filed for registration in three, zero, and one countries, respectively, out of 11 possible priority countries. Additional priority countries for registration can include, Dem. Rep. Congo, Ethiopia, Mozambique, Nigeria, Pakistan, Tanzania and Uganda.

Expand access via voluntary licensing. Eisai can consider terms for voluntary licences of its patented anti-epileptic perampanel (Fycompa®) and any future anti-epileptic medicines. While Fycompa® (perampanel) is not yet first-line or on the 2017 WHO Model List of Essential Medicines (WHO EML), the company is expanding its indications, including for partial onset seizures in children as young as four.

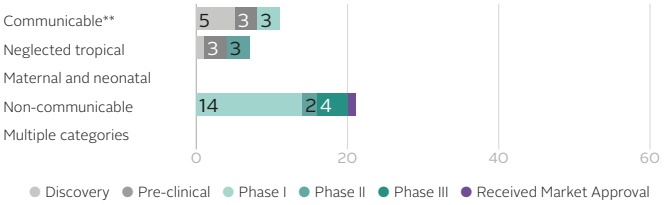
CHANGE SINCE 2016

- Established a process to develop access provisions, including equitable pricing strategies and patent waivers, for projects targeting neglected tropical diseases in countries in scope.
- Extended partnerships with Charles River Laboratories and the Broad Institute to continue developing projects in collaboration that target diseases in scope including malaria.
- Joined Access Accelerated with its Remember I Love You initiative in China. It has also committed to measure impact and share results publicly via Access Observatory.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Has publicly committed to the UN Global Compact since 2017.

PIPELINE *for diseases and countries in scope*

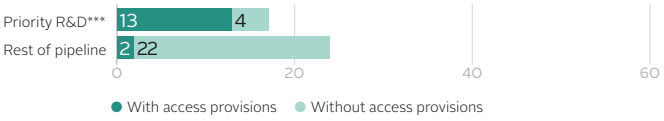
Mid-sized pipeline: 41 R&D projects for diseases in scope (40 medicines; 1 therapeutic vaccine).
Clinical candidates: 28, including eritoran for the treatment of influenza and two Phase II candidates for the treatment of Chagas disease and mycetoma.
Regulatory approvals: 1, perampanel (Fycompa®) for the treatment of partial-onset seizures.
R&D focus: non-communicable diseases (cancer and epilepsy), communicable diseases (malaria) and neglected tropical diseases (e.g. mycetoma).
Access provisions: for 15 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 41*



Most of Eisai's projects for communicable diseases are early-stage. However eritoran, which was previously examined as a possible therapy for severe sepsis, is being studied as a potential treatment for both influenza and Ebola.

Projects for R&D priority targets with access provisions: 13

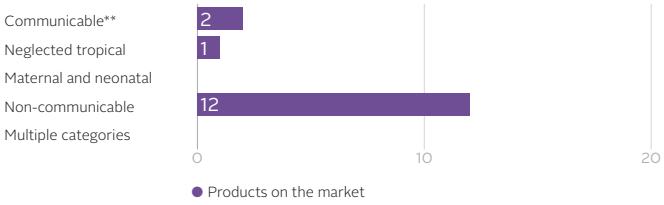


Of Eisai's 41 R&D projects, 15 are supported by access provisions: e.g., fosravuconazole, a Phase II candidate for the treatment of mycetoma, includes a commitment to register in countries in scope. Three of its ten late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

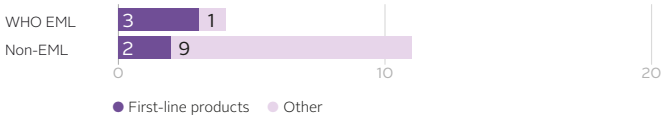
Comparatively small portfolio: 15 products for diseases in scope (all medicines).
Portfolio focus: non-communicable diseases (epilepsy).
Essential medicines: 27% of Eisai's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 33% of Eisai's medicines have first-line indications for diseases in scope.

Products on the market: 15



Eisai's portfolio includes products such as the antiepileptic drugs eslicarbazepine acetate (Zebinix®), rufinamide (Inovelon®), zonisamide (Zonegran®) and valproic acid (Val.O.K.®).

Essential medicines with first-line indications: 3



40% of Eisai's medicines are listed on the WHO EML and/or as first-line treatments: e.g., diethylcarbamazine citrate (DEC), for the treatment of lymphatic filariasis, and warfarin.

BUSINESS CONTEXT

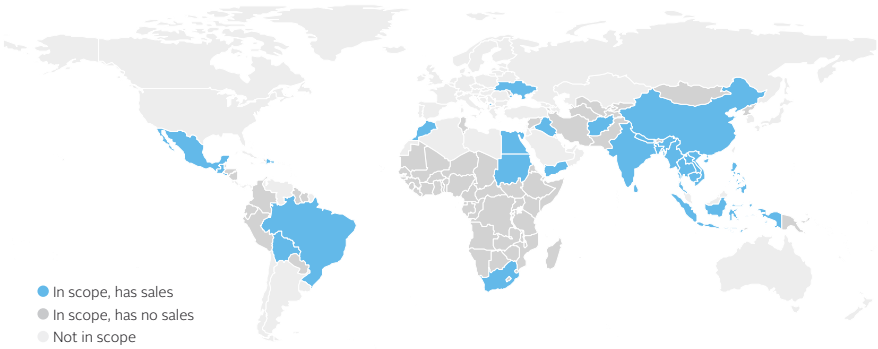
Two business units: Pharmaceuticals and other businesses. Its pharmaceutical business has three areas: prescription pharmaceuticals, consumer healthcare and generic medicines. Its prescription pharmaceutical business has two therapeutic areas: neurology and oncology.
M&A news: No mergers or acquisitions since 2016.

Presence in emerging markets: In 2018, Eisai reports sales in 27 countries in scope; one more than in the 2016 Index. It reports that slightly more than 10% of its sales in 2017 came from China.

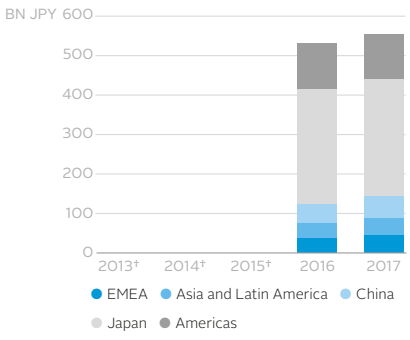
Revenue by segment (2017) - JPY

Pharmaceutical Business	553,200 MN
Other Business	46,800 MN
Total	600,100 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes two projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

** Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
*** See Appendix IV for definition.
† Data not comparable due to changes in company reporting practices

Eisai Co. Ltd.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 12 SCORE 3.08

Has a strong access-to-medicine strategy with executive-level responsibility. Eisai is one of 14 companies that performs strongly with regards to its access-to-medicine strategy which includes access-related goals, and aligns with its corporate strategies. The strategy is focused on long-term sustainable solutions, that explicitly views young emerging markets as opportunities for long-term investments. The highest level of responsibility for access sits with an executive manager.

Financial and non-financial access-related incentives to reward employees. Eisai performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include bonuses rewarding performance and non-financial awards.

One of 16 companies working on impact measurement. Eisai measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, and targets. For example, for its partnership with WHO on eliminating lymphatic filariasis, the company reports committing to provide 2.2 billion tablets free of charge to WHO by 2020. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Some transparency about stakeholder engagement approach. Eisai publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with. Neither does it report incorporating local stakeholder perspectives into the development of access strategies. However, Eisai publicly shares a specific policy for ensuring responsible engagement — in order to deal with stakeholders in a responsible way, with respect and trust and which includes a no tolerance policy for bribery or corrupt behaviour.

MARKET INFLUENCE & COMPLIANCE

RANK 3 SCORE 3.19

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Eisai has a code of conduct and policy relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets, but rather on the uptake of patient screening and treatment.

Internal control framework meets some Index criteria. Eisai's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, and performs *ad hoc* evaluations that also apply to third parties. It reports that it regularly conducts fraud-specific risk assessments. It also has procedures to segregate duties, so that decisions are checked by another party. It does not, however, demonstrate evidence of a monitoring system in place to track compliance in the workplace.

Below average transparency regarding access-related practices. Eisai publicly discloses its policy positions on access-related topics (e.g., its position on intellectual property). It does not disclose political contributions in countries in scope. Eisai publicly discloses its membership of relevant organisations for access, but not its financial contributions. The company also discloses its policies for responsible engagement within its code of conduct. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 6 SCORE 2.80

PROJECTS: 41 IN CLINICAL DEVELOPMENT: 28

Publicly commits to R&D to meet public health needs. Eisai has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale by following external targets including the United Nations Sustainable Development Goals. Further, it has time-bound strategies for completing R&D projects conducted in partnership for diseases in scope and evaluates progress toward these targets. Eisai has a mid-sized pipeline in the Index, with 41 projects. For diseases in scope where priorities exist, Eisai is active in 19 projects; 17 of these target priority R&D gaps.

Access provisions in place for 30% (3/10) of late-stage candidates. Eisai has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for neglected tropical diseases. In general, Eisai develops access plans for R&D projects for neglected tropical diseases in early-stage development but does not have such clear timelines for other diseases. To date, Eisai has project-specific access provisions in place for three of its late-stage R&D projects. All three are being conducted in partnership with the Drugs for Neglected Diseases initiative (DNDi). The Global Health Innovative Technology Fund (GHIT) is also involved in one of the projects.

Policy to ensure post-trial access; commits to registering trialed products. Eisai has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Eisai commits to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 14 SCORE 2.07

PRODUCTS: 15

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 3

Does not commit publicly to equitable pricing or report a commitment to file to register new products in scope. Eisai does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

No new products in scope filed for registration in the majority of priority countries. Eisai has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for epilepsy, is registered in three out of 11 possible priority countries. However, it publicly shares detailed registration information for a minority of its products.

20% of products have equitable pricing strategies targeting priority countries. Eisai's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 20% of its products for diseases in scope. These strategies apply to an average of 14% of priority countries. All of these strategies apply inter- and intra-country pricing; these take into account an average of six and four socioeconomic factors, respectively.

Globally consistent recall guidelines for countries in scope but no processes to track products. Eisai has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 11 SCORE 1.84

Publicly discloses detailed information on patent statuses. Like most of its peers, Eisai publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Eisai does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares many IP assets with 3rd-party researchers. Compared to its peers, Eisai shares many IP assets with third-party researchers developing products for diseases in scope. This includes ten shared with research institutions and neglected disease drug discovery initiatives, such as the Medicines for Malaria Venture (MMV) and the TB Alliance. The assets shared include molecule libraries and performing assays for drug discovery.

Public commitment not to enforce patents in countries in scope. Eisai commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries, low-income countries and Low Human Development Countries.

CAPACITY BUILDING

RANK 11 SCORE 2.00

Eight initiatives included for evaluation. Eisai has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Eisai submitted 22.

Strong focus on strengthening local R&D capacity and health systems. Eisai has initiatives which meet inclusion criteria in all areas of capacity building, except pharmacovigilance. Most of these initiatives are focused on R&D capacity building and health system strengthening. Most of its health system strengthening initiatives are active in East Asia.

Most initiatives meet most good practice standards. None of Eisai's included initiatives meet all the good practice standards looked for by the Index. While most of its initiatives have good governance structures in place, the standard it most commonly falls short on is monitoring the progress and outcomes of its initiatives.

Timely approach to confirming and reporting substandard or falsified medicines. Eisai provides evidence that it systematically confirms suspected cases of substandard or falsified medicines and then reports confirmed cases to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days for each, confirmation and reporting).

PRODUCT DONATIONS

RANK 4 SCORE 4.04

STRUCTURED DONATION PROGRAMMES: 1

Has policy for responding to emergencies or humanitarian crises. While Eisai did not make any *ad hoc* donations during the period of analysis, it has policies in place to respond directly to need. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO). The company tracks the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Eisai's programme is focused on neglected tropical diseases (NTDs). The programme is carried out in partnership with WHO and has been ongoing since 2013. Its NTD programme for lymphatic filariasis supplies diethylcarbamazine citrate (DEC) in 24 countries. As of June 2017, Eisai reports that over 1.1 billion tablets have been provided through WHO's elimination programme.

Addresses long-term access by aiming to eliminate disease. Eisai commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its DEC donation programme aims to eliminate lymphatic filariasis in 24 countries. It plans to supply DEC tablets continuously after 2020, until lymphatic filariasis is completely eliminated in all endemic countries where the treatment is needed.

BEST PRACTICES

Continued commitment to combat NTDs

GLOBAL

One of five companies running donation programmes to eliminate or eradicate NTDs.

RANK	SCORE
9▼	2.48
7 (2016)	

AstraZeneca plc

Stock Exchange: London Stock Exchange • Ticker: AZN • HQ: Cambridge, UK • Employees: 61,100

PERFORMANCE

Falls 2 places to 9th. AstraZeneca maintains a strong performance in 2018, notably in the application of advanced methods for determining prices for different population subsets. It falls two places in part due to a lack of impact measurements on its access approaches.

Management: Falls 6 places to 11th. It maintains strong governance and strategy, but fails to emulate peers in its commitment to measure the impact of its access initiatives.

Compliance: Falls 3 places to 13th. Reaches a settlement under the Foreign Corrupt Practices Act concerning improper payments to health-care professionals in China.

R&D: Holds 10th place. Has the largest pipeline with a process for access-planning, but does not disclose project-specific access plans for its late-stage projects.

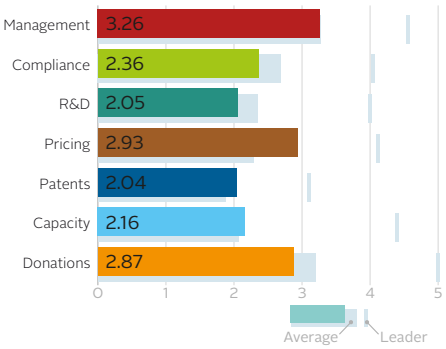
Pricing: Rises 4 places to 4th. Substantial increase in the coverage of the company's portfolio with equitable pricing strategies.

Patents: Falls 4 places to 10th. Despite consistent performance in transparency, it lags behind leading performers in IP-sharing.

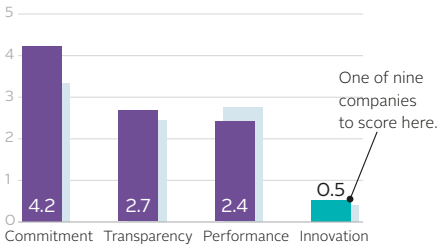
Capacity: Falls 6 places to 10th. Strong performance in health systems strengthening, but falls short on consistently monitoring progress and outcomes of initiatives.

Donations: Rises 4 places to 11th with the inclusion of structured donations programmes for breast cancer and cardiovascular diseases.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Strengthen planning for access for R&D projects. AstraZeneca can improve its access planning process by applying it to more candidates across its entire pipeline and earlier in development (so that plans can be in place before Phase II). This can ensure more successful and rapid access.

Expand intra-country equitable pricing approach. The company's Brazil Mosaic model of segmented intra-country equitable pricing is a best practice for others to follow. It is applied to products listed under the Faz Bem programme, including, for example, Candesartan (Atacand®), ticagrelor (Brilinta®) and rosuvastatin (Crestor®). AstraZeneca can consider expanding the model to other countries, with similar demographics, including China, India and Mexico.

Expand access to key products through registration. For example, AstraZeneca's ticagrelor (Brilinta®) for ischaemic heart disease is an on-patent, first-line treatment product and registered in 6 out of 13 possible priority countries. Broader registration in more priority countries would help increase access to the product for more people in need, including Afghanistan, the Democratic Republic of Congo, Iran, Islamic Rep., Nepal and Pakistan.

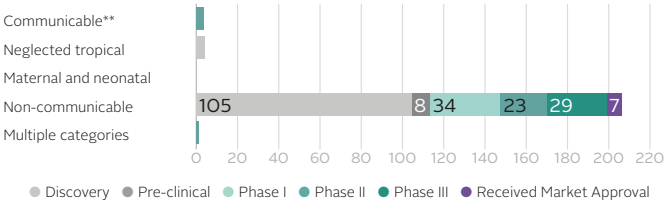
CHANGE SINCE 2016

- Implemented an intra-country tiered pricing model to evaluate the maximum population that could be reached based on cost of goods to determine if a sustainable affordability programme can be developed for particular markets.
- Expanded its Healthy Heart Africa programme beyond Kenya to include Ethiopia and Tanzania. It has also partnered with PEPFAR to integrate HIV and hypertension care in Kenya.
- Launched the Healthy Lung Asia programme in 2017 which focuses on improved awareness, prevention, and treatment of respiratory diseases in Asia.
- Published and incorporated its 5R framework (right target, patient, tissue, safety and commercial potential) for R&D into its Innovative Medicines and Early Development (IMED) Biotech Unit.

PIPELINE *for diseases and countries in scope*

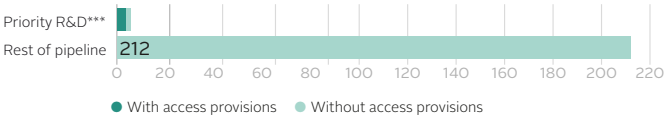
Largest Pipeline: 218 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 90, including a monoclonal antibody for the treatment and prophylaxis of influenza type A and a monoclonal antibody for the prophylaxis of respiratory syncytial virus (RSV) .
Regulatory approvals: 7, including durvalumab (Imfinzi®) for the treatment of lung and bladder cancer.
R&D focus: non-communicable diseases (cancer, diabetes mellitus and asthma).
Access provisions: for 4 projects, all applied through access-oriented partnerships.

Projects in the pipeline: 218*



AstraZeneca aims much of its attention at non-communicable diseases, with an emphasis on cancer (58% of its relevant pipeline). Notably, its MEDI8897 monoclonal antibody aims to provide prophylaxis for respiratory syncytial virus in infants with a single injection.

Projects for R&D priority targets with access provisions: 4

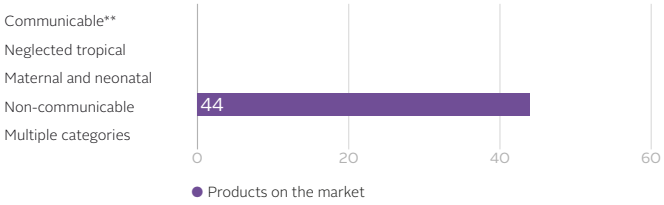


Of AstraZeneca's 218 R&D projects, four are supported by access provisions. All four projects are in collaboration with DNDi, which incorporates access into partnerships. None of its 63 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

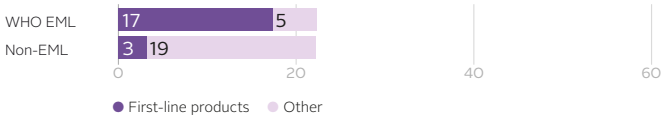
Mid-sized portfolio: 44 products for diseases in scope (all medicines).
Portfolio focus: non-communicable diseases (hypertensive heart disease, asthma and diabetes mellitus).
Essential medicines: 50% of AstraZeneca's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 45% of AstraZeneca's medicines have first-line indications for diseases in scope.

Products on the market: 44



AstraZeneca's portfolio includes products such as inhaled aclidinium bromide/formotorol fumerate (Duaklir®/Genuair®) and glycopyrrolate/formoterol fumarate (Bevespi Aerosphere®) for the treatment of COPD.

Essential medicines with first-line indications: 17



57% of AstraZeneca's medicines are listed on the WHO EML and/or as first-line treatments: e.g., zolmitriptan (Zomig®), budesonide/formoterol (Symbicort®) and isosorbide mononitrate (Imdur®).

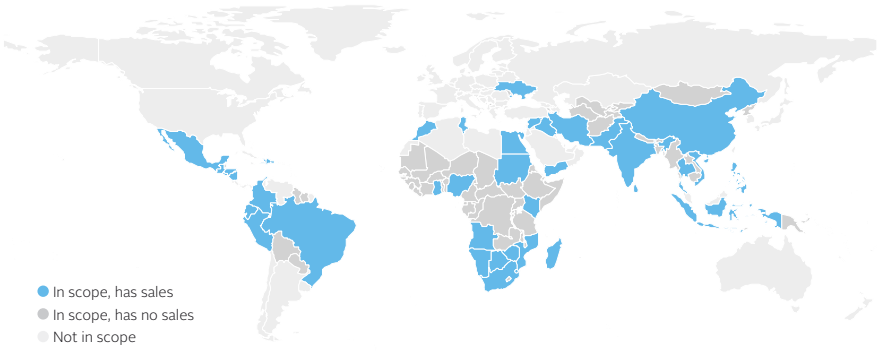
BUSINESS CONTEXT

One business unit: Biopharmaceuticals, with five main therapeutic areas (cardiovascular, renal and metabolism diseases; oncology; respiratory, inflammation and autoimmunity diseases; infection and vaccines; and neuroscience).
M&A news: 2016 sale of small-molecule anti-infectives business and late-stage pipeline to Pfizer; divestment of its global anaesthetics portfolio outside the US to Aspen Global Incorporated (AGI). 2017 acquisition of Takeda's respiratory business.
Presence in emerging markets: In 2018, AstraZeneca reports sales in 40 countries in scope; one less than in the 2016 Index. It reports that around 30% of its sales in 2017 came from emerging markets.

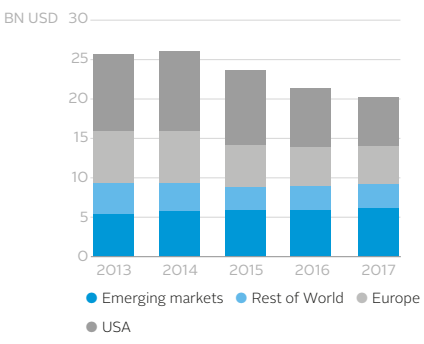
Revenue by segment (2017) - USD

Biopharmaceuticals Business	20,152 MN
Total	20,152 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

*Figure excludes 4 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

** Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
*** See Appendix IV for definition.

AstraZeneca plc

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 11 SCORE 3.26

Has a strong access-to-medicine strategy with board-level responsibility. AstraZeneca is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The company aims to take a commercially sustainable approach to access. The strategy centres around expanding disease prevention, awareness, treatment and capacity building in areas with limited infrastructure. The highest level of responsibility for access sits with a board member.

Non-financial access-related incentives in place for employees. AstraZeneca has non-financial incentives in place to motivate employees to perform on access-related issues. These incentives are centred around providing a good working environment and delivering on performance.

Measures and monitors outcomes and progress; not impact. AstraZeneca measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, targets and performance information. For example, the company reports a target of reaching 25 million patients by 2025 through a variety of Health Systems Development programmes. However, it does not report measuring the impact of its initiatives.

Some transparency about stakeholder engagement. AstraZeneca publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with. Neither does it report on how it incorporates local stakeholder perspectives into the development of its access strategies. However, AstraZeneca publicly shares a specific policy for ensuring responsible engagement — in order to strengthen transparency and multi-stakeholder engagement (including with patient groups and other healthcare organisations aimed at improving patients' lives) and comply with local regulations.

MARKET INFLUENCE & COMPLIANCE

RANK 13 SCORE 2.36

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. AstraZeneca has a code of conduct and policy relating to ethical marketing and anti-corruption, and provides compliance training for employees on an annual basis. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities, such as accountability and integrity in the workplace.

Internal control framework meets some Index criteria. AstraZeneca's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, and it reports that it regularly conducts fraud-specific risk assessments. It also has a monitoring system for compliance. However, it did not demonstrate evidence of procedures to segregate duties, so that decisions are checked by another party.

Above average transparency regarding access-related practices. AstraZeneca publicly discloses its policy positions on access-related topics (e.g., its positions on intellectual property). It discloses political contributions in countries in scope. AstraZeneca publicly discloses its membership of relevant institutions to access, but does not disclose whether it provides financial support. The company also discloses its policies for responsible engagement through its Global Policy on Ethical Interactions. During the period of analysis, AstraZeneca did not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope. Following the period of analysis, the company shared plans to disclose such payments, including countries in North Africa and Latin America.

RESEARCH & DEVELOPMENT

RANK 10 SCORE 2.05

PROJECTS: 218 IN CLINICAL DEVELOPMENT: 90

Commits to R&D to meet public health needs. AstraZeneca has made a specific commitment to R&D for diseases and countries in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale through its "5R framework" (to help ensure the right target, patient, tissue, safety and commercial potential). Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. AstraZeneca has the largest pipeline in the Index with 218 projects. For diseases in scope where priorities exist, AstraZeneca is active in eight projects; six of these target priority R&D gaps.

No access provisions; process in place for setting them. AstraZeneca has a general process in place to develop access plans during R&D. It is unclear whether this applies to all or some of the company's R&D projects. Mainly, AstraZeneca develops access plans for R&D projects in Phase III of clinical development. To date, AstraZeneca does not have any project-specific access provisions in place for its late-stage R&D projects.

Policy to ensure post-trial access; commits to registering trialed products. AstraZeneca has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, AstraZeneca commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 4 SCORE 2.93

PRODUCTS: 44

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 26

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. AstraZeneca does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a majority of its products for diseases in scope, including for future products. Its public commitments also apply to intra-country equitable pricing strategies.

Some new products in scope filed for registration in the majority of priority countries. AstraZeneca has filed 10% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share the registration status for any of its products.

60% of products have equitable pricing strategies targeting priority countries. AstraZeneca's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for

60% of its products for diseases in scope. These strategies apply to an average of 19% of priority countries. Almost all of these strategies apply inter-country pricing; these take into account an average of three socioeconomic factors.

Has both globally consistent recall guidelines for countries in scope and processes to track products. AstraZeneca has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 10 SCORE 2.04

Publicly discloses some information on patent statuses. AstraZeneca publicly self-discloses information relating to the status of its patents for products in scope, this includes: name of the medicine, nature of the patent, expiry date and jurisdiction. However, it does not include patent numbers.

No use of non-assert or licensing arrangements. AstraZeneca does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. AstraZeneca reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Public commitment not to enforce patents in countries in scope. AstraZeneca commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies to most Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

CAPACITY BUILDING

RANK 10 SCORE 2.16

Nine initiatives included for evaluation. AstraZeneca has nine capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; AstraZeneca submitted the maximum.

Performs strongest in strengthening health systems. AstraZeneca has initiatives which meet inclusion criteria in three areas of capacity building: manufacturing, pharmacovigilance and health system strengthening. It performs strongest in health system strengthening, with programmes focused on non-communicable disease prevention and treatment.

Five initiatives meet all applicable good practice standards:
- Healthy Heart Africa (pharmacovigilance)
- Young Health Programme
- Healthy Lung Asia
- Phakamisa South Africa
- Healthy Heart Africa (health system strengthening)

AstraZeneca's remaining included initiatives typically aim for sustainability and long-term improvements, but most commonly fall short on monitoring progress and outcomes.

Does not provide evidence of reporting substandard or falsified medicines within the recommended time frame. AstraZeneca has a policy for reporting cases of substandard or falsified medicines to local regulatory authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 11 SCORE 2.87

STRUCTURED DONATION PROGRAMMES: 2

Responds to emergencies, humanitarian crises and tracks delivery. AstraZeneca donated medicines on the request of relief agencies. For example, during the period of analysis, it donated the antibiotic meropenem (Merrem®) in response to paediatrician requests for a sepsis programme in Cambodia. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americares and Direct Relief International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Two donation programmes covering diseases and countries in scope. AstraZeneca's programmes are focused on non-communicable diseases, namely cancer and cardiovascular disease. Both programmes are carried out in partnership with its long-term partners Americares and the Red Cross. Its breast cancer programme supplies anastrozole (Arimidex®) in Cambodia and has been ongoing since 2008. During the period of analysis, AstraZeneca reports that this has reached almost 800 patients.

No transition plans in place. AstraZeneca does not provide evidence that it considers longer-term access to donated products, for example, once a programme ends, or through transition planning.

BEST PRACTICES

Sophisticated pricing model tailors discounts to population groups

BRAZIL

Customised approach to assigning discounts to patients based on ability to pay (known as mosaic segmentation).

INNOVATIVE PRACTICES

New pilot programme considers more than just health

KENYA

Dunga Beach Biogas Project, that aims to reduce air pollution and improve respiratory health, also contributes to local economic and employment development.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
10▲	2.38
19 (2016)	

Roche Holding AG

Stock Exchange: SIX Swiss Exchange • Ticker: ROG • HQ: Basel, Switzerland • Employees: 93,734

PERFORMANCE

Roche lands at 10th, rising 9 places since the 2016 Index and 2 places compared with 2014. Roche focuses on access to cancer care and improvements in performance can in part be attributed to the inclusion of cancer in scope.

Management: Rises 17 places to 2nd due to a refreshed access-to-medicine strategy governed by board members, and an innovative global access programme aimed at access to HIV diagnostics.

Compliance: Holds steady at 4th through ensuring third-party compliance with its standards, and rewards for sales agents are not solely based sales targets.

R&D: Rises 5 places to 14th but places in third quartile as it lacks a clear process for the development of access plans for its late-stage projects.

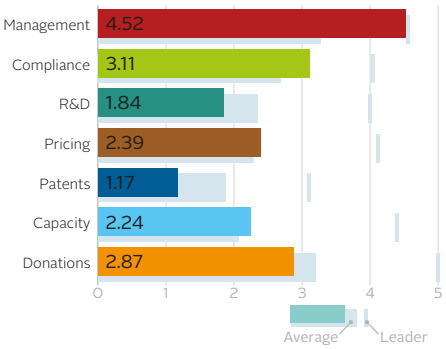
Pricing: Rises 12 places to 8th due to an improvement in the range of products that have equitable pricing strategies, extended to further countries.

Patents: Falls 6 places to 17th. Overtaken by peers in IP sharing, with no current engagement in licensing.

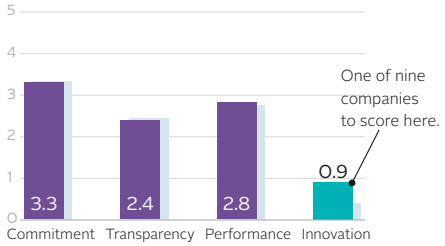
Capacity: Rises 10 places to 9th with multiple capacity building initiatives with a focus on cancer control.

Donations: Rises one place to 11th. Engages in three structured donation programmes focused on cancer, including for trastuzumab (Herceptin®).

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Improve access plans for R&D projects during development. Roche can improve its process to develop access plans by expanding this process to all projects for diseases in scope. Currently, Roche considers access in an *ad hoc* manner and utilises a general market access approach for its R&D projects without tailored access plans for diseases and countries in scope. Considering the unique barriers to access that affect those living in low- and middle-income countries, Roche can help ensure more patients globally can access products as soon as possible following market approval.

Build on strong capacity building initiatives. Breast cancer has the highest incidence of all cancers in countries in scope. Roche's Partnership to Improve Breast Cancer in Kenya is focused on increasing awareness and screening, improving diagnosis and treatment, and training healthcare professionals. This initiative meets all good practice standards. It is working in line with Kenya's national strategies to improve non-communicable disease (NCD) care, including breast cancer. Roche can identify other countries with national strategies for NCD or cancer control and partner to improve breast cancer care.

Expand access through increasing supply. Roche can identify generic medicine manufacturing partners for the non-exclusive voluntary licensing of products for high-burden diseases. Products could include rituximab (MabThera®) listed on the 2017 WHO Model List of Essential Medicines (WHO EML) for diffuse large B-cell lymphoma, chronic lymphocytic leukaemia, and follicular lymphoma. This can be facilitated through the newly expanded Medicines Patent Pool (MPP) mandate to include patented medicines on the WHO EML in its patent pooling and voluntary licensing strategy.

Focus expertise in diagnostic devices to address more priority R&D product gaps. Roche has an extensive portfolio of diagnostic devices and the largest number of diagnostic candidates in the pipeline. It can use its expertise to expand its diagnostic development to address more identified priority R&D product gaps in priority areas where it is currently active or has been active (HIV, viral hepatitis B and C and tuberculosis) as well as expanding its arsenal of diagnostic tests for specific pathogens, such as those responsible for diarrhoeal diseases, including *V. cholerae* and *Shigella* species.

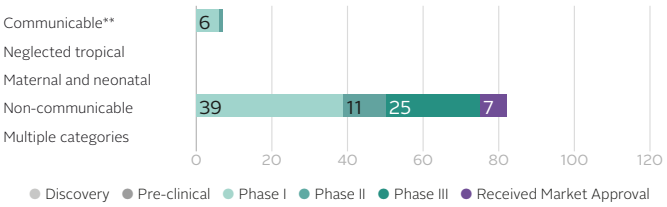
CHANGE SINCE 2016

- Refreshed its access-to-medicine strategy with clear targets through its Access Planning Framework, which focuses on ensuring availability by working on awareness, diagnosis, healthcare capacity and funding.
- Partnered with the government of Niger State, Nigeria to provide high-quality drugs and free treatment for breast cancer patients and build capacity for prevention and care.
- Joined Access Accelerated with multiple initiatives focused on cancer care. It has also committed to measure impact and share results publicly via Access Observatory.
- Participates in Brazil's Partnerships for Productive Development to transfer production of biologic products, and provides training as part of the transfer.
- Launched in August 2016, a five-year partnership with the Kenya Ministry of Health in order to improve care and treatment for breast cancer.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.

PIPELINE *for diseases and countries in scope*

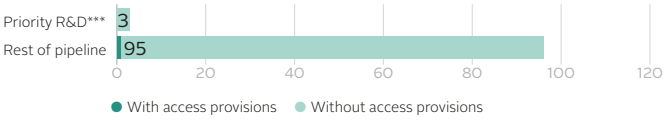
Comparatively large pipeline: 100 R&D projects for diseases in scope (89 medicines; 11 diagnostics).
Clinical candidates: 82, including a novel inhibitor for the treatment of influenza and five Phase I medicines for the treatment of hepatitis B virus.
Regulatory approvals: 7, including atezolizumab (Tecentriq®) for the treatment of bladder and lung cancers.
R&D focus: non-communicable diseases (cancer and diabetes mellitus) and communicable diseases (viral hepatitis B).
Access provisions: for 2 projects, one of which has an equitable pricing commitment and the other with registration and supply strategies.

Projects in the pipeline: 100*



Roche is one of only five companies in the scope of the Index developing diagnostics for diseases in scope. These include diagnostics for human papilloma virus (HPV), HIV/AIDS, *C. difficile* and the priority pathogen *S. aureus*.

Projects for R&D priority targets with access provisions: 0

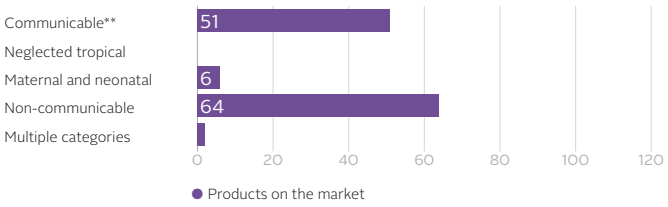


Of Roche's 100 R&D projects, two are supported by access provisions: e.g., Perjeta® for the treatment of breast cancer has a commitment for equitable pricing in all LMICs. Two of its 44 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

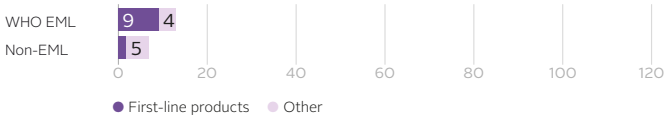
Comparatively large portfolio: 123 products for diseases in scope (90 diagnostics; 20 medicines; 13 platform technologies).
Portfolio focus: non-communicable diseases (cancer and ischaemic heart disease) and communicable diseases (viral hepatitis B and C and HIV/AIDS).
Essential medicines: 65% of Roche's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 55% of Roche's medicines have first-line indications for diseases in scope.

Products on the market: 123



Roche's portfolio includes products such as the cobas® Plasma Separation Card which is used for HIV plasma viral load testing and keeps blood samples intact even in areas of extreme heat and humidity for transport.

Essential medicines with first-line indications: 9



75% of Roche's medicines are listed on the WHO EML and/or as first-line treatments: e.g., trastuzumab (Herceptin®), oseltamivir (Tamiflu®) and epoeitin beta (NeoRecormon®).

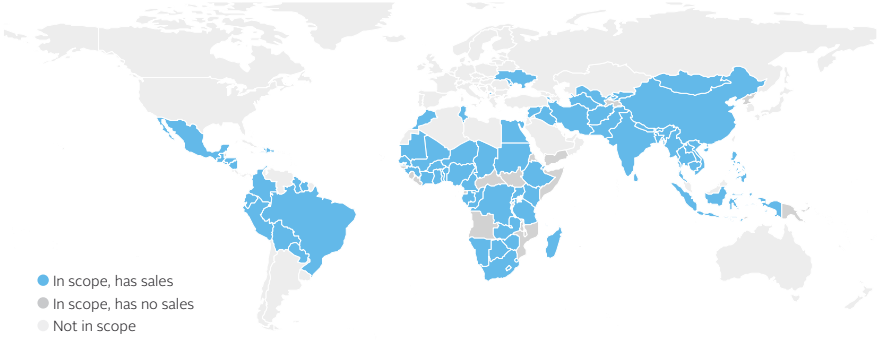
BUSINESS CONTEXT

Two business units: Pharmaceuticals and Diagnostics. Its pharmaceutical business has five therapeutic areas (oncology; infectious diseases; immunology; ophthalmology; and neuroscience). Its diagnostics business has four business units (Centralised and Point of Care Solutions, Diabetes Care, Molecular Diagnostics and Tissue Diagnostics).
M&A news: Activity includes the 2018 acquisition of Ignyta, a biotechnology company focused on oncology therapeutics; merger with Foundation Medicine, which develops and markets genomic analysis diagnostics for cancer.
Presence in emerging markets: In 2018, Roche reports sales in 77 countries in scope; 11 less than in the 2014 Index. It reports that more than 25% of its sales in 2017 came from Asia and Latin America.

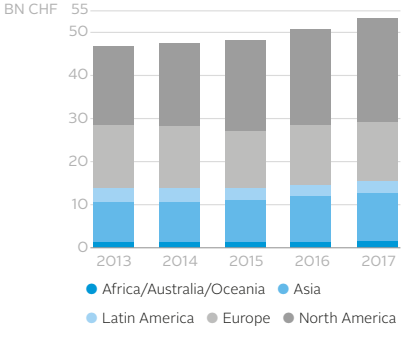
Sales by segment (2017) - CHF

Pharmaceuticals	41,220 MN
Diagnostics	12,079 MN
Total	53,299 MN

Sales in countries in scope



Sales by geographic region



Statistics relate only to diseases and countries in scope.

*Figure excludes 11 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
***See Appendix IV for definition.

Roche Holding AG

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 2 SCORE 4.52

Has a strong access-to-medicine strategy with board-level responsibility. Roche is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The strategy centres around identifying access-related issues with local stakeholders and developing country-specific plans using its Access Planning Framework. This framework is focused on four areas: awareness; diagnosis; healthcare capacity; and funding. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Roche performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include annual performance-related goals, and internal recognition and awards. Senior management has a separate incentive that supports the company's long-term access-oriented objectives.

One of 16 companies working on impact measurement. Roche measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments and performance information. For example, for its Patient Access Dashboard initiative, Roche reports having increased access to standard of care treatment for blood cancers and breast cancer in 14 low- and middle-income countries. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Roche publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by conducting a materiality assessment and an engagement activity. Local stakeholder perspectives are incorporated into the development of its access strategies. However, it does not publicly share its policy for ensuring responsible engagement.

MARKET INFLUENCE & COMPLIANCE

RANK 4 SCORE 3.11

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Roche has a code of conduct relating to ethical marketing and anti-corruption, and provides continuous compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities relating to diversity, sustainability and the environment.

Internal control framework meets some Index criteria. Roche's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has a monitoring system in place to track compliance, and auditing processes. It also has procedures to segregate duties, so that decisions are checked by another party. It does not, however, demonstrate evidence of having fraud-specific risk assessment.

Above average transparency regarding access-related practices. Roche publicly discloses its policy positions on access-related topics (e.g., its position on counterfeit medicine and human rights). It does not disclose its political contributions in countries in scope. It publicly discloses its financial support and membership of relevant organisations to access, and is the only company in scope to disclose its policy for managing conflicts of interest with these institutions. The company also discloses its policies for responsible engagement. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 14 SCORE 1.84

PROJECTS: 100 IN CLINICAL DEVELOPMENT: 82

Publicly commits to R&D to meet public health needs. Roche has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on data from external sources like WHO related to global disease burden. It lacks time-bound strategies for completing R&D projects for diseases in scope. Roche has one of the largest pipelines in the Index with 100 projects. For diseases in scope where priorities exist, Roche is active in five projects; three of these target priority R&D gaps.

Access provisions in place for 5% (2/44) of late-stage candidates. Roche does not have a clear process in place to develop access plans during R&D. Instead, Roche considers access on a case-by-case basis. In general, Roche develops access plans for these R&D projects in Phase I or II of clinical development. To date, Roche has project-specific access provisions in place for two of its late-stage R&D projects. Of these, one is being conducted in partnership with Shionogi Inc.

Public policy to ensure post-trial access; commits to registering trialed products. Roche has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Roche commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 8 SCORE 2.39

PRODUCTS: 123

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 6

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Roche does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. This does not explicitly apply to future products. It also commits to implementing intra-country pricing strategies, albeit to only some of its products.

Many new products in scope filed for registration in the majority of relevant priority countries. Roche has filed 70% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

5% of products have equitable pricing strategies targeting priority countries. Roche's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 5% of its products for diseases in scope. These strategies apply to an average of 84% of priority countries. Some of these strategies apply both inter- and intra-country pricing; these take into account an average of one and three socioeconomic factors, respectively.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Roche has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 17 SCORE 1.17

Publicly discloses detailed information on patent statuses. Like most of its peers, Roche publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Roche does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. Roche reported existing agreements with product development partnerships, such as the TB Alliance. During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Public commitment not to enforce patents in countries in scope. Roche commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries. The company also do not file or enforce patents for any of its antiretroviral HIV medicines in sub-Saharan African countries.

CAPACITY BUILDING

RANK 9 SCORE 2.24

10 initiatives included for evaluation. Roche has 10 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Roche submitted 21.

Focused on supporting pharmacovigilance and strengthening health systems. Roche has initiatives that meet inclusion criteria in all five areas of capacity building. Most of these initiatives are focused on pharmacovigilance and health system strengthening. These initiatives are most active in Africa.

Two initiatives meet all applicable good practice standards:

- Strengthening the Supply Chain in sub-Saharan Africa
- Partnership to Improve Breast Cancer Care in Kenya

Roche's remaining included initiatives typically have goals in place, but fall short on monitoring progress and outcomes.

Timely approach to reporting substandard or falsified medicines to relevant authorities. Roche provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days).

PRODUCT DONATIONS

RANK 11 SCORE 2.87

STRUCTURED DONATION PROGRAMMES: 3

Has policy for responding to emergencies or humanitarian crises. While Roche did not make any *ad hoc* donations during the period of analysis, it has policies in place to respond directly to need, which are aligned with international guidelines. It has plans in place to ensure products are rapidly made accessible and to track the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Roche's programmes are focused on non-communicable diseases (NCDs), namely cancer. All three programmes are carried out in collaboration with partners such as local ministries of health. Its breast cancer programmes supply trastuzumab (Herceptin®) in China, Pakistan and the Philippines. The programme in China began in 2011 with Roche reporting that nearly 20,000 breast cancer patients benefited from trastuzumab (Herceptin®) in 2016.

Ensures long-term access through transition planning. Roche has transition plans in place for its trastuzumab (Herceptin®) donation programme to ensure ongoing access for patients once the programme ends. The company will work with both national and local government units, health institutions and other stakeholders to ensure public reimbursement for trastuzumab (Herceptin®) so that patients can obtain it via the public health system. This will involve mobilising alternative sources of funding for cancer patients, such as the development of private health insurance for cancer.

BEST PRACTICES

Leading platforms to track access activities

GLOBAL

Systems that enable them to track how local access strategies are implemented, and how activities progress.

Comprehensive overview of stakeholder engagement

GLOBAL

Only company in scope to share publicly, via its website, a clear overview of the way it engages with each specific stakeholder.

INNOVATIVE PRACTICES

Systematic approach to identify access challenges

GLOBAL

A comprehensive Access Planning Framework Patient Access Dashboard to determine current access levels in countries, and how its initiatives contribute to access.

Global Access Program provides better access to diagnostic testing for HIV/AIDS in 82 countries

GLOBAL

Combining equitable pricing policies with capacity building and diagnostics R&D.

RANK	SCORE
11▲	2.34
14 (2016)	

Pfizer Inc.

Stock Exchange: New York Stock Exchange • Ticker: PFE • HQ: New York City, New York, United States • Employees: 90,200

PERFORMANCE

Rises 3 places to 11th. Pfizer improves its performance since 2016, with a refreshed access-to-medicine strategy and a strong approach to health systems strengthening.

Management: Rises 4 places to 9th place due to a newly reviewed access-to-medicine strategy focused on commercially viable business models, with responsibility at the board level.

Compliance: Rises 11 places to 8th publicly disclosing financial support and membership of institutions which may impact access to medicine.

R&D: Rises 1 place to 13th, with a general approach to planning for access applied to comparatively few of its late-stage R&D projects.

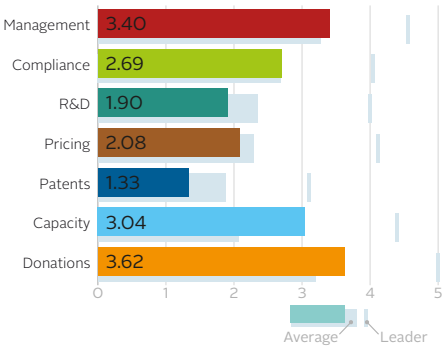
Pricing: Rises 2 places to 13th, improving slightly compared to peers in registration, but has a below average approach to equitable pricing.

Patents: Falls 1 place to 15th. Newly discloses its patent statuses via Pat-INFORMED, but does not commit not to file or to enforce patents even in Least Developed Countries.

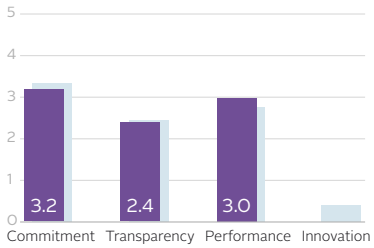
Capacity: Rises 4 places to 5th, with 7 initiatives meeting all good practice standards. Health systems strengthening is its strongest area.

Donations: Falls one place to 6th. Extends commitment to eliminating trachoma until 2025.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand access on family planning. Pfizer's Integrated Immunization and Family Planning Portfolio project has been active since 2016 in Ethiopia, Uganda, Kenya, Benin, and Malawi. The project integrates family planning services into routine immunization visits and it meets all good practice standards looked for by the Index. An assessment is expected to be published at the end of 2018. Based on these results, Pfizer can consider extending its commitment (currently set until the end of 2019) and expand to more countries with family planning needs.

Improve access plans for R&D projects during development. Pfizer can improve its process to develop access plans by expanding this process to all projects for diseases in scope. Currently, Pfizer plans for access in an *ad hoc* manner. It can also establish a firmer timeline for establishing these access plans by Phase II of clinical development. Pfizer can establish access plans for more late-stage projects, including both in-house and collaborative R&D projects. For example, Pfizer can establish access plans for its late-stage candidates that target bacterial infections, including the beta-lactamase inhibitor-containing aztreonam-avibactam to address antimicrobial resistance.

Join peers in patent filing and enforcement commitment. Pfizer is one of five companies that does not yet make a public commitment to not file for and/or not enforce patents in the poorest countries. Pfizer can look to adopt a general public stance to not file for and/or not enforce patents related to diseases in scope in Least Developed Countries, low-income countries, and in a subset of middle income countries.

Expand registration of key antibiotic. Ceftazidime/avibactam (Zavicefta™) for lower respiratory infections has been filed to register in one out of 10 possible priority countries. This product can provide an important last line of defence where resistance to third-generation cephalosporins and other antibiotics has been observed. Alongside appropriate product stewardship, Pfizer could register the product in more priority countries, including, for e.g., Afghanistan, Congo, Dem. Rep., Ethiopia, Niger, Nigeria, Pakistan, and Uganda.

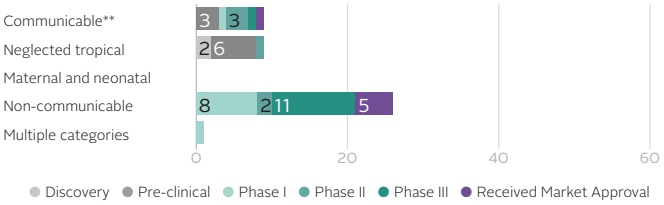
CHANGE SINCE 2016

- Announced an extension of its initiative in collaboration with the Bill & Melinda Gates Foundation and the Children's Investment Fund Foundation (CIFF) to further broaden access to Pfizer's all-in-one injectable contraceptive, Sayana®Press (medroxyprogesterone acetate).
- Joined Access Accelerated with multiple initiatives. It has also committed to measure impact and share results publicly via the Access Observatory.
- Became a funding partner for the drone delivery company, Zipline, in order to expand the programme for delivery of essential medicines.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Newly established a Global Health Committee, strengthening governance of its access to medicine strategy.
- Extended commitment to the elimination of trachoma until 2025 through the donation of azithromycin (Zithromax®) in partnership with the International Trachoma Initiative.

PIPELINE *for diseases and countries in scope*

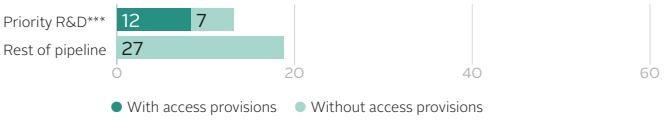
Mid-sized pipeline: 46 R&D projects for diseases in scope (40 medicines; 6 preventive vaccines).
Clinical candidates: 28, including a therapy for human African trypanosomiasis and a preventive vaccine for *Staphylococcus aureus*.
Regulatory approvals: 6, including ceftazidime/avibactam (Zavicefta™) for the treatment of lower respiratory infections and diarrhoeal diseases.
R&D focus: non-communicable diseases (cancer and diabetes mellitus), communicable diseases (lower respiratory infections and diarrhoeal diseases) and neglected tropical diseases (Chagas disease and onchocerciasis).
Access provisions: for 12 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 46*



Pfizer is developing several preventive vaccines for communicable diseases including a Phase III candidate for *Clostridium difficile* and two Phase II candidates for the priority pathogens *S. pneumoniae* and *S. aureus*.

Projects for R&D priority targets with access provisions: 12

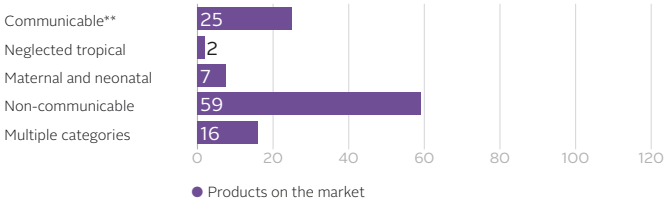


Of Pfizer's 46 R&D projects, 12 are supported by access provisions: e.g., a Phase II pneumococcal vaccine will be manufactured locally to ensure sufficient supply. Two of its 24 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

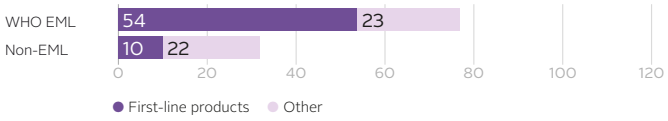
Comparatively large portfolio: 109 products for diseases in scope (101 medicines; 4 contraceptive methods; 4 preventive vaccines).
Portfolio focus: non-communicable diseases (cancer, hypertensive heart disease and ischaemic heart disease) and communicable diseases (lower respiratory infections and diarrhoeal diseases).
Essential medicines: 71% of Pfizer's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 59% of Pfizer's medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 109



Pfizer's portfolio includes products such as tigecycline (Tygacil®) and the beta-lactamase resistant antibiotics ceftazidime/avibactam (Zavicefta™) and ampicillin sodium/sulbactam sodium (Unasyn®).

Essential medicines with first-line indications: 54



80% of Pfizer's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., oxytocin (Pitocin®), medroxyprogesterone acetate (Sayana® Press; Depo Provera®) and several anti-tuberculosis agents.

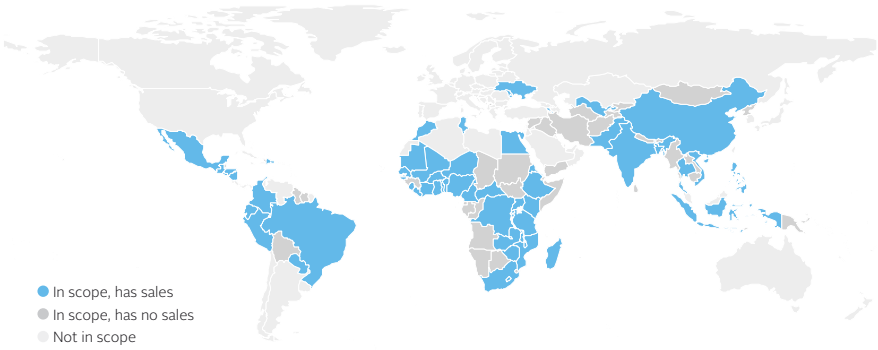
BUSINESS CONTEXT

Two business units: Pfizer Essential Health (PEH); and Pfizer Innovative Health (PIH). PEH has five business units (anti-infectives; biosimilars; emerging markets; global brands; and sterile injectables). PIH has six therapeutic areas (consumer healthcare; inflammation and immunology; internal medicine; oncology; rare diseases; and vaccines). Its vaccines portfolio focuses on meningococcal disease, pneumococcal disease and tick-borne encephalitis. Pfizer holds a 11.7% equity share in ViiV Healthcare - a joint HIV/AIDS medicine venture with GSK and Shionogi.
M&A news: 2016 acquisition of AstraZeneca's small-molecule anti-infectives business and late-stage pipeline.
Presence in emerging markets: In 2018, Pfizer reports sales in 58 countries in scope; 28 less than in the 2016 Index. It reports that around 20% of its sales in 2017 came from emerging markets.

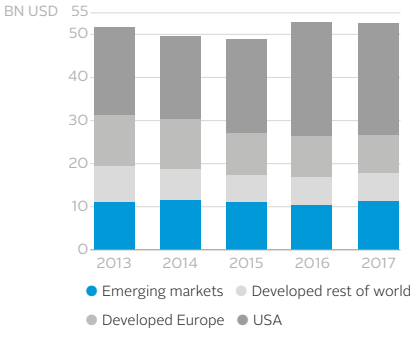
Revenue by segment (2017) - USD

Pfizer Innovative Health (PIH)	31,422 MN
Pfizer Essential Health (PEH)	21,124 MN
Total	52,546 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

*Figure excludes 1 project that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

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***See Appendix IV for definition.

Pfizer Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 9 SCORE 3.40

Has a strong access-to-medicine strategy with board-level responsibility. Pfizer is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. The newly reviewed strategy centres around the development of commercially viable business models providing sustainable, long-term access for patients at all socioeconomic levels. The highest level of responsibility for access sits with a board-level committee.

Non-financial access-related incentives in place for employees. Pfizer has non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include awards for employees focused on patient and health impact and a dedicated access-to-medicine incentive.

One of 16 companies working on impact measurement. Pfizer measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its International Trachoma Initiative, the company reports committing to continue its donation of azithromycin for blinding trachoma until at least 2025, with 81 million doses already donated to 26 countries in 2017. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Pfizer publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, or its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 8 SCORE 2.69

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Pfizer has a code of conduct relating to ethical marketing and anti-corruption. The company provides compliance training for employees upon hire and periodically. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, the company also considers non-sales driven components, depending on the specific market situation and product portfolio.

Internal control framework meets some Index criteria. Pfizer's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place; it performs regular evaluations that also apply to third parties. Pfizer also has procedures to segregate duties, so that decisions are checked by another party. It does not, however, demonstrate evidence of having fraud-specific risk assessment.

Below average transparency regarding access-related practices. Pfizer publicly discloses its policy positions on access-related topics (e.g., its position on counterfeit medicines, importation and intellectual property). It does not disclose political contributions in countries in scope. Pfizer publicly discloses its membership of relevant organisations to access, but not its financial contributions to such organisations. It does not, however, publicly disclose its policies for responsible engagement, nor its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 13 SCORE 1.90

PROJECTS: 46 IN CLINICAL DEVELOPMENT: 28

R&D commitment has limited public health rationale. Pfizer has made a general commitment to R&D for diseases in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries lacks an evidence-based public health rationale including internal assessments and calls for action from external sources like WHO. It lacks time-bound strategies for completing R&D projects for diseases in scope. Pfizer has a mid-sized pipeline in the Index with 46 projects. For diseases in scope where priorities exist, Pfizer is active in 20 projects; 19 of these target priority R&D gaps.

Access provisions in place for 8% (2/24) of late-stage candidates. Pfizer has a general process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely vaccines and products for maternal and children's health conditions. To date, Pfizer has project-specific access provisions in place for two of its late-stage R&D projects. Of these, one is being conducted in partnership with the Drugs for Neglected Diseases initiative (DNDi).

Policy to ensure post-trial access; commits to registering trialed products. Pfizer has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Pfizer commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 13 SCORE 2.08

PRODUCTS: 109

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 14

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Pfizer does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. It also commits to implementing intra-country pricing strategies, albeit to only some of its products.

Almost a third of new products in scope filed for registration in the majority of priority countries. Pfizer has filed 30% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

13% of products have equitable pricing strategies targeting priority countries. Pfizer's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 13% of its products for diseases in scope. These strategies apply to an average of 14% of priority countries. Two strategies apply inter-country pricing to individual products for meningitis and lower respiratory infections, these take into account one and seven socioeconomic factors, respectively.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Pfizer has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 15 SCORE 1.33

Publicly discloses detailed information on patent statuses. Like most of its peers, Pfizer publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Makes ARV patent available for licensing on pro-access terms. Pfizer (as ViiV Healthcare) has made the patent it holds on maraviroc (Selzentry®) available for non-exclusive voluntary licensing.

Shares some IP assets with 3rd-party researchers. During the period of analysis, Pfizer newly shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with research institutions such as the Bill & Melinda Gates Foundation. The assets shared include molecule libraries. This new agreement is in addition to previously agreed IP sharing agreements with WIPO Re:Search Collaboration.

No public commitment not to enforce patents in countries in scope. Pfizer does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 5 SCORE 3.04

18 initiatives included for evaluation. Pfizer has 18 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Pfizer submitted 22.

Strong focus on strengthening health systems. Pfizer has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least one initiative in all areas which meet all good practice standards, except R&D capacity building. Pfizer performs strongest in health system strengthening with multiple initiatives focused on non-communicable diseases.

Seven initiatives meet all applicable good practice standards:
- REUNIFY
- Zipline partnership
- Project Smart Safety Surveillance
- Integrated Immunization and Family Planning Portfolio
- SMARThealth Extend

A full list of Pfizer's capacity building initiatives which meet all good practice standards can be found online.
Its remaining included initiatives typically miss only one or two of the good practice standards. For example, two of its pharmacovigilance initiatives fall short on measuring progress or outcomes.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Pfizer has a policy for reporting cases of substandard or falsified medicines to local regulatory authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 6 SCORE 3.62
STRUCTURED DONATION PROGRAMMES: 2

Responds to emergencies and humanitarian crises and tracks delivery. Pfizer donated medicines on the request of relief agencies. For example, during the period of analysis, it donated the antibiotic tigecycline (Tygacil®) upon request from Americares. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Direct Relief, Americares and MAP International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Pfizer's programmes are focused on neglected tropical diseases (NTDs), communicable and non-communicable diseases. All three programmes are carried out in partnership with partners such as WHO and Direct Relief. Its NTD programme for trachoma supplies azithromycin (Zithromax®) in 19 countries and has been ongoing since 1998. In 2016, Pfizer reports that 85.2 million benefited from the azithromycin (Zithromax®) donations.

Extends commitment to donate for trachoma. Pfizer does not explicitly commit to eliminating trachoma in countries in scope. However, it has recently extended its commitment to continue donating the treatment azithromycin (Zithromax®) until 2025.

BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
12▼	2.32
5 (2016)	

Merck & Co., Inc.

Stock Exchange: New York Stock Exchange • Ticker: MRK • HQ: Kenilworth, New Jersey, United States • Employees: 69,000

PERFORMANCE

Falls to 12th place from 5th. Merck & Co., Inc.* delivers a below average performance in access planning for R&D, and falls in multiple areas. Yet it has increased public transparency across all Technical Areas.

Management: Falls 6 places to 10th, with governance for access placed at the executive committee level.

Compliance: Falls 4 places to 11th as its internal control framework does not meet all the criteria looked for by the Index.

R&D: Falls 4 places to 15th as it reports a below-average application of access plans to its late-stage R&D projects.

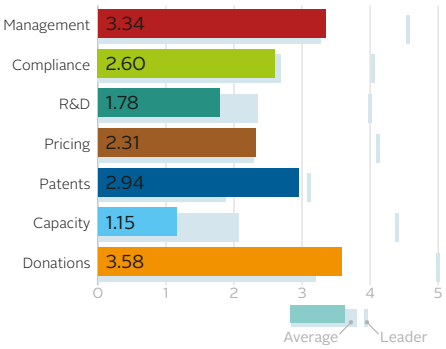
Pricing: Holds 9th place as it publicly shares detailed registration information for some products, and registers them in a range of priority countries.

Patents: Rises two places to 2nd through increased transparency of its patent statuses via Pat-INFORMED and the comparatively broad geographic scope of its licence for the paediatric formulation of raltegravir (Isentress®).

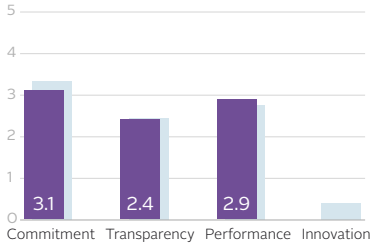
Capacity: Falls 10 places to 15th. Strong focus on health system strengthening, however, weak evidence of engagement in other areas of capacity building.

Donations: Falls 5 places to 7th. While it delivers a strong performance through its ivermectin (Mectizan®) programme, it publicly discloses comparatively less about the scale and impact of other programmes.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand equitable pricing for more products. The company can apply, for example, equitable pricing strategies to mometasone furoate (Asmanex®). This product is an on-patent first-line product on the 2017 WHO Model List of Essential Medicines (WHO EML) for the treatment of asthma. Data about the company's approach to this product has not been disclosed. The company could apply these strategies to the following priority countries where the burden of disease is high, e.g., Bangladesh, Brazil, China, Dem. Rep. Congo, Ethiopia, India, Myanmar, Nepal, Nigeria, Tanzania and Uganda.

Systematically plan for access throughout the R&D process. Merck & Co., Inc. can improve its commitment to R&D for diseases and countries in scope by considering the unique needs of low- and middle-income countries throughout development. By setting clear, time-bound targets for systematically considering and incorporating different access plans into each project at different points of development, Merck & Co., Inc. can ensure that its projects, which include novel antibiotics and therapies for maternal health, reach more patients. This includes providing post-trial access to clinical trial participants and registering all new products in every country where a clinical trial for these products has taken place, following market approval.

Further expand access via use of voluntary licensing. Merck & Co., Inc. can expand its use of voluntary licensing as a mechanism for boosting the affordability and supply of key medicines in countries in scope. This could include expanding licensing to adult formulations of raltegravir (Isentress®). It can also assess the need for elbasvir/grazoprevir (Zepatier®) in countries with a high prevalence of hepatitis C virus (HCV) genotype 1 or 4, with a view towards licensing.

Review sales incentive structures. Merck & Co., Inc. can decouple sales incentives from sales targets to better incentivise responsible sales practices. This is especially critical for a company that is a major producer of antibiotics. Removing an emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

CHANGE SINCE 2016

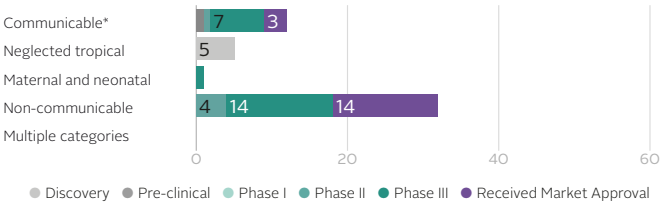
- WHO used Merck & Co., Inc.'s investigational Ebola vaccine in the 2018 outbreak in the Democratic Republic of Congo.
- Joined Access Accelerated with two initiatives including the Access and Affordability Initiative. It has also committed to measure impact and share results publicly via Access Observatory.
- Completed the transition of management for the Informed Push Model to the government of Senegal in late 2017.
- Launched a new partnership with the Global Financing Facility (GFF), the Bill & Melinda Gates Foundation, and The UPS Foundation to improve supply chains in low- and middle-income countries, drawing on the experience of the Informed Push Model.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Announced an expansion of its ivermectin (Mectizan®) donation programme in 2017, to reach up to an additional 100 million people annually through 2025 as part of the global effort to eliminate lymphatic filariasis.
- Working in collaboration with Ferring Pharmaceuticals and WHO through its Merck for Mothers Initiative to support the advancement of Ferring's proprietary and investigational heat-stable carbetocin for the prevention of postpartum haemorrhage. This collaboration aims to make heat-stable carbetocin available at an affordable and sustainable price in the public sector of low- and lower middle-income countries.

*All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. In 2018, Merck & Co., Inc. declined to submit data to the Access to Medicine Index.

PIPELINE *for diseases and countries in scope*

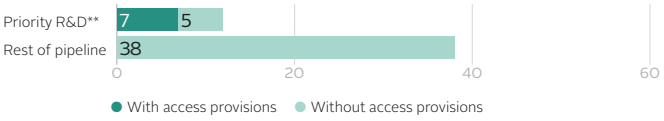
Mid-sized pipeline: 50 R&D projects for diseases in scope (47 medicines; 3 preventive vaccines).
Clinical candidates: 27, including a preventive vaccine for Ebola and three Phase III antibiotics for the treatment of lower respiratory infections.
Regulatory approvals: 17, including raltegravir (Isentress®) for the treatment of HIV/AIDS in infants weighing more than 2 kg.
R&D focus: non-communicable diseases (cancer and diabetes mellitus), communicable diseases (HIV/AIDS, lower respiratory infections) and neglected tropical diseases (Chagas disease).
Access provisions: for 7 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 50



Merck & Co., Inc.'s Phase III rVSV-ZEBOV vaccine was used by WHO to vaccinate those at greatest risk of contracting Ebola in the 2018 Ebola outbreak in the Democratic Republic of Congo.

Projects for R&D priority targets with access provisions: 7

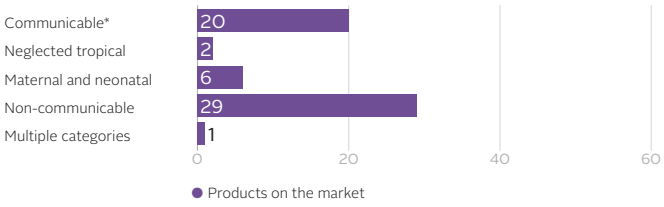


Of Merck & Co., Inc.'s 50 R&D projects, seven are supported by access provisions: e.g., its rVSV-ZEBOV Ebola vaccine will be made available at the lowest possible access price in Gavi-eligible countries. Two of its 44 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

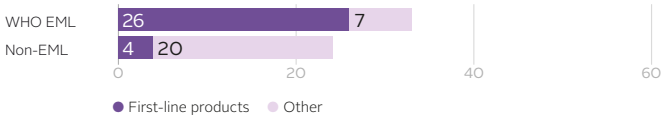
Mid-sized portfolio: 58 products for diseases in scope (41 medicines; 10 preventive vaccines; 6 contraceptive methods; 1 vector control product).
Portfolio focus: non-communicable diseases (hypertensive heart disease and diabetes mellitus), communicable diseases (HIV/AIDS and viral hepatitis C) and maternal & neonatal health conditions (contraceptive methods).
Essential medicines: 58% of Merck & Co., Inc.'s medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 53% of Merck & Co., Inc.'s medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 58



Merck & Co., Inc.'s portfolio includes products such as the HIV integrase inhibitor raltegravir (Isentress®), two preventive vaccines for lower respiratory infections and six contraceptive methods.

Essential medicines with first-line indications: 26



65% of Merck & Co., Inc.'s medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., the HPV vaccine Gardasil®9 and a contraceptive etonogestrel implant (Implanon®; Nexplanon®).

BUSINESS CONTEXT

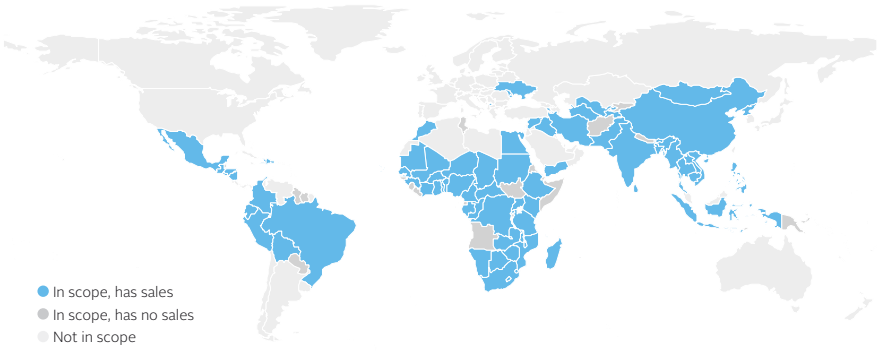
Two business units: Human Health and Animal Health. Human Health is divided into pharmaceuticals and vaccines. Its pharmaceuticals unit has four therapeutic areas (primary care and women's health; hospital and specialty; oncology; and diversified brands). Its vaccine portfolio focuses on traditional childhood vaccines and newer vaccines with few other suppliers, including for HPV and rotavirus.

M&A news: 2016 conclusion of joint vaccines venture with Sanofi in Europe to independently manage their product portfolios.
Presence in emerging markets: In 2016, Merck & Co., Inc. reported sales in 81 countries in scope. Data for 2018 not available. It reports that around 25% of its sales in 2017 came from the region of Europe, Middle East and Africa.

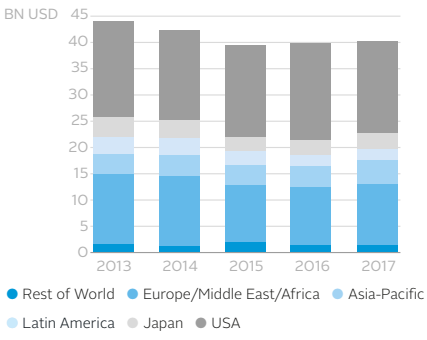
Sales by segment (2017) - USD

Pharmaceuticals	35,390 MN
Animal Health	3,875 MN
Other Revenues	857 MN
Total	40,122 MN

Sales in countries in scope



Sales by geographic region



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
**See Appendix IV for definition.

Merck & Co., Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 10 SCORE 3.34

Has a strong access-to-medicine strategy with executive-level responsibility. Merck & Co., Inc. is one of 14 companies that performs strongly with regards to its access-to-medicine strategy which includes access-related goals, and aligns with its corporate strategies. The strategy centres around R&D, manufacture and supply, registration, commercialisation and community investment. The highest level of responsibility for access sits with the executive committee, which reports to the board.

Financial and non-financial access-related incentives to reward employees. Merck & Co., Inc. performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include a human resources performance strategy to reward employees.

One of 16 companies working on impact measurement. Merck & Co., Inc. measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its activities based on its Institutional Business Africa principles, the company reports having vaccinated 120,000 girls in Rwanda for HPV. Furthermore, it is one of the companies that is measuring the impact for at least one access initiative, the Informed Push Model.

Discloses who it engages with, incorporates local perspectives into strategies. Merck & Co., Inc. publicly discloses which stakeholder groups it engages with on access issues, but it does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 11 SCORE 2.60

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Merck & Co., Inc. has a code of conduct relating to ethical marketing and anti-corruption. The company provides regular compliance training for employees via classroom courses and online classes. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Merck & Co., Inc.'s internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving both internal and external resources and applying to third parties, in all countries the company operates in. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Average transparency regarding access-related practices. Merck & Co., Inc. publicly discloses its policy positions on access-related topics (e.g., its position on intellectual property and counterfeit medicines). It does not disclose political contributions in countries in scope. The company discloses its membership of relevant institutions and whether it provides financial support. It publicly shares standards for engagement with stakeholder groups through its code of conduct. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 15 SCORE 1.78

PROJECTS: 50 IN CLINICAL DEVELOPMENT: 27

Publicly commits to R&D to meet public health needs. Merck & Co., Inc. has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale including internal assessments and calls for action from external sources like WHO. It does not report time-bound strategies for completing R&D projects for diseases in scope. Merck & Co., Inc. has a mid-sized pipeline in the Index with 50 projects. For diseases in scope where priorities exist, Merck & Co., Inc. is active in 18 projects; 12 of these target priority R&D gaps.

Access provisions in place for 5% (2/44) of late-stage candidates. Merck & Co., Inc. has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for neglected tropical diseases in least-developed countries. Information is publicly available on project-specific access provisions for two of Merck & Co., Inc.'s late-stage R&D projects. Both projects are being conducted in partnership.

Public policy to ensure post-trial access; no stated commitment to registering trialed products. Merck & Co., Inc. has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. However, the policy is not completely aligned with the standards set in the Declaration of Helsinki. Merck & Co., Inc. does not state a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 9 SCORE 2.31

PRODUCTS: 58

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 16

Does not publicly commit to intra-country pricing or report a commitment to file to register new products in scope. Merck & Co., Inc. does not commit to filing its newest products for registration in countries in scope within one year of first market approval. It publicly commits to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope. This does not explicitly apply to future products. However, it does not commit to implementing intra-country pricing strategies.

Almost a third of new products in scope filed for registration in the majority of priority countries. Merck & Co., Inc. has filed 30% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). It also publicly shares detailed registration information for some of its products.

28% of products have equitable pricing strategies targeting priority countries. Merck & Co., Inc.'s overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 28% of its products for diseases in scope. These strategies apply to an average of 46% of priority countries. Half of its equitable pricing

strategies apply both inter- and intra-country pricing; these take an average of three socioeconomic factors into account.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Merck & Co., Inc. has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 2 SCORE 2.94

Publicly discloses detailed information on patent statuses. Like most of its peers, Merck & Co., Inc. publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Uses licensing to enable generic supply. Merck & Co., Inc. has a non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence, for its paediatric formulation of raltegravir (Isentress®), encompasses 89 countries including 58 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Comparatively few IP assets shared with 3rd-party researchers. During the period of analysis, Merck & Co., Inc. newly shared one IP asset with third- party researchers developing products for diseases in scope. The assets shared include performing assays for drug discovery with George Washington University located in the USA. This new agreement is in addition to previously agreed IP sharing agreements with, for example, the University of California, San Diego, Walter and Eliza Hall Institute of Medical Research, DNDi and the Macrofilaricide Drug Accelerator Program.

Public commitment not to enforce patents in countries in scope. Merck & Co., Inc. commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries.

CAPACITY BUILDING

RANK 15 SCORE 1.15

Five initiatives included for evaluation. Merck & Co., Inc. has five capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment. Merck & Co., Inc.'s initiatives were identified for selection based on publicly available information.

Focused on strengthening health systems. Merck & Co., Inc. has initiatives included for analysis by the Index in two areas of capacity building: supply chain and health system strengthening. Most of these initiatives are focused on health system strengthening, with multiple initiatives targeting maternal health. It does not publicly disclose initiatives which meet inclusion criteria for any of the other areas of capacity building.

Two initiatives meet all applicable good practice standards:
- Informed Push Model (IPM-3PL)
- Merck/MSD for Mothers

Merck & Co., Inc.'s remaining included initiatives most commonly fall short on having good governance structures in place. The company reported no information to the Index about its health system strengthening initiatives, and publicly available information is limited.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Merck & Co., Inc. has a policy for the prevention and handling of counterfeit medicines. It reports to the Index that they report cases of substandard and falsified medicines within the legitimate supply chain to relevant health authorities, however it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 7 SCORE 3.58

STRUCTURED DONATION PROGRAMMES: 2

Responds to emergencies and humanitarian crises and tracks delivery. Merck & Co., Inc. donated medicines on the request of relief agencies. For example, during the period of analysis, it donated various products in Haiti. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with Direct Relief, Americares and MAP International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Merck & Co., Inc.'s programmes are focused on neglected tropical diseases (NTDs), namely lymphatic filariasis, onchocerciasis and rabies. All three programmes are carried out in collaboration with partners such as WHO and Afya. Its NTD programme for lymphatic filariasis supplies ivermectin (Mectizan®) in 27 countries and has been ongoing since 1987. In 2016, Merck & Co., Inc. reports that 141 million treatments were approved for lymphatic filariasis.

Addresses long-term access by aiming to eliminate disease. Merck & Co., Inc. commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For its ivermectin (Mectizan®) programme, the company is committed to continuing to donate as much ivermectin (Mectizan®) as is necessary to eliminate river blindness globally, and to eliminate lymphatic filariasis in African countries and in Yemen.

BEST PRACTICES

Continued commitment to combat NTDs.
GLOBAL
One of five companies running donation programmes to eliminate or eradicate NTDs.

Informed Push Model strengthens supply chain for contraceptives.
SENEGAL
Model removes the burden of tracking and ordering inventory from pharmacies by using logistics operators to regularly deliver and track supplies to ensure sufficient stock.

Merck for Mothers invests $500 million to improve maternal health
GLOBAL
A $500 million, 10-year initiative, to design scalable solutions to help end preventable maternal deaths.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
13▼	2.29
8 (2016)	

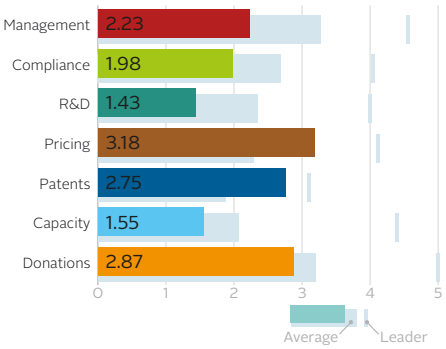
Gilead Sciences Inc.

Stock Exchange: NASDAQ • Ticker: GILD • HQ: Foster City, California, United States • Employees: 10,193

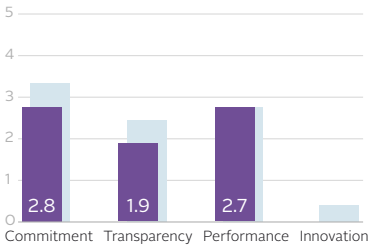
PERFORMANCE

Falls 5 places to 13th due to a comparatively poor performance in governance and compliance. It maintains a strong performance in some areas, for example, in its licensing strategy and its application of equitable pricing strategies across a high proportion of its products.
Management: Falls 6 places to 18th. It does not have direct board responsibility for its access approach, and does not commit to measuring the impact of its access initiatives.
Compliance: Falls 15 places to 16th. Comparatively poor performance, with below-average transparency and lacking components of an internal control system looked for by the Index.
R&D: Falls 2 places to 18th. Gilead performs on average in access planning, lags in R&D investment transparency and performance, and lacks a public policy for post-trial access.
Pricing: Rises 5 places to 2nd. Strong registration commitment and transparency, with a leading performance in the application of equitable pricing strategies.
Patents: Falls 2 places to 3rd. Leading performance in its licensing approach compared to peers, but falls in patent filing/enforcement policy.
Capacity: Rises 5 places to 13th. Improves performance against new metrics, with initiatives in three areas of Capacity Building.
Donations: Rises 2 places to 11th. Maintains three donation programmes focused on NTDs, but fails to provide evidence of its sustainability.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand access plans across pipeline. Gilead has an opportunity to develop a pipeline-wide approach to planning for access. For example, Gilead's access planning process currently focuses on HIV/AIDS and hepatitis B and C. The company can also expand such planning to R&D projects for projects targeting communicable diseases, including presatovir for the treatment of RSV, and non-communicable diseases, including three late-stage oral anti-cancer agents.

Strengthen transparency, policies and procedures to ensure compliance. Gilead falls behind peers due to overall lack of transparency across the Market Influence and Compliance Technical Area. Gilead can publicly disclose which stakeholder groups (e.g., patient groups in countries in scope) the company participates in and whether it provides financial support to such groups. The company can also publicly disclose whether political contributions have been made in low- and middle-income countries. The company can improve its internal control framework to ensure compliance through the implementation of a fraud-specific risk assessment, and procedures to segregate duties. It can also help improve responsible sales practices by decoupling sales incentives from sales targets.

Expand access further by maximising effectiveness of licensing approach. Gilead consistently applies inter- and intra-country equitable pricing strategies and licensing approaches across its portfolio. Gilead can maximise the effectiveness of its licensing-based approach by reviewing generic company activity in countries within the scope of agreed licences where Gilead does not have sales. In cases where generic company activity is absent/limited, Gilead can consider proactively registering and pricing equitably within these countries to facilitate competition and access, or by identifying mechanisms within licences to incentivise generic market entry. Gilead commits to filing its newest products in scope for registration in countries in scope within 12 months of first market approval.

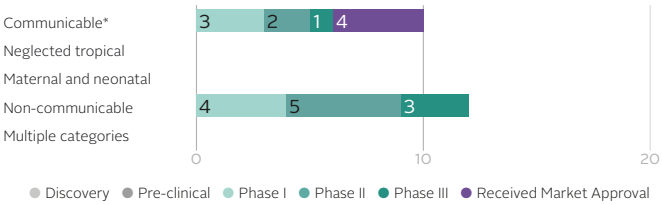
CHANGE SINCE 2016

- Developed a comprehensive process to develop access plans for all R&D projects targeting HIV/AIDS, viral hepatitis B and C and leishmaniasis during development.
- Launched the Gilead Public Health Award: Viral Hepatitis Program in 2017 to provide research grants to researchers in low- and middle-income countries focused on viral hepatitis care and treatment.
- Joined the MenStar Coalition that was launched in 2018 and aims to improve diagnosis and treatment of HIV in men, particularly in sub-Saharan Africa.
- Expanded its HIV licences signed with the MPP to include three additional countries with the inclusion of Malaysia and Ukraine as middle-income countries within the scope of the Index.
- Received FDA approval for the first pangenotypic hepatitis C treatment, sofosbuvir/velpatasvir (Epclusa®) in June 2016, followed by FDA approval for the second, sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) in July 2017.

PIPELINE *for diseases and countries in scope*

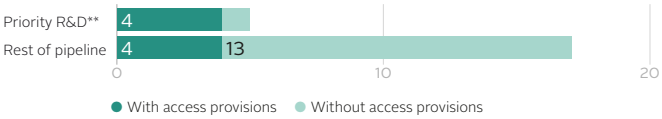
Comparatively small pipeline: 22 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 18, including remdesivir for the treatment of Ebola and emtricitabine and tenofovir alafenamide (Descovy®) for HIV pre-exposure prophylaxis.
Regulatory approvals: 4, including sofosbuvir/velpatasvir (Epclusa®) for the treatment of hepatitis C virus (pan-genotypic).
R&D focus: non-communicable diseases (cancer) and communicable diseases (HIV/AIDS and viral hepatitis B and C)
Access provisions: for 8 projects, all with registration and equitable pricing strategies and plans for non-exclusive voluntary licensing and WHO prequalification.

Projects in the pipeline: 22



Gilead's Phase I clinical candidate remdesivir was one of a select few experimental treatments recommended by a WHO expert review panel for use in the 2018 Ebola outbreak in the Democratic Republic of Congo.

Projects for R&D priority targets with access provisions: 4

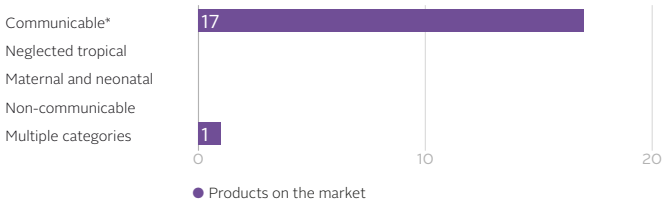


Of Gilead's 22 R&D projects, eight are supported by access provisions: e.g., emtricitabine/tenofovir alafenamide (Descovy®) for HIV pre-exposure prophylaxis includes registration and equitable pricing strategies, among others. Five of its 15 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

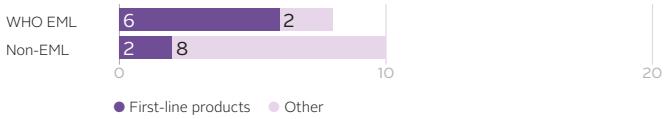
Comparatively small portfolio: 18 products (all medicines) for diseases in scope.
Portfolio focus: communicable diseases (HIV/AIDS and viral hepatitis B and C).
Essential medicines: 44% of Gilead's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 44% of Gilead's medicines have first-line indications for diseases in scope.

Products on the market: 18



Gilead's portfolio includes products such as bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy®) and the pharmacokinetic booster cobicistat (Tybost®), both used in the treatment of HIV/AIDS.

Essential medicines with first-line indications: 6



56% of Gilead's medicines are listed on the WHO EML and/or as first-line treatments: e.g., liposomal amphotericin B (AmBisome®) and tenofovir alafenamide (Vemlidy®).

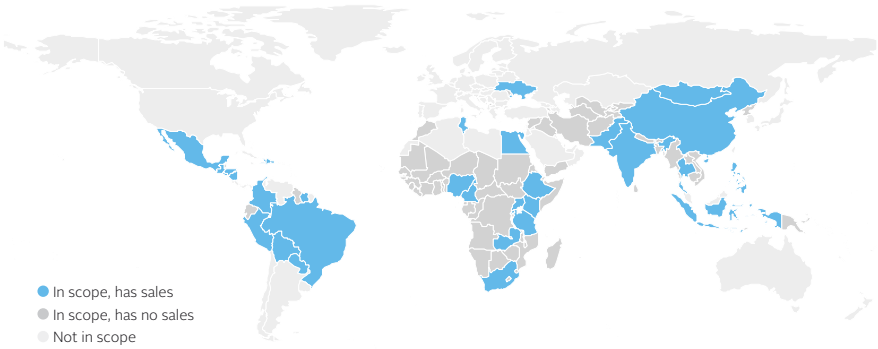
BUSINESS CONTEXT

One business unit: Human Therapeutics, which has five therapeutic areas (HIV/AIDS, liver diseases, haematology and oncology, inflammatory and respiratory diseases and cardiovascular diseases).
M&A news: 2017 acquisition of Kite Therapeutics, specialising in cancer immunotherapy products; acquisition of Cell Design Labs, Inc., specialising in cell-based therapies for cancer and other diseases.
Presence in emerging markets: In 2018, Gilead reports sales in 32 countries in scope.

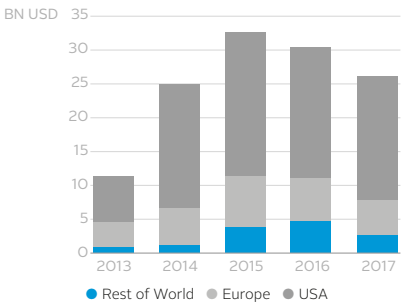
Revenue by segment (2017) - USD

Medicines (Product)	26,107 MN
Total	26,107 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
** See Appendix IV for definition.

Gilead Sciences Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 18 SCORE 2.23

Has an access-to-medicine strategy with executive-level responsibility. Gilead has an access-to-medicine strategy with a business rationale. The strategy focuses on pricing and licensing approaches to improve access to the company's HIV and viral hepatitis products, in countries where the burden is comparably high. The highest level of responsibility for access sits with an executive committee member.

Financial access-related incentives in place for employees. Gilead has financial incentives in place to motivate employees to perform on access-related issues. These incentives include bonuses relating to performance rates.

Measures and monitors outcomes and progress; not impact. Gilead measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives and targets. For example, for the PEPFAR-led DREAMS initiative, the company reports reaching millions of people living with HIV/AIDS in developing countries with its medicines. However, it does not report measuring the impact of its initiatives.

Limited transparency about stakeholder engagement. Gilead performs relatively poorly when it comes to the disclosure of its stakeholder engagement. It discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. Gilead has, however, internal guidelines for incorporating the views of local stakeholders.

MARKET INFLUENCE & COMPLIANCE

RANK 16 SCORE 1.98

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Gilead has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. The company does not disclose evidence of specific incentives targeted at sales agents to motivate ethical sales practice.

Internal control framework meets some Index criteria. Gilead's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving both internal and external resources, that also applies to third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Below average transparency regarding access-related practices. Gilead publicly discloses its policy positions on access-related topics. For example, it published its position on fair drug pricing, patient access to treatment and intellectual property. It does not have a policy prohibiting political contributions in countries in scope, but reports that no such contributions occurred during the period of analysis. It discloses its membership of relevant organisations but not whether it provides financial support. Further, it does not disclose its policies for responsible engagement, nor does it publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 18 SCORE 1.43

PROJECTS: 22 IN CLINICAL DEVELOPMENT: 18

Commits to R&D to meet public health needs. Gilead has made a specific commitment to R&D for diseases and countries in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on disease burden in low- and middle-income countries. It lacks time-bound strategies for completing R&D projects for diseases in scope. Gilead has one of the smallest pipelines in the Index with 22 projects. For diseases in scope where priorities exist, Gilead is active in eight projects; five of these target priority R&D gaps.

Access provisions in place for 33% (5/15) of late-stage candidates. Gilead has a general process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for HIV/AIDS and viral hepatitis B and C. Mainly, Gilead develops access plans for R&D projects in Phase III of clinical development that have clear timelines and processes in place. To date, Gilead has project-specific access provisions in place for five of its late-stage R&D projects. All five are being conducted in-house.

No policy for post-trial access. Gilead does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 2 SCORE 3.18

PRODUCTS: 18

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 17

Commits publicly to equitable pricing and reports a commitment to file to register new products in scope. Gilead commits to filing its newest products for registration in countries in scope within one year of first market approval, where possible. It also publicly commits to implementing inter-country equitable pricing strategies for the majority of its products for diseases in scope. However, this does not explicitly apply to future products. Its public commitments also apply to intra-country equitable pricing strategies.

Some new products in scope filed for registration in the majority of priority countries. Although Gilead commits to filing its newest products for registration in countries in scope within one year of first market approval, it has filed 10% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it publicly shares detailed registration information for almost all of its products.

94% of products have equitable pricing strategies targeting priority countries. Gilead's overall performance is strong compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 94% of its products for diseases in scope. These strategies apply to all priority countries. All of the strategies apply to both inter- and intra-country pricing strategies; these take into account an average of four socioeconomic factors. Gilead also applies equitable pricing strategies to 17 additional products informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Gilead has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 3 SCORE 2.75

Publicly discloses some information on patent statuses. Gilead discloses the patent status of its products for HIV/AIDS and hepatitis C through its voluntary licensing agreements.

Uses licensing to enable generic supply. Gilead leads in this area. The company has non-exclusive voluntary licensing agreements in place for ten compounds (for diseases in scope). Its broadest licence, for bictegravir, encompasses 91 countries including 61 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Shares some IP assets with 3rd-party researchers. Compared to its peers, Gilead shares some IP assets with third-party researchers developing products for diseases in scope. This includes five shared with research institutions, such as the Bill & Melinda Gates Foundation. The assets shared include molecule libraries, data and performing assays for drug discovery.

No public commitment not to enforce patents in countries in scope. Gilead does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 13 SCORE 1.55

Eight initiatives included for evaluation. Gilead has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Gilead submitted 14.

Focused on strengthening health systems. Gilead has initiatives which meet inclusion criteria in three areas of capacity building: manufacturing, R&D, and health system strengthening. Most of these initiatives are focused on health system strengthening with a disease focus on HIV/AIDS and viral hepatitis (B and C).

Two initiatives meet all applicable good practice standards:
-Gilead Technology Transfers
-Test-and-Treat Demonstration Project
Gilead's remaining included initiatives have goals in place, but fall short on monitoring their progress and outcomes.

Does not provide evidence of reporting substandard or falsified medicines to relevant authorities. Gilead has a policy for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

PRODUCT DONATIONS

RANK 11 SCORE 2.87
STRUCTURED DONATION PROGRAMMES: 3

Responds to emergencies and humanitarian crises. Gilead donated medicines on the request of relief agencies. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it has systems in place to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Gilead programmes are focused on neglected tropical diseases (NTDs) and communicable diseases. All three programmes are carried out in partnership with partners such as WHO, AHF-Uganda Cares and Jhpiego. Its NTD programme for visceral leishmaniasis supplies amphotericin B (AmBisome®) in six endemic countries and has been ongoing since 1992. Since 2011, Gilead reports donating more than 800,000 total vials of amphotericin b (AmBisome®).

No transition plans in place. Gilead does not provide evidence that it considers long-term access to donated products, once a programme ends through, for example transition planning.

BEST PRACTICES

Widest use of non-exclusive voluntary licensing
GLOBAL
Gilead licenses its entire on-patent portfolio of products for diseases in scope to speed the entry of generics into market.

Full transparency on where products are registered
GLOBAL
Only company to publish full details of the registration status of its products. A full list is available on company website.

RANK	SCORE
14▲	2.11
16 (2016)	

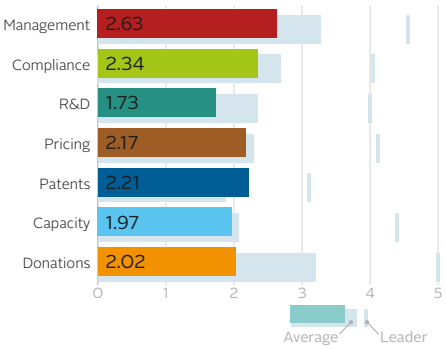
Boehringer Ingelheim GmbH

Stock Exchange: n.a. • Ticker: n.a. • HQ: Ingelheim am Rhein, Germany • Employees: 49,610

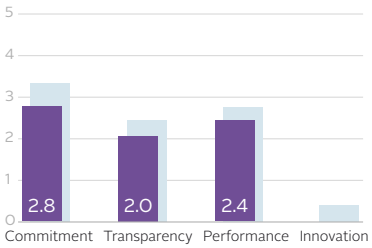
PERFORMANCE

Rises 2 places to 14th. Boehringer Ingelheim launched a new access-to-medicine strategy that is directly overseen by the Board. It improves in Pricing and Capacity Building, but is comparatively weaker in R&D, Market Influence & Compliance and Product Donations.
Management: Falls 3 places to 17th. Launched a new access strategy, but fails to incentivise staff to achieve access objectives.
Compliance: Rises 4 places to 14th. Discloses policies for responsible engagement, but fails to publicly disclose financial support to relevant institutions.
R&D: Falls 3 places to 16th. Its R&D strategy lacks a public health rationale for diseases in scope, but improves its access plans during R&D.
Pricing: Rises 6 places to 12th. Significant improvement, with 84% of its portfolio covered by equitable pricing strategies, targeting priority countries.
Patents: Falls 2 places to 9th. Despite a broad geographic scope for its non-assert declaration, the company lags behind peers in patent transparency.
Capacity: Rises 5 places to 12th. Notable improvement in capacity building, with a focus on pharmacovigilance and health system strengthening.
Donations: Rises 2 places to 15th. Donates products in response to natural disasters, but has no long-term structured donation programmes.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Expand process to establish more access plans for all R&D projects. Boehringer Ingelheim can expand its process to develop access plans during R&D to all in-house and collaborative R&D projects for all diseases in scope. It can follow a structured timeline to ensure that these plans are in place as soon as possible. Boehringer Ingelheim has an opportunity to ensure that access plans for both its marketed and investigational biosimilars in scope are established. Biosimilars have the potential to support affordability if access plans are developed. This applies to products such as Boehringer Ingelheim's insulin glargine biosimilar (Basaglar®) developed in collaboration with Eli Lilly, and its Phase III clinical biosimilar candidate, bevacizumab.

Apply lessons from well-structured initiatives. Boehringer Ingelheims's Angel's Initiative works to optimise the availability and quality of treatment for stroke patients. The initiative meets all of the good practice standards looked for by the Index, including good governance structures, processes to mitigate conflicts of interest, and monitoring and evaluation procedures. One of Boehringer Ingelheim's pillars of its new strategy for access is focused on solutions for adherence and awareness. When developing country-level initiatives under this pillar, the company can ensure that all initiatives meet the same standards as this one.

Implement strategies to minimise the risk of non-compliance. Boehringer Ingelheim can establish formal processes to ensure third-party compliance with standards of anti-corruption and ethical marketing. Alongside this, Boehringer Ingelheim can decouple its sales incentives from sales targets to incentivise responsible sales practices.

Establish a clear and public post-trial access policy. Boehringer Ingelheim can develop a clear stance on post-trial access that is aligned with the Declaration of Helsinki, detailing the conditions through which a clinical trial participant will be eligible for post-trial access. In addition, it can commit to registering all new products in the countries where clinical trials for these products have taken place.

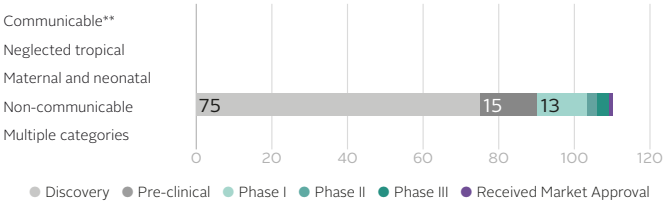
CHANGE SINCE 2016

- Strengthened its commitment to access with responsibility at the board-level, and the establishment of the position of Head of Access to Healthcare and Global Health Policy.
- Reviewed and updated its access to medicine strategy with clear objectives focused on three strategic pillars: availability, sustainable access models, and innovative solutions for awareness and adherence.
- Expanded its patent filing and enforcement policy to abstain from enforcing patents in most low-income and low human development countries, and many middle-income countries across the company's entire human pharmaceuticals portfolio.
- In 2018, launched the 'In Reach Africa' programme, which aims to improve human and animal healthcare access in 10 African countries.
- Implemented a new Global Code of Conduct for ethical marketing and compliance in 2018, aligned with the IFPMA Code of Practice and the UN Global Compact principles.

PIPELINE *for diseases and countries in scope*

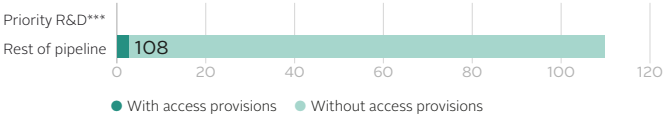
Comparatively large pipeline: 111 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 20, including a bevacizumab biosimilar candidate for the treatment of lung cancer.
Regulatory approvals: 1, afatinib (Gilotrif®) as an expanded indication for the treatment of metastatic non-small cell lung cancer.
R&D focus: non-communicable diseases (cancer, diabetes mellitus, kidney diseases and asthma).
Access provisions: for 3 projects, all including equitable pricing, registration and supply strategies.

Projects in the pipeline: 111*



Boehringer Ingelheim's pipeline includes a Phase III biosimilar for bevacizumab for the treatment of lung cancer. The original bevaziumab (Avastin®) has been approved for several cancer types including breast and colorectal.

Projects for R&D priority targets with access provisions: 0

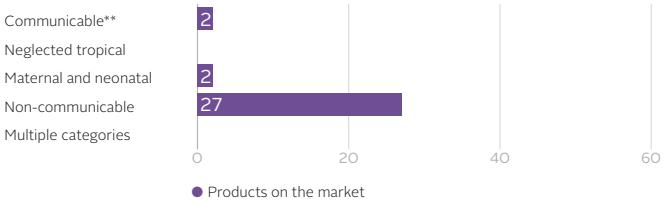


Of Boehringer Ingelheim's 111 R&D projects, three are supported by access provisions: e.g., nintedanib for colorectal cancer will have equitable pricing, registration and supply strategies. Two of its seven late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

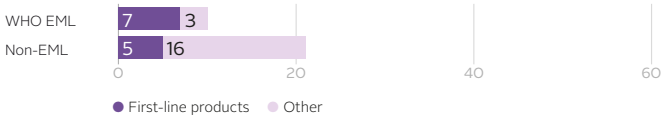
Comparatively small portfolio: 31 products for diseases in scope (30 medicines; 1 contraceptive method).
Portfolio focus: non-communicable diseases (diabetes mellitus, chronic obstructive pulmonary disease and asthma).
Essential medicines: 32% of Boehringer Ingelheim's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 39% of Boehringer Ingelheim's medicines have first-line indications for diseases in scope.

Products on the market: 31



Boehringer Ingelheim's portfolio includes products such as fenoterol hydrobromide (Partusisten®) for preterm labour/birth and several medicines for diabetes mellitus.

Essential medicines with first-line indications: 7



48% of Boehringer Ingelheim's medicines are listed on the WHO EML and/or as first-line treatments: e.g., the sulfonylurea gliquidone (Glurenorm®) and the insulin glargine biosimilar Basaglar®, respectively, for diabetes mellitus.

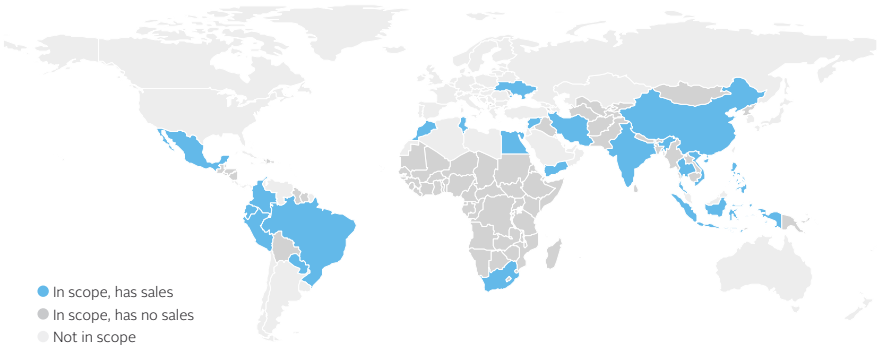
BUSINESS CONTEXT

Three business units: Prescription Medicine; Animal Health; and Biopharmaceuticals. Its prescription medicine segment has six therapeutic areas (respiratory disorders; cardiovascular diseases; metabolic diseases; central nervous system diseases; oncology; and immunology).
M&A news: 2017 divestment of consumer healthcare business to Sanofi, in exchange for Merial, Sanofi's animal health business.
Presence in emerging markets: In 2018, Boehringer Ingelheim reports sales in 20 countries in scope; three less than in the 2016 Index. It reports that almost 25% of its sales in 2017 came from the Asia, Australia and Africa region.

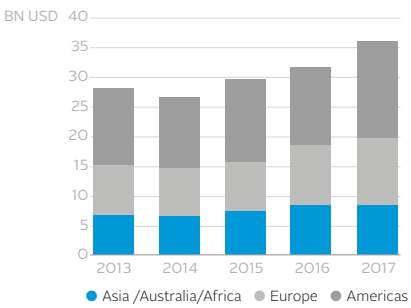
Net sales by segment (2017) - EUR

Human Pharmaceuticals	12,621 MN
Animal Health	3,901 MN
Biopharmaceuticals	678 MN
Other Sales	43 MN
Discontinued Operations	813 MN
Total	18,056 MN

Sales in countries in scope



Net sales by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes one project that does not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

** Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.

*** See Appendix IV for definition.

Boehringer Ingelheim GmbH

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 17 SCORE 2.63

Has a strong access-to-medicine strategy with board-level responsibility. Boehringer Ingelheim is one of 14 companies that performs strongly with regards to its newly launched access-to-medicine strategy, which is aligned with its corporate strategies. The strategy has a focus on availability, sustainable access models, awareness and adherence. The highest level of responsibility for access sits with a board-level committee.

No evidence of access-related incentives for employees. Boehringer Ingelheim does not disclose details of how it incentivises employees (financially and non-financially) to perform on access-related issues. It is one of only two companies that do not demonstrate evidence of such incentives.

Measures and monitors outcomes and progress; not impact. Boehringer Ingelheim measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on objectives and targets. For example, for its Angels Initiative on patient care, Boehringer Ingelheim reports having trained 33,936 healthcare workers across various countries in the last two years. However, it does not report measuring the impact of its initiatives.

Discloses who it engages with, incorporates local perspectives into strategies. Boehringer Ingelheim publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 14 SCORE 2.34

Does not report processes for ensuring third-party compliance with standards. Boehringer Ingelheim has a code of conduct relating to ethical marketing and anti-corruption, namely its Anti-Bribery and Anti-Corruption Policy. It provides compliance training for employees on an annual basis. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Boehringer Ingelheim's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an internal auditing department for the whole company, involving both internal and external resources—that also applies to third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of having a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Below average transparency regarding access-related practices. Boehringer Ingelheim publicly discloses its policy positions on access-related topics (e.g., its corporate policy on supply chain integrity). It does not disclose political contributions in countries in scope. Boehringer Ingelheim discloses its membership of relevant institutions but not whether it provides financial support. The company discloses its policies for responsible engagement through its code of conduct. It does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 16 SCORE 1.73

PROJECTS: 111 IN CLINICAL DEVELOPMENT: 20

R&D commitment has limited public health rationale. Boehringer Ingelheim has made a specific commitment to R&D for diseases in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries lacks an evidence-based public health rationale including internal assessments and calls for action from external sources like WHO. It lacks time-bound strategies for completing R&D projects for diseases in scope and evaluating progress toward these targets. Boehringer Ingelheim has one of the largest pipelines in the Index with 111 projects. Boehringer Ingelheim is active in R&D for non-communicable diseases, for which a globally accepted priority list does not exist.

Access provisions in place for 29% (2/7) of late-stage candidates. Boehringer Ingelheim has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for non-communicable diseases where it is actively involved in low- and middle-income countries. In general, Boehringer Ingelheim develops access plans for R&D projects in Phase III of clinical development. To date, Boehringer Ingelheim has project-specific access provisions in place for two of its late-stage R&D projects, both of which are being conducted in-house.

No policy for post-trial access. Boehringer Ingelheim does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 12 SCORE 2.17

PRODUCTS: 31

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 26

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Boehringer Ingelheim does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

No new products in scope filed for registration in the majority of priority countries. Boehringer Ingelheim has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for diabetes mellitus, is registered in five out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

84% of products have equitable pricing strategies targeting priority countries. Boehringer Ingelheim's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 84% of its products for diseases in scope. These strategies apply to an average of 41% of priority countries. All of these strategies apply inter-country pricing strategies; these take into account an average of two socioeconomic factors. Boehringer Ingelheim also applies an

equitable pricing strategy to one further product informed by a public health rationale.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Boehringer Ingelheim has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 9 SCORE 2.21

Does not publicly disclose patent statuses. Unlike most of its peers, Boehringer Ingelheim does not disclose the status of its products for diseases and countries in scope.

Uses non-assert declarations to enable generic supply. Boehringer Ingelheim has a non-assert declaration in place for one compound (for diseases in scope). Its non-assert declaration, for nevirapine (Viramune XR®), encompasses 135 low- and middle-income countries in scope. It has not issued any non-exclusive voluntary licensing agreements for products in scope.

Does not share IP assets with 3rd-party researchers. Boehringer Ingelheim reports no instances where it shares IP assets with third-party researchers developing products for diseases in scope, during the period of analysis.

Public commitment not to enforce patents in countries in scope. Boehringer Ingelheim commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies to most low-income, low-development countries, and in a subset of lower-middle income countries and upper-middle income countries.

CAPACITY BUILDING

RANK 12 SCORE 1.97

Eight initiatives included for evaluation. Boehringer Ingelheim has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Boehringer Ingelheim submitted 24.

Focused on supporting pharmacovigilance systems. Boehringer Ingelheim has initiatives which meet inclusion criteria in all areas of capacity building, except R&D. Most of these initiatives are focused on pharmacovigilance capacity building and health system strengthening. Two of these health system strengthening initiatives are focused on stroke.

One initiative meets all applicable good practice standards:
-Angels Initiative
Boehringer Ingelheim's remaining included initiatives typically have goals in place, but fall short on monitoring progress and outcomes and ensuring good governance structures are in place.

Timely approach to reporting substandard or falsified medicines to relevant authorities. Boehringer Ingelheim provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to local regulatory authorities within the period recommended by stakeholders (maximum seven days).

PRODUCT DONATIONS

RANK 15 SCORE 2.02
STRUCTURED DONATION PROGRAMMES: 0

Responds to emergencies and humanitarian crises and tracks delivery. Boehringer Ingelheim donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to hurricanes in Haiti and the Dominican Republic. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americares, MAP International and Direct Relief to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

No donation programmes covering diseases and countries in scope. Boehringer Ingelheim does not have any structured donations programmes that were active during the period of analysis in any countries in scope.

BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.

RANK	SCORE
15▼	2.03
13 (2016)	

Bristol-Myers Squibb Co.

Stock Exchange: New York Stock Exchange • Ticker: BMY • HQ: New York City, New York, United States • Employees: 23,700

PERFORMANCE

Falls from 13th place in 2016, to 15th. It continues to show strong performance in its approach to the pro-access management of IP, but its processes for access planning in R&D are weak. Its equitable pricing approach is average.

Management: Rises 2 places to 13th. The company does not assign responsibility for access at the board level (only executive level), but improves with commitments to measure impact.

Compliance: Rises 9 places to 7th. Prohibits political financial contributions outside of the US, and discloses financial support to patients' organisations.

R&D: Rises 3 places to 17th. Remains in last quartile. No clear process for access planning during development, and none of its late-stage projects have plans for access.

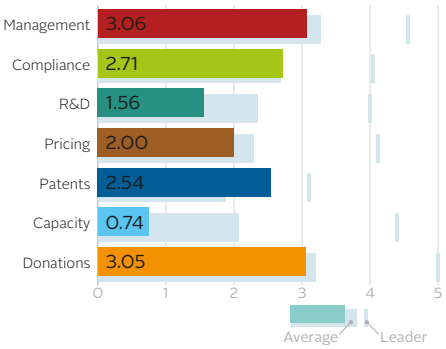
Pricing: Falls 4 places to 16th. Fails to commit clearly to the rapid registration of products, with an average performance in equitable pricing.

Patents: Falls 1 place to 4th. A continued strong approach to licensing maintains its performance, and newly discloses patent statuses via Pat-INFORMED.

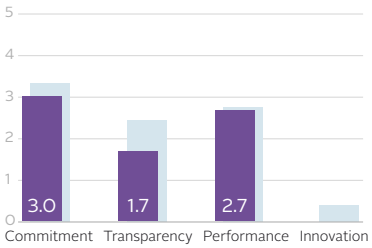
Capacity: Falls 2 places to 18th. A focus on health systems strengthening, however, no included initiatives meet all good practice standards.

Donations: Rises 4 places to 10th. Newly included donation programme focused on chronic myeloid leukaemia, in partnership with the Max Foundation.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Develop a process to establish more access plans for R&D. Bristol-Myers Squibb can develop a clear approach to establishing access plans for R&D projects during development that takes into account the specific considerations necessary for each project, especially for its late-stage projects. Currently, none of its projects have access provisions in place.

Expand use of equitable pricing. Dasatinib (Sprycel®) for the treatment of leukaemia is an on-patent first-line product on the WHO EML that has no equitable pricing strategies in place. Applying equitable pricing strategies to this product, to countries where disease burden is high, would help increase affordability for those most in need: for example, Brazil, Indonesia, Pakistan, Afghanistan, Bangladesh and Nigeria.

Review incentives for sales agents. Bristol-Myers Squibb can improve its commitment to ensure responsible sales practices by decoupling sales incentives from sales targets. Removing the emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

Expand access by engaging in voluntary licensing. Bristol-Myers Squibb can expand access for more products against high-burden diseases (outside of HIV/AIDS) by utilising voluntary licensing to increase generic supply. Possible products could include dasatinib (Sprycel®), listed on the 2017 WHO Model List of Essential Medicines (WHO EML) for imatinib-resistant chronic myeloid leukaemia, as well as apixaban (Eliquis®) for ischaemic heart disease and management of stroke and other blood clots.

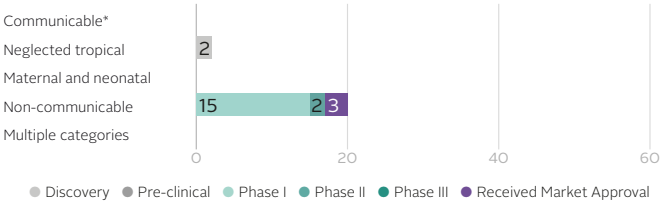
CHANGE SINCE 2016

- Joined Access Accelerated with multiple initiatives such as its Secure the Future programmes focused on NCDs. It has also committed to measure impact and share results publicly via Access Observatory.
- Takes affordability and some socioeconomic factors into account for all intra-country equitable pricing strategies.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Expanded its non-exclusive voluntary licence for Atazanavir (Reyataz®) indicated for HIV to include 12 new countries, eight of which are middle-income countries within the scope of the Index.
- Moved a substantial portion of its R&D projects along the pipeline.
- Committed to $50 million over five years to support the Global HOPE initiative, which aims to train approximately 4,800 healthcare workers to provide quality paediatric cancer care.

PIPELINE *for diseases and countries in scope*

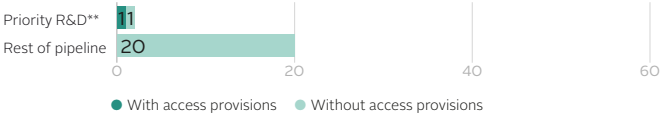
Comparatively small pipeline: 25 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 18, including a factor XIa inhibitor for ischaemic heart disease and lirilumab for the treatment of multiple cancer types.
Regulatory approvals: 5, for additional indications for nivolumab (Opdivo®) in the treatment of five different cancers in scope.
R&D focus: non-communicable diseases (cancer).
Access provisions: for 1 project, with provisions incorporated in partnership with the Drugs for Neglected Diseases initiative (DNDi).

Projects in the pipeline: 22



Bristol-Myers Squibb has the highest portion of projects progressing through the clinical pipeline. This pipeline is almost entirely comprised of projects targeting cancer with two projects for neglected tropical diseases.

Projects for R&D priority targets with access provisions: 1

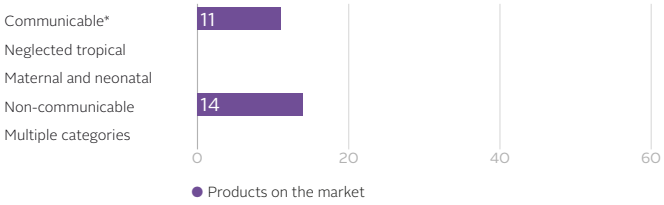


Of Bristol-Myers Squibb's 25 R&D projects, one is supported by access provisions: a screening partnership with DNDi for Chagas disease, leishmaniasis and human African trypanosomiasis. None of its eight late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

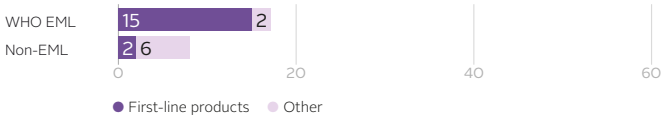
Comparatively small portfolio: 25 products (all medicines) for diseases in scope.
Portfolio focus: non-communicable diseases (cancer and ischaemic heart disease) and communicable diseases (HIV/AIDS).
Essential medicines: 68% of Bristol-Myers Squibb's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 68% of Bristol-Myers Squibb's medicines have first-line indications for diseases in scope.

Products on the market: 25



Bristol-Myers Squibb's portfolio includes products such as nivolumab (Opdivo®), which has been approved for several different cancer types, and the antipsychotic agent aripiprazole (Abilify®).

Essential medicines with first-line indications: 15



76% of Bristol-Myers Squibb's medicines are listed on the WHO EML and/or as first-line treatments: e.g., daclatasvir (Daklinza™), efavirenz (Sustiva®) and aztreonam (Azactam®).

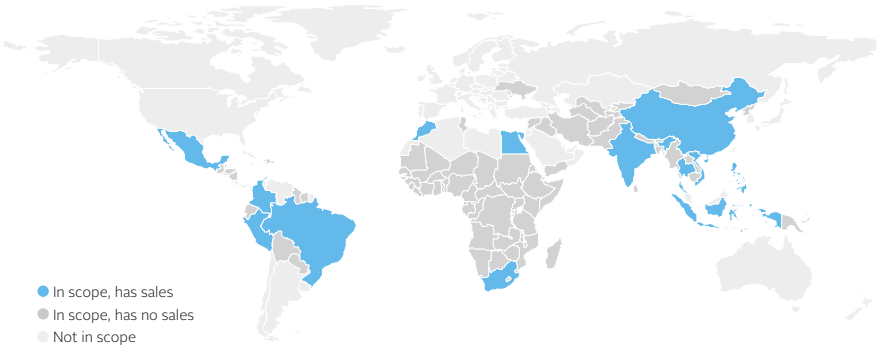
BUSINESS CONTEXT

One business unit: Biopharmaceuticals, with four main therapeutic areas (oncology; immunology; cardiovascular diseases; and fibrotic diseases).
M&A news: 2016 acquisition of Padlock Therapeutics, a biotechnology company specialising in autoimmune diseases. 2017 acquisition of IFM Therapeutics, a biopharmaceutical company specialising in immunotherapy for cancer and inflammatory diseases.
Presence in emerging markets: In 2018, Bristol-Myers Squibb reports sales in 13 countries in scope; 24 less than in the 2016 Index. It reports that around 20% of its sales in 2017 came from regions outside of Europe and the USA.

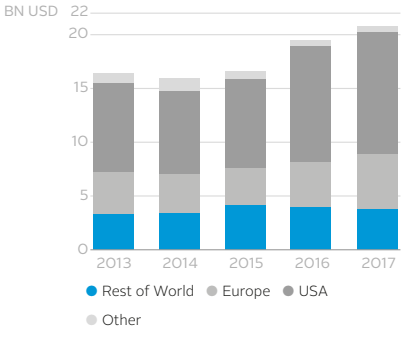
Revenue by segment (2017) - USD

Medicines (product)	20,776 MN
Total	20,776 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
** See Appendix IV for definition.

Bristol-Myers Squibb Co.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 13 SCORE 3.06

Has an access-to-medicine strategy with executive-level responsibility. Bristol-Myers Squibb has an access-to-medicine strategy with a business rationale. The strategy includes measures such as equitable pricing, licensing, philanthropy and capacity building. The highest level of responsibility for access sits with its Worldwide Access Council, at the executive level.

Financial and non-financial access-related incentives to reward employees. Bristol-Myers Squibb performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include awards for performance and public recognition by senior company leaders in internal meetings and through internal social media for objectives reached.

One of 16 companies working on impact measurement. Bristol-Myers Squibb measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, targets, objectives and performance information. For its HIV and hepatitis C medicines that are available in countries in scope, the company reports tracking the number of patients benefiting from its medicines. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Bristol-Myers Squibb publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 7 SCORE 2.71

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Bristol-Myers Squibb has a code of conduct relating to ethical marketing and anti-corruption and provides biannual compliance training for employees and third parties. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Bristol-Myers Squibb's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an internal auditing department for the whole company, involving both internal and external resources and applying to all third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Above average transparency regarding access-related practices. Bristol-Myers Squibb publicly discloses its policy positions on access-related topics (e.g., its policy committing to provide appropriate patient access to medicines). It is one of the few companies in scope to have a policy that prohibits political financial contributions outside the USA. The company publicly discloses its membership of patient organisations, including the financial support it provides. It discloses policies for responsible engagement within its Principles of Integrity. It does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 17 SCORE 1.56

PROJECTS: 25 IN CLINICAL DEVELOPMENT: 18

Publicly commits to R&D to meet public health needs. Bristol-Myers Squibb has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale linked to sources including the United Nations Sustainable Development Goals. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Bristol-Myers Squibb has one of the smallest pipelines in the Index with 25 projects. For diseases in scope where priorities exist, Bristol-Myers Squibb is active in two projects; both of these target priority R&D gaps.

No clear process to consider access during development. Bristol-Myers Squibb does not have a clear process in place to develop access plans during R&D. Instead, Bristol-Myers Squibb considers access on a case-by-case basis. In general, Bristol-Myers Squibb develops access plans for R&D projects late in the development process and close to submission for market approval. To date, Bristol-Myers Squibb does not have any project-specific access provisions in place for its eight late-stage R&D projects. Five of these projects were approved during the period of analysis.

Public policy to ensure post-trial access; commits to registering trialed products. Bristol-Myers Squibb has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Bristol-Myers Squibb commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 16 SCORE 2.00

PRODUCTS: 25

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY:5

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Bristol-Myers Squibb does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it publicly commits to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. Its public commitments also apply to intra-country equitable pricing strategies, albeit to only some of its products.

Some new products in scope filed for registration in the majority of priority countries. Bristol-Myers Squibb has filed 10% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

20% of products have equitable pricing strategies targeting priority countries. Bristol-Myers

Squibb's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 20% of its products for diseases in scope. These strategies apply to an average of 65% of priority countries. Most of these strategies apply inter-country pricing; these take into account an average of three socioeconomic factors. Bristol-Myers Squibb also applies an equitable pricing strategy to one further product informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Bristol-Myers Squibb has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 4 SCORE 2.54

Publicly discloses detailed information on patent statuses. Like most of its peers, Bristol-Myers Squibb publicly discloses the patent statuses for small molecules in scope via the PatINFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Uses licensing to enable generic supply. Bristol-Myers Squibb has non-exclusive voluntary licensing agreements in place for two compounds (for diseases in scope). Its broadest licence, for atazanavir sulfate (Reyataz®), encompasses 97 countries including 66 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. Bristol-Myers Squibb reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No public commitment not to enforce patents in countries in scope. Bristol-Myers Squibb does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 18 SCORE 0.74

Eight initiatives included for evaluation. Bristol-Myers Squibb has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Bristol-Myers Squibb submitted 22.

Focused on strengthening health systems. Bristol-Myers Squibb has initiatives that meet inclusion criteria in three areas of capacity building: manufacturing, R&D, and health system strengthening. Most of these initiatives are focused on health system strengthening in the disease areas of HIV/AIDS, viral hepatitis (B and C) and cancer.

Most initiatives meet most good practice standards. None of Bristol-Myers Squibb's included initiatives meet all the good practice standards looked for by the Index. While its health system strengthening projects have good governance structures in place, some initiatives fall short on setting clear, measurable goals and objectives.

Does not provide evidence of reporting substandard or falsified medicines to relevant authorities. Bristol-Myers Squibb has a policy for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

PRODUCT DONATIONS

RANK 10 SCORE 3.05

STRUCTURED DONATION PROGRAMMES: 1

Responds to emergencies and humanitarian crises and tracks delivery. Bristol-Myers Squibb donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to the 2017 Mexico earthquake. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with Americares and Direct Relief to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Bristol-Myers Squibb's ongoing donation programme is focused on cancer. The programme is carried out in partnership with the the Max Foundation and has been ongoing since 2016. The company's cancer programme for chronic myeloid leukemia supplies dasatinib (Sprycel®) in 15 countries. In 2017, Bristol-Myers Squibb reports to have reached 118 patients. During the period of analysis Bristol-Myers Squibb also donated products for the treatment of hepatitis C in a demonstration project with several partners.

Ensures long-term access through transition planning. Bristol-Myers Squibb has transition plans in place for its dasatinib (Sprycel®) donation programme, to ensure ongoing access for patients once the programme ends. It commits to contractually agree to continue providing the product to patients once the programme has ended, as long as patients meet certain eligibility criteria (e.g., recommendation from physician, there are no other means available to access the product, etc.).

BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.

RANK	SCORE
16▼	1.88
12 (2016)	

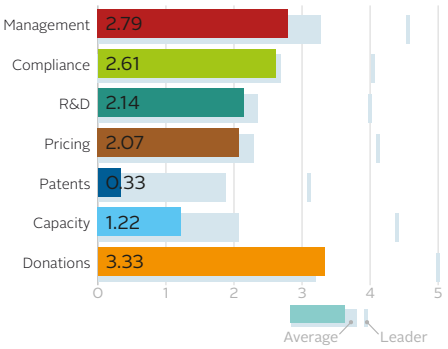
Bayer AG

Stock Exchange: Frankfurt Stock Exchange • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 123,352

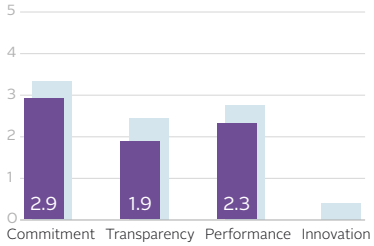
PERFORMANCE

Falls from 12th place in 2016 to 16th. Despite maintaining key donation programmes, Bayer performs comparatively poorly in its approach to equitable pricing, and its transparency around IP management is low.
Management: Falls 5 places to 16th. Comparatively poor performance on reporting access commitments.
Compliance: Rises 4 places to 10th. Although it holds a comparatively average standard of transparency, it continues to incentivise sales agents against sales targets.
R&D: Rises 4 places to 8th. With a mid-ranking performance, it lacks a process to develop access plans during R&D, but considers access for a key paediatric product.
Pricing: Falls 4 places to 15th, with a comparatively low proportion of equitable pricing strategies applied in priority countries.
Patents: Holds 18th place. One of only two companies without a public commitment to not enforce and/or file patents in countries in scope. Fails to disclose patent statuses.
Capacity: Falls 1 place to 14th. Focus on pharmacovigilance, with no initiatives meeting all good practice standards.
Donations: Holds at 8th place. Maintains three structured donation programmes committed to the elimination of two NTDs.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Review IP management approaches. Bayer can look to adopt a public, access-oriented IP management approach. This would include a public stance on not filing for or enforcing patents related to diseases in scope in Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries. Eighteen other companies in the Index have already taken this step. Bayer can also publicly disclose the status of its patents, clearly showing where products are on- and off-patent, and when patents are due to expire. This can be achieved either through self-disclosure or through Pat-INFORMED, a platform to promote the accessibility of patent information for health agencies tasked with procurement of medicines.

Expand consideration of affordability across contraceptive products. Currently the company has equitable pricing strategies for two products in the scope of the Index. Recalling its 2012 commitment at the London Family Planning Summit, Bayer could apply equitable pricing strategies to more of its contraceptive products, including drosperinone/ethinylestradiol (Yasmin®), estradiol valerate/norethisterone enantate (Norigynon®), levonorgestrel (Microlut®) and levonorgestrel releasing intrauterine system (Mirena®) - all first line products on the 2017 WHO Model List of Essential Medicines (WHO EML).

Develop a process to establish more access plans for R&D projects. Bayer can develop a clear approach to establish access plans for R&D projects earlier in the development phase that take into account the specific considerations necessary for each project. It can develop this approach for both in-house and collaborative projects for all diseases in scope, with a clear timeline for developing, refining and executing access plans to ensure broad and rapid access.

Review incentives for sales agents. Bayer can improve its commitment to ensure responsible sales practices by decoupling sales incentives from sales targets. Removing an emphasis on sales targets is recognised as a mechanism for ensuring rational prescribing, and critical for a company like Bayer that produces antibiotics and other products which are often inappropriately used.

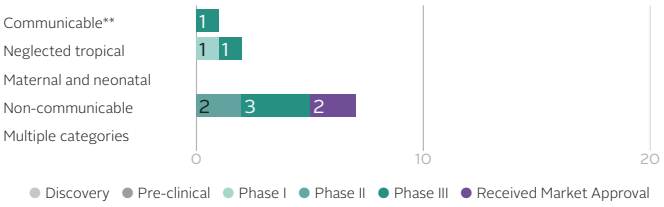
CHANGE SINCE 2016

- Joined Access Accelerated with a pilot programme focused on deep vein thrombosis (DVT) in Ghana.
- Partnered with Goodbye Malaria with commitments to expand access to WHO-recommended vector control products and to continuing to develop new vector control products to control and eliminate malaria.
- Files to register the majority of its most recently approved products in the majority of corresponding priority countries.
- Commits to expand its successful youth-centric health programmes under the umbrella of the World Contraception Day (WCD) and the associated “It’s Your Life – It’s Your Future” campaign.
- Reports that it newly extends enforcement processes for its code of conduct to third parties.

PIPELINE *for diseases and countries in scope*

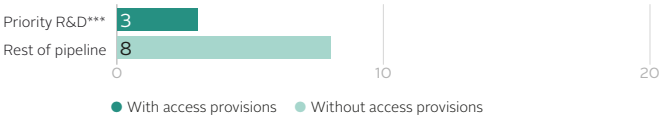
Comparatively small pipeline: 11 R&D projects for diseases in scope (10 medicines; 1 vector control product).
Clinical candidates: 9, including finerenone for the treatment of diabetic kidney disease and tedizolid (Sivextro®) for the treatment of pneumonia.
Regulatory approvals: 2, including copanlisib (Aliqopa™) for the treatment of follicular lymphoma.
R&D focus: non-communicable diseases (cancer) and neglected tropical diseases (Chagas disease).
Access provisions: for 3 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 11*



Bayer's pipeline is made up entirely of clinical candidates and newly approved products. This includes a Phase III candidate for an expanded indication of the antibiotic Sivextro® (tedizolid) for lower respiratory infections.

Projects for R&D priority targets with access provisions: 3

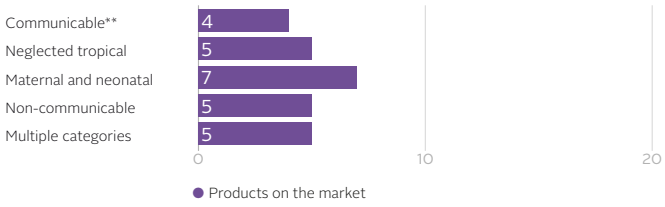


Of Bayer's 11 R&D projects, three are supported by access provisions (3 out of 11): e.g., paediatric nitrofurane (Lampit®) for Chagas disease has plans for WHO prequalification and registration. One of its nine late-stage projects has provisions.

PORTFOLIO *for diseases and countries in scope*

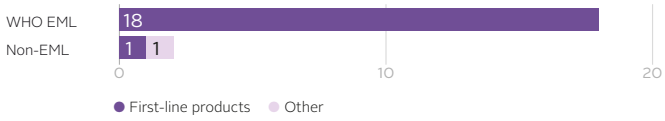
Comparatively small portfolio: 26 products for diseases in scope (13 medicines; 7 contraceptive methods; 6 vector control products).
Portfolio focus: maternal & neonatal health conditions (contraceptive methods), communicable diseases (malaria) and neglected tropical diseases (dengue and chikungunya).
Essential medicines: 90% of Bayer's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 95% of Bayer's medicines have first-line indications for diseases in scope.

Products on the market: 26



Bayer's portfolio includes products such as several insecticides for application on bed nets including Aqua Reslin®, Ficam® and Aqua K-Othrine® to prevent the transmission of malaria and other insect-borne diseases.

Essential medicines with first-line indications: 18



95% of Bayer's medicines are listed on the WHO EML and/or as first-line treatments: e.g., nifurtimox (Lampit®) and contraceptives including the levonorgestrel-containing implant Jadelle®.

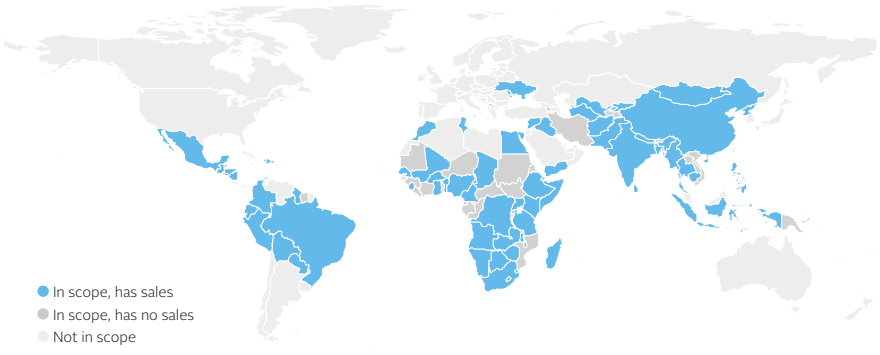
BUSINESS CONTEXT

Four business units: Pharmaceuticals; Consumer Health; Crop Science; and Animal Health. Its pharmaceutical segment has five main therapeutic areas (cardiology, oncology, gynaecology, haematology and ophthalmology).
M&A news: 2018 acquisition of Monsanto, an agrochemical and agricultural biotechnology company; divestment of the agricultural business assets to German company BASF, the largest chemical producer in the world.
Presence in emerging markets: In 2018, Bayer reports sales in 70 countries in scope; 32 less than in the 2016 Index. It reports that more than one-third of its sales in 2017 came from Asia-Pacific and Latin America.

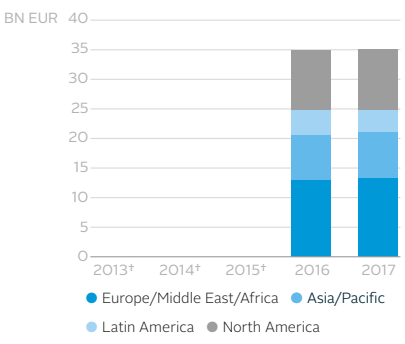
Net sales by segment (2017) - EUR

Pharmaceuticals	16,847 MN
Consumer Health	5,862 MN
Crop Science	9,577 MN
Animal Health	1,571 MN
All other segments	1,142 MN
Reconciliation	16 MN
Total	35,015 MN

Sales in countries in scope



Net sales by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes one project that does not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

** Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.

*** See Appendix IV for definition.

† Data not comparable due to changes in company reporting practices.

Bayer AG

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 16 SCORE 2.79

Has an access-to-medicine strategy with board-level responsibility. Bayer has an access-to-medicine strategy with a business rationale. Bayer's access approach has as a key focus on family planning and maternal and neonatal health. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Bayer performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include variable performance-related compensations. Bayer's senior management has a separate incentive that supports the company's long-term access oriented objectives.

One of 16 companies working on impact measurement. Bayer measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, for example, it reports to commit to supply medicines to fight African sleeping sickness to WHO. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Bayer publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by a process based on expertise, activity and geographic coverage. Local stakeholder perspectives are incorporated into the development of its access strategies. It publicly shares its policy for ensuring responsible engagement; namely with its principles of responsible lobbying.

MARKET INFLUENCE & COMPLIANCE

RANK 10 SCORE 2.61

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Bayer has a policy relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Bayer's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it audits compliance following an annual audit plan. It does not report conducting fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system in place to track compliance in the workplace. However, Bayer does not demonstrate evidence of having procedures to segregate duties, so that decisions are checked by another party.

Average transparency regarding access-related practices. Bayer publicly discloses its policy positions on access-related topics (e.g., its positions on intellectual property, and TRIPS). It also publicly discloses political contributions in countries in scope. Bayer publicly discloses its memberships of relevant organisations to access in countries in scope, but not the financial contributions it provides. It discloses its policies for responsible engagement within its code of conduct. However, the company does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 8 SCORE 2.14

PROJECTS: 11 IN CLINICAL DEVELOPMENT: 9

Commits to R&D to meet public health needs. Bayer has made a specific commitment to R&D for diseases and countries in scope, but it is not publicly available. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on goals published by external sources like WHO. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Bayer has one of the smallest pipelines in the Index with 11 projects. For diseases in scope where priorities exist, Bayer is active in four projects; three of these target priority R&D gaps.

Access provisions in place for 11% (1/9) of late-stage candidates. Bayer does not have a clear process in place to develop access plans during R&D. It does, however, consider access for some R&D projects for diseases in scope, namely for collaborative projects. To date, Bayer has project-specific access provisions in place for one of its late-stage R&D projects. This project, to develop a paediatric formulation of nifurtimox (Lampit®) for the treatment of Chagas disease, is being conducted in-house and includes a registration strategy and plan to apply for WHO prequalification.

No policy for post-trial access. Bayer does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 15 SCORE 2.07

PRODUCTS: 26

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 2

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Bayer does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does the company publicly commit to implement equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

Many new products in scope filed for registration in the majority of relevant priority countries. Bayer has filed 70% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration information for any of its products.

12% of products have equitable pricing strategies targeting priority countries. Bayer's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 12% of its products for diseases in scope. These strategies apply to an average of 9% of priority countries. One of these strategies applies inter-country pricing; this strategy, for contraceptive methods, takes into account one socio-economic factor. Bayer also applies an equitable pricing strategy to one further product informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Bayer has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 18 SCORE 0.33

Does not publicly disclose patent statuses. Unlike most of its peers, Bayer does not disclose the status of its products for diseases and countries in scope.

No use of non-assert or licensing arrangements. Bayer does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. Bayer reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No public commitment not to enforce patents in countries in scope. Bayer does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 14 SCORE 1.22

Six initiatives included for evaluation. Bayer has six capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Bayer submitted 21.

Focused on supporting pharmacovigilance systems. Bayer has initiatives which meet inclusion criteria in two areas of capacity building: pharmacovigilance and health system strengthening. Most of these initiatives are focused on pharmacovigilance capacity building in sub-Saharan Africa.

Some initiatives meet some good practice standards. None of Bayer's included initiatives meet all the good practice standards looked for by the Index. Most of its initiatives have goals in place, but it commonly falls short on monitoring progress and outcomes.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Bayer has a policy for reporting cases of substandard or falsified medicines to local regulatory authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 8 SCORE 3.33

STRUCTURED DONATION PROGRAMMES: 3

Responds to emergencies and humanitarian crises and tracks delivery. Bayer donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to the 2017 Mexico earthquake. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with Direct Relief and Health Partners International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Bayer's programmes are focused on neglected tropical diseases (NTDs), namely Chagas disease and human African trypanosomiasis (HAT) of the type *T. b. gambiense* and *T. b. rhodesiense*. All three programmes are carried out in partnership with its long-term partner, WHO. Its NTD programme for Chagas disease supplies nifurtimox (Lampit®) in 14 countries in scope and has been ongoing since 2004. During the period of analysis, Bayer reports that this has reached almost 8000 patients.

Addresses longer-term needs by committing to eliminate disease. Bayer's structured donation programmes aim to eliminate the diseases targeted. For example, its nifurtimox (Lampit®) donation programme aims to support control and elimination of Chagas disease in 14 countries in scope. For its three neglected tropical diseases programmes, Bayer commits to supplying the drug as long as WHO requires it; i.e., until elimination of the disease.

BEST PRACTICES

Continued commitment to combat NTDs

GLOBAL

One of five companies running donation programmes to eliminate or eradicate NTDs.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
17▼	1.88
9 (2016)	

AbbVie Inc.

Stock Exchange: New York Stock Exchange • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: 29,000

PERFORMANCE

Falls from 9th to 17th place. AbbVie* continues to lack evidence of a clear access-to-medicine strategy, despite having key products in scope for the treatment of hepatitis C.

Management: Rises 2 places to 15th, but remains in the last quartile with no evidence of an access-to-medicine strategy, and no public intention to measure impact.

Compliance: Falls 9 places to 17th for failing to disclose how company associates are held accountable, and does not report several expected components of an internal control framework.

R&D: Falls 6 places to 12th as it lacks a public policy for post-trial access, and has access plans in place for a comparatively small proportion of late-stage projects.

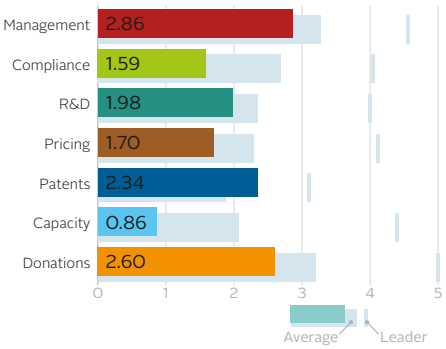
Pricing: Falls 8 to places 18th for failing to disclose data concerning volume of sales and price disclosures.

Patents: Holds 8th place. Has licensed key HIV products through the MPP, and publicly discloses patent statuses via Pat-INFORMED.

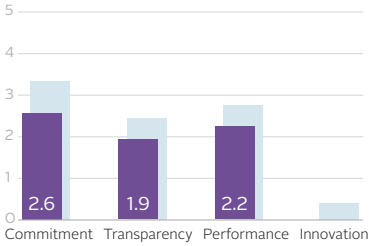
Capacity: Falls 4 places to 16th, with limited information on its activity in capacity building.

Donations: Falls 4 places to 13th. Despite having four structured programmes, these reach a comparatively small number of countries.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Establish an overarching access strategy. AbbVie can consolidate its access approaches into an overall strategy and clearly align it with its corporate strategy.

Expand process to establish more access plans for R&D projects. While AbbVie has a process in place to establish access provisions for R&D projects during development, it appears to cover R&D projects for only a subset of the diseases in scope. Further, it does not have a clear timeline in place to develop these provisions as early as possible. By refining its process to include the consideration of all projects for diseases in scope and to establish access plans earlier in the development process, AbbVie can ensure that products are available to more patients as soon as possible following market approval.

Strengthen internal controls against non-compliance. AbbVie can incorporate additional processes to mitigate the risk of non-compliance with ethical standards. For example, it can establish formal processes that hold third-parties accountable to the companies' standards. It can develop fraud-specific risk assessments, processes for continuous monitoring of compliance and procedures to segregate duties. The company can also expand its auditing mechanism to incorporate both internal and external resources, and apply these standards to third parties that it engages with in countries in scope.

Expand access further by maximising effectiveness of licensing approach. In order to improve availability of the essential medicines which AbbVie has agreed voluntary licences for (glecaprevir/pibrentasvir [Mavyret™] and lopinavir/ritonavir [Aluvia®/Kaletra®]), AbbVie can: boost the geographic scope of these licences further, incorporating further countries with a high prevalence of HIV/AIDS and hepatitis C. AbbVie can also maximise the effectiveness of its licensing approach to access by reviewing future generic company activity in countries within the scope of agreed licences where AbbVie itself does not have sales. In cases where generic company activity remains absent/limited, AbbVie can consider proactively registering and pricing equitably within these countries to facilitate competition and access, or by identifying mechanisms within licences to incentivise generic market entry.

CHANGE SINCE 2016

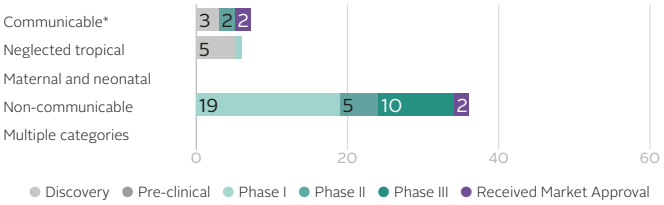
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Received FDA approval for the pangenotypic viral hepatitis C treatment glecaprevir/pibrentasvir (Mavyret™) in August 2017; it is the third pangenotypic treatment to market but the first eight-week treatment.
- Joined the Drugs for Neglected Diseases initiative's NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis through compound library sharing.
- Partnered with the Philippines Society of Newborn Medicine to reduce the prevalence of respiratory distress syndrome (RDS).
- Partnered with the Medicines Patent Pool in fall of 2018 to provide a non-exclusive voluntary licence for glecaprevir/pibrentasvir (Mavyret™), increasing access to the important 8 week treatment for hepatitis C by enabling generic production of the pangenotypic medicine.

*All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. In 2018, AbbVie Inc. declined to submit data to the Access to Medicine Index.

PIPELINE *for diseases and countries in scope*

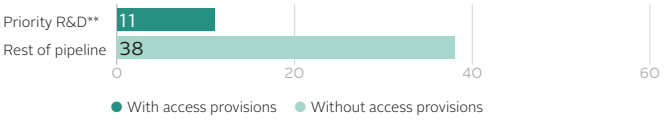
Mid-sized pipeline: 49 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 37, including two Phase II clinical candidates that are part of two potential single-exposure cures for malaria.
Regulatory approvals: 4, including glecaprevir/pibrentasvir (Mavyret™) for the treatment of hepatitis C virus (pangenotypic).
R&D focus: medicines: non-communicable diseases (cancer), communicable diseases (malaria) and neglected tropical diseases (Chagas disease and leishmaniasis).
Access provisions: for 11 projects, all applied through access-oriented partnerships.

Projects in the pipeline: 49



The bulk of AbbVie's neglected tropical diseases projects are in the discovery stage with the notable exception of its Phase I tylosin analogue macrofilaricides (TylAMac™), a potential therapy for filariatic diseases developed in collaboration with the Drugs for Neglected Diseases initiative (DNDi).

Projects for R&D priority targets with access provisions: 11

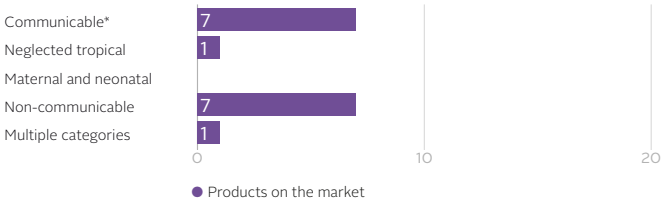


Of AbbVie's 49 R&D projects, 11 are supported by access provisions: e.g., two malaria projects include equitable pricing and registration strategies. Two of its 21 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

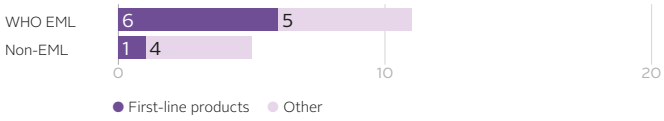
Comparatively small portfolio: 16 products (all medicines) for diseases in scope.
Portfolio focus: medicines: non-communicable diseases (hypertensive heart disease and epilepsy) and communicable diseases (viral hepatitis C).
Essential medicines: 69% of AbbVie's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 44% of AbbVie's medicines have first-line indications for diseases in scope.

Products on the market: 16



AbbVie's portfolio includes products such as palivizumab (Synagis®) for the prevention of respiratory syncytial virus (RSV) in high-risk paediatric patients and an oral powder formulation of ritonavir (Norvir®) to treat HIV/AIDS in children.

Essential medicines with first-line indications: 6



75% of AbbVie's medicines are listed on the WHO EML and/or as first-line treatments: e.g., lopinavir/ritonavir (Kaletra®) for HIV/AIDS and beractant (Survanta®) for neonatal respiratory distress syndrome.

BUSINESS CONTEXT

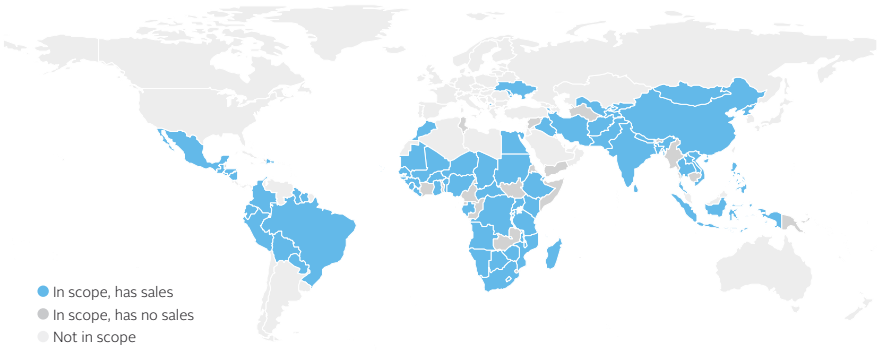
One business unit: Pharmaceuticals, with four main therapeutic areas (immunology, oncology, virology and neuroscience).
M&A news: 2016 acquisition of Stemcentrx, specialising in developing oncology medicines targeting small cell lung cancer and other solid tumours.

Presence in emerging markets: In 2016, AbbVie reported sales in 81 countries in scope. Data for 2018 not available.

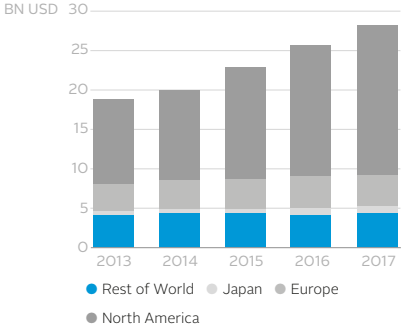
Revenue by segment (2017) - USD

Pharmaceutical products	28,216 MN
Total	28,216 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

*Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
**See Appendix IV for definition.

AbbVie Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 15 SCORE 2.86

Lacks overarching access-to-medicine strategy; responsibility for access lies at board-level. AbbVie does not have an overarching access-to-medicine strategy, but shows evidence of some activities guided by access-related goals. For example, it conducts research to develop new medicines for neglected diseases, supported by its Executive Council on Neglected Tropical Diseases and its corporate responsibility commitments to access to medicine. The highest level of responsibility for access sits with a board-level committee.

Financial access-related incentives in place for employees. AbbVie has financial incentives in place to motivate employees to perform on access-related issues. These incentives include awards based on access efforts.

Measures and monitors outcomes and progress; not impact. AbbVie measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its Foundation's partnership with Direct Relief International, AbbVie reports having established a data management and order tracking system to ensure effective monitoring of its HIV testing programmes in Least Developed Countries. However, it does not report measuring the impact of its initiatives.

Stakeholder engagement: incorporates local perspectives into strategies. AbbVie publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, or its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 17 SCORE 1.59

Does not report processes for ensuring third-party compliance with standards. AbbVie has a code of conduct relating to ethical marketing and anti-corruption. It provides regular compliance training for employees. The company performs relatively poorly when it comes to enforcing compliance measures and non-sales incentives. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, its incentives for sales agents are based solely on sales targets.

Internal control framework lacks Index criteria. AbbVie's internal control framework for ensuring compliance meets one of the criteria looked for by the Index. This is an auditing and review mechanism, however, it does not report that this mechanism involves both internal and external resources, nor that it applies to all third parties in countries where AbbVie operates. The company does not report conducting fraud-specific risk assessments, nor does it demonstrate evidence of having a monitoring system in place to track compliance, or having procedures to segregate duties to ensure decisions are checked by another party.

Below average transparency regarding access-related practices. AbbVie does not publicly disclose policy positions that impact access to medicine. Neither does it disclose political contributions in countries in scope. AbbVie publicly discloses its financial support and membership of relevant organisations for access. It does not, however, publish its policies for responsible engagement. Neither does it publicly disclose its its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 12 SCORE 1.98

PROJECTS: 49 IN CLINICAL DEVELOPMENT: 37

Publicly commits to R&D to meet public health needs. AbbVie has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on external guidance including the United Nations Sustainable Development Goals. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. AbbVie has a mid-sized pipeline in the Index with 49 projects. For diseases in scope where priorities exist, AbbVie is active in 13 projects; 11 of these target priority R&D gaps.

Access provisions in place for 10% (2/21) of late-stage candidates. AbbVie has a general process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for neglected tropical diseases and tuberculosis. Information is publicly available on project-specific access provisions for two of AbbVie's late-stage R&D projects. Both projects are being conducted in partnership with the Medicines for Malaria Venture (MMV).

No public disclosure of post-trial access policy. AbbVie does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants, and it does not provide an internal policy that can be evaluated.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 18 SCORE 1.70

PRODUCTS: 16

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 4

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. AbbVie does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implementing inter-country equitable pricing strategies for a minority of its products for diseases in scope. This does not explicitly apply to future products. Its public commitments also apply to intra-country equitable pricing strategies, albeit to only some of its products.

A third of new products in scope filed for registration in the majority of priority countries. AbbVie has filed 33% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share the registration status for any of its products.

25% of products have equitable pricing strategies targeting priority countries. AbbVie's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 25% of its products for diseases in scope. These strategies apply to an average of 76% of the relevant priority countries and take an average of three socio-economic factor into account.

Globally consistent recall guidelines for countries in scope but no processes to track products. AbbVie has guidelines for drug recalls that apply to all countries in scope. It does not

demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 8 SCORE 2.34

Publicly discloses detailed information on patent statuses. Like most of its peers, AbbVie publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Uses licensing to enable generic supply. AbbVie has non-exclusive voluntary licensing agreements in place for two compounds (for diseases in scope). Its broadest licence, for paediatric iopinavir/ritonavir (LPV/r) (Aluvia®/ Kaletra®), encompasses 93 countries, including 62 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. AbbVie reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi) and the Medicines for Malaria Venture (MMV). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No public commitment not to enforce patents in countries in scope. AbbVie does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 16 SCORE 0.86

One initiative included for evaluation. AbbVie has one capacity building initiative that was included for analysis by the Index: i.e., the initiative demonstrably addresses a specific local need and involves local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment. AbbVie's initiatives were identified for selection based on publicly available information.

Initiative aimed at building local R&D capacity. AbbVie has one initiative which meets inclusion criteria in R&D capacity building. It provides scholarships for students to study science at The Asian University for Women in Bangladesh. AbbVie does not publicly disclose initiatives which meet inclusion criteria in any of the other areas of capacity building.

Limited publicly available data on initiatives. AbbVie's included initiative meets the criteria for inclusion, but no additional good practice standards looked for by the Index. The company reported no information to the Index about its R&D capacity building initiative, and publicly available information is limited.

Timely approach to confirming and reporting substandard or falsified medicines. AbbVie provides evidence that it systematically confirms suspected cases of substandard or falsified medicines and then reports confirmed cases to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days for each, confirmation and reporting).

PRODUCT DONATIONS

RANK 13 SCORE 2.60

STRUCTURED DONATION PROGRAMMES: 4

Responds to emergencies, humanitarian crises and tracks delivery. AbbVie donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to the 2017 Mexico earthquake. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works with independent organisations, such as Americares, to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Four donation programmes covering diseases and countries in scope. AbbVie's programmes are focused on communicable and non-communicable diseases. All four programmes are carried out in partnership with independent partners. Its programme for respiratory distress in newborns supplies the treatment beractant (Survanta®) in four countries and has been ongoing since 2015. Meenakshi Medical Mission Hospital in India reports that beractant (Survanta®) has already helped to treat over 400 infants and preterm babies a year.

Ensures long-term access through transition planning. AbbVie has transition plans in place for one of its programmes to ensure ongoing access for patients once the programme ends. It commits to continuing this programme and fulfilling local product needs as identified by its partner Americares.

BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.

RANK	SCORE
18=	1.77
18 (2016)	

Daiichi Sankyo Co. Ltd.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 32,791

PERFORMANCE

Holds 18th place, with a continued lack of an overarching access-to-medicine strategy, and a weak performance in the Capacity Building, Pricing, Manufacturing & Distribution, and Product Donations. However, the company has made key gains in areas such as Patents & Licensing and R&D.

Management: Rises 1 place to 19th. Lacks a coordinated access-to-medicine strategy and responsibility for access governance is not at board level.

Compliance: Falls 3 places to 18th. Its internal control framework performs poorly against peers e.g., lacking procedures to segregate duties.

R&D: Rises 2 places to 7th. Has access plans in place for 38% of its late-stage projects, despite lacking a process for access plans during R&D.

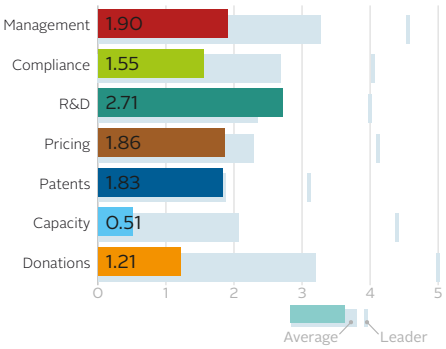
Pricing: Falls 4 places to 17th. Weak commitments to ensure equitable pricing and registrations, with no new products filed for registration in the majority of priority countries.

Patents: Rises 7 places to 12th. Improves transparency with a public commitment not to file patents in countries in scope, and new disclosure of patent status via Pat-INFORMED.

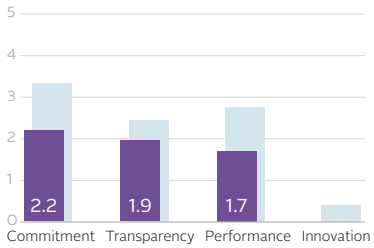
Capacity: Falls 8 places to 19th. Two included initiatives focused on manufacturing, which fail to meet all good practice standards.

Donations: Rises 1 place to 17th, with no structured donation programmes, but working with trusted partners to make *ad hoc* donations.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Establish an overarching access strategy. Daiichi Sankyo can consolidate its various access approaches into an overall strategy, clearly aligning it with its corporate strategy and assigning board level responsibility for it. The company can focus on priority countries, and develop appropriate mechanisms, e.g., through equitable pricing and licensing strategies, for ensuring its products reach those most in need. Daiichi Sankyo is one of three companies in scope that does not have such a strategy.

Develop a process to establish more access plans for R&D projects. Daiichi Sankyo can develop a clear approach to establishing access provisions for R&D projects during development that takes into account the specific considerations necessary for each project. It can develop this approach for both in-house and collaborative projects for all diseases in scope, with a clear timeline for developing, refining and executing access provisions to ensure broad and rapid access. This includes developing access provisions for projects such as its late-stage vaccines for measles and DTaP-IPV-Hib.

Strengthen compliance framework. Daiichi Sankyo can strengthen its framework to ensure compliance by incorporating additional processes to mitigate the risk of non-compliance with ethical standards. For example, it can develop a fraud-specific risk assessment, a monitoring system for compliance and procedures to segregate duties. The company could expand its existing auditing mechanism to third parties it engages with in countries in scope. It can apply formal processes that help to ensure third-party compliance with the company's standards.

Review incentive structures. Daiichi Sankyo can strengthen its access governance by providing access-specific incentives (financial or non-financial) for staff at all levels. Alongside this , Daiichi Sankyo can decouple sales incentives from sales targets to better incentivise responsible practices. Removing the emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing. Removing an emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

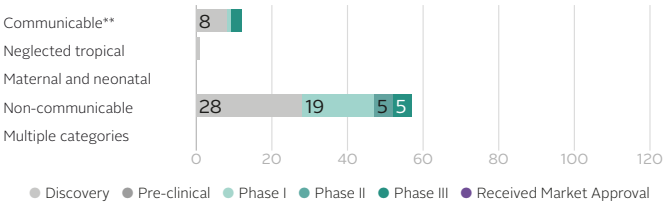
CHANGE SINCE 2016

- Established a new global code of conduct for marketing in 2016 and a policy for anti-bribery and anti-corruption in 2017.
- Joined Access Accelerated with two initiatives in Tanzania and China. It has also committed to measure impact and share results publicly via Access Observatory.
- Discloses public commitments to not file or enforce patents in sub-Saharan African countries (except South Africa), Least Developed Countries, low-income countries and some middle-income countries.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Launched new Access to Healthcare policy in April 2018, establishing a strong commitment to conducting R&D for diseases and countries in scope.

PIPELINE *for diseases and countries in scope*

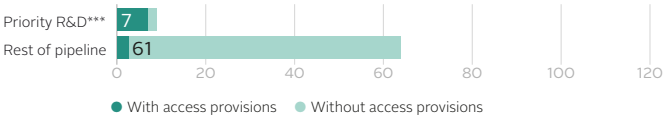
Mid-sized pipeline: 73 R&D projects for diseases in scope (66 medicines; 4 preventive vaccines; 3 diagnostics).
Clinical candidates: 36, including a preventive vaccine for measles and a preventive vaccine for *Haemophilus influenzae*, pertussis and tetanus.
Regulatory approvals: 0 for diseases in scope.
R&D focus: non-communicable diseases (cancer and kidney diseases) and communicable diseases (diarrhoeal diseases and tuberculosis).
Access provisions: for 10 projects, most commonly registration strategies.

Projects in the pipeline: 73*



Daiichi Sankyo's late-stage pipeline includes three diagnostic tests for Genoscholar®, in collaboration with the Nipro Corporation. These tests can detect tuberculosis including pyrazinamide- and multidrug-resistant tuberculosis infections.

Projects for R&D priority targets with access provisions: 7

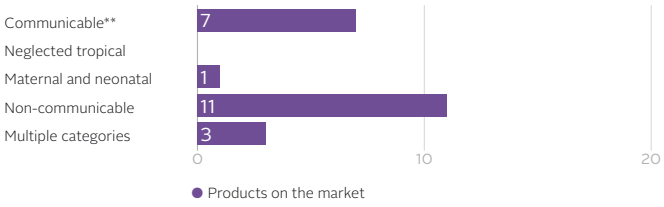


Of Daiichi Sankyo's 73 R&D projects, ten are supported by access provisions: e.g., two malaria projects have equitable pricing and non-exclusive voluntary licensing plans. Six of its 16 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

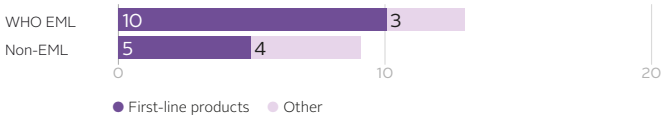
Comparatively small portfolio: 22 products for diseases in scope (19 medicines; 3 preventive vaccines).
Portfolio focus: communicable diseases (lower respiratory infections) and non-communicable diseases (ischaemic heart disease).
Essential medicines: 59% of Daiichi Sankyo's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 68% of Daiichi Sankyo's medicines and vaccines have first-line indications for diseases in scope.

Products on the market: 22



Daiichi Sankyo's portfolio includes products such as the antibiotics amoxicillin/sulbactam (Trifamox®), panipenem/betamipron (Carbenin®) and meropenem (Ropenem®) for the treatment of lower respiratory infections.

Essential medicines with first-line indications: 10



82% of Daiichi Sankyo's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., tranexamic acid (Transamin®) for the treatment of postpartum haemorrhage and paclitaxel (Panataxel®).

BUSINESS CONTEXT

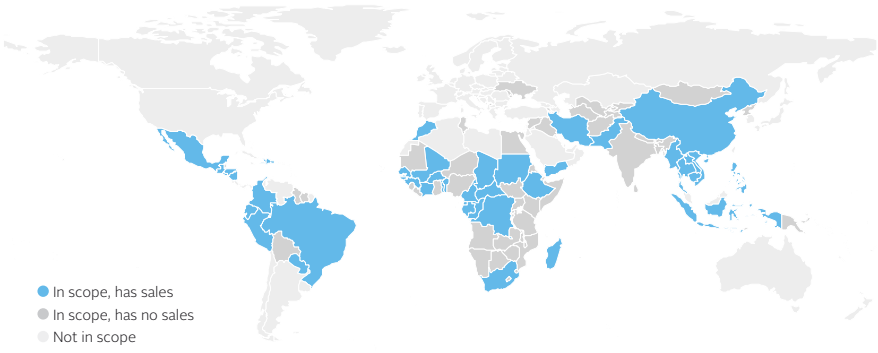
Three business units: Pharmaceuticals; Vaccines; and Over-the-Counter Medicines. Its pharmaceutical business has two therapeutic areas (oncology; and cardiovascular and metabolic diseases) and its vaccine portfolio covers traditional childhood vaccines, including for diphtheria, tetanus, pertussis, measles, mumps and rubella (including four combination vaccines).

M&A news: 2017 consolidation of Kitasato Daiichi Sankyo Vaccine subsidiary into wholly owned subsidiary via acquisition of shares from The Kitasato Institute, a private research institute in Japan.
Presence in emerging markets: In 2018, Daiichi Sankyo reports sales in 43 countries in scope; one less than in the 2016 Index.

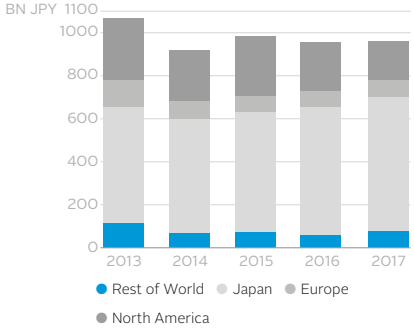
Revenue by segment (2017) - JPY

Pharmaceutical	884,907 MN
Healthcare (OTC)	72,943 MN
Others	2,344 MN
Total	960,194 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes three projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

** Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.

*** See Appendix IV for definition.

Daiichi Sankyo Co. Ltd.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 19 SCORE 1.90

Lacks an overarching access-to-medicine strategy; responsibility for access lies at executive level. Daiichi Sankyo does not have an access-to-medicine strategy but shows evidence of some activities guided by access-related goals. For example, it operates mobile healthcare clinics in Tanzania. Access is discussed by its Global Management Committee, which entails executive leadership.

Financial and non-financial access-related incentives in place for employees. Daiichi Sankyo performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include rewards and awards.

One of 16 companies working on impact measurement. Daiichi Sankyo measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments and performance information. For example, for its initiative on mobile healthcare clinics in Tanzania, the company reports the rates of infants receiving measles vaccinations and mothers undergoing prenatal checkups. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Limited transparency about stakeholder engagement. Daiichi Sankyo performs relatively poorly when it comes to the disclosure of its stakeholder engagement. Daiichi Sankyo publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. Neither does it report incorporating local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 18 SCORE 1.55

Does not report processes for ensuring third-party compliance with standards. Daiichi Sankyo has a code of conduct and policy relating to ethical marketing and anti-corruption: namely, it has a global anti-bribery and anti-corruption policy. It provides compliance training for employees. The company performs relatively poorly when it comes to enforcing compliance measures and non-sales incentives. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, expected performance for sales agents is based solely on sales targets.

Internal control framework lacks Index criteria. Daiichi Sankyo's internal control framework for ensuring compliance meets one of the criteria looked for by the Index. This is an auditing and review mechanism (that performs evaluations once every three years). However, it does not report that this mechanism applies to third parties. Daiichi Sankyo does not report conducting fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system in place to track compliance, or evidence of having procedures to segregate duties, to ensure decisions are checked by another party.

Average transparency regarding access-related practices. Daiichi Sankyo publicly discloses its policy positions on access-related topics (e.g., its policy on intellectual property rights and access to medicine). It does not have a policy prohibiting political contributions in countries in scope, but states that no such contributions occurred during the period of analysis. The company publicly discloses its membership of relevant organisations for access, but not its financial contributions to such organisations. It shares its policies for responsible engagement for employees' interactions with healthcare professionals. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 7 SCORE 2.71

PROJECTS: 73 IN CLINICAL DEVELOPMENT: 36

Publicly commits to R&D to meet public health needs. Daiichi Sankyo has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale by following external targets including the United Nations Sustainable Development Goals. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Daiichi Sankyo has a mid-sized pipeline in the Index with 73 projects. For diseases in scope where priorities exist, Daiichi Sankyo is active in 15 projects; nine of these target priority R&D gaps.

Access provisions in place for 38% (6/16) of late-stage candidates. Daiichi Sankyo does not have a clear process in place to develop access plans during R&D. Instead, Daiichi Sankyo considers access on a case-by-case basis. To date, Daiichi Sankyo has project-specific access provisions in place for six of its late-stage R&D projects. Of these, three are being conducted in partnership, all with the Nipro Corporation for GenoScholar® diagnostic tests for tuberculosis.

No policy for post-trial access. Daiichi Sankyo does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Additionally, it does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 17 SCORE 1.86

PRODUCTS: 22

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 8

Does not publicly commit to equitable pricing or report a commitment to file to register products in scope. Daiichi Sankyo does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

No new products in scope filed for registration in the majority of priority countries. Daiichi Sankyo has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for hypertensive heart disease, is registered in two out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

36% of products have equitable pricing strategies targeting priority countries. Daiichi Sankyo's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 36% of its products for diseases

in scope. These strategies apply to an average of 10% of priority countries. One of these strategies, for asthma and chronic obstructive pulmonary disease (COPD), applies both inter-and intra-country pricing.

Globally consistent recall guidelines for countries in scope but no processes to track products. Daiichi Sankyo has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 12 SCORE 1.83

Publicly discloses detailed information on patent statuses. Like most of its peers, Daiichi Sankyo publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Daiichi Sankyo does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. Daiichi Sankyo reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi) and the Medicines for Malaria Venture (MMV). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Public commitment not to enforce patents in countries in scope. Daiichi Sankyo commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in some Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

CAPACITY BUILDING

RANK 19 SCORE 0.51

Two initiatives included for evaluation. Daiichi Sankyo has two capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Daiichi Sankyo submitted 13.

Two initiatives aimed at enhancing local manufacturing. Daiichi Sankyo's initiatives which meet inclusion criteria are in manufacturing capacity building. The initiatives are active in China and Vietnam. It did not disclose initiatives which meet inclusion criteria in any of the other areas of capacity building.

Initiatives meet inclusion criteria only. Neither of Daiichi Sankyo's initiatives meet all the good practice standards looked for by the Index. This includes not setting clear, measurable goals that aim for long-term sustainable improvements.

Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe. Daiichi Sankyo states that it reports cases of substandard or falsified medicines to relevant authorities. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.*

PRODUCT DONATIONS

RANK 17 SCORE 1.21

STRUCTURED DONATION PROGRAMMES: 0

Has policy for responding to emergencies or humanitarian crises. Daiichi Sankyo donated medicines on the request of relief agencies. For example, during the period of analysis, it donated cancer medicines in Armenia upon request from Americares. The company discloses that such *ad hoc* donations are aligned with the requirements of local regulatory standards. It also monitors the delivery of the product until received by end user.

No donation programmes covering diseases and countries in scope. Daiichi Sankyo does not have any structured donations programmes that were active during the period of analysis in any countries in scope.

BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.

*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.

RANK	SCORE
19▲	1.46
20 (2016)	

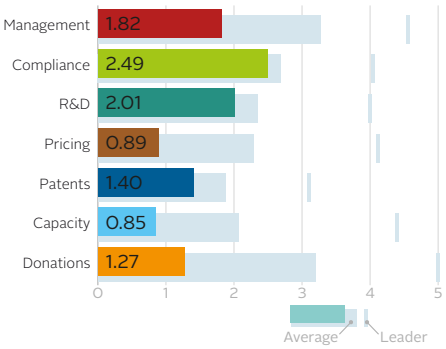
Astellas Pharma Inc.

Stock Exchange: Tokyo Stock Exchange • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 17,202

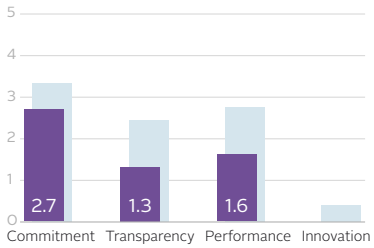
PERFORMANCE

Rises 1 place to 19th. Although it has made notable improvements, such as joining the TB Alliance, Astellas placed comparatively poorly in every Technical Area.
Management: Falls 2 places to 20th. While some activities are guided by access-related goals, the company continues to lack an overall access-to-medicine strategy. Newly joined Access Accelerated.
Compliance: Rises 5 places to 12th. One of only two companies who report having all components of an internal control framework looked for by the Index.
R&D: Rises 6 places to 11th, with strengthened R&D commitments, and a higher proportion of projects carried out in collaboration.
Pricing: Holds 19th position for its continued lack of equitable pricing strategies for any of its marketed products for priority countries.
Patents: Falls 1 place to 14th, despite new engagement with Pat-INFORMED. It is affected negatively by a lack of transparency in remaining areas.
Capacity: Falls 7 places to 17th, for failing to demonstrate initiatives which meet all good practice standards looked for by the Index.
Donations: Rises 3 places to 16th. Remains in last quartile. Does not have any structured donation programmes in place, nor does it disclose evidence of *ad hoc* donations.

Performance by technical area



Performance by strategic pillar



OPPORTUNITIES

Develop a process to establish access plans for R&D projects during development. Astellas lacks a clear process for establishing access plans for R&D projects during development, instead it considers access on an *ad hoc* basis. It can improve in this area by publicly committing to develop access plans for R&D projects for diseases in scope with a clear timeline. It could consider the unique requirements for each of these projects. This includes developing access plans for projects such as its Phase III clinical candidate, gilteritinib, a potential oral treatment for leukaemia.

Develop access plans for key cancer products. Leuprorelin acetate (Eligard®) is a patented, first-line treatment on the 2017 WHO Model List of Essential Medicines (WHO EML) for the management of advanced prostate cancer. There is currently no evidence of any access plans for this product. The company could consider the application of, for example, equitable pricing strategies to support accessibility of this product.

Establish an overarching access strategy. Astellas can consolidate its access approaches into an overall strategy and clearly align it with its corporate strategy. The company could take this as an opportunity to incorporate its position on access to health into concrete objectives to improve access to medicine in low- and middle-income countries, and to expand access planning across their pipeline.

Strengthen processes to minimise the risk of non-compliance. Astellas can establish formal processes to ensure third-party compliance with the company's standards of anti-corruption and ethical marketing. Astellas can also provide non-sales based incentives for sales agents. Removing the emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

Establish a clear and public post-trial access policy. Astellas' approach to post-trial access is broadly defined and carried out on a case-by-case basis. By developing a clear stance and protocol on post-trial access, and committing to register all new products in the countries where clinical trials for these products have taken place, it can expand access to medicine and ensure post-trial access for clinical trial participants.

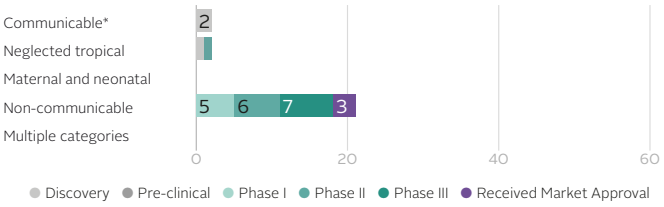
CHANGE SINCE 2016

- Joined Access Accelerated with its Action on Fistula programme in Kenya. It has also committed to measure impact and share results publicly via Access Observatory.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Joined the Drugs for Neglected Diseases initiative's (DNDi) NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis through compound library sharing.
- Joined the UN Shot@Life campaign in 2017 by supporting the measles campaign in Latin America.

PIPELINE *for diseases and countries in scope*

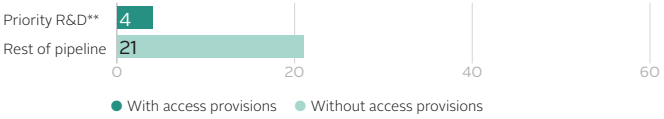
Comparatively small pipeline: 25 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 19, including praziquantel for the treatment of schistosomiasis in children and ipragliflozin for type I diabetes mellitus.
Regulatory approvals: 3, including extended-release quetiapine for the treatment of bipolar affective disorder.
R&D focus: non-communicable diseases (cancer and diabetes mellitus).
Access provisions: for 4 projects, most commonly applied through access-oriented partnerships.

Projects in the pipeline: 25



Astellas developed new paediatric praziquantel formulations for the Pediatric Praziquantel Consortium. This project aims to provide access to schistosomiasis treatments for children, more than 30 years after praziquantel entered the market.

Projects for R&D priority targets with access provisions: 4

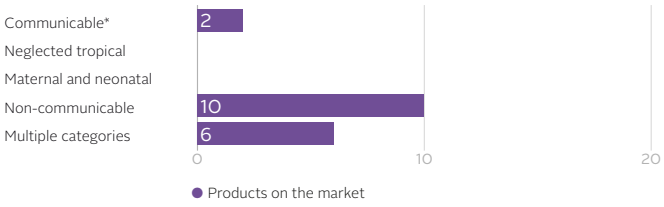


Of Astellas' 25 R&D projects, four are supported by access provisions: e.g., paediatric praziquantel has plans for not-for-profit pricing and non-exclusive voluntary licensing. One of its 17 late-stage projects has provisions.

PORTFOLIO *for diseases and countries in scope*

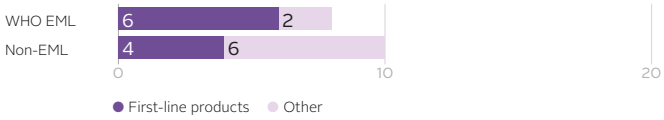
Comparatively small portfolio: 18 products (all medicines) for diseases in scope.
Portfolio focus: non-communicable diseases (hypertensive heart disease and epilepsy) and communicable diseases (viral hepatitis C).
Essential medicines: 44% of Astellas' medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 56% of Astellas' medicines have first-line indications for diseases in scope.

Products on the market: 18



Astellas's portfolio includes products such as micafungin (Mycamine®) for the treatment of invasive fungal infections, including those secondary to HIV/AIDS, in patients of all ages.

Essential medicines with first-line indications: 6



67% of Astellas' medicines are listed on the WHO EML and/or as first-line treatments: e.g., leuprorelin acetate (Eligard®) and the antibiotics doxycycline (Unidox®) and amoxicillin/clavulanate (Flemoclav®).

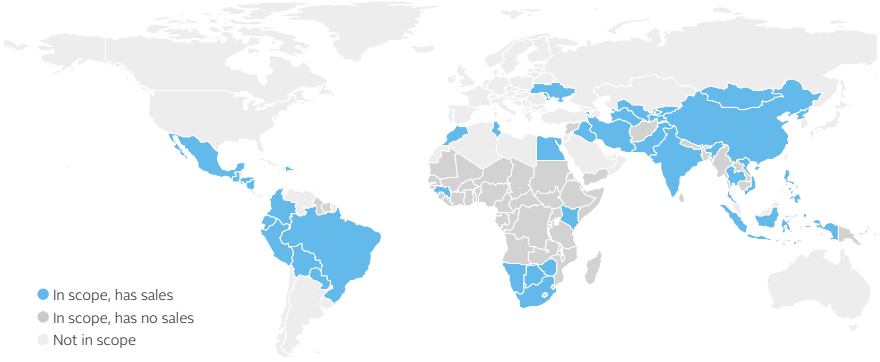
BUSINESS CONTEXT

One business unit: Pharmaceuticals, with five main therapeutic areas (urology, oncology, immunology, nephrology, and neuroscience).
M&A news: 2016 acquisition of Ganymed Pharmaceuticals, specialising in oncology. 2017 acquisition Ogeda SA, a clinical-stage drug discovery company for women's health. 2018 acquisition of Universal Cells, with a pipeline focused on stem cell technology; acquisition of Mitobridge, a start-up focused on discovering and developing small-molecule therapeutics that enhance mitochondrial function.
Presence in emerging markets: In 2018, Astellas has sales in 39 countries in scope; six less than in the 2016 Index.

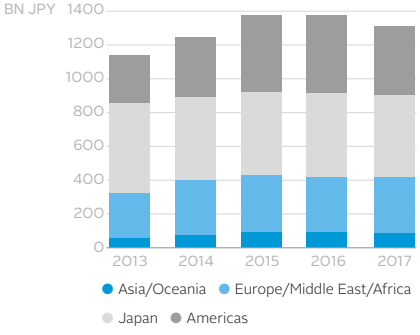
Sales by segment (2017) - JPY

Pharmaceuticals business	1,311,665 MN
Total	1,311,665 MN

Sales in countries in scope



Sales by geographic region



Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
** See Appendix IV for definition.

Astellas Pharma Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 20 SCORE 1.82

Lacks overarching access-to-medicine strategy; responsibility for access lies at the executive level. Astellas does not have an overarching access-to-medicine strategy, but shows evidence of some activities guided by access-related goals. For example, it aims to discover, develop and provide innovative medicines for patients, supported by its goal to improve access to health.The highest level of responsibility for access sits with its Corporate Social Responsibility Committee, which reports to a board-level committee.

No evidence of access-related incentives for employees. Astellas does not disclose details of how it incentivises employees (financially and non-financially) to perform on access-related issues. It is one of only two companies which do not demonstrate evidence of such incentives.

One of 16 companies working on impact measurement. Astellas measures and monitors progress and outcomes of access-to-medicine activities, for example its Action on Fistula initiative. It also publicly reports on its commitments and performance information. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Astellas publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, or its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 12 SCORE 2.49

Does not report processes for ensuring third-party compliance with standards. Astellas has a code of conduct relating to ethical marketing and anti-corruption, that is aligned with WHO Guidelines. It provides compliance training for employees. The company performs relatively poorly when it comes to enforcing compliance measures and non-sales incentives. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, expected performance for sales agents is based solely on sales targets.

Internal control framework meets all Index criteria. Astellas has all the components looked for by the Index for an effective internal control framework to ensure compliance. Namely, it reports that it regularly conducts fraud-specific risk assessments. It also has a monitoring system in place to track compliance, it conducts audits involving both internal and external resources—which also apply to third parties. Astellas also demonstrates evidence of having procedures to segregate duties, so that decisions are checked by another party.

Below average transparency regarding access-related practices. Astellas publicly discloses its policy positions on access-related topics (e.g., its policy statement on access to healthcare, which includes its position on intellectual property). The company does not disclose political contributions in countries in scope. It publicly discloses its memberships of relevant organisations but does not disclose whether it provides financial support. It publicly discloses its position on Patient Organisation Engagement. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 11 SCORE 2.01

PROJECTS: 25 IN CLINICAL DEVELOPMENT: 19

Publicly commits to R&D to meet public health needs. Astellas has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Astellas has one of the smallest pipelines in the Index with 25 projects. For diseases in scope where priorities exist, Astellas is active in four projects; all four target priority R&D gaps.

Access provisions in place for 6% (1/17) of late-stage candidates. Astellas does not have a clear process in place to develop access plans during R&D. Instead, it considers access on a case-by-case basis. To date, Astellas has project-specific access provisions in place for one of its late-stage R&D projects. This project is being conducted in partnership as part of the Pediatric Praziquantel Consortium.

No policy for post-trial access. Astellas does not have a policy for ensuring post-trial access to treatments for clinical trial participants. Instead, it takes a case-by-case approach to post-trial access, mostly for participants on clinical trials for cancer products. Astellas does not disclose a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 19 SCORE 0.89

PRODUCTS: 18

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 0

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Astellas does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies.

No new products in scope filed for registration in the majority of priority countries. Astellas has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for HIV/AIDS and neonatal sepsis and infections, is registered in one out of 21 possible priority countries. It also does not publicly share the registration status for any of its products.

No products have equitable pricing strategies targeting priority countries. Astellas' overall performance is below average compared to peers in equitable pricing. The company does not demonstrate evidence of having equitable pricing strategies in place.

Globally consistent recall guidelines for countries in scope but no processes to track products. Astellas has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 14 SCORE 1.40

Publicly discloses detailed information on patent statuses. Like most of its peers, Astellas

publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Astellas does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Shares some IP assets with 3rd-party researchers. Compared to its peers, Astellas shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with neglected disease drug discovery initiatives, such as the Medicines for Malaria Venture (MMV) and the TB Alliance. The assets shared include molecule libraries and research data.

Public commitment not to enforce patents in countries in scope. Astellas commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

CAPACITY BUILDING

RANK 17 SCORE 0.85

Three initiatives included for evaluation. Astellas has three capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Astellas submitted 17.

Focused on enhancing local manufacturing. Astellas has initiatives which meet inclusion criteria in two areas of capacity building: manufacturing and health system strengthening. Most of its initiatives are in manufacturing, but it performs best in health system strengthening with its Action on Fistula initiative in Kenya.

One initiative meets most good practice standards. None of Astellas's included initiatives meet all the good practice standards looked for by the Index. Its health system strengthening initiative meets most standards, but falls short on ensuring good governance structures are in place.

Does not provide evidence of reporting substandard or falsified medicines to relevant authorities. Astellas has procedures for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

PRODUCT DONATIONS

RANK 16 SCORE 1.27

STRUCTURED DONATION PROGRAMMES: 0

Has a policy for responding to emergencies or humanitarian crises. While Astellas did not make such donations during the period of analysis, it has policies in place to respond directly to need, which are aligned with international guidelines. The company tracks the delivery of the product until received by end user.

No donation programmes covering diseases and countries in scope. Astellas does not have any structured donations programmes that were active during the period of analysis in any countries in scope.

BEST PRACTICES

Three companies incorporate framework of strict guidelines to reduce non-compliance.

GLOBAL

Astellas, GSK and Novartis stand out for their comprehensive internal control frameworks.

RANK	SCORE
20▼	1.27
17 (2016)	

Eli Lilly & Co.

Stock Exchange: New York Stock Exchange • Ticker: LLY • HQ: Indianapolis, Indiana, United States • Employees: 40,655

PERFORMANCE

Falls 3 places to 20th. Eli Lilly & Co.* falls across all Technical Areas, with weak performance, for example, in R&D, compounded by a comparative lack of public transparency in most areas of analysis.

Management: Falls 5 places to 14th. Despite public commitments associated with its 30x30 Program, it falls short on its public reporting of initiatives and discloses limited information about stakeholder engagement approaches.

Compliance: Falls 3 places to 15th. Compared to peers, it lacks a comprehensive ethical marketing code.

R&D: Falls 1 place to 19th. Eli Lilly falls to the lower ranks in R&D. It does not disclose access plans for any of its late-stage candidates.

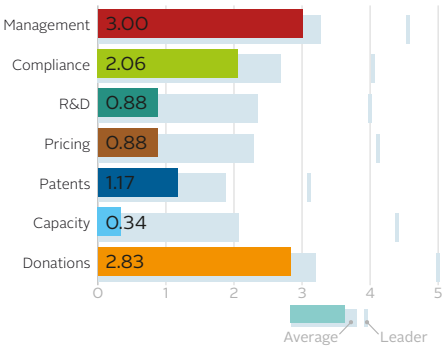
Pricing: Falls 3 places to 20th. Falls behind peers primarily due to a lack of data transparency and lack of public commitments to equitable pricing.

Patents: Falls 2 places to 17th. Despite new engagement in patent transparency via Pat-INFORMED, falls back against stronger performers in the sharing of intellectual property.

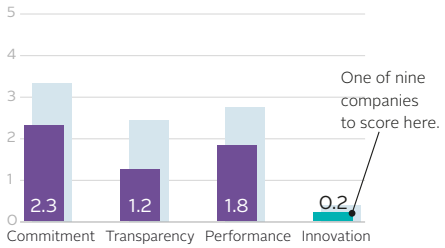
Capacity: Falls 5 places to 20th. Evidence of initiatives only found for health system strengthening, but not enough information was disclosed to show they meet all good practice standards.

Donations: Falls 1 to 12th. Engaged in a structured donation programme for cancer, but lacks evidence of long-term sustainability.

Performance by technical area



Performance by strategic pillar



CHANGE SINCE 2016

- Commits to improving global health with its new Lilly Global Health: 30x30 Program, with a goal to reach 30 million people in resource-limited settings annually by 2030.
- Joined Access Accelerated with is Lilly Global Health Partnership. It has also committed to measure impact and share results publicly via Access Observatory for one of its projects.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.

OPPORTUNITIES

Improve transparency around access activities, objectives and outcomes. For example, Eli Lilly can publicly disclose measurable goals and key milestones for its newly announced 30x30 Program. Alongside this, the company can implement plans to measure the impact of this initiative, reporting on the results (whether positive or negative).

Develop access plans for key marketed products. Eli Lilly does not report having access plans in place for its cancer product vinblastine (Velban®/Velsar®), an off-patent first-line product on the 2017 WHO Model List of Essential Medicines (WHO EML) for the treatment of Kaposi sarcoma, Hodgkin lymphoma, and testicular cancer. Countries in scope shoulder a large proportion of the burden of Kaposi's sarcoma. To alleviate this burden, equitable pricing strategies could be applied to priority countries such as Bangladesh, Brazil, China, Egypt, India, Malawi and Nigeria. Similarly, human insulin [rDNA origin] (Humulin®) for diabetes mellitus is an on-patent first-line product on the WHO EML with no reported access plans. The company could provide equitable pricing strategies for the product in priority countries including, Brazil, China, Dem. Rep.Congo, Ethiopia, India, Indonesia, Mexico, Tanzania and Uganda.

Establish access plans for more late-stage projects. Eli Lilly can establish access plans for projects across its pipeline, particularly those that are in late-stage development, including its nasal glucagon project for severe hypoglycaemia and DACRA-042, a novel oral medication for diabetes mellitus.

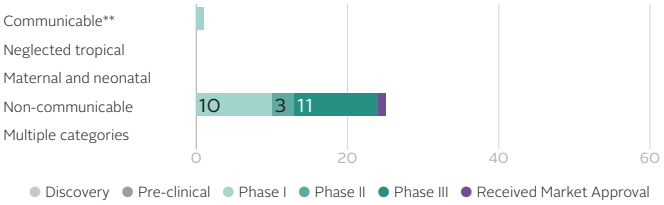
Review sales incentive structures. Eli Lilly can improve its commitment to ensure responsible sales practices by decoupling sales incentives from sales targets.

*All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. In 2018, Eli Lilly & Co. declined to submit data to the Access to Medicine Index.

PIPELINE *for diseases and countries in scope*

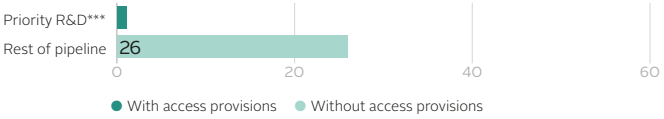
Comparatively small pipeline: 27 R&D projects for diseases in scope (26 medicines; 1 platform technology).
Clinical candidates: 26, including lasmiditan for the treatment of acute migraine and a novel inhibitor for the treatment of tuberculosis.
Regulatory approvals: 1, abemaciclib (Verzenio™) for the treatment of HR+, HER2- metastatic breast cancer in combination with aromatase inhibitors.
R&D focus: non-communicable diseases (cancer and diabetes mellitus).
Access provisions: for 1 project, with provisions incorporated in partnership with the TB Alliance.

Projects in the pipeline: 27*



Eli Lilly's relevant pipeline is mainly split between cancer and diabetes mellitus projects. Its pipeline includes one of only seven platform technology projects in the collective pipeline: an automated insulin delivery (AID) system.

Projects for R&D priority targets with access provisions: 1

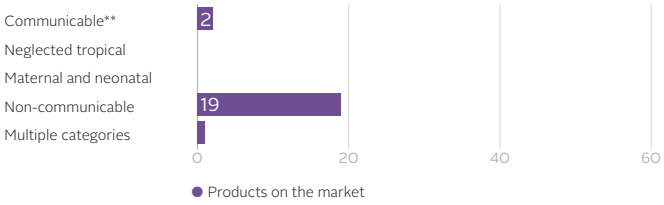


Of Eli Lilly's 27 R&D projects, one is supported by access provisions: e.g., a Phase I candidate for the treatment of tuberculosis developed with the TB Alliance involves equitable pricing and supply strategies. None of its 15 late-stage projects have provisions.

PORTFOLIO *for diseases and countries in scope*

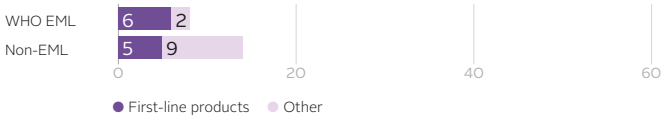
Comparatively small portfolio: 22 products (all medicines) for diseases in scope.
Portfolio focus: non-communicable diseases (diabetes mellitus and cancer).
Essential medicines: 36% of Eli Lilly's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 50% of Eli Lilly's medicines have first-line indications for diseases in scope.

Products on the market: 22



Eli Lilly's portfolio includes products such as glucagon (GlucaGen®) for the treatment of severe hypoglycemia and several oral agents for the treatment of type 2 diabetes mellitus.

Essential medicines with first-line indications: 6



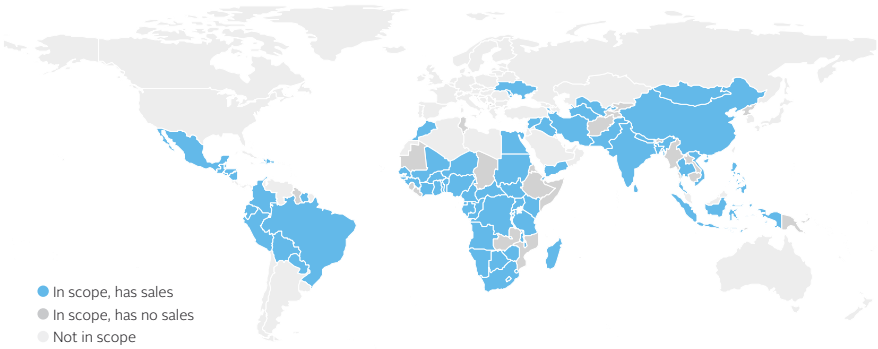
59% of Eli Lilly's medicines are listed on the WHO EML and/or as first-line treatments: e.g., intravenous/oral vancomycin (Vancocin®) and the insulin glargine biosimilar Basaglar®.

Two business units: Human Pharmaceutical Products and Animal Health (Elanco). Its Human Pharmaceutical segment has five therapeutic areas (endocrinology; neuroscience; oncology; cardiovascular diseases; and immunology). Its prescription pharmaceutical business has two therapeutic areas (neurology; and oncology).
M&A news: 2017 acquisition of CoLucid, specialising in pain management for migraines. 2018 acquisition of ARMO BioSciences and AurKa Pharma, both focused on therapies for cancer.
Presence in emerging markets: In 2016, Eli Lilly reported sales in 72 countries in scope. Data for 2018 not available.

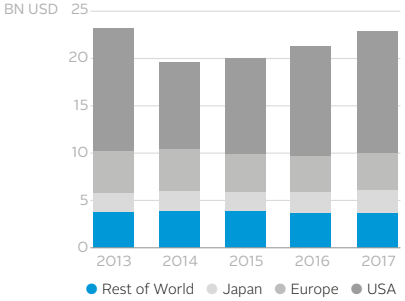
Revenue by segment (2017) - USD

Human pharmaceutical products	19,785 MN
Animal health products	3,085 MN
Total	22,871 MN

Sales in countries in scope



Revenue by geographic region



Statistics relate only to diseases and countries in scope.

* Figure excludes one project that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
***See Appendix IV for definition.

Eli Lilly & Co.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 14 SCORE 3.00

Has a strong access-to-medicine strategy with executive-level responsibility. Eli Lilly is one of the 14 companies that performs strongly with regard to its access-to-medicine strategy, which aligns with its corporate strategies and includes access-related goals. The strategy currently centres around its Lilly 30x30 Program, aimed at delivering access to quality healthcare for 30 million people in resource-limited settings by 2030. The highest level of responsibility for access sits with an executive committee member.

Financial and non-financial access-related incentives to reward employees. Eli Lilly performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include compensation rewards, and its Access Excellence Awards recognising individual contributions.

One of 16 companies working on impact measurement. Eli Lilly measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments. For example, for its Lilly Expanding Access for People (LEAP) programme in China, the company reports committing to address local realities and medical needs, to help populations lacking effective access to healthcare. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Limited transparency about stakeholder engagement. Eli Lilly performs relatively poorly when it comes to the disclosure of its stakeholder engagement. It publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. Neither does it report incorporating local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 15 SCORE 2.06

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Eli Lilly has the Red Book Code of Business Conduct for governing business ethics. The company provides compliance training for employees on an annual basis. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Eli Lilly's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place and maintains an ethics and compliance monitoring programme. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of procedures to segregate duties, to ensure decisions are checked by another party.

Below average transparency regarding access-related practices. Eli Lilly publicly discloses its policy positions on access-related topics (e.g., its position on intellectual property and trade policy). It is one of the few companies in scope to have a policy that prohibits political financial contributions. The company discloses its membership of relevant organisations but not whether it provides financial support. It does not publicly disclose its policies for responsible engagement, nor its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 19 SCORE 0.88

PROJECTS: 27 IN CLINICAL DEVELOPMENT: 26

Publicly commits to R&D to meet public health needs. Eli Lilly has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on an internal review of needs unique to these countries. It does not report time-bound strategies for completing R&D projects for diseases in scope. Eli Lilly has one of the smallest pipelines in the Index with 27 projects. For diseases in scope where priorities exist, Eli Lilly is active in one project, which targets a priority R&D gap for tuberculosis.

No access provisions; process in place for setting them. Eli Lilly has a general process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for malaria and tuberculosis that are developed in collaboration. Eli Lilly has not disclosed project-specific access provisions for any of its 15 late-stage R&D projects.

Public policy to ensure post-trial access; commits to registering trialed products. Eli Lilly has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Eli Lilly commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 20 SCORE 0.88

PRODUCTS: 22

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 3

Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope. Eli Lilly does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

No new products in scope filed for registration in the majority of priority countries. Eli Lilly has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for diabetes mellitus, is registered in three out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

14% of products have equitable pricing strategies targeting priority countries. Eli Lilly's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 14% of its products for diseases in scope. These strategies apply to an average of 19% of priority countries. None of the strategies take into account any socioeconomic factors.

Globally consistent recall guidelines for countries in scope but no processes to track products. Eli Lilly has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 17 SCORE 1.17

Publicly discloses detailed information on patent statuses. Like most of its peers, Eli Lilly publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

No use of non-assert or licensing arrangements. Eli Lilly does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. Eli Lilly reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi) and the Medicines for Malaria Venture (MMV). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Public commitment not to enforce patents in countries in scope. Eli Lilly commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries.

CAPACITY BUILDING

RANK 20 SCORE 0.34

Two initiatives included for evaluation. Eli Lilly has two capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment. Eli Lilly's initiatives were identified for selection based on publicly available information.

Two initiatives aimed at strengthening health systems. Eli Lilly has two initiatives which meet inclusion criteria in health system strengthening: the Lilly MDR-TB Partnership and their partnership with AMPATH. It does not publicly disclose initiatives which meet inclusion criteria for any other areas of capacity building.

Limited publicly available data on initiatives. None of Eli Lilly's included initiatives meet all the good practice standards looked for by the Index. The company reported no information to the Index about its health system strengthening initiatives, and publicly available information is limited.

Does not provide evidence of reporting substandard or falsified medicines to relevant authorities. Eli Lilly has mechanisms in place for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

PRODUCT DONATIONS

RANK 12 SCORE 2.83

STRUCTURED DONATION PROGRAMMES: 3

Responds to emergencies and humanitarian crises and tracks delivery. Eli Lilly donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to the 2017 Mexico earthquake. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with American Red Cross and United Way Worldwide to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Eli Lilly's programmes are focused on non-communicable diseases. All three programmes are carried out in partnership with partners including the International Diabetes Foundation and numerous universities. Its Life for a Child programme for type 1 diabetes mellitus supplies the insulin product lispro (Humalog®) in 23 countries and has been ongoing since 2009. As of 2017, the company reports that 1.4 million vials of insulin were donated.

No transition plans in place. Eli Lilly does not provide evidence that it considers longer-term access to donated products, once a programme ends through, for example transition planning.

INNOVATIVE PRACTICES

Lilly Expanding Access for People (LEAP) builds capacity in diabetes care.

CHINA

Training for primary care physicians in China to increase their confidence and skills in managing diabetes across all stages of the disease.

Appendices

APPENDIX I

Company scope

The Index assesses 20 of the world's largest research-based pharmaceutical companies on their policies and practices to improve access to medicine for people living in low- and middle-income countries. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine. The 2018 Index measures the same 20 companies included in the 2016 Index, facilitating trend analysis and comparability between Indices. The Index has measured these companies for 12 years, meaning their performance can be tracked over time. Pharmaceutical companies that exclusively produce generic medicines remain excluded from the Index in 2018. The Access to Medicine Foundation recognises that these companies play a significant role in access to medicine, particularly in low- and middle-income countries. Generic medicines marketed by the 20 research-based companies or any of their generic medicine subsidiaries in which they have more than 50% ownership are included.

Table 1. Companies in scope of the 2018 Access to Medicine Index

Company	Ticker	Stock Exchange	Bloomberg	Reuters	Country	MarketCap* (billion USD)	Revenue** (billion USD)
AbbVie	ABBV	New York Stock Exchange	ABBV US	ABBV.N	USA	101.76	25.64
Astellas Pharma	4,503.00	Tokyo Stock Exchange	4503 JT	4503.T	JPN	29.98	12.15
AstraZeneca	AZN	London Stock Exchange	AZN LN	AZN.L	GBR	69.30	23.00
Bayer	BAYN	Frankfurt Stock Exchange	BAYN GY	BAYGn.DE	DEU	86.46	46.77
Boehringer Ingelheim	n.a.	n.a.	n.a.	n/a	DEU	n/a	15.85
Bristol-Myers Squibb	BMY	New York Stock Exchange	BMY US	BMY.N	USA	97.67	19.43
Daiichi Sankyo	4,568.00	Tokyo Stock Exchange	4568 JT	4568.T	JPN	14.54	986.64
Eisai	4,523.00	Tokyo Stock Exchange	4523 JT	4523.T	JPN	17.06	539.10
Eli Lilly and Company	LLY	New York Stock Exchange	LLY US	LLY.N	USA	81.20	21.22
Gilead Sciences	GILD	NASDAQ	GILD US	GILD.O	USA	94.34	30.39
GlaxoSmithKline	GSK	London Stock Exchange	GSK LN	GSK.L	GBR	94.68	27.89
Jonhnson & Johnson	JNJ	New York Stock Exchange	JNJ US	JNJ.N	USA	313.43	71.89
Merck & Co.	MRK	New York Stock Exchange	MRK US	MRK.N	USA	162.31	39.81
Merck KGaA	MRK	Frankfurt Stock Exchange	MRK GY	MRCG.DE	DEU	45.47	15.02
Novartis	NOVN	SIX Swiss Exchange	NOVN VX	NOVN.VX	CHE	191.38	48.52
Novo Nordisk	NOVO B	Copenhagen Stock Exchange	NOVOB DC	NOVOb.CO	DNK	92.13	111.78
Pfizer	PFE	New York Stock Exchange	PFE US	PFE.N	USA	197.10	52.82
Roche	ROG	SIX Swiss Exchange	ROG VX	ROG.VX	CHE	198.09	50.58
Sanofi	SAN	EURONEXT Paris	SAN FP	SASY.PA	FRA	104.70	33.82
Takeda Pharmaceutical Co.	4,502.00	Tokyo Stock Exchange	4502 JT	4502.T	JPN	32.76	1,732.05

*Source: Bloomberg terminal
**Exchange rate 31 Dec 2016 vs USD, from oanda.com

APPENDIX II

Disease scope

Diseases are included based on their global burden of disability-adjusted life years (DALYs)[1], other WHO classifications and the relevance of pharmaceutical interventions. Index diseases are defined according to the WHO International Classification of Diseases, 10th Revision (ICD-10) codes. The disease scope for the 2018 Index has expanded from 51 to 77 diseases, conditions and pathogens. Cancer is now in scope (see Appendix III). 12 pathogens have been brought into the disease scope for the 2018 Index R&D analysis. These have been identified by the WHO priority pathogens list. Pathogens on this list are deemed by WHO as priority R&D targets for new and effective antibiotics active against the pathogens themselves and the diseases they cause. This WHO priority pathogens list does not define specific products needed. R&D projects targeting these pathogens are grouped under 'Other prioritised antibiotic-bacterial infections' in figures and tables. See Appendix IV for the full list of priority pathogens. DALY burden and mortality data was collected from WHO's 2015 Global Health Estimates (GHE).

Table 2. Diseases, conditions and pathogens in scope of the 2018 Access to Medicine Index

NON-COMMUNICABLE DISEASES (14)	TOTAL DALYS (LICS & MICS)
Anxiety disorders	17,637,255.00
Asthma	22,489,628.00
Bipolar affective disorder	6,542,313.00
Cancer	DALY not applicable
Chronic obstructive pulmonary disease (COPD)	59,841,914.00
Diabetes mellitus	53,660,514.00
Epilepsy	12,610,507.00
Hypertensive heart disease	17,053,619.00
Ischaemic heart disease	137,803,915.00
Kidney diseases	30,361,404.00
Migraine	19,608,650.00
Schizophrenia	11,707,269.00
Stroke	113,999,836.00
Unipolar depressive disorders	40,359,896.00

COMMUNICABLE DISEASES* (21)	TOTAL DALYS (LICS & MICS)
Arenaviral haemorrhagic fevers (including Lassa fever)	N/A
Coronaviruses (including MERS-CoV and SARS-CoV)	N/A
Crimean-Congo haemorrhagic fever (CCHF)	N/A
Diarrhoeal diseases	83,764,595
Filoviral diseases (Ebola and Marburg)	N/A
Henipaviral diseases (including Nipah virus)	N/A
HIV/AIDS	59,213,043
Leptospirosis	N/A
Lower respiratory infections	131,150,237
Malaria	38,491,119
Measles	12,264,045
Meningitis**	22,781,461
Other prioritised antibiotic-resistant bacterial infections	N/A
Pertussis	5,950,007
Rheumatic fever	N/A
Rift Valley fever (RVF)	N/A
Severe fever with thrombocytopenia syndrome (SFTS)	N/A
Sexually transmitted infections (STIs)***	10,092,695
Tetanus	4,662,932
Tuberculosis	54,332,361
Viral hepatitis (B and C)†	24,703,328
Zika	N/A

NEGLECTED TROPICAL DISEASES (20)	TOTAL DALYS (LICS & MICS)
Buruli ulcer	DALY not available in GHE 2016
Chagas disease	191,781.00
Dengue and chikungunya	2,575,517.00
Dracunculiasis	DALY not available in GHE 2018
Echinococcosis	607,742.00
Food-borne trematodiases	DALY not available in GHE 2015
Human African trypanosomiasis	371,657.00
Leishmaniasis	1,346,249.00
Leprosy	484,820.00
Lymphatic filariasis	2,069,423.00
Mycetoma, chromoblastomycosis and other deep mycoses	DALY not available in GHE 2019
Onchocerciasis	1,135,571.00
Rabies	1,654,232.00
Scabies and other ectoparasites	DALY not available in GHE 2020
Schistosomiasis	3,478,062.00
Snakebite envenoming	DALY not available in GHE 2021
Soil transmitted helminthiasis	4,179,035.00
Taeniasis/cysticercosis	1,846,098.00
Trachoma	275,741.00
Yaws	DALY not available in GHE 2017

MATERNAL AND NEONATAL HEALTH CONDITIONS (10)	TOTAL MORTALITY (LICS & MICS)
Abortion	30,886
Birth asphyxia and birth trauma	726,826
Contraceptive methods	Mortality not applicable
Hypertensive disorders of pregnancy	46,270
Maternal haemorrhage	82,447
Maternal sepsis	17,399
Neonatal sepsis and infections	342,069
Obstructed labour	23,020
Other neonatal conditions	208,149
Preterm birth complications	768,639

Green text = newly in scope for the 2018 Index
Exclusions: none in 2018

* The 11 communicable diseases with the highest DALY burdens in countries in scope of the 2018 Index, plus 10 further diseases and 12 pathogens (grouped under 'other prioritised antibiotic-resistant bacterial infections') that have been identified as R&D priorities. Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
** Projects targeting cryptococcal meningitis are included for the analysis of specified R&D priorities.
*** Includes chlamydia, genital herpes, gonorrhoea, syphilis and trichomoniasis.
† Includes acute hepatitis (B and C) and cirrhosis caused by hepatitis (B and C).

REFERENCE

1 World Health Organization. Global Health Estimates 2015: Disease burden by Cause, Age, Sex, by Country and by Region, 2000-2015. 2016. http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html

APPENDIX III

Cancers in scope

Cancer is included in the Index disease scope for the first time in 2018. Cancer types have been selected for the Index disease scope using two approaches: (a) cancer types based on high incidence both globally and in countries in the scope of the Index, with incidence being seen as an indication of where further R&D needs to be incentivised; and (b) cancer types based on the products registered on the 2017 WHO Model List of Essential Medicines (WHO EML).[1]

There are 27 cancer types in scope: 17 cancers with high disease burdens are in scope for R&D, while 19 cancers with relevant products on the WHO EML are in scope for the Technical Areas relating to pricing, patenting and donations. Nine cancers are in both sets.

Defining the cancer scope for the R&D Technical Area

The 2018 Access to Medicine Index examines 17 cancer types in the R&D Technical Area (see table 3). These cancers have been brought into scope for having either the highest burden by incidence globally, or the highest incidence and/or percentage of global burden in countries in scope of the Index, based on data from GLOBOCAN (2012). Which R&D projects will be analysed will depend on their clinical trial stage. Projects that target any cancer types up to and including those in Phase I clinical trials will be included. For Phase II projects and onwards, projects will only be included if they target one of the 17 prioritised cancer types.

Defining the cancer scope for analysis of product deployment

The 2018 Access to Medicine Index measures pharmaceutical companies' efforts to address availability and affordability during product deployment, as covered in the Pricing, Manufacturing & Distribution, Patents & Licensing and Product Donations Technical Areas. The scope of analysis in these Technical Areas includes 19 cancer types with relevant registered products on the WHO EML and the 2017 WHO Model List of Essential Medicines for Children (WHO EMLc) as shown in table 4 (50 products). As in the methodology for the 2016 Index, products for the management of pain and supportive treatments (e.g. anti-emetics) will not be included.

Table 3. Cancer types in scope and basis for inclusion for the R&D Technical Area

There are three criteria for including cancer types in the 2018 Index R&D analysis. Each cancer type had to meet one or more criteria to qualify. The table shows the 17 cancer types included, indicates which criteria they met and provides the corresponding data.

	Inclusion criteria		
Cancer types in scope (17)	Ten cancer types with: Highest global incidence rates	Ten cancer types with: Highest incidence in countries in scope	Ten cancer types where: Countries in scope account for highest % of global incidence
Bladder	429,793		
Brain, nervous system			59%
Breast	1,671,149	776,202	
Cervical	527,624	419,829	80%
Colorectal	1,360,602	528,152	
Gallbladder			57%
Head and neck: Lip, oral cavity		185,884	62%
Head and neck: Nasopharynx			83%
Head and neck: Other pharynx			59%
Kaposi sarcoma			90%
Leukaemia		190,975	
Liver	782,451	606,369	77%
Lung	1,824,701	974,521	
Lymphoma: Non-Hodgkin lymphoma	385,741		
Oesophageal	455,784	355,421	78%
Prostate	1,094,916	279,388	
Stomach	951,594	617,516	65%

Table 4. Cancer types in scope and basis for inclusion for product deployment analyses

ATMI cancer type	Indication as described on WHO EML/EMLc	WHO EML*	WHO EMLc**	Number of medicines on WHO EML	Products on WHO EML/EMLc
Breast	Early-stage breast cancer	●		10	carboplatin, cyclophosphamide, docetaxel, doxorubicin, fluorouracil, methotrexate, paclitaxel, anastrozole☐, leuprorelin☐, tamoxifen
	Early-stage HER2 positive breast cancer	●		1	trastuzumab
	Metastatic breast cancer	●		8	capecitabine, cyclophosphamide, docetaxel, doxorubicin, paclitaxel, vinorelbine, anastrozole☐, tamoxifen
	Metastatic HER2 positive breast cancer	●		1	trastuzumab
Cervical	Cervical cancer	●	●	2	cisplatin***, HPV vaccine†
Colorectal	Early-stage colon cancer	●		4	calcium folinate, capecitabine, fluorouracil, oxaliplatin
	Early-stage rectal cancer	●		3	calcium folinate, capecitabine, fluorouracil
	Metastatic colorectal cancer	●		5	calcium folinate, capecitabine, fluorouracil, irinotecan, oxaliplatin
Gastrointestinal stromal tumour‡	Gastrointestinal stromal tumour	●		1	imatinib
General ‡	Refer to EML/EMLc for information on specification			4	allopurinol, filgrastim, procarbazine, zoledronic acid§
Gestational neoplasia‡	Gestational trophoblastic neoplasia	●		6	calcium folinate, cyclophosphamide, dactinomycin, etoposide, methotrexate, vincristine
Head and neck: Nasopharynx	Nasopharyngeal cancer	●		4	carboplatin, cisplatin***, fluorouracil, paclitaxel
Head and neck: other‡	Head and neck cancer	●		1	cisplatin***
Kaposi sarcoma	Kaposi sarcoma	●		5	bleomycin, doxorubicin, paclitaxel, vinblastine, vincristine
Kidney	Wilms tumour	●	●	3	dactinomycin, doxorubicin, vincristine
Leukaemia	Acute lymphoblastic leukaemia	●	●	14	asparaginase, cyclophosphamide, cytarabine, daunorubicin, doxorubicin, etoposide, mercaptopurine, methotrexate, tioguanine, vincristine, dexamethasone, hydrocortisone, methylprednisolone, prednisolone☐
	Acute myelogenous leukaemia	●		2	cytarabine, daunorubicin
	Acute promyelocytic leukaemia	●		5	all-trans retinoic acid, cytarabine, daunorubicin, mercaptopurine, methotrexate
	Chronic lymphocytic leukaemia	●		6	bendamustine, chlorambucil, cyclophosphamide, fludarabine, rituximab, prednisolone☐
	Chronic myeloid leukaemia	●		4	dasatinib||, hydroxycarbamide, imatinib, nilotinib||
Lung	Non-small cell lung cancer	●		6	carboplatin, cisplatin, etoposide, gemcitabine, paclitaxel, vinorelbine
Lymphoma: Hodgkin lymphoma	Hodgkin lymphoma	●	●	8	bleomycin¶, cyclophosphamide, dacarbazine¶, doxorubicin¶, etoposide, vinblastine¶, vincristine, prednisolone
Lymphoma: Non-Hodgkin lymphoma	Burkitt lymphoma	●	●	7	calcium folinate, cyclophosphamide, cytarabine, doxorubicin, etoposide, vincristine, prednisolone☐
	Diffuse large B-cell lymphoma	●		5	cyclophosphamide, doxorubicin, rituximab, vincristine, prednisolone☐
	Follicular lymphoma	●		6	bendamustine, cyclophosphamide, doxorubicin, rituximab, vincristine, prednisolone☐
Ovarian	Epithelial ovarian cancer	●		3	carboplatin, gemcitabine, paclitaxel
	Ovarian germ cell tumours	●	●	7	bleomycin, cisplatin, etoposide, ifosfamide, mesna, paclitaxel, vinblastine
Prostate	Metastatic prostate cancer	●		3	docetaxel, bicalutamide☐, leuprorelin☐
Testicular	Testicular germ cell tumours	●	●	6	bleomycin, cisplatin, etoposide, ifosfamide, mesna, vinblastine
Retinoblastoma‡	Retinoblastoma	●	●	3	carboplatin, etoposide, vincristine
Sarcomas‡	Ewing sarcoma, osteosarcoma and rhabdomyosarcoma	●	●	11	calcium folinate, carboplatin, displatin, cyclophosphamide, dactinomycin, doxorubicin, etoposide, ifosfamide, mesna , methotrexate, vincristine

Data and cancer type nomenclature follows GLOBOCAN 2012, with the exception of those marked ‡. Data is missing from this set for Kiribati, Kosovo, Sau Tomé And Principe, Tonga and Tuvalu.
Regarding cancer, product deployment analyses will only look at relevant products on the 2017 WHO Model List of Essential Medicines (WHO EML) or on the 2017 WHO EML for Children (WHO EMLc). Product Deployment analyses cover the Technical Areas of Pricing, Manufacturing & Distribution, Patents & Licensing and Product Donations. For products for other diseases in scope, this restriction does not apply.

The list uses the data and nomenclature by GLOBOCAN 2012 for naming the cancer types. Exceptions to this are marked with ‡.

☐ Square box: The WHO EML incorporates square box symbols (☐) to indicate similar clinical performance within a pharmacological class. A medicine which is not specifically mentioned on the WHO EML but is part of same class for the same indication as a listed squarebox market medicine, will be evaluated as if on the WHO EML
* WHO EML: 2017 WHO Model List of Essential Medicines
** WHO EMLc: 2017 WHO Model List of Essential Medicines for Children
*** Indicated as a radio-sensitiser in adults only
† For the prevention of cervical cancer
‡ Exceptions to the data and nomenclature by GLOBOCAN 2012. Listed on the WHO EML.
§ Malignancy-related bone disease
|| Indicated for imatinib-resistant chronic myeloid leukaemia
¶ Indicated for Hodgkin lymphoma in adults only

REFERENCE

1 WHO. WHO updates Essential Medicines List with new advice on use of antibiotics, and adds medicines for hepatitis C, HIV, tuberculosis and cancer [Internet]. WHO. World Health Organization; 2017. Available from: http://www.who.int/mediacentre/news/releases/2017/essential-medicines-list/en/ [accessed August 07 2017].

APPENDIX IV

R&D priorities

Table 5. Priority diseases and pathogens analysed in the Research & Development Technical Area.

The 2018 Access to Medicine Index has placed further emphasis on R&D for projects that address specific priority product gaps. The table below provides an overview of the criteria and priority lists used to identify diseases with R&D priority gaps. The diseases in scope for R&D include 45 (out of 77) diseases with an identified priority product gap.
Some diseases are included in more than one priority list. Pathogens have been brought into the disease scope for the 2018 Index for the first time.

Diseases, conditions and pathogens	Specific disease target	Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (for reproductive health only)	Policy Cures Research G-FINDER neglected diseases	Policy Cures G-FINDER reproductive health areas	WHO R&D Blueprint	WHO Initiative for Vaccine Research gaps	WHO Pathogen Priority List	Also analysed in other TAs
Arenaviral haemorrhagic fevers	Lassa fever	●	●	●	●						●			
Buruli ulcer		●	●		●				●					●
Chagas disease		●	●	●	●		●		●					●
Coronaviruses (including MERS-CoV and SARS-CoV)		●	●	●	●		●				●			
Contraceptive methods	Reproductive health products1	●						●		●				●
Crimean-Congo haemorrhagic fever (CCHF)		●	●	●	●		●				●			
Dengue		●	●		●		●		●			●		●
Diarrhoeal diseases	Cholera	●	●		●				●					●
	Cryptosporidiosis	●	●		●				●					●
	Enterotoxigenic *E. coli* (ETEC)		●		●				●					●
	Giardiasis (lambliasis)				●				●					●
	Shigellosis	●	●		●				●					●
	Rotaviral gastroenteritis		●						●					●
	Enteroaggregative *E. coli* (EAggEC)		●		●				●					●
	Typhoid and paratyphoid fever (*S. typhi*, *S. paratyphi* A)	●	●		●				●					●
	Non-typhoidal *S. enterica* (NTS)	●	●		●				●					
Filoviral diseases	Ebola	●	●	●	●						●			
	Marburg	●	●	●	●						●			
Henipaviral diseases	Nipah	●	●	●	●						●			
HIV/AIDS		●	●	●	●	●			●			●		●
Human African trypanosomiasis		●	●		●		●		●					●
Leishmaniasis		●	●	●	●				●					●
Leprosy		●			●				●					●
Leptospirosis					●				●					
Lower respiratory infections	*S. pneumonia*		●		●				●					●
	Influenza		●									●		●
	Respiratory syncytial virus (RSV)		●									●		●
Lymphatic filariasis		●			●		●		●					●
Malaria		●	●		●		●		●			●		●
Maternal haemorrhage	Postpartum haemorrhage	●								●				●
Maternal sepsis	Group B *Streptococcus*		●									●		●
Meningitis	*N. meningitidis*		●		●				●			●		●
	S. pneumoniae		●		●				●					●
	Cryptococcal meningitis	●							●					
Onchocerciasis		●	●		●		●		●					●
Rheumatic fever			●						●					
Rift Valley fever (RVF)		●	●	●	●		●				●			
Schistosomiasis		●	●		●		●		●					●
Severe fever with thrombocytopenia syndrome (SFTS)		●	●	●	●		●				●			
Sexually transmitted infections (STIs)	Syphilis (incl. congenital syphilis)	●						●		●				●
Soil-transmitted helminthiasis	Hookworm diseases	●	●						●					●
	Strongyloidiasis	●	●		●				●					●
	Trichuriasis	●							●					●
	Ascariasis	●							●					●
Taeniasis/cysticercosis		●					●		●					●
Trachoma			●		●				●					●
Tuberculosis		●	●	●	●				●			●		●
Viral hepatitis (B and C)	Hepatitis C (genotypes 4-6)	●	●		●				●					●
Zika		●	●	●	●		●				●	●		

● Gap identified

Definition: High-priority product gap identified for the disease, condition or pathogen on one or more of the R&D Priority Lists.

● Specific gap

Definition: Specific product gap identified, e.g., for a new route of administration to be developed, or serotypes to be targeted.

Table 6. Priority pathogens

12 pathogens have been brought into the disease scope for the 2018 Index R&D analysis. These have been identified by the WHO pathogen priority list. Pathogens on this list are deemed by WHO as priority R&D targets for new and effective antibiotics active against the pathogens themselves and the diseases they cause. This WHO pathogen priority list does not define specific products needed.

Pathogens	Policy Cures Research G-FINDER neglected diseases	Policy Cures G-FINDER reproductive health areas	WHO R&D Blueprint	WHO Initiative for Vaccine Research gaps	WHO Pathogen Priority List	Also analysed in other TAs
Acinetobacter baumannii (carbapenem-resistant)					●	
Campylobacter (fluoroquinolone-resistant)					●	
Enterobacteriaceae (carbapenem-resistant, 3rd generation cephalosporin-resistant)	●				●	●
Enterococcus faecium (vancomycin-resistant)					●	
Haemophilus influenzae (ampicillin-resistant)					●	●
Helicobacter pylori (clarithromycin-resistant)					●	
Neisseria gonorrhoeae (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)					●	●
Pseudomonas aeruginosa (carbapenem-resistant)					●	
Salmonella (spp., fluoroquinolone-resistant)	●				●	●
Shigella (spp., fluoroquinolone-resistant)	●				●	●
Staphylococcus aureus (methicillin-resistant, vancomycin intermediate and resistant)					●	
Streptococcus pneumoniae (penicillin-non-susceptible)	●				●	●

● Gap identified

Definition: High-priority product gap identified for the disease, condition or pathogen on one or more of the R&D Priority Lists.

● Specific gap

Definition: Specific product gap identified, e.g., for a new route of administration to be developed, or serotypes to be targeted.

General notes

In addition to the above diseases and specific targets, the priority lists also include non-specific diseases (multiple or other) which are not further defined.

In some cases of duplicates (an R&D gap has been identified on more than one list) one list may define specific restriction for this gap. The ATMI will consider projects targeting either the general gap or restricted gap equally.

APPENDIX V

Countries in scope

The geographic scope for the 2018 Access to Medicine Index comprises 106 countries. All countries defined by the World Bank as low income or lower middle-income are included.[1] All countries defined by the UNDP as either low or medium human development are included.[2] This ensures that several central measures of human development (life expectancy, education, and standard of living) are taken into account. All countries that receive a score of less than 0.6 on the UN Inequality-Adjusted Human Development Index are included.[2] This measure takes account of how health, education and income are distributed within each country. Finally, all Least Developed Countries (LDCs), as defined by the Committee for Development Policy of the UN Economic and Social Council (ECOSOC), are included.[3]

Table 7. Countries in scope of the 2018 Access to Medicine Index

Country	*Classification*
EAST ASIA & PACIFIC	
Cambodia	LMIC
China	HiHDI
Indonesia	LMIC
Kiribati	LMIC
Korea, Dem. People's Rep.	LIC
Lao PDR	LMIC
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LMIC
Papua New Guinea	LMIC
Philippines	LMIC
Samoa	LMIC
Solomon Islands	LMIC
Timor-Leste	LMIC
Thailand	HiHDI
■ Tonga	LMIC
Tuvalu	LDC
Vanuatu	LMIC
Vietnam	LMIC
EUROPE & CENTRAL ASIA	
Armenia	LMIC
Kosovo	LMIC
Kyrgyz Republic	LMIC
Moldova	LMIC
Tajikistan	LMIC
Turkmenistan	MHDC
Ukraine	LMIC
Uzbekistan	LMIC
LATIN AMERICA & CARIBBEAN	
Belize	HiHDI
Bolivia	LMIC
Brazil	HiHDI
Colombia	HiHDI
Dominican Republic	HiHDI
Ecuador	HiHDI
El Salvador	LMIC
Guatemala	LMIC
Guyana	MHDC
Haiti	LIC
Honduras	LMIC
Mexico	HiHDI
Nicaragua	LMIC
Paraguay	MHDC
Peru	HiHDI
Suriname	HiHDI
MIDDLE EAST & NORTH AFRICA	
Djibouti	LMIC
Egypt, Arab Rep.	LMIC
Iran	HiHDI
Iraq	MHDC
Morocco	LMIC
Palestine, State of/West Bank Gaza	LMIC
Syrian Arab Republic	LMIC
■ Tunisia	LMIC
Yemen, Rep.	LMIC
SOUTH ASIA	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
India	LMIC
Maldives	HiHDI
Nepal	LIC
Pakistan	LMIC
Sri Lanka	LMIC
SUB-SAHARAN AFRICA	
Angola	LHDC
Benin	LIC
Botswana	MHDC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cameroon	LMIC
Central African Republic	LIC
Chad	LIC
Comoros	LIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	MHDC
Eritrea	LIC
Ethiopia	LIC
Gabon	MHDC
Gambia, The	LIC
Ghana	LMIC
Guinea	LIC
Guinea-Bissau	LIC
Kenya	LMIC
Lesotho	LMIC
Liberia	LIC
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
Mozambique	LIC
Namibia	MHDC
Niger	LIC
Nigeria	LMIC
Rwanda	LIC
São Tomé and Principe	LMIC
Senegal	LIC
Sierra Leone	LIC
Somalia	LIC
South Africa	MHDC
South Sudan	LIC
Sudan	LMIC
Swaziland	LMIC
Tanzania	LIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LIC

■ New inclusion

New inclusions: Tonga & Tunisia (LMICs)
Exclusions: Jamaica (HiHDI >0.6), Panama (HiHDI >0.6), & Georgia (UMIC)

CLASSIFICATION KEY

	Key	Data Source
LIC	Low-income country	World Bank
LMIC	Lower middle-income country	World Bank
LDC	Least Developed Country	ECOSOC (UN Economic and Social Council)
LHDC	Low Human Development	Country UNDP- UN Human Development Index (HDI)
MHDC	Medium Human Development Country	UNDP- UN Human Development Index (HDI)
HiHDI	High Human Development	
	Country with high inequality	UNDP- UN Human Development Index (HDI)

REFERENCES

1 The World Bank. World Bank Country and Lending Groups – World Bank Data Help Desk. https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups. Accessed April 30, 2017.

2 UNDP. Human Development Index. http://hdr.undp.org/en/composite/HDI. Accessed April 30, 2017

3 LDCs at a Glance | Development Policy & Analysis Division. https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.html. Accessed April 30, 2017.

APPENDIX VI

Priority countries

For each disease in the scope of the 2018 Index, the Index has a defined list of 'priority countries'. These defined lists of countries are used for certain indicators in the Technical Area Pricing, Manufacturing & Distribution.

Priority countries have been identified as having one of the highest burdens for the disease in question, based on WHO data (2012), or IHME data (2015), and adjusted for multi-dimensional inequality (UNDP, 2012).

Table 8. Priority countries

This table shows the priority countries identified for each disease/condition – dots denote priority country status. Individual priority country lists exist for viral hepatitis (B and C) and the sexually transmitted infections included in the scope of the 2018 Index (chlamydia, genital herpes, gonorrhoea, syphilis and trichomoniasis). Countries in the scope of the 2018 Index that have not been designated as priority countries for any disease/condition are not included in this table.

For certain neglected tropical diseases and maternal and neonatal health conditions, where DALY data was not available, other criteria were used. Other criteria were also used to identify priority countries for cancer, to ensure alignment with the inclusion of cancer in the 2018 Index. Where DALY data was not used, Kosovo and Tuvalu are no longer listed as priority countries, unless identified based on the alternative criteria noted below.

Disease/condition	Afghanistan	Angola	Bangladesh	Benin	Bolivia	Brazil	Burkina Faso	Burundi	Cambodia	Cameroon	Central African Rep.	Chad	China	Colombia	Comoros	Congo, Dem. Rep.	Congo, Rep.	Côte d'Ivoire	Ecuador	Egypt, Arab Rep.	El Salvador	Equatorial Guinea	Ethiopia	Gabon	Ghana	Guatemala	Guinea	Haiti	Honduras	India	Indonesia
Non-communicable																															
Anxiety disorders	•		•			•							•			•							•						•	
Asthma			•			•							•			•							•						•	
Bipolar affective disorder						•							•			•							•						•	•
Cancer (all except Kaposi Sarcoma)			•			•							•							•									•	•
Cancer (Kaposi sarcoma)																							•							
Chronic obstructive pulmonary disease			•										•			•							•						•	•
Diabetes mellitus	•					•							•			•							•						•	•
Epilepsy													•			•							•						•	
Hypertensive heart disease	•					•							•			•							•						•	•
Ischaemic heart disease	•					•							•			•							•						•	
Kidney diseases			•										•			•							•						•	
Migraine	•		•			•	•						•			•							•						•	
Schizophrenia						•							•			•							•						•	•
Stroke	•					•							•			•							•						•	•
Unipolar depressive disorders	•					•							•			•							•						•	•
Communicable																															
Chlamydia													•			•							•						•	
Diarrhoeal diseases	•	•										•				•							•						•	
Genital herpes						•							•			•							•						•	•
Gonorrhoea	•															•				•			•						•	
HIV/AIDS																							•						•	
Lower respiratory infections	•															•							•						•	
Malaria		•					•					•				•													•	
Measles	•															•							•						•	
Meningitis		•										•				•							•						•	
Pertussis	•															•							•						•	
Syphilis		•										•				•							•						•	
Tetanus	•	•										•				•							•						•	
Trichomoniasis						•							•			•							•						•	
Tuberculosis	•		•													•							•						•	
Viral hepatitis B			•									•	•			•							•				•		•	•
Viral hepatitis C	•															•				•			•						•	•
Neglected tropical																															
Buruli ulcer		•		•		•	•			•	•		•			•	•	•				•		•	•		•			•
Chagas disease					•	•								•							•					•		•	•		
Chikungunya				•				•	•	•	•				•	•						•					•			•	•
Dengue						•			•							•							•					•		•	•
Dracunculiasis		•										•				•		•					•		•						
Human African trypanosomiasis											•	•				•											•				
Leishmaniases			•													•							•						•	
Leprosy						•							•	•		•							•						•	
Lymphatic filariasis																		•												•	•
Mycetoma, chromoblastomycosis and other deep mycoses																														•	
Onchocerciasis										•	•	•				•							•								
Rabies	•											•				•							•						•	
Scabies and other ectoparasites						•							•			•							•						•	•
Schistosomiasis																•							•							
Snakebite envenoming	•		•										•			•							•		•				•	•
Soil-transmitted helminthiases			•										•			•							•						•	•
Trachoma							•						•							•			•								
Yaws				•						•	•					•	•	•	•						•					•	•
Maternal & neonatal																															
Abortion													•			•							•							•	•
Birth asphyxia and birth trauma	•												•			•							•							•	
Contraceptive methods							•					•	•			•							•					•		•	•
Hypertensive disorders of pregnancy	•		•													•							•							•	•
Maternal haemorrhage	•															•							•							•	•
Maternal sepsis			•													•							•							•	•
Neonatal sepsis and infections	•		•													•							•							•	
Obstructed labour	•		•										•			•							•							•	•
Other neonatal conditions	•		•										•			•							•							•	•
Prematurity and low birth weight	•												•			•							•							•	

Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

Where data gaps exist, countries are automatically included. If a country has one of the highest DALY burdens for a disease, but its inequality coefficient is unknown or where DALY data for a country does not exist, it is included as a priority country. For example, for Kosovo and Tuvalu, no DALY data is available for any diseases in scope.

For diseases that were in scope in 2016, the priority countries are unchanged. For diseases that are newly in scope, the most current data (WHO, 2015; IHME, 2015; UNDP, 2015) has been used to determine the priority countries.

Iran, Islamic Rep.	Kenya	Kiribati	Korea, Dem. Rep.	Kosovo	Lao PDR	Liberia	Madagascar	Malawi	Maldives	Mali	Mauritania	Mexico	Micronesia, Fed. Sts.	Mozambique	Myanmar	Nepal	Niger	Nigeria	Pakistan	Papua New Guinea	Peru	Philippines	São Tomé & Principe	Senegal	Sierra Leone	Solomon Islands	Somalia	South Africa	South Sudan	Sri Lanka	Sudan	Suriname	Tanzania	Thailand	Timor Leste	Togo	Tonga	Tuvalu	Uganda	Vanuatu	Vietnam	Zambia	Zimbabwe	Disease/condition
																																											Non-communicable
				•												•			•													•				•						Anxiety disorders
				•											•	•		•														•				•	•					Asthma
			•	•												•		•														•				•	•					Bipolar affective disorder
•		•		•								•	•					•	•				•												•	•						Cancer (all except Kaposi Sarcoma)
	•	•		•				•					•	•				•					•					•	•							•	•			•	•	Cancer (Kaposi sarcoma)
			•	•												•			•													•				•						Chronic obstructive pulmonary disease
				•								•																				•				•	•					Diabetes mellitus
				•										•				•	•													•				•	•					Epilepsy
			•	•															•													•				•						Hypertensive heart disease
•			•	•												•			•													•				•						Ischaemic heart disease
				•										•				•	•													•				•	•					Kidney diseases
				•												•			•																							Migraine
			•	•														•													•				•	•					Schizophrenia
			•	•			•											•																		•						Stroke
				•															•													•				•	•					Unipolar depressive disorders
																																											Communicable
			•	•										•				•										•				•				•	•					Chlamydia
				•														•	•												•						•	•					Diarrhoeal diseases
			•	•										•				•											•				•				•	•					Genital herpes
•				•										•				•	•										•		•						•	•					Gonorrhoea
				•				•					•	•				•								•	•					•		•			•	•	•				HIV/AIDS
				•													•	•	•																		•	•					Lower respiratory infections
				•													•	•																			•	•					Malaria
				•														•	•						•		•																Measles
				•						•								•																			•	•					Meningitis
				•														•	•																		•	•					Pertussis
				•														•															•				•	•					Syphilis
				•														•	•								•																Tetanus
				•										•				•										•				•				•	•					Trichomoniasis
				•										•	•			•	•						•																		Tuberculosis
			•	•						•					•			•																									Viral hepatitis B
			•	•											•			•	•										•				•				•	•					Viral hepatitis C
																																											Neglected tropical
	•	•				•		•				•						•		•	•			•	•				•	•		•				•		•					Buruli ulcer
				•								•																									•						Chagas disease
	•				•		•	•	•						•			•	•			•		•				•			•		•	•	•			•		•		•	Chikungunya
				•	•										•							•											•					•						Dengue
	•									•							•	•									•	•	•		•												Dracunculiasis
	•			•																											•						•	•					Human African trypanosomiasis
				•										•				•													•		•				•	•					Leishmaniases
				•			•							•	•	•		•																			•						Leprosy
				•			•			•				•				•														•				•	•					Lymphatic filariasis
											•	•					•						•				•				•												Mycetoma, chromoblastomycosis and other deep mycoses
				•		•												•											•	•	•							•						Onchocerciasis
				•													•	•	•									•			•						•						Rabies
			•	•											•	•			•														•					•	•					Scabies and other ectoparasites
	•			•			•							•				•													•	•					•						Schistosomiasis
												•				•		•	•			•																	•					Snakebite envenoming
																		•	•			•																•						Soil-transmitted helminthiases
				•										•				•													•	•					•	•					Trachoma
																				•						•								•	•				•					Yaws
																																											Maternal & neonatal
				•				•						•				•											•			•					•						Abortion
				•														•	•													•					•	•					Birth asphyxia and birth trauma
				•													•	•					•									•					•	•					Contraceptive methods
				•				•										•										•				•					•						Hypertensive disorders of pregnancy
				•													•	•										•				•					•						Maternal haemorrhage
				•				•		•								•										•				•					•						Maternal sepsis
				•						•							•	•	•												•						•						Neonatal sepsis and infections
				•			•											•										•		•		•					•						Obstructed labour
				•						•							•	•									•										•						Other neonatal conditions
				•						•								•	•													•					•						Prematurity and low birth weight

Table 9. Exceptions that have been included in the priority country table, as specific countries could be identified (WHO data unless otherwise noted).

Disease	Variable used to determine priority countries
Buruli ulcer	Countries with new reported cases of Buruli ulcer in 2013 and/or 2014; countries with no data in 2013 or 2014; actively reporting countries; and previously reported countries, cross-checked with WHO Weekly Epidemiological Record, 2004.
Cancer	Countries with the highest incidence of cancer (GLOBOCAN, 2012), adjusted for multi-dimensional inequality (UNDP, 2015); plus countries with no data. A separate priority country list was identified for Kaposi sarcoma, due to its disproportionately high burden in low-income countries. However, for both lists, no additional adjustment was made to ensure the inclusion of low-income countries, due to potential barriers in capacity for regulatory approval and safe and effective administration of cancer products in these countries.
Chikungunya	Countries with documented, endemic or epidemic chikungunya.
Contraceptive methods	Based on DALYs for maternal conditions; plus top 5 countries by unmet need for family planning.
Dracunculiasis	Endemic countries and countries not yet certified free of dracunculiasis (with no recent history or in pre-certification phase).
Mycetoma, chromoblastomycosis and other deep mycoses	Countries with the highest number of cases and highest average prevalence (van de Sande, 2013).
Prematurity and low birth weight	Based on DALYs for preterm birth complications, but compared with list of 10 countries that account for 60% of the world's preterm births by rank-in-numbers.
Snakebite envenoming	Countries with the highest number of cases and deaths (Kasturiratne *et al.*, 2008).
Soil-transmitted helminthiases	Countries with 20 million or more children (preschool-age children and school-age children) requiring preventive chemotherapy for soil-transmitted helminthiases; countries with no data.
Yaws	Currently endemic countries, and countries with interrupted transmission.

Exceptions that have not been included in the priority country table, as specific countries could not be identified.

Disease	Priority countries
Echinococcosis	All countries in scope
Food-borne trematodiases	All countries in scope
Taeniasis/cysticercosis	All endemic countries in scope

APPENDIX VII

Product types in scope

This scope is deliberately broad in order to capture the wide-ranging product types available to support the prevention, diagnosis and treatment of relevant conditions and diseases in the countries covered by the Access to Medicine Index. In 2018, the Index continues to use the same eight product types within the product scope. These product types correspond with those in the 2016 Policy Cures Research G-FINDER report and the 2014 Policy Cures G-FINDER Reproductive Health report.[1, 2]

Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

Microbicides

These include topical microbicides specifically intended to prevent HIV.

Therapeutic Vaccines

This covers vaccines intended to treat infection.

Preventive Vaccines

This covers vaccines intended to prevent infection.

Diagnostics

This covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable, easier to use in the field).

Vector Control Products

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides intended for global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors associated with transmitting Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Contraceptive Methods & Devices

This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used to control contraception (e.g., condoms or diaphragms). It also includes combination products that deliver medicines (e.g., hormone-delivery contraceptive rings).

Platform Technologies

Only products that are specifically directed at meeting the needs of people living in the countries covered by the Index are included. These comprise, for example, general diagnostic platforms, adjuvants, immunomodulators and delivery technologies and devices. Implants and platform technologies for reproductive health are also included in this category.

REFERENCES

1 Policy Cures Research | G-FINDER. http://policycures.org/gfinder.html. Accessed July 17, 2017

2 Pablo Alzate Granados J, Chowdhary V, Gonzalez Ramirez L, et al. Reproductive Health: R&D for the Developing World.; 2014. http://policycures.org/downloads/RH full report.pdf.

APPENDIX VIII

Stakeholder engagement 2017

Between January and October 2017, the Index engaged with a variety of stakeholders to build a more complete, up-to-date view on the changing access to medicine landscape.

The principles that guided the process of stakeholder engagement were:

1. To reflect changes in the access to medicine landscape and the role for pharmaceutical companies;
2. To preserve the capacity for fine-grained comparison between companies' performances;
3. To maintain capacity for trend analysis between successive indices;
4. To ensure data could be collected by companies.

A process of both internal review and external engagement was carried out.

Internal analyses

The Foundation's research team reconfirmed the quality and robustness of each indicator, using quantitative tests such as correlation, response rate and distribution analyses. These tests were used to pinpoint risks of redundancy, where scoring guidelines could be tightened for 2018 and where data quality could be enhanced.

Company engagement

The foundation offered all 20 companies evaluated in 2016 the opportunity to give their feedback on Index methodology and to discuss their results with the Index team. In addition, companies were given an opportunity to provide feedback on the data collection process. Efficiencies identified from the review were incorporated into the 2018 data collection process.

Stakeholder dialogue

The Foundation also reached out to a broad range of experts through a targeted stakeholder engagement exercise. Their insights helped to ensure that the methodology was up-to-date. This process helped identify a consensus regarding the appropriate role for pharmaceutical companies in addressing access to medicines.

Stakeholders contacted included academic experts, investors, non-governmental organisations, governments and multilateral organisations. A full list of named respondents in this process is included in the Access to Medicine Index Methodology 2017. Expert-to-expert meetings were held at the World Health Organization, and a specific workshop for product development partnerships was held in Geneva, and further engagements were conducted by teleconference, and by email.

Expert Review Committee

The Foundation's team met with the Expert Review Committee (ERC) in June and July 2017. The role of the ERC is to provide the Foundation with strategic guidance with regard to the Index's scope and indicators. This group ratified the methodology prior to its publication.

Expert Review Committee

Hans Hogerzeil - Chair
Sanne Frost Helt
Fumie Griego
Suzanne Hill
Frasia Karua
Dennis Ross-Degnan
Dilip Shah
Yo Takatsuki
Joshua Wamboga
Prashant Yadav

Technical Subcommittees

Between February and September 2017 the Foundation convened groups of experts to serve as Technical Subcommittees (TSCs) to support the methodology enhancement.

These committees responded to and advised on various proposals made by the Index team for enhancing the areas of Market Influence & Compliance; Research & Development; Pricing, Manufacturing & Distribution and Patents & Licensing. The remaining Technical Areas did not convene TSCs, but did consult experts individually.

Technical Subcommittees

Market Influence & Compliance
Michele Forzley
Jillian Kohler

Research & Development
Jennifer Dent
Nick Chapman

Pricing Manufacturing & Distribution
Niranjan Konduri

Patents & Licensing
Esteban Burrone
Warren Kaplan

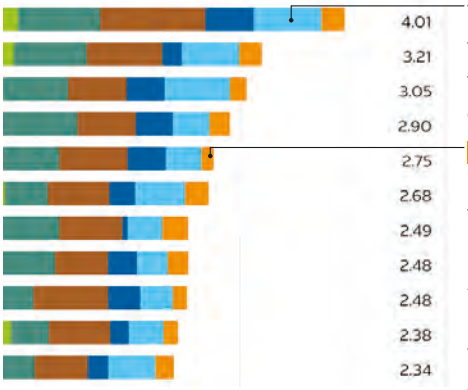
Other sources of feedback

The Access to Medicine Foundation remains open to feedback from other entities willing to provide comments and suggestions. Maintaining openness through engaging and building partnerships with all the stakeholder groups is crucial to the long-term success, legitimacy and impact of the Index.

No single feedback mechanism has disproportionately affected the Index methodology. Rather, the output of the survey, in depth consultations and other feedback processes were studied by the Expert Review Committee. We maximised our efforts to ensure that all the stakeholders receive equal representation in the stakeholder engagement process.

APPENDIX IX

Ranking, scoring and review process



The size of each colour represents the contribution of each technical area to the overall score. The size of the bar depends on the company score for the technical area and the weight of the technical area compared to the other technical areas.

Each of the color bars comprises indicators for Commitments (15%), Transparency (25%), Performance (50%) and Innovation (10%).

A score of zero is the lowest possible score in an indicator. A five is the highest possible score. A company's overall score is an aggregate of individual indicator scores, adjusted by the respective indicator, strategic pillar and technical area weights.

SUMMARY OF THE SCORING PROCESS

R&D pipeline and product portfolio inclusion process Before inclusion for analysis, the Index team reviewed both marketed products and projects in company R&D pipelines. This review was to ensure they were within the scope of the 2018 Index and met relevant inclusion criteria. Both the pipeline and portfolio were pre-populated with projects and products submitted for the 2018 Access to Medicine Index. Further, they were verified and updated against public sources of information to ensure that the most up-to-date and accurate pipelines and portfolios were represented before scoring and analysis began. Public data could include pipeline and portfolio information found on company websites, based on approvals from stringent regulatory approvals, from clinicaltrials.gov and relevant product development partnership pipelines. Companies verified ongoing R&D projects and noted when a project had been divested or discontinued while also confirming each product in their portfolios. These final, verified pipelines and product portfolios were then included in the final questionnaire sent to companies at the beginning of the data collection cycle.

Process for R&D pipeline project inclusion

For R&D products inclusion criteria were applied based upon the product type and disease target, according to the Index scopes.

- All medicines and vaccines targeting a disease defined in one of the four disease categories were included, with a single exception of medicines used only for symptomatic relief.
- Diagnostics, vector control products and platform technologies were included only if they were designed and intended for use in countries in scope with a focus on the needs unique to the people living in these countries.
- Products were included for early-stage (discovery, pre-clinical and Phase I) and late-stage (Phase II, Phase III and market approval) development, as well as those in Phase IV/pharmacovigilance studies (only if conducted in countries in scope), technical lifecycle or other phases of development that did not fit the other categories.
- All R&D had to be ongoing during the period of analysis, including projects that received first global marketing approval during the period of analysis. Projects that were discontinued during the period of analysis were removed from the pipeline.
- Projects designated as being in technical lifecycle management were only included where evidence was provided that a need specific to low- and middle- income countries was being addressed.
- Following the first submission, companies were asked for clarifications, if needed, to support this verification process. After final submission, all R&D projects were evaluated according to this standardised procedure.

Process for registered product inclusion

Registered products also went through a verification process. This was to assess whether they were suitable for use under the disease indication(s) as described by the company, and as covered by the ICD-10 codes described in the Methodology Report 2017. Product indications were verified using information from regulatory authorities (such as the FDA and EMA). Any products that remained unclear following this process were verified with the company. Further, products identified through external validation that the company had not submitted but appeared to be within scope were clarified with the company, with a request to either include these products or to explain why they were not within scope.

Products were determined as being on the 2017 WHO Model List of Essential Medicines (WHO EML) if the product (a) appeared directly on the list or (b) was in the same pharmacological class as a product listed on the WHO EML indicated with a square box. Products were allocated to disease categories (communicable diseases, non-communicable diseases, neglected tropical diseases or maternal and neonatal health conditions) based on indications listed by regulatory authorities (e.g. FDA/EMA) in the product information. Where products were noted as appropriate for indications across more than one disease category, all relevant disease categories were listed, and these products were listed in the Index as 'multiple categories'.

Groups of medicines always excluded were medicines intended for treatment of cancer that were not listed on WHO EML, painkillers, anaesthetics and supportive medicines without specific indications, such as IV fluids and blood transfusions. Products may be used for multiple diseases in scope. Products were scored according to diseases listed by the company. Scoring for product-specific Technical Areas (R&D; Pricing, Manufacturing & Distribution; Patents & Licensing; and Product Donations) were based only on company-verified product portfolios.

Quantitative indicators

Quantitative indicators, such as the proportion of a company's R&D investment relevant to diseases within the scope of the Index from a company's total R&D investments, are adjusted based on total revenues from 2016 and 2017, or other relevant figures indicative of company size, most commonly overall pipeline size. Consistent with the relative ranking approach of the Access to Medicine Index, the adjusted numbers are then scaled for scoring from zero to five. In the case of pricing indicators, and donations, the number of products within the scope of the Index per portfolio were used as an additional differentiator of company size, so that both large and small companies' performances were scored relative to peers of similar size.

Neutral scoring protocol

Neutral scoring is used to avoid double penalising a company for a policy, strategy, programme or initiative it lacks for which its score has already been impacted negatively once, and for which it is impossible for the company to achieve the additional expectation. For example, when a company has no equitable pricing strategies within scope, it is assessed for scoring in the relevant commitment indicator (D.I.1) and the primary performance indicator on the existence of and equitable pricing commitment and corresponding per-product equitable pricing strategies (D.III.1). Companies are expected to have both a commitment, and strategies, and will be scored in both. However, for the transparency indicators related to disclosure of volume of sales and price point information for products with equitable pricing strategies (D.II.1 and D.II.2), and subsequent performance indicator related to the consideration of socioeconomic factors within existing equitable pricing strategies (D.III.2), a neutral score is applied, as the company has already been penalised for not having the equitable pricing strategies in place. An alternative way of looking at it is that it is impossible for a company to disclose pricing and volume data for strategies that it does not have, and therefore should not be penalised in those indicators.

Researchers first identified indicators that could potentially result in a double penalisation and should be neutrally scored. Then a proxy measure was identified for that indicator. Potential proxy measures can include:

- All other indicators in the Technical Area, except those in the subtheme that are neutrally scored and any innovation indicator(s).
- All other Technical Areas.
- In some cases, specific indicators were selected as a proxy based on appropriateness (i.e. closest comparator to the indicator being neutrally scored).

The scores from the proxy (indicators or technical area) were used to calculate the neutral score. The company would then receive the calculated neutral score for that indicator rather than the score they would receive following normal scoring guidelines.

In 2018, neutral scoring was applied within the areas of Market Influence & Compliance; Pricing, Manufacturing & Distribution; Patents & Licensing and Product Donations.

Determining patent status

Patent status for each product in scope of the Index was determined through a process of external research combined with verification from participating companies. This process was developed in consultation with experts from Boston University and Harvard Medical School. Patent status was first researched through the use of the appropriate regulatory authority websites (for example, the US FDA Orange Book and Health Canada) and later verified with companies during scoring and the period of company clarification. Patent statuses were also cross-referenced where possible with existing literature, for e.g, the 2017 article "In which developing countries are patents on essential medicines being filed?" (Beall & Attaran, 2017). In cases where the patent status referenced across multiple sources did not align, additional clarification questions were posed to companies. The methodology clarifies patent status in the US, and in some cases (for e.g. biologics) Canada, but it is not intended to be a presentation of patent rights worldwide. Nor does it capture all patents that might be in place for a product. It is reasonable to assume that this methodology may therefore underreport where patents are in place, should only be used as a proxy description and cannot be used as an indication of patent status outside of the US and Canada. In some instances, for example, the patent status of a particular product was identified as off-patent in the US or Canada but on-patent in other jurisdictions.

IP sharing

In collaboration with BIO Ventures for Global Health, the Access to Medicine Foundation developed a new framework for evaluating industry IP-sharing agreements for R&D. The framework compares different IP-sharing agreements in terms of risk, effort and potential value to accelerating R&D. Companies provide evidence of sharing intellectual capital (e.g., molecule libraries, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g., WIPO Re: Search, Conserved Domain Database [CDD] and Open Source Drug Discovery [OSDD]) that develop products for diseases relevant to the Index on terms conducive to access to medicine for countries within the scope of the Index. This IP-sharing metric was used to provide credit to companies for reaching new agreements within the period of analysis to share IP with research institutions that develop products for high-burden and priority diseases on terms that support access to resulting innovations in LMICs. Each IP-sharing agreement a company entered into between 2016 and 2018 that met the inclusion criteria was classified and weighted using the new framework. Companies were assigned a score based on the overall weight of the IP sharing agreements they entered into, relative to the performances of other companies evaluated. The results of this analysis recognised the different risks and efforts companies take when sharing IP, along with the different values of this IP to supporting R&D for global health needs. The agreements were verified with partners, where possible.

Scoring

Scoring is carried out based on data from a wide range of information sources including companies' submissions; independent reports; databases from the World Health Organization (WHO), other multilateral organisations, governmental and non-Governmental organisations; legal databases such as LexisNexis; and news databases such as Bloomberg.

Public data sources including information shared on company websites and in annual reports as well as through local health authorities, helped to triangulate data. Additional information retrieved from the US FDA Orange Book, Health Canada and the European Medicines Agency provided deeper insight and analysis pertaining to patent information. The Medicine's Patent Pool's MedsPal and WIPO's new Pat-INFORMED databases were also beneficial resources used for the purpose of analysis.

The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process beginning with scoring per company by the technical area analyst during the first round of the data collection period, followed by re-scoring after companies have provided further clarification in areas identified by the analyst. This was followed by verification by the technical area analyst, including an extensive quantitative and qualitative check of each indicator for each company.

Further, a crosscheck was performed by a second expert from the Foundation team along with each Technical Area expert. The research manager performs a quality assurance check on all scores to ensure consistency, with senior management performing a final spot-check. Each Technical Area analyst then cross-checked their Technical Area's ranking, before the final ranking was cross-checked and verified by the research manager.

REVIEW PROCESS

Following clarification with companies, cross-check of company scores and consultation with experts, the Index research team wrote the various sections of the Index report. Each Technical Area was reviewed by Technical Subcommittee members or additional experts. Following internal review by the Foundation's management team, the entire Index was reviewed by the chair of the Expert Review Committee, Professor Hans Hogerzeil.

LIMITATIONS OF THE METHODOLOGY

Limitations exist in every study of this design. Significant limitations specific to this study are discussed here. These and other methodological limitations will be reviewed for the 2020 Access to Medicine Index, as part of the 2019 multi-stakeholder Methodology Review process.

Disease and country comparability

The outputs analysed in this study and the findings generated relate only to the geographical, disease, product and company scopes, as determined by the Expert Review Committee (ERC) during the methodology review process, and as published in The Access to Medicine Index Methodology 2017.

Although the Foundation recognises that all products, diseases, countries, access and product initiatives are not the same, in general, in most Technical Areas in this study they are treated equally. For example, in R&D, nearly all compounds (with the exception of early-stage cancer projects with no defined target) are treated equally if they meet the inclusion criteria, regardless of their mechanism of action or expected efficacy. In one indicator, C.III.3 in the R&D Technical Area projects are differentiated based on whether or not they target priority product gaps, as defined by WHO and Policy Cures Research's G-FINDER tool, or whether companies provide specific evidence of how an identified R&D need is being addressed which does not appear on those lists.

The Index used additional methods in other Technical Areas to correct for variations between products and countries within the scope of the Index. In equitable pricing and filing for registration, for example, priority countries for diseases that a product targets were given credit in indicators D.III.1 and D.III.4, rather than including all countries within scope for every product.

Longitudinal comparability

Comparability between companies over successive indices was not always possible or appropriate, especially for new areas of evaluation or where the scoring criteria of an indicator had been refined. During the period of analysis (1 June 2016 to 31 May 2018), where trend analysis was useful, the Index team compared raw data from 2014 and 2016 with raw data from 2018.

Company comparability

The objective of the Index is to produce a standardised relative ranking of companies' access-to-medicine performances. However, not all companies are the same. Some have large portfolios and pipelines. Some have a comparatively narrow disease focus. Some have a comparatively narrow scope of country operations. Others have generic pharmaceuticals subsidiaries.

Companies of different sizes have different capacities to report information. For example, larger companies may be less likely to have all data available in a centralised repository/database and may have more data to report on. This can be further complicated where there are generic medicine subsidiaries to account for. Companies have idiosyncratic systems for recording and reporting information, which can give rise to complications when comparing the performance of different companies. For example, companies have different mechanisms for calculating the value of donation programmes.

Companies also often have individual ways of categorising information, for example, how different pricing strategies are referred to. In order to minimise the variability of information sourced from companies, all companies were provided with training on the data submission process, and the questionnaire had help text to provide definitions and examples for Index jargon. In addition to this, a clarification round was carried out, giving companies an opportunity to provide additional data where there were gaps, inconsistencies identified or clarifications necessary.

The Index uses various methods to correct for these variations between companies.
In several indicators that measure quantitative elements (relating to pricing, R&D and patents and licensing), in general, the Index makes adjustments for company size. These are made against the size of the relevant portfolio of products, or against company revenue for 2016 and 2017. Further, in the case of pricing indicators in this Index, the number of products within the scope of the Index – either in a company's market portfolio or with equitable pricing strategies – was used as an additional differentiator to group companies together, so that both large and small companies' performances were scored relative to peers of similar size.

For several quantitative indicators, companies are evaluated on a per-product basis with one cumulative performance score awarded. The scoring process utilized the one-dimensional k-means clustering algorithm. For each of these indicators, a statistical software program was used to partition companies' performance into as many clusters as defined by the indicator's scoring guidelines, in such a way that each company was assigned to the cluster with the nearest mean performance. Results were visualised on a one-dimensional graph in order to identify and resolve borderline cases, where companies could be placed in one grouping or another. Some indicators were scored purely based on absolute values. Alternatively, for indicators where scaling was deemed necessary, variability in the size of a given company's portfolio was taken into account when allocating final scores.

Data availability

Companies are sometimes unwilling or unable to disclose commercially sensitive data, or, if they do, may do so only partially. For example the content of R&D contracts, early-stage research and sensitive pricing information may be treated more cautiously by companies.

Occasionally, where sensitive data could be analysed, complete results could not be published due to legal constraints related to public disclosure (e.g., price data). In other cases, collection of very specific data (e.g., volume of sales data for different sectors within a country) which may require disaggregation, or country-level collection, was not always possible. This issue remains an obstacle to finding and reporting reliable trends and very specific relationships and conclusions in several areas.

Additionally, in some areas it may not be possible to provide a complete picture of the area of analysis due to external constraints on the collection of data. For example, in 2018, only settlements and judgements regarding breaches which occurred in countries within the scope of the Index were counted when evaluating companies in the areas of ethical marketing, corruption and anti-competitive behaviour. Given regulatory and reporting capacity issues in low- and middle- income countries, it is not possible to be confident that all breaches were captured. Sources of data collection include LexisNexis, the websites of government departments such as the US Department of Justice and registers maintained and published by a selection of industry self-regulatory bodies. Even given this review, we acknowledge that breaches may have occurred which were not captured. We continue to acknowledge that breaches in countries in scope are likely to be under-reported. Similarly, a complete picture of breaches of clinical trial conduct is difficult to capture, due to the absence of a central registry of such information, and the fact that these incidents are typically not routinely monitored by research ethics committees, and tend not to be prosecuted.

Measuring Outcomes and Impacts

The study as currently designed is not intended to measure the direct impact of companies' access initiatives on patients and other groups. For example, within Capacity Building, the impact of a company's training activities is not measured, although the Index may consider whether a company measures the impact of its own activities. Alternative measures are used as proxies for patient access or considerations of impact. For example, within Pricing, Manufacturing & Distribution, disclosure of the volume of sales within a country is taken as a proxy measure of the success of an equitable pricing strategy being implemented.

APPENDIX X

Identifying best & innovative practices

The diffusion of best practices is one of the Access to Medicine Index's mechanisms for supporting the pharmaceutical industry in achieving greater access to medicine. Similarly, recognising those companies trialing or scaling up innovative unique-in-industry policies or initiatives is an important way of acknowledging those companies prepared to stand out from peers and to risk new approaches.

Best practices

Best practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best practices are not new practices – they have already been conceived of, applied and proven to meet at least some of the following criteria:

- Sustainability;
- Replicability;
- Alignment with external standards/stakeholder expectations; and
- Proven effectiveness.

In different areas of analysis (for example, in Research & Development vs. in Pricing Manufacture and Distribution) how a best practice is identified may be different. A best practice need not be unique amongst companies. A best practice might be an example of a 'gold standard' of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations. Best practices should be considered as the exemplar of positive practices in the corresponding technical area in comparison to those of the other companies that submitted data within the current period of analysis. These best practices are identified based on evidence of progress submitted in the data collection period and verified with public information and through consultation with experts, where appropriate.

Innovations

Innovations have been defined in successive iterations of the Access to Medicine Index as:

"a novel activity/business/model/policy/strategy being piloted/trialed by companies, aimed at supporting access to medicine in low- and middle- income countries, which (where relevant) has evidence of financial or personnel resources invested in it (as proof of implementation)."

Innovative activities are often (but not always) unique amongst the set of 20 companies. An exception to the requirement for uniqueness is when multiple companies jointly cooperate in the same innovative activity. The definition of Innovation includes scaling up. Therefore, a practice which was being newly trialed/piloted in the previous Index cycle, where evidence is shown that it has been scaled up, or expanded, can qualify for further recognition as Innovation in the subsequent cycle. Best practices, by their definition, cannot be considered innovations.

Process

To determine which of the company's practices would be highlighted as best practice or innovative, the Foundation's research team evaluated all aspects of company practices, compiling those that met the criteria used for the purpose of scoring with additional standards for each Technical Area, where necessary. Practices that met this outlined criteria were reviewed and finalised by the Foundation's senior management with additional input from experts in the corresponding field, when required.

APPENDIX XI.

Indicators and scoring guidelines

A GENERAL ACCESS TO MEDICINE MANAGEMENT 10%

A.I COMMITMENTS 13.3%

A.I.1 Governance: Management structures

45% 5 The company has a board member or board-level committee responsible for its access-to-medicine approach.

3 The company has an executive manager or executive committee, that directly reports to a board member or to a board-level committee, responsible for its access-to-medicine approach.

0 The company has no board or executive level responsibility for its access-to-medicine approach.

A.I.2 Access-to-medicine strategy

55% The company sets objectives to improve access to medicine, and aligns its access-to-medicine strategy with its core business.

5 The company has a clear access-to-medicine strategy with a strong business rationale, including a detailed set of objectives to improve access to medicine.

3.5 The company has an access-to-medicine strategy with a strong business rationale.

2 The company has a goal to improve access to medicine but does not have an access-to-medicine strategy.

0 The company does not have an access-to-medicine strategy and does not set objectives for improving access to medicine.

A.II TRANSPARENCY 23.2%

A.II.1 Managing for access-to-medicine outcomes: Public reporting

45% The company publicly reports on its commitments, objectives, targets and performance information related to improving access to medicine.

5 The company publicly discloses its commitments, objectives, targets and performance information related to improving access to medicine.

3.5 The company publicly discloses its objectives and targets related to improving access to medicine.

2.5 The company publicly discloses commitments related to improving access to medicine.

1 The company discloses via the Index at least partial information from the above list, related to improving access to medicine.

0 The company does not publicly disclose any of the above information.

A.II.2 Stakeholder engagement: Public reporting

55% The company publicly discloses summaries of: its stakeholder selection process; stakeholder groups it engages with; engagement activities related to access to medicine; and key outcomes and rationales.

5 The company publicly discloses detailed information regarding stakeholder engagement related to access to medicine including:

a) an overview of relevant stakeholder groups;
b) its stakeholder selection process;
c) a summary of relevant stakeholder engagement activities, which demonstrate both local and global stakeholder engagement; and d) a summary of the key outcomes and rationales for these activities.

3 The company publicly discloses at least two out of four of the above list of information

2 The company publicly discloses only general information regarding its stakeholder engagement activities related to access to medicine.

0 The company does not publicly disclose information on its stakeholder engagement activities related to access to medicine.

A.III PERFORMANCE 54.1%

A.III.1 Managing for access-to-medicine outcomes: Performance management system

30% The company has a performance management system to monitor and measure the outcomes and impact of its access-to-medicine activities across its global operations.

5 The company has a centralised performance management system that uses quantitative and qualitative measures to collect data and appraise performance of its access-to-medicine activities across its global operations, and is evaluating the impact of at least one of its access-to-medicine initiatives and/or has explicit plans to monitor the impact of at least one of its access initiatives.

3 The company has a centralised performance management system but does not collect data or appraises performance of its access-to-medicine activities across its global operations.

1 The company has qualitative and quantitative targets for its access-to-medicine strategy but does not have a centralised performance management system which explicitly includes access-to-medicine activities.

0 The company does not have targets for or measure its access-to-medicine performance.

A.III.2 Stakeholder engagement

40% The company engages with relevant stakeholders, including universities, industry peers, patient groups, local governments, employees, and local and international non-governmental organisations, with the aim of improving access to medicine. The company has a system in place to incorporate local and other external perspectives on access-to-medicine in the development and implementation of its access strategies.

5 The company provides evidence of stakeholder engagement related to access to medicine during the period of analysis and

has both a system to incorporates local stakeholders' perspectives in the development and implementation of its access strategies AND a policy for responsible engagement.

4 The company provides evidence of stakeholder engagement related to access to medicine during the period of analysis and either has a system to incorporate local stakeholder perspectives in the development and implementation of its access strategies OR a policy for responsible engagement.

3 The company provides evidence of stakeholder engagement related to access to medicine during the period of analysis and incorporates local stakeholders' perspectives in the development and implementation of its access strategies.

2 The company provides evidence of stakeholder engagement related to access to medicine during the period of analysis.

0 The company provides no evidence of stakeholder engagement related to access to medicine during the period of analysis

A.III.3 Governance: Performance management & incentives

30% The company has internal incentive structures to reward the effective delivery of initiatives that improve access to medicine in countries within the Index scope, for diseases within the scope of the Index.

5 The company has a Human Resources (HR) performance management strategy and supporting processes; and provides clear evidence of financial and non-financial incentives for relevant performance of employees. Incentives for senior management are oriented towards long-term objectives.

3 The company has a HR performance management strategy and supporting processes which provide financial and/or non-financial incentives for relevant performance of employees, but does not have specific incentives oriented towards long-term objectives for senior management.

1 The company has internal incentive structures for relevant performance for at least some employees working on access-to-medicine initiatives.

0 The company does not provide incentives to reward any employees for the effective delivery of access-to-medicine initiatives.

A.IV INNOVATION 9.4%

A.IV.1 Innovation in business models

60% The company has contributed to the development of innovative business models that meet the access needs of patients in countries within the Index scope.

5 The company has contributed to the development of an innovative (unique in the sector) business model that improves access, with a focus on the needs of the poor and provides evidence of the model's financial sustainability.

4 The company has contributed to the development of multiple innovative (unique in the sector) business models that improves access, with a focus on the needs of the poor. However, there is limited evidence of the model's financial sustainability.

3 The company has contributed to the development of an innovative (unique in the sector) business model that improves access, with a focus on the needs of the poor. However, there is limited evidence of the model's financial sustainability.

2 The company has expanded an existing financially sustainable innovative business model that focuses on the needs of the poor.

0 No innovative business models identified in this area.

A.IV.2 Innovation in governance and stakeholder engagement

40% The company has developed innovative (unique in the sector) approaches to its access governance, its performance management systems and/or its stakeholder engagement.

2 The company has developed innovative (unique in the sector) approaches to governance and/or performance management systems and/or stakeholder engagement and supports this with evidence of progress or resources.

2.5 The company has adopted existing innovative (unique in sector) approaches to governance and/or performance management systems and/or stakeholder engagement.

0 No innovative initiatives identified in this area.

B MARKET INFLUENCE & COMPLIANCE 10%

B.I COMMITMENTS 13.3%

B.I.1 Governance of ethical marketing

50% The company commits to enforcing a code of conduct for ethical marketing practices that: extends to third parties; is consistent with existing industry standards; and incentivises responsible sales practice.

5 The company has:
a) an ethical marketing code consistent with industry standards;
b) training related to ethical marketing;
c) formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries within the scope of the Index; and
d) sales agent incentives not driven exclusively by sales targets.

2.5 The company has:
a) an ethical marketing code consistent with industry standards;
b) training related to ethical marketing; and
c) formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries within the scope of the Index.

1 The company has in place a code of conduct or policies for ethical marketing consistent with industry standards, but is not able to demonstrate how it enforces its code of conduct across all sales agents, including third parties.

0 The company does not have a code of conduct for ethical marketing practices consistent with industry standards.

B.I.2 GOVERNANCE OF ANTI-CORRUPTION

50% The company commits to proactively engaging in addressing corruption through: its internal policies, oversight of third parties, external commitments; and memberships.

- 5 The company meets all of the following criteria:
  a) a code of conduct that addresses anti-corruption and specifically applies to all employees, agents, intermediaries, and third parties, with an enforcement provision for third parties;
  b) membership of the World Economic Forum's Partnering Against Corruption Initiative (PACI) AND/OR Signatory to the UN Global Compact; and c) whistleblower facilities with a provision for anonymity AND a policy of non-retaliation.
- 3 The company meets two of the above criteria.
- 1 The company meets one of the above criteria.
- 0 The company meets none of the above criteria.

B.II TRANSPARENCY 23.2%

B.II.1 Market influence: Policy positions

25% The company is transparent about political contributions made, and the policy positions it seeks to promote that have an impact on access to medicine in countries within the scope of the Index.

- 5 The company publicly either discloses its policy positions which impact access to medicine, and its political (financial) contributions which impact countries within the scope of the Index, OR it has a policy that forbids political financial contributions.
- 3 The company publicly discloses its policy positions which impact access to medicine in countries within the scope of the Index. In addition, it discloses to or via the Index its political (financial) contributions which impact countries within the scope of the Index.
- 1 The company publicly discloses its public policy positions which impact access to medicine in countries within the scope of the Index.
- 0 The company does not disclose publicly or via the Index its political financial contributions or public policy positions which have an impact upon access to medicines in countries within the scope of the Index.

B.II.2 Market influence: Memberships

25% The company publicly discloses board seats and memberships held, and financial support provided to organisations through which it may advocate policies relevant to access to medicine in countries within the Index scope. The company also discloses policies for responsible engagement and management of conflicts of interest.

- 5 The company publicly discloses:
  a) its financial support and membership of all institutions, including relevant board seats held of all the named categories;* b) how it manages conflicts of interest, with these institutions; or
  c) its policy for responsible engagement.
- 3 The company publicly discloses:
  a) its membership of all institutions (including board seats held where relevant) of the named categories,* but not its financial support;
  and the company discloses to/via the index:
  b) how it manages conflicts of interest; or
  c) its policy for responsible engagement.
- 1 The company discloses to/via the Index:
  a) its membership of all institutions (including board seats held where relevant) of the named categories,* and either:
  b) how it manages conflicts of interest; or
  c) its policy for responsible engagement.
- 0 The company makes no public disclosure in this area or does not have policies for the management of conflict of interest and responsible external engagement.

* Trade associations, think tanks, interest groups or other organisations.

B.II.3 Disclosure of marketing strategy and practice

30% The company publicly discloses detailed information regarding its marketing and promotional programmes in countries within the Index scope (such as payments to or promotional activities directed at healthcare professionals and opinion leaders).

- 5 The company publicly discloses detailed information related to pharmaceutical marketing and promotional programmes in countries within the scope of the Index. This includes, for example, payments made to healthcare professionals and methods for incentivising healthcare providers, pharmacies, and key opinion leaders, as well as decentralised activities and activities of third party sales agents.
- 2.5 The company discloses to/via the Index its policy approach for pharmaceutical marketing in countries within the scope of the Index without disclosing exact contribution figures in this area.
- 0 The company makes no disclosure in this area.

B.II.4 Ethical marketing and corruption: Disclosure of breaches

20% The company publicly discloses information regarding breaches in countries within the scope of the Index of internationally recognised codes of conduct, laws and regulations that govern ethical marketing and corruption in the last two years.

- 5 The company publicly discloses detailed, current information (i.e. location, time, year, action taken) on its website or in its annual report, about settlements reached and cases concluded during the period of analysis. This includes breaches of national or international codes of conduct, and national laws and regulations which cover ethical marketing, bribery and corruption.
- 3 The company publicly discloses aggregate numbers or limited information related to all breaches as outlined above, either in its annual report or on its website.
- 2 The company discloses via the Index information related to some breaches and/or settlements reached during the period of analysis.
- 1 The company discloses to the Index detailed information related to some breaches and/or settlements reached during the period of analysis.

0 The company either provides no information on settlements reached or cases concluded of breaches, or has been found the subject of settlements but does not disclose them to the Index.

NS Companies that have not been the subject of any settlements for criminal, civil or regulatory infractions in countries within the scope of the Index over the period of analysis receive a neutral score.

B.III PERFORMANCE 54.1%

B.III.1 Ethical marketing and anti-corruption: Incidence of breaches

40% The company has not been the subject of settled cases for corrupt practice or incidents of unethical marketing practice in countries within the scope of the Index during the past two years.

5 The company has not been the subject of any settlements for criminal, civil or regulatory infractions in countries within the scope of the Index during the past two years (pending cases, allegations and cases under appeal are not included).

3 The company has not been the subject of any criminal or civil infractions in countries within the scope of the Index, but has been the subject of one breach of a code of practice in one of the countries within the scope of the Index.

2 The company has been the subject of more than one breach of a code of practice in countries within the scope of the Index.

0 The company has been the subject of at least one civil or criminal settlement with a negative ruling in a country within the scope of the Index.

B.III.2 Ethical marketing and anti-corruption: Enforcement

30% The company has clearly defined enforcement procedures and (where there has been misconduct) provides evidence of taking disciplinary action against employees or third parties who have violated its code of conduct for ethical marketing or anti-corruption. The company provides evidence of follow-up actions taken to mitigate the risk of future breaches.

5 The company has clearly defined enforcement processes and disciplinary measures with regards to: lobbying, corruption and marketing, and there is no evidence of violations.

3 The company has clearly defined enforcement processes and disciplinary measures and provides detailed (but anonymised) evidence that disciplinary action has been taken for lobbying, corruption and marketing violations, in addition to evidence of follow-up action to mitigate the risk of future breaches.

1.5 The company has defined enforcement processes and disciplinary measures for lobbying, corruption and marketing violations but does not disclose information about disciplinary actions taken.

0 The company does not have clearly defined enforcement processes and disciplinary measures or, where violations have taken place, shows no evidence of action having been taken.

B.III.3 Compliance: Internal control framework

30% The company demonstrates that it has an internal control framework, which includes the following components:
a) fraud-specific risk assessment;
b) a monitoring system for compliance (other than auditing);
c) auditing and review mechanisms, which involve the use of both internal and external resources, apply to all third parties and all countries where it has operations, based on risk assessment;
d) procedures for segregation of duties between: management tasks and authorisation tasks; custody of assets and verification tasks; accounting tasks and payment tasks.

5 The company has all of the above mentioned elements in place.

3 The company has at least 2 of the above mentioned elements in place.

1 The company has 1 of the above mentioned elements in place

0 The company does not have any of the above mentioned elements in place or does not disclose information.

B.IV INNOVATION 9.4%

B.IV.1 Innovation in market influence and compliance

100% The company has adopted an innovative approach to improving ethical business performance in countries within the scope of the Index relating to ethical marketing, responsible lobbying, and anti-corruption.

5 The company has developed innovative (unique in the sector) approaches to promoting ethical behaviour and anti-corruption which extends to countries within the scope of the Index, and supports this with evidence of progress and/or the human or financial resources invested.

2.5 The company has adopted innovative (unique in the sector) approaches to promoting ethical behaviour and anti-corruption which extend to countries within the scope of the Index, but does not disclose progress or resources invested.

0 No innovative initiatives identified in this area.

C RESEARCH & DEVELOPMENT 20%

C.I COMMITMENTS 13.3%

C.I.1 Product development: R&D commitment and strategy

40% The company publicly commits to conduct R&D of products for diseases within the scope of the Index with the goal of improving access to medicine in countries within scope. It operationalises its commitments with an R&D strategy that takes public health needs into account and has a system for setting targets and evaluating progress over time.

5 The company publicly commits to conduct product R&D for diseases within the scope of the Index with the goal of improving access to medicine for countries in scope. The company's R&D strategy and decision-making processes are informed by an evidence-based public health rationale. The company has time-bound strategies for its access-oriented R&D projects and evaluates progress towards these targets over time.

3 The company commits to conduct product R&D for diseases within the scope of the Index with the goal of improving access to medicine for countries in scope. The company's R&D strategy and decision-making processes are informed by an evidence-based public health rationale. The company has time-bound strategies for its access-oriented R&D projects and evaluates progress towards these targets over time.

1 The company makes a general commitment to conduct product R&D for diseases within the scope of the Index for countries in scope and/or has operationalising strategies for diseases and countries within the scope of the Index.

0 The company has no commitments or strategies in this area.

C.I.2 Planning for access: Structured process

25% The company has a process through which equitable access is planned for products successfully developed in-house and through R&D partnerships.

5 The company has a structured process in place to develop access provisions during development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different provisions for different product types, disease targets and target populations. Access provisions are developed as early in the product development process as possible with clear timelines.

3 The company has a structured process in place to develop access provisions during development for a subset of its R&D projects targeting diseases and countries within the scope of the Index. The process includes consideration of different provisions for different product types, disease targets, and target populations. Access provisions are developed as early in the product development process as possible with clear timelines.

1 The company has a general process in place to include access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.

0 The company has no processes in place in this area or applies access planning on an ad-hoc basis

C.I.3 Clinical trial conduct: Policies and compliance systems

25% The company commits to and has processes to ensure compliance with standards of quality assurance, control and ethics when conducting clinical trials in countries within the Index scope. These standards are consistent with codes such as Good Clinical Practice (GCP), and the Declaration of Helsinki, regardless of whether the trials are conducted in-house or through a third-party, e.g., contract research organisation (CRO).

5 The company provides evidence that, for both in-house and outsourced trials in countries in scope, it:
a) has policies in place to ensure compliance with Good Clinical Practice;
b) has policies in place to ensure compliance with the Declaration of Helsinki, addressing at least two of the following elements: use of placebo; scientific requirements and research protocols; research registration and public dissemination of results;
c) audits and monitors clinical trial conduct to comply with the above policies;
d) has procedures in place for selecting third parties; and
e) has procedures in place for taking disciplinary action against any violations.

3 The company provides evidence that, for both in-house and outsourced trials in countries in scope, it:
a) has policies in place to ensure compliance with Good Clinical Practice;
b) audits and monitors clinical trial conduct to comply with the above policies;
c) has procedures in place for selecting third parties; and
d) has procedures in place for taking disciplinary action against any violations.

1 The company provides evidence that it has policies to ensure compliance with Good Clinical Practice.

0 The company makes no commitments in this area.

C.I.4 Clinical trial conduct: Post-trial access

10% The company publicly commits to ensure post-trial access to treatments tested through clinical trials in countries within the scope of the Index.

5 The company has a publicly available policy on post-trial access, including: incorporation of articles 22 and 34 of the Declaration of Helsinki and a commitment to register products in all countries where clinical trials have taken place. The company has provided at least one example of the applied approach or policy in countries within the scope of the Index.

3 The company has an available policy on post-trial access, including: incorporation of articles 22 and 34 of the Declaration of Helsinki and a commitment to register products in all countries where clinical trials have taken place.

1 The company has an available policy on post-trial access, including incorporation of articles 22 and 34 of the Declaration of Helsinki.

0 The company has no policies in this area or applies post-trial access on an ad hoc basis.

C.II TRANSPARENCY 23.2%

C.II.1 Disclosure of resources dedicated to R&D

100% The company publicly discloses the resources dedicated to its R&D activities conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.

5 The company publicly discloses data on R&D investments for diseases within the scope of the Index at the Index Disease and/or Index Disease category level for some of its relevant pipeline. The company also discloses, via the Index, R&D investments disaggregated at the Index Disease and/or Index Disease category level for all of its relevant pipeline.

4 The company discloses via the Index data on R&D investments at the Index Disease and/or Index Disease category level for all of its relevant pipeline.

3 The company discloses via the Index investments disaggregated at the Index Disease and/or Index Disease category level for some of its relevant pipeline.

2 The company discloses to the Index investments disaggregated at the Index Disease and/or Index Disease category level for all of its relevant pipeline.

1 The company discloses to the Index aggregate investments for diseases within the scope of the Index.

0 The company does not disclose to the Index any R&D investment data specific to diseases within the scope of the Index.

C.III PERFORMANCE 54.1%

C.III.1 Resources dedicated to R&D

15% The financial R&D investment dedicated to diseases within the scope of the Index out of the company's total revenue.

5-1 Each company's R&D investment for diseases within the scope of the Index is divided by total company revenue from 2016 & 2017, and is then scaled across all companies and scored.

0 The company does not provide its total R&D investment for diseases within the scope of the Index.

C.III.2 R&D pipeline

15% The size of the R&D pipeline within the scope of the Index, including innovative and adaptive R&D, and in-house and collaborative R&D.

5-1 The total size of each company's pipeline for diseases within the scope of the Index is adjusted to give early-stage cancer projects for which a target has not yet been specified a lower weight, then scaled across all companies and scored.

0 The company has no projects within the scope of the Index in its research pipeline.

C.III.3 High-priority R&D

20% The share of the company's R&D pipeline within the scope of the Index targeting specific needs of populations in countries also within the scope of the Index.

5-1 The share of the company's pipeline within the scope of the Index for which the company targets specific needs in countries in scope (either through target product characteristics or targeting an externally-defined R&D gap), scaled across all companies and scored.

0 The company has no projects within the scope of the Index in its research pipeline for which it targets specific needs in countries in scope.

C.III.4 Collaborative R&D: Share of pipeline

10% The share of the company's research pipeline (both innovative and adaptive) within the scope of the Index that is being developed in partnership.

5 The share of the company's pipeline within the scope of the Index developed in collaboration is equal to or above 80%.

4 The share of the company's pipeline within the scope of the Index developed in collaboration is between 60% and 79%.

3 The share of the company's pipeline within the scope of the Index developed in collaboration is between 40% and 59%.

2 The share of the company's pipeline within the scope of the Index developed in collaboration is between 20% and 39%.

1 The share of the company's pipeline within the scope of the Index developed in collaboration is between 1% and 19%.

0 The company has no active research collaborations in its pipeline within the scope of the Index.

C.III.5 Product development: Movement through the pipeline

10% The number of candidates relating to diseases within the scope of the Index moving through the R&D life cycle from early research phases to more advanced phases.

5-1 The phase of development of each company's pipeline projects within the scope of the Index is compared with the phase each one was in during the 2016 Access to Medicine Index's period of analysis. The number of projects that have progressed from discovery to pre-clinical, pre-clinical to clinical and from clinical to regulatory approval, is added together, weighted and adjusted against the size of the company's total pipeline within the scope of the Index. These values are scaled across all companies and scored. The company, or set of companies, with the strongest performance, receives a score of five.

0 No pipeline projects within the scope of the Index progressed from one stage of development to another since the 2016 Access to Medicine Index.

C.III.6 Planning for access: Project-specific plans

20% The company provides evidence that its R&D projects (both in-house and collaborative) are supported by commitments and strategies to improve access to products that target diseases relevant to the Index in countries within the scope of the Index.

5 All of the company's late-stage R&D projects within the scope of the Index have at least one access provision in place.

4 40% to 99% of the company's late-stage R&D projects within the scope of the Index have at least one access provision in place.

3 20% to 39% of the company's late-stage R&D projects within the scope of the Index have at least one access provision in place.

2.5 Fewer than 20% of the company's late-stage R&D projects within the scope of the Index have at least one access provision in place. Alternatively, the company has been engaged in partnerships with access-oriented organisations without providing evidence of pro-access terms and conditions.

0 The company provides no evidence of any late-stage R&D projects within the scope of the Index having at least one access provision in place. Nor does it provide evidence of any partnerships with access-oriented organisations.

C.III.7 Clinical trial conduct: Breaches

10% The company has not been the subject of any breach of international codes or lawsuits related to its clinical trial practices in countries within the scope of the Index during the last two years.

5 The company has not been the subject of any regulatory notices or legal cases with negative rulings related to its clinical trial conduct in countries within the scope of the Index.

2 The company has been the subject of at least one regulatory notice or market rejection but no legal cases with legal rulings in countries within the scope of the Index.

0 The company has been the subject of at least one legal case with a negative ruling in countries within the scope of the Index.

C.IV INNOVATION 9.4%

C.IV.1 Innovation in R&D

100% The company has adopted innovative (unique in the sector), sustainable or open business models to further the global R&D agenda for the development of products for diseases relevant to the Index.

5 The company has provided evidence that it invested in designing innovative (unique in the sector) approaches to R&D for all diseases within the scope of the Index in which the company is active, with the potential to improve access to medicine in countries in scope.

2.5 The company has provided evidence that it invested in designing innovative (unique in the sector) approaches to R&D for some diseases within the scope of the Index in which the company is active, with the potential to improve access to medicine in countries in scope.

1 The company has provided evidence that it is part of a small group of companies who are investing in similar innovative R&D approaches for diseases within the scope of the Index in which the company is active, with the potential to improve access to medicine in countries in scope.

0 No innovative initiatives identified in this area.

D PRICING, MANUFACTURING AND DISTRIBUTION 25%

D.I COMMITMENTS 13.3%

D.I.1 Commitment to equitable pricing

55% The company publicly commits to implementing equitable pricing strategies for its products for diseases within the Index scope, in countries within scope.

5 The company publicly commits to apply inter- and intra-country equitable pricing models to the majority of diseases within the scope of the Index for which it has products on the market, in the majority of countries within the scope of the Index. The commitment explicitly applies to future products.

4 The company publicly commits to apply inter-country equitable pricing to the majority of diseases within the scope of the Index for which it has products on the market, in the majority of countries in the scope of the Index. It commits to apply intra-country equitable pricing models to the minority of diseases for which it has products on the market and countries within the scope of the Index.

2.5 The company publicly commits to apply inter- and/or intra-country equitable pricing models to the minority of diseases for which it has products on the market and countries within the scope of the Index.

1 The company makes a general public commitment to apply inter-country equitable pricing to products that target diseases within the scope of the Index and/or to countries within the scope of the Index, or it makes an equitable pricing commitment to the Index that adheres to the standards described in any of the above tiers.

0 The company makes no public commitment in this area and either no commitment to the Index in this area or a commitment to the Index does not meet standards described in the above tiers.

D.I.2 Filing for marketing approval/registration targets

45% The company commits to filing for marketing approval or product registration within a specific timeframe in sub-Saharan Africa and low-income countries for products for diseases within the scope of the Index, considering public health need.

5 The company has specific targets to file to register its products for the majority of diseases within the scope of the Index for which it has marketed products in sub-Saharan Africa and all LICs within 12 months of first global market launch. The company provides evidence that its targets are informed by a public health rationale.

4 The company has specific targets to file to register its products for the majority of diseases within the scope of the Index for which it has marketed products in sub-Saharan Africa and all low-income countries. The company has committed to file to register these products within 12 months of first global market launch or evidence is provided that the targets are informed by a public health rationale.

2.5 The company has committed to file to register a subset of its products for diseases within the scope of the Index for which it has marketed products in a subset of sub-Saharan African countries and/or low-income countries, but has committed to no timeframe and/or does not provide evidence of informing the targets with a public health rationale.

1 The company has made commitments to file to register its products for diseases within the scope of the Index scope in countries within the scope of the Index, but these commitments exclude sub-Saharan Africa and low-income countries.

0 The company makes no commitments in this area.

D.II TRANSPARENCY 23.2%

D.II.1 Equitable pricing strategies: Volume of sales disclosure

30% The company discloses the volume of sales for products covered under equitable pricing programmes within the scope of the Index.

5 The company discloses the volume of sales covered by equitable pricing programmes during the period of analysis to the public and/or private sector in all relevant countries* for all of its tracer products.**

4 The company discloses the above information for the majority of its tracer products.**

2.5 The company discloses a subset of the above information (such as regional or representative figures) for all of its tracer products** or discloses complete volume of sales data for a minority of its tracer products** or fails to identify a sufficient number of tracer products but discloses complete or partial volume of sales data.

1 The company discloses a subset of the above information (such as regional or representative figures) for a minority of its tracer products.**

0 The company has equitable pricing strategies for products and countries within the the scope of the Index, but makes no disclosure in this area.

NS Companies without any equitable pricing strategies within the scope of the Index receive a neutral score.

* Up to five countries within the scope of the Index that are targeted by the equitable pricing strategy for a given tracer product.
** Products that account for the highest sales revenue in countries within the scope of the Index for which equitable pricing strategies are applied.

D.II.2 Equitable pricing strategies: Price disclosure

30% The company discloses ex-manufacturer prices for products covered under equitable pricing programmes within the scope of the Index.

5 The company discloses the price point offered to the public and/or private sector in all relevant countries* during the period of analysis for all of (100%) its tracer products** covered by equitable pricing programmes.

4 The company discloses the above information for the majority of its tracer products.**

2.5 The company discloses a subset of the above information (such as regional or representative figures) for the majority (50-99%) of its tracer products** or discloses complete/full price point data for a minoritysubset (less than 50%) of its tracer products**or fails to identify a sufficient number of tracer products but discloses complete or partial price point data.

1 The company discloses a subset of the above information (such as regional or representative figures) for a minority of its tracer products.**

0 The company has equitable pricing strategies for products and countries within the Index scope but makes no disclosure in this area.

NS Companies without any equitable pricing strategies within the Index scope receive a neutral score.

* Up to five countries within the scope of the Index that are targeted by the equitable pricing strategy for a given tracer product.
** Products that account for the highest sales revenue in countries within the Index scope for which equitable pricing strategies are applied.

D.II.3 Public disclosure of registration status

40% The company publicly discloses the status of marketing approvals for products in countries in scope.

5 The company publicly discloses detailed information about the registration status of the majority of its products that target diseases within the scope of the Index in countries within the scope of the Index.

4 The company publicly discloses detailed information about the registration status of the minority of its products that target diseases within the scope of the Index scope in countries within the scope of the Index, or partial information about the registration status of the majority of its products that target diseases within the scope of the Index in countries within the scope of the Index.

3 The company publicly discloses partial information about the registration status of the minority of its products that target diseases within the scope of the Index in countries within the scope of the Index.

2 The company discloses via the Index the registration status of its most recently launched products* that target diseases within the scope of the Index in countries within the scope of the Index.

1 The company discloses via the Index partial information about the registration status of its most recently launched products* that target diseases within the scope of the Index in countries within the scope of the Index.

0 The company makes no disclosure in this area.

* Most recently launched refers to the date the product was first approved to be marketed anywhere globally. The Index analyses information for up to 10 of the company's most recently launched products, depending on the size of the company's portfolio.

D.III PERFORMANCE 54.1%

D.III.1 Equitable pricing strategies: Market and product scope

18% The company's equitable pricing strategies cover a significant percentage of the company's products that target diseases within the scope of the Index and a significant percentage of priority countries*.

5 Companies with a majority of marketed products that target diseases within the scope of the Index: between 50-75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target at least 75% of corresponding priority countries or at least 75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 50-75% of corresponding priority countries. Companies with a minority of marketed products that target diseases within the scope of the Index: at least 75% of the company's relevant products have equitable pricing strategies that target priority countries* and these strategies target at least 75% of corresponding priority countries.

4 Companies with a majority of marketed products that target diseases within the scope of the Index: the minority of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 50-75% of corresponding priority countries or between 50-75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target the minority of corresponding priority countries. Companies with a minority of marketed products that target diseases within the scope of the Index: between 50-75% of the company's relevant products have equitable pricing strategies that target priority countries and these strategies target at least 75% of corresponding priority countries OR at least 75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 50-75% of corresponding priority countries.

3 Companies with greater than or equal to 50 marketed products that target diseases within the scope of the Index: Between 25-50% of the company's relevant products have equitable pricing strategies that target priority countries and these strategies target between 25-50% of corresponding priority countries. Companies with less than 50 marketed products that target diseases within the scope of the Index: Less than 50% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 50-75% of corresponding priority countries or between 50-75% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target less than 50% of corresponding priority countries.

2.5 Companies with a majority of marketed products that target diseases within the scope of the Index: A minority of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 25-49% of corresponding priority countries or between 25-49% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target a minority of corresponding priority countries. Companies with a minority of marketed products that target diseases within the scope of the Index: Between 25-50% of the company's relevant products have equitable pricing strategies that target priority countries and these strategies target between 25-50% of corresponding priority countries.

2 Companies with a majority of marketed products that target diseases within the scope of the Index: Between 10-24% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 10-24% of corresponding priority countries. Companies with a minority of products that target diseases within the scope of the Index: A minority of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target between 25-49% of corresponding priority countries* or between 25-49% of the company's relevant products are covered by equitable pricing strategies that target priority countries and these strategies target a minority of corresponding priority countries.

1 Companies with a majority of marketed products that target diseases within the scope of the Index: Less than 10% of the company's relevant products have equitable pricing strategies that target any corresponding priority countries. Companies with a minority of marketed products that target diseases within the scope of the Index: Less than 25% of the company's relevant products have equitable pricing strategies that target any corresponding priority countries.

0 None of the company's marketed products that target diseases within the scope of the Index have equitable pricing strategies that target any priority countries.

* Priority countries are defined by the Index for each disease covered within the scope of the Index. They are those countries that have been identified as having one of the highest burdens for the disease in question, adjusted for multi-dimensional inequality. Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

D.III.2 Equitable pricing strategies: Inter-country

18% The company takes into consideration needs-based affordability and other relevant socioeconomic factors* when making inter-country pricing decisions.

5 Companies with greater than or equal to the average number of products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and demonstrate the applied use of some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 4.Companies with less than average number of products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and demonstrate the applied use of some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 5.

4 Companies with greater than or equal to 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 3.Companies with less than 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 4.

3 Companies with greater than or equal to the average number of products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 2. Companies with less than the average number of products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 3.

2 Companies with greater than or equal to the average number of products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and demonstrate an applied use of some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 1. Companies with less than the average number of products within scope of the Index that have equitable pricing strategies: for the majority of its products that have an inter-country equitable pricing strategy, the company takes into account affordability and demonstrate an applied use of some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 1-2.

1 For the majority of its products within the scope of the Index that have an inter-country equitable pricing strategy, the company takes affordability into account, but no socioeconomic factors.

0 The company has intra-country equitable pricing strategies but no inter-country equitable pricing strategies.

NS Companies without any equitable pricing strategies receive a neutral score.

* Including: disease burden, healthcare system financing, healthcare system infrastructure, demography, level of economic and human development, cost of R&D/manufacturing, commitment from government, demand, level of inequality, ensuring patient education and disease awareness, alternative treatments/competition/generic medicine alternatives, unmet need, ensuring appropriate use, supply chain factors, and regulatory systems.

D.III.3 Equitable pricing strategies: intra-country

18% The company takes into consideration needs-based affordability and other relevant socioeconomic factors* when making intra-country pricing decisions.

5 Companies with greater than or equal to 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 4. Companies with less than 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 5.

4 Companies with greater than or equal to 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 3. Companies with less than 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 4.

3 Companies with greater than or equal to 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 2. Companies with less than 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 3.

2 Companies with greater than or equal to 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 1. Companies with less than 15 products within the scope of the Index that have equitable pricing strategies: for the majority of its products that have an intra-country equitable pricing strategy, the company takes into account affordability and some socioeconomic factors. Among these products, the average number of socioeconomic factors taken into account per product is 1-2.

1 For the majority of its products within the scope of the Index that have an intra-country equitable pricing strategy, the company takes affordability into account, but no socioeconomic factors.

0 The company has inter-country equitable pricing strategies but no intra-country equitable pricing strategies for its products that target diseases within the scope of the Index.

NS Companies without any equitable pricing strategies receive a neutral score.

* Including disease burden, healthcare system financing, healthcare system infrastructure, demography, level of economic and human development, cost of R&D/manufacturing, commitment from government, demand, level of inequality, ensuring patient education and disease awareness, alternative treatments/competition/generic medicine alternatives, unmet need, ensuring appropriate use, supply chain factors, and regulatory systems.

D.III.4 Filing for marketing approval/registration: Needs-based

18% The company has filed to register its newest products targeting diseases both within the scope of the Index scope in countries in need within scope.

5 The company has filed to register all of its most recently launched products* that target diseases in scope, in the majority of corresponding priority countries.**

4 The company has filed to register the majority of its most recently launched products in the majority of corresponding priority countries

3 The company has filed to register the majority of its most recently launched products that target diseases in scope, in the minority of corresponding priority countries or it has filed to register the minority of its most recently launched products that target diseases in scope, in the majority of corresponding priority countries.

1 The company has filed to register the some of its most recently launched products* that target diseases in scope, in the minority of corresponding priority countries.**

0 The company provides no evidence of filing to register any of its most recently launched products that target diseases in the Index scope in any countries in scope.

* Most recently launched refers to the date the product was first approved to be marketed anywhere globally. The Index analyses information for up to 10 of the company's most recently launched products, depending on the size of the company's portfolio.

** Priority countries are defined by the Index for each disease covered by the scope of the Index. They are those countries that have been identified as having one of the highest burdens for the disease in question, adjusted for multi-dimensional inequality. Per disease, the set of priority countries includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries

D.III.5 Drug recall system

10% The company has in place policies and processes, procedures and resources needed to carry out effective drug recalls (product and packaging) in countries within the scope of the Index, and provides details of its recall system effectiveness.

- 5 The company has guidelines for drug recalls that apply consistently to all countries within the scope of the Index where its products are available. The company also has processes specifically to track products in countries within the scope of the Index to ensure effective recalls.
- 2.5 The company has guidelines for drug recalls that apply consistently to all countries within the scope of the Index where its products are available. The company provides no evidence of processes specifically to track products in countries within the scope of the Index to ensure effective recalls.
- 0 The company has guidelines for drug recalls which are not applied consistently to all countries within the scope of the Index where its products are available, or has no guidelines for drug recalls.

D.III.6 Brochure and packaging adaptation: Rationale use

10% The company provides evidence of needs-based brochure and packaging adaptations to facilitate rational use for its products destined for countries within the scope of the Index.

- 5 The company discloses evidence of product brochure and packaging adaptations that aim to facilitate rational use for communities in countries within the scope of the Index, at various levels of the health system,* for 4 or 5 of the relevant needs identified by the Index.**
- 3.5 The company discloses evidence of product brochures and packaging adaptations that aim to facilitate rational use for communities in countries within the scope of the Index, for 3-4 of the relevant needs identified by the Index.
- 2 The company discloses evidence of product brochure and packaging adaptations that aim to facilitate rational use for communities in countries within the scope of the Index, for 2 of the relevant needs identified by the Index.
- 1 The company discloses evidence of product brochure and packaging adaptations that aim to facilitate rational use for communities in countries within the scope of the Index, for 1 of the relevant needs identified by the Index.
- 0 The company provides no evidence of brochure or packaging adaptations that aim to facilitate rational use.

* Including: for example, needs of physicians, nurses, health workers or pharmacists, at the point of dispensing or administration.

** Needs identified by the Index include: literacy, language, cultural, demographic and environmental considerations.

D.III.7 Aligning supply and demand

8% The company makes efforts to understand product distribution and demand behaviour in countries in the scope of the Index beyond first product hand-off, and takes informed action to ensure products are made available in sufficient quantities in a timely manner.

- 5 The company has a system in place to align its global, regional and country supply planning processes for all products it markets in countries within the Index scope with demand in these countries. This system involves: a) making efforts to understand product distribution and demand behaviour in countries in scope, beyond the point of first product hand-off; b) applying this information to ensure sufficient, timely supply to these countries; and c) specific efforts to address supply to Least Developed Countries, low income countries, and/or poor and rural population segments in countries within the scope of the Index.
- 4 The company has a system in place to align its global, regional and country supply planning processes for a subset of products it markets in countries within the Index scope with demand in these countries. This system involves: a) making efforts to understand product distribution and demand behaviour in countries in scope, beyond the point of first product hand-off; b) applying this information to ensure sufficient, timely supply to these countries; and c) specific efforts to address supply to Least Developed Countries, low income countries, and/or poor and rural population segments in countries within the scope of the Index.
- 2.5 The company has a system in place to align its global, regional and country supply planning processes for products it markets in countries within the Index scope with demand in these countries. This system involves: 1) making efforts to understand product distribution and demand behaviour in countries in scope, beyond the point of first product hand-off; and 2) applying this information to ensure sufficient, timely supply to these countries. The company provides no evidence of specific efforts to address supply to Least Developed Countries, low income countries, and/or poor and rural population segments in countries within the scope of the scope of the Index.
- 1 The company provides evidence of making some efforts to align its supply planning processes for products it markets in countries within the scope of the Index with demand in those countries, but has no specific system or processes in place to achieve this aim.
- 0 The company provides no evidence of making efforts to align its supply planning processes for products it markets in countries within the scope of the Index with demand in those countries.

D.IV.1 INNOVATION 9.4%

D.IV.1 Innovation in Pricing, Manufacturing and Distribution

100% The company has introduced innovative approaches (unique in the sector) to equitable pricing, manufacturing and distribution that help with sustainable delivery of products for diseases within the Index scope to individuals in the countries relevant to the Index. If the approach focuses on equitable pricing, it targets those who face the highest financial barriers to access.

5 The company has introduced innovative approaches (unique in the sector) to equitable pricing, manufacturing and distribution that help with sustainable delivery of products for diseases within the scope of the Index to individuals in the countries within the scope of the Index. Approaches focusing on equitable pricing target those who face the highest financial barriers to access.Only innovative projects for which either progress made, or human and/or financial resources are disclosed, are taken into consideration.

2.5 The company has introduced innovative approaches (unique in the sector) to equitable pricing, manufacturing and distribution that help with sustainable delivery of products for diseases within the scope of the Index to individuals in the countries within the scope of the Index. Approaches focusing on equitable pricing target those who face the highest financial barriers to access. No progress or resources are disclosed.

0 No innovative approaches identified in this area.

E PATENTS & LICENSING 15%

E.I COMMITMENTS 13.3%

E.I.1 Patent filing and enforcement

100% The company publicly commits to not filing for or enforcing patents related to diseases within the Index scope in Least Developed Countries, low income countries, and a subset of lower-middle income countries and upper-middle income countries.

5 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products for diseases in the Index scope in all Least Developed Countries, low-income countries, and a subset of lower-middle income countries and upper-middle income countries.

4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in the Index scope in all Least Developed Countries, low-income countries, and a subset of lower-middle income countries.

3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in the Index scope in all Least Developed Countries and/or all low-income countries.

2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in the Index scope in a specific region or regions (e.g., Least Developed Countries, sub-Saharan Africa, etc.)

0 The company makes no commitment in this area.

E.II TRANSPARENCY 23.2%

E.II.1 Endorsement of TRIPS flexibilities

45% The company publicly discloses its support of the policy flexibilities intended to protect public health confirmed by the Doha Declaration on TRIPS and Public Health.

5 The company publicly discloses explicit support for the Doha Declaration and the usage of three or four of the following TRIPS flexibilities in relation to countries in the Index scope, with no caveats on the appropriate use of these flexibilities: a) compulsory licences; b) parallel imports; c) Bolar provisions; d) exemptions for LDCs.

4 The company publicly discloses explicit support for two out of four of the above flexibilities, with no caveats on the appropriate use of these flexibilities.

2 The company publicly discloses general support for the Doha Declaration and the usage of TRIPS flexibilities, though caveats are applied.

0 The company does not publicly disclose support for the Doha Declaration.

E.II.2 Patent disclosure

25% The company publicly discloses the patent status of its products for diseases relevant to the Index, in countries within the Index scope.

5 The company publicly discloses the patent status for all products in the Index scope in all countries within the scope of the Index. This information is updated periodically and the standard of transparency achieved is analogous to or greater than that set out by the US FDA's Orange Book*.

4 The company publicly discloses the patent status for a subset of products in the Index scope in all countries within the scope of the Index. This information is updated periodically and the standard of transparency achieved is analogous to or greater than that set out by the US FDA's Orange Book.

2.5 The company publicly discloses patent status for some products within the Index scope patent status information for its products in the Index scope in countries in the Index scope, but this information is provided for a subset of products and/or countries. There is no evidence that this information is updated periodically and/or that the standard of transparency achieved is less than that set out by the US FDA's Orange Book.

0 The company makes no public disclosure in this area.

* The FDA Orange Book includes product patent data, patent number and expiry date.

E.II.3 Disclosure of licensing practice

30% The company publicly discloses detailed information about the voluntary licences and non-assert agreements it is engaged in, for products within the Index scope, in countries within the Index scope.

5 The company publicly discloses the complete contents of all voluntary licences and non-assert declarations agreed for products within the scope of the Index.

4 The company publicly discloses the complete contents of all voluntary licences and non-assert declarations agreed for a subset of products within the scope of the Index for which it has agreed voluntary licences and non-assert declarations.

2 The company publicly discloses partial information on the terms of all or a subset of the voluntary licences and non-assert declarations it has agreed for products within the scope of the Index.

1 The company discloses information via the Index about the licences and non-assert declarations it has agreed for products within the scope of the Index.

0 The company makes no disclosure in this area.

NS Companies without any voluntary licences for products within the scope of the Index receive a neutral score.

E.III PERFORMANCE 54.1%

E.III.1 Licensing: scale

35% The company actively engages in issuing multiple voluntary licences and/or non-assert declarations for patented products within the Index scope, in countries within the Index scope.

5 The company has issued five or more non-exclusive voluntary licences and/or non-assert declarations to generic manufacturers for 91-100% of its patented products within the scope of the Index.

4 The company has issued more than or equal to five non-exclusive voluntary licences and/or non-assert declarations to generic manufacturers for between 25-90% of its patented products within the scope of the Index.

3 The company has issued more than or equal to five non-exclusive, voluntary licences and/or non-assert declarations for less than 25% of its patented products within the scope of the Index.

0 The company has patented products within the scope of the Index but has not issued any non-exclusive voluntary licences or non-assert declarations.

NS Companies without any patented products within the scope of the Index receive a neutral score.

E.III.2 IP sharing

10% The company provides evidence of sharing its intellectual capital (e.g., molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g., WIPO Re: Search, Conserved Domain Database (CDD), Open Source Drug Discovery (OSDD)) that develop products for diseases relevant to the Index on terms conducive to access to medicine for countries within the scope of the Index.

5-1 The agreements that each company has made during the period of analysis to share its intellectual capital with research institutions or drug discovery initiatives on terms which promote access to resulting products in countries relevant to the Index are weighted, added together, scaled across all companies and scored.

0 The company does not provide evidence of sharing its intellectual property according to the above criteria.

E.III.3 Access-oriented licensing

17.50% The company includes access-oriented terms and conditions within the voluntary licences it agrees for products relevant to the Index, in countries within the Index scope.

5 The company includes an average of at least seven of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in countries relevant to the Index.

4 The company includes an average of five to six of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in countries relevant to the Index.

3 The company includes an average of four to five of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in countries relevant to the Index.

2 The company provides evidence that it includes an average of two to three of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in countries relevant to the Index.

1 The company provides evidence that it includes an average of one of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in countries relevant to the Index.

0 The company does not provide evidence of including any of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in countries relevant to the Index.

NS Companies without any voluntary licences for patented products within the Index scope receive a neutral score.

* Licence agreed with long patent life remaining, optional provision for technology transfer, ability to manufacture and source active pharmaceutical agreements without restriction, ability to supply to countries issuing compulsory licences, ability to supply where no patents are in force, absence of no challenge clauses, waiver on data exclusivity, outcome or impact assessments conducted in relation to licence.

E.III.4 Licensing: Geographic scope

17,50% The company includes a broad range of countries within the geographic scope of its licences, including middle-income countries outside of sub-Saharan Africa with comparatively high burdens of disease.

5 The company has issued voluntary licences which include all Least Developed Countries, low income countries, and middle income countries.

4 The company has issued voluntary licences which include all Least Developed Countries, all low income countries, all of Sub-Saharan Africa, and 6 to 10 of the middle income countries with the ten highest burdens of disease outside of sub-Saharan Africa.

3 The company has issued voluntary licences which include all Least Developed Countries, all low income countries, all of Sub-Saharan Africa, and 1 to 5 of the middle income countries with the highest burdens of disease outside of sub-Saharan Africa.

0 The company does not include in its voluntary licences any of the middle income countries with the ten highest burdens of disease outside of sub-Saharan Africa.

NS Companies without any voluntary licences for patent products within the scope of the Index receive a neutral score.

E.III.5 Anti-competitive behaviour: Trade policy

10% There is evidence that the company employs an intellectual property (IP) strategy that is conducive to access to medicine, operating in accordance with the international consensus on IP standards as it pertains to public health, confirmed by the Doha Declaration.

5 There is no evidence that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.

2 The company has been involved in one IP-related anti-competitive practice* via industry association, but has a clear policy for dissent from industry association position.

1 The company has been involved in one IP-related anti-competitive practice* (either direct/or via industry association), and has no clear policy for dissent from industry association position.

0 The company has been involved in multiple examples of anti-competitive IP-related practices*.

* Patenting in Least Developed Countries, lobbying against the usage of TRIPS flexibilities by country governments within the Index scope, lobbying for strengthening of IP standards beyond TRIPS in countries within the scope of the Index.

E.III.6 Anti-competitive behaviour: No-IP

10% There is evidence that the company has engaged in anti-competitive behaviour outside of its intellectual property strategy that impacts access to medicine.

5 The company has not been the subject of any negative rulings or settlements related to anti-competitive behaviour in any country within the scope of the Index, over the period of analysis.*

1 The company has been the subject of one negative ruling or settlement in any country within the scope of the Index, over the period of analysis.*

0 The company has been the subject of more than one negative ruling or settlement in a country within the scope of the Index, over the period of analysis.*

E.IV INNOVATION 9.4%

E.IV.1 Innovation in Patents & Licensing

100% The company has adopted innovative (unique in sector) programmes aimed at managing the exclusivity conferred by patent protection to support competition for products relevant to the Index, in countries within the Index scope.

5 The company has adopted an innovative activity(ies) aimed at mitigating the potential public health impact of the exclusivity conferred by patent protection of products within the Index scope, in countries within the scope of the Index.

2.5 The company has publicly committed to activities aimed at mitigating the potential public health impact of the exclusivity conferred by patent protection of products within the Index scope in countries within the scope of the Index.

0 No innovative initiatives identified in this area.

F CAPACITY BUILDING 15%

F.II TRANSPARENCY 23.2%

F.II.1 Pharmacovigilance: Sharing safety data

50% The company shares post-marketing surveillance data with relevant authorities beyond legal requirements and updates product safety and/or efficacy labels (regardless of product life cycle stage) in countries within the scope of the Index.

5 The company voluntarily discloses post-marketing surveillance safety data for its products to national regulatory authorities and/or other relevant authorities AND provides evidence to/via the Index of updating safety and/or efficacy labels in countries within the scope of the Index, regardless of a product's patent status.

4 The company discloses post-marketing surveillance safety data for its products upon request to national regulatory authorities and/or other relevant authorities AND provides evidence to/via the Index of updating safety and/or efficacy labels in countries within the scope of the Index, regardless of a product's patent status.

2.5 The company provides evidence to the Index of EITHER of a) disclosing post-marketing surveillance safety data (either voluntarily or up on request) to national regulatory authorities OR b) evidence of updating safety and/or efficacy labels in countries within the scope of the Index, regardless of product's patent status (but not evidence of doing both a & b).

0 The company does not provide evidence of voluntary disclosure of safety data and/or updating safety/efficacy labels in countries within the scope of the Index.

F.II.2 Supply chain management: Reporting falsified and substandard medicines

50% The company has a policy/protocol for reporting sub-standard and falsified (SF) medicines in countries within the scope of the Index that specifies timeframes for reporting to relevant stakeholders (i.e., national regulatory authorities and WHO Rapid Alert).

5 The company provides evidence of a policy or approach to confirming suspected cases of SF medicines within seven days and then reporting confirmed cases to WHO Rapid Alert and/or local regulatory authorities within seven days of the confirmation in countries within the scope of the Index.

4 The company provides evidence of a policy or approach to reporting confirmed SF cases to WHO Rapid Alert and/or local regulatory authorities within seven days of the confirmation in countries within the scope of the Index.

2.5 The company provides evidence to the Index of reporting cases of SF medicines on a case-by-case basis, in countries within the scope of the Index, to relevant authorities.

1 The company discloses to/via the Index a detailed policy or approach for addressing falsified and/or substandard medicines in countries within the scope of the Index.

0 The company does not provide evidence of such a policy or approach

F.III PERFORMANCE 54.1%

F.III.1 Capacity building in manufacturing

20% The company undertakes manufacturing capacity building initiatives with local manufacturers aimed at achieving international Good Manufacturing Practice (GMP). These initiatives meet good practice standards* in countries within the scope of the Index.

5 The company provided evidence of five initiatives to build manufacturing capacity with third party manufacturers or other parties (i.e., universities) which address local needs, and at least three initiatives met all additional good practice standards (guided by clear goals and measurable objectives, measures progress or outcomes, and aims for sustainability and long-term impact).

4 The company provided evidence of four to five initiatives to build manufacturing capacity which address local needs, where more than one initiative met all additional good practice standards (see list above).

3 The company provided evidence of one or more initiative(s) to build manufacturing capacity which address local needs, where only one initiative met all good practice standards (see list above).

2 The company provided evidence of one or more initiative(s) to build manufacturing capacity which address local needs, but only met some or none of the other good practice standards.

0 The company does not provide any examples of initiatives to build manufacturing capacity in Index countries that address local needs during the period of analysis.

F.III.2 Capacity building in R&D

20% The company undertakes R&D capacity building initiatives in partnership with local universities and public sector research organisations that meet good practice standards in countries within the scope of the Index with the aim of increasing local capacity for health research (including clinical trial capacity) and product development.

5 The company provided evidence of five initiatives to build R&D capacity in partnership with a local university or public research institution which address local needs, and at least three initiatives met all additional good practice standards (good governance structures in place, align goals and objectives with university/institution, measures progress or outcomes, aims for sustainability & long-term impact).

4 The company provided evidence of multiple (less than 5, more than 1) initiatives to build R&D capacity where at least one initiative met all good practice standards (addresses local needs, in partnership with a local university or public research institution in a country in the scope of the Index, the partnership has good governance structures in place, goals align with that of the institution or university, measures progress or outcomes, and aims for sustainability and long-term impact).

3 The company provided evidence of multiple (less than 5, more than 1) initiatives to build R&D capacity where at least one initiative met most of the good practice standards (see list in previous scoring tier).

1 The company provided evidence of only one initiative in partnership with a local university or public research institution which addresses local needs that meets some or none of the other good practice standards.

0 The company does not provide any examples of initiatives to build R&D capacity in partnership with a local university or public research institution which addresses local needs in Index countries during the period of analysis.

F.III.3 Capacity building in supply chain management

20% The company undertakes supply chain capacity building initiatives in countries within the scope of the Index in partnership with local stakeholders (e.g., ministries of health, procurement, logistics and distribution agencies) that meet good practice standards with the aim of improving the affordability, accessibility and quality of products.

5 The company provided evidence of five initiatives to build local supply chain capacity in partnership* which address local needs, and at least three initiatives met all additional good practice standards (guided by clear goals and measurable objectives, measures progress or outcomes, aims for sustainability & long-term impact).

4 The company provided evidence of multiple (less than five, more than one) initiatives to build local supply chain capacity where more than one initiative met all good practice standards (addresses local needs, in partnership*, guided by clear goals and measurable objectives, measures progress or outcomes, and aims for sustainability and long-term impact).

3 The company provided evidence of one or more initiative(s) to build supply chain capacity where only one initiative met all good practice standards (see list in previous scoring tier).

2 The company provided evidence of one or more initiative(s) to build supply chain capacity in partnership* which address local needs, but only met some or none of the other good practice standards.

0 The company did not provide any examples of initiatives to build supply chain capacity in partnership* which met local needs in Index countries during the period of analysis.

* In partnership with local supply chain actors (public or private sector) in countries within the scope of the Index or with nonprofits, NGOs, or multilateral organizations

F.III.4 Capacity building in pharmacovigilance

20% The company undertakes pharmacovigilance capacity building initiatives with reputable partners that meet good practice standards* with the aim of developing and strengthening national pharmacovigilance systems in countries within the scope of the Index.

5 The company provided evidence of five initiatives to build pharmacovigilance capacity in partnership which address local needs, and at least one initiative met all additional good practice standards (good governance structures in place with processes to mitigate conflict of interest, guided by clear goals and measurable objectives, measures progress and/or outcomes, aims for sustainability & long-term impact).

4 The company provided evidence of multiple (less than five, more than one) initiatives to build pharmacovigilance capacity in partnership which address local needs, where at least one initiative met all additional good practice standards (see list above).

3 The company provided evidence of multiple (less than five, more than one) initiatives to build pharmacovigilance capacity where at least one initiative met most (but where none met all) of the good practice standards (addresses local needs, in partnership, good governance structures in place with processes to mitigate conflict of interest, guided by clear goals and measurable objectives, measures progress and/or outcomes, aims for sustainability & long-term impact).

1 The company provided evidence of one or two initiative(s) done in partnership and that meet local needs, and meets only some or none of the other good practice standards (see list above).

0 The company did not provide any examples of initiatives to build pharmacovigilance capacity in partnership which address local needs in countries in the scope of the Index during the period of analysis.

F.III.5 Health system strengthening

20% The company undertakes health system strengthening initiatives related to access to medicine in partnerships with local stakeholders (where there is no conflict of interest) that meet good practice standards* in countries within the scope of the Index.

5 The company provided evidence of five health system strengthening initiatives done in partnership which address local needs and have processes in place to mitigate conflict of interest. At least three of these initiatives met all additional good practice standards (good governance structures in place, guided by clear goals and measurable objectives, aims for long-term impact and sustainability, and measures outcomes and/or impact), INCLUDING at least one initiative which measures or has plans to measure impact.

4 The company provided evidence of four to five health system strengthening initiatives done in partnership which address local needs and have processes in place to mitigate conflict of interest, where more than one of these initiatives met all additional good practice standards (see above).

3 The company provided evidence of three to five health system strengthening initiatives done in partnership which address local needs and have processes in place to mitigate conflict of interest where only one of these initiatives met all additional good practice standards (see above).

2 The company provided evidence of one or more health system strengthening initiatives, where none of the initiatives met all of the good practice standards (address local needs, in partnership, good governance structures in place with processes to mitigate conflict of interest, guided by clear goals and measurable objectives, measures outcomes &/or impact, aims for sustainability & long-term impact).

0 The company does not provide any examples of health system strengthening initiatives done in partnership which address local needs and have processes in place to mitigate conflict of interest during the period of analysis in countries in the scope of the Index.

F.IV INNOVATION 9.4%

F.IV.1 Innovation in Capacity Building

100% The company has developed or adopted innovative (i.e., unique in sector) approaches to building capacity related to access to medicine through partnerships with relevant stakeholders in countries within the scope of the Index.

5 The company provides more than one example of an innovative capacity building initiative (unique to sector) where at least one meets all good practice standards.

4 The company provides one example of an innovative capacity building initiative (unique to sector) which meets all good practice standards AND one example of scaling up a previous innovation in the period of analysis.

2.5 The company provides one example of an innovative capacity building initiative (unique to sector) which meet all or most good practice standards.

0 No innovative initiatives identified in this technical area.

G PRODUCT DONATIONS 5%

G.I COMMITMENTS 13.3%

G.I.1 Ad-hoc donation programmes

100% The company has policies and processes in place to ensure ad-hoc donations are carried out in alignment with international guidelines and in response to an expressed need.

5 The company meets all of the following criteria with respect to ad-hoc donations: a) it has a policy in place to ensure all of its ad-hoc donations are carried out in alignment with international guidelines; b) it has processes in place to ensure it can respond rapidly to requests for ad-hoc donations; and c) it monitors delivery of donations until receipt by the end-user.

3 The company meets two of the following criteria with respect to ad-hoc donations: a) it has a policy in place to ensure all of its ad-hoc donations are carried out in alignment with international guidelines; b) it has processes in place to ensure it can respond rapidly to requests for ad-hoc donations; and c) it monitors delivery of donations until receipt by the end-user.

1 The company meets one of the following criteria with respect to ad-hoc donations: a) it has a policy in place to ensure all of its ad-hoc donations are carried out in alignment with international guidelines; b) it has processes in place to ensure it can respond rapidly to requests for ad-hoc donations; and c) it monitors delivery of donations until receipt by the end-user.

0 The company meets none of the following criteria with respect to ad-hoc donations: a) it has a policy in place to ensure all of its ad-hoc donations are carried out in alignment with international guidelines; b) it has processes in place to ensure it can respond rapidly to requests for ad-hoc donations; and c) it monitors delivery of donations until receipt by the end-user.

NB The first criterion will only be considered satisfied if companies that made ad-hoc donations of products within the Index scope to countries within the scope of the Index during the period of analysis provided evidence that such donations were made in response to expressed country needs.

G.II TRANSPARENCY 23.2%

G.II.1 Transparency in product donation management

100% The company publicly discloses the scale of the programme (financial value, units donated, beneficiaries), impact assessments and outcome measures (regardless of who conducted these) of its structured donation programmes in countries within the scope of the Index.

5 The company and/or its partners publicly disclose: a) the scale (financial value, units donated, beneficiaries); and b) impact assessments and outcome measures for all of its structured donation programmes, during the period of analysis and/or since the start of the programme.

3 The company and/or its partners publicly disclose: a) the scale (financial value, units donated, beneficiaries); and b) impact assessments and outcome measures, during the period of analysis and/or since the start of the programme for a subset of its structured donation programmes, or partially discloses the listed details for all of its structured donation programmes.

2 The company and/or its partners publicly disclose partial information regarding: a) the scale (financial value, units donated, beneficiaries); and/or b) impact assessments and outcome measures for a subset of its structured donation programmes.

1 The company discloses to/ or via the Index details about: a) the scale (financial value, units donated, beneficiaries); and/or b) impact assessments and outcome measures for some of its structured donation programmes.

0 The company does not disclose publicly or to the Index any information in this area.

NS Companies without any structured donation programmes receive a neutral score.

G.III PERFORMANCE 54.1%

G.III.1 Quality of product donations

60% The company and/or its partner(s) monitors the outcomes and impact of its structured donation programmes, and engages in capacity building activities to support the quality of the initiatives.

5 For all structured donation programmes, the company provides evidence of: a) integrating (either in-house or via a partner) outcome or impact assessments on public health (e.g., number of patients reached, epidemiology)(directly or via a partner); b) evidence of monitoring and auditing delivery of supply units until receipt by the end user (directly or via a partner); c) engaging in capacity building activities to support the quality of the programme (directly or via a partner); and d) taking sustainability into account over the long-term, either through a commitment to donate until elimination or eradication of the targeted disease, or through transition planning to support continued access for beneficiaries after the donation programme ends.

4 For the majority of its structured donation programmes, the company provides evidence of: a) conducting outcome or impact assessments on public health (directly or via a partner); b) monitoring and auditing delivery of supply until receipt by the end user (directly or via a partner); c) engaging in capacity building activities to support the quality of the programme (directly or via a partner); and d) taking sustainability into account over the long-term, either through a commitment to donate until elimination or eradication of the targeted disease, or through transition planning to support continued access for beneficiaries after the donation programme ends. Alternatively, for all of its structured donation programmes, the company provides evidence of the majority of the factors described.

2.5 For the minority of its structured donation programmes, the company provides evidence of the majority of the following factors: a) conducting outcome or impact assessments on public health (directly or via a partner); b) monitoring and auditing delivery of supply until receipt by the end user (directly or via a partner); c) engaging in capacity building activities to support the quality of the programme (directly or via a partner); and d) taking sustainability into account over the long-term, either through a commitment to donate until elimination or eradication of the targeted disease, or through transition planning to support continued access for beneficiaries after the donation programme ends. . Alternatively, for the majority of its structured donation programmes, the company provides evidence of the minority of the factors described.

1 For the minority of its structured donation programmes, the company provides evidence of the minority of the following factors: a) conducting outcome or impact assessments on public health (directly or via a partner); b) monitoring and auditing delivery of supply until receipt by the end user (directly or via a partner); c) engaging in capacity building activities to support the quality of the programme (directly or via a partner); and d) taking sustainability into account over the long-term, either through a commitment to donate until elimination or eradication of the targeted disease, or through transition planning to

support continued access for beneficiaries after the donation programme ends.

o The company does not provide evidence of the factors described.

NS Companies without structured donation programmes receive a neutral score.

G.III.2 Scale of product donations

40% The number of countries and the number of beneficiaries reached through all of the company's structured donation programmes during the period of analysis.

5-1 The number of countries and beneficiaries reached through each company's structured donation programmes during the period of analysis are summed, scaled and scored. Structured donation programmes that involve similar courses of treatment are scaled against one another.

o The company does not provide the above details for its structured donation programmes.

APPENDIX XII

Report card analysis: Further explanation

Pipeline and portfolio

Data sources for the R&D pipeline include projects submitted by the company for scoring and analysis in the Index, as well as any projects for diseases in scope identified on the company's website or through other sources including verification with product development partnerships (PDPs).

Data sources for the product portfolio text and graphs include products submitted by the company for scoring and analysis in the Index, as well as any registered products in scope identified from the FDA, EMA, PMDA and the company's own website.

The category 'multiple categories' includes products and projects that are indicated for multiple diseases within the Index scope and that cover multiple disease categories (e.g. broad-spectrum antibiotics). Contraceptive methods and devices are included under maternal and neonatal health conditions.

Essential medicines with first-line indications (graph)

The sources used to determine if a product is listed on the WHO EML and/or as a first-line treatment/prophylaxis are: the 2017 WHO Model List of Essential Medicines (WHO EML) and disease-specific treatment guidelines from the World Health Organization (WHO), the Centers for Disease Control (CDC), the National Institute for Health and Care Excellence (NICE), the American Academy of Family Physicians (AAFP) and the National Comprehensive Cancer Network (NCCN). This graph only covers medicines and vaccines. The total number of products differs from the products per disease category graph if the company has diagnostics, vector control products and/or platform technologies in its portfolio. This is because these products are not within the scope of the WHO EML.

Projects for R&D priority targets with access provisions (graph)

The sources used to determine if a project targeted an R&D priority target are:

- Policy Cures Research G-FINDER neglected diseases, products and technologies (2017)
- Policy Cures G-FINDER reproductive health areas, products and technologies (2014)
- WHO R&D Blueprint (2017)
- WHO Initiative for Vaccine Research gaps (2017)
- WHO priority pathogens list for R&D of new antibiotics (2017)

In some instances, companies submitted additional rationale for a project to be designated as priority R&D. These projects were accepted if they provided clear evidence of targeting a specific, unaddressed need in low- and middle-income countries.

APPENDIX XIII

The good practice standards framework for capacity building

The good practice standards framework has been developed to convey stakeholder expectations for good practice in capacity building. The framework is tailored for each subtheme in the Capacity Building Technical Area and is comprised of six standards. All company initiatives are measured against this framework.

Good practice standards for initiatives:

1. Addresses local needs, priorities, and/or skills gap;
2. Guided by clear, measurable goals or objectives;
3. Aims for long-term impact and sustainability;
4. Carried out in partnership with relevant stakeholders;
5. Includes regular monitoring, evaluation and public sharing of approaches, progress and learnings;
6. Has good governance structures in place (including for mitigating or preventing conflicts of interest).

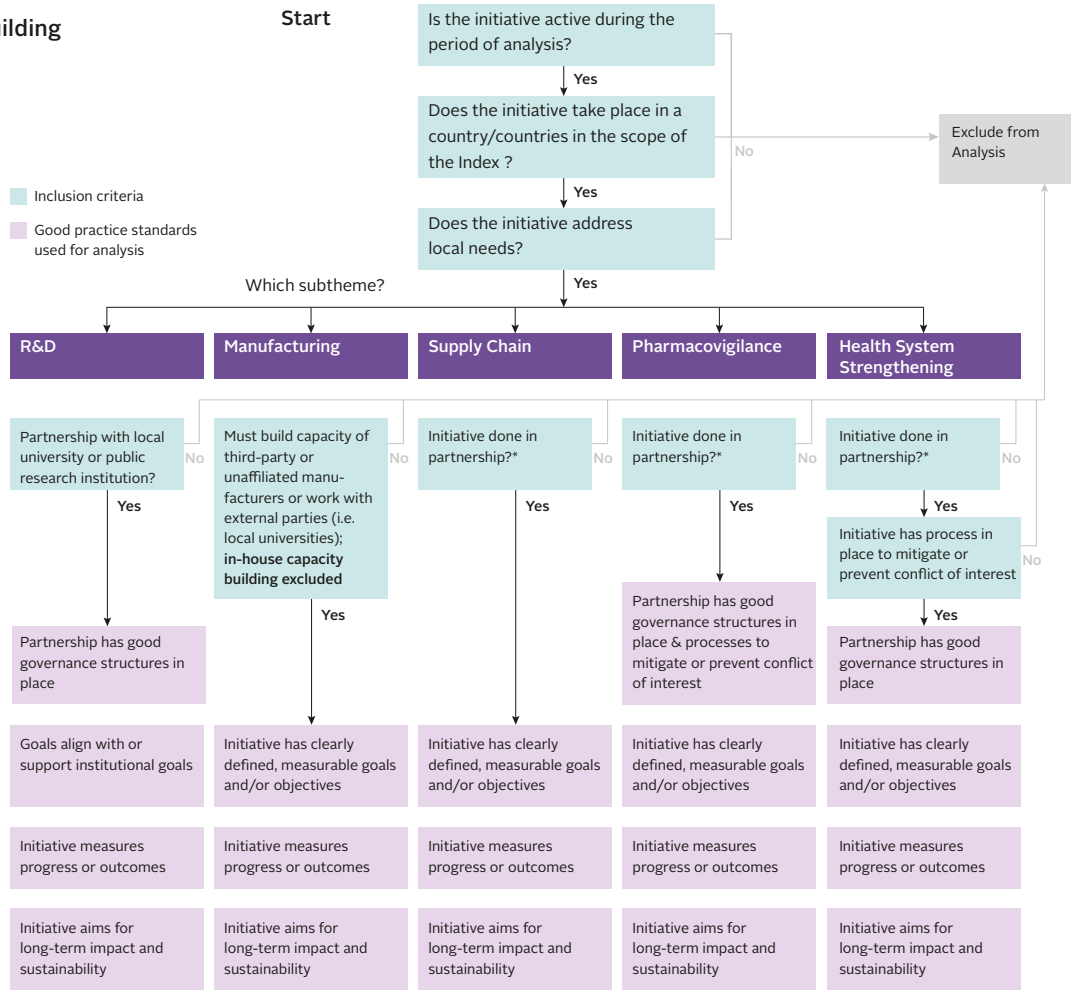
When companies submit examples of capacity building initiatives, they must first meet certain criteria ('inclusion criteria') in order to be included for analysis. Some of the good practice standards are considered inclusion criteria for analysis in the Index. The remaining good practice standards are used to guide the qualitative analysis.

The chart illustrated in table 10 provides a guide to the criteria by which submitted company initiatives are included for analysis in the Index and the criteria by which they are analysed. There are three basic criteria that all initiatives must meet: initiatives must 1) be active during the period of analysis; 2) take place in a country/countries in scope; and 3) address a clearly defined local need. Initiatives in all subthemes, except manufacturing are expected to be done in partnership. Health system strengthening initiatives must also have processes in place to prevent conflict of interest in order to be eligible for analysis. After this, the chart is broken down by subtheme/area of capacity building. The expectations from stakeholders vary slightly for each area based on the nature of the activities which typically fall within that area.

Initiatives which do not meet all inclusion criteria are excluded from analysis, meaning they are not considered for scoring or further analysis. Initiatives that meet all inclusion criteria are then assessed against the remaining good practice standards.

This chart was provided as a tool for companies to guide them in selection of their five initiatives per area during the data collection process.

Table 10. Capacity building initiative flowchart



*Done with appropriate,relevant partners including local partners

APPENDIX XIV

Definitions

Access plans

[Working definition, used for analysis]

Plans to ensure that public health needs are taken into consideration during R&D. Access plans can be developed in-house or in collaboration and include commitments and strategies as well as more concrete access provisions, agreed-upon measures typically developed in partnership to enforce accountability. These plans facilitate availability, accessibility and affordability for patients in countries within the scope of the Index (e.g., registration commitments, equitable pricing strategies, sufficient supply commitments, non-exclusivity in specified territories, waiving patent rights, royalty-free provisions and applying for WHO prequalification).

Access initiatives

[working definition, used for analysis]

An access initiative - within the context of the Access to Medicine Index - is an initiative a company is involved in which seeks to address access to medicine constraints in low- and middle- income countries. This may or may not be in partnership with others, and may or may not involve improving access to specific pharmaceutical products. Where access initiatives relate to products, it may be either an equitable pricing strategy, a non-exclusive voluntary licensing approach or a structured donation programme. Examples of access initiatives which do not involve products include, for e.g., awareness-raising activities in health system strengthening. Where products are involved in an access initiative, this is clearly identified within the text of the Access to Medicine Index report.

Access-to-medicine strategy

[Working definition, used for analysis]

A strategy specifically intended to improve access to medicine, that includes all the typical elements of a strategy (a clear rationale, targets, objectives and expected outcomes).

Ad hoc **donation programmes**

[Working definition, used for analysis]

A gift of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on the explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

Adaptive product R&D

[Working definition, used for analysis]

The adaptation of existing/registered New Chemical Entities (NCEs), New Biological Entities (NBEs) or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides to address an unmet need in countries in scope e.g., new demographic segments (e.g., infants/children, pregnant women), environmental conditions (e.g., heat-resistant formulations) or new formulations (e.g., fixed-dose combinations).

Affordability

[Working definition, used for analysis]

A measure of the payer's ability to pay for a product (whether or not they are the end user). The Index takes this into account when assessing pricing strategies for relevant products. Pharmaceutical companies use many different criteria to assess affordability.

Conflict of interest

A conflict of interest is the conflict that arises when the commercial interests of a company are potentially at odds with the interests of the partnership, the partner (i.e. local stakeholders) or the health and well-being of the population the partnership intends to help.

Equitable pricing strategy

[Working definition, used for analysis]

A targeted pricing strategy which aims at improving access to medicine for those in need by taking the abilities to pay of individuals and healthcare systems into account in a manner that is locally appropriate.

Ethical marketing

Promotional activities that are aimed at the general public, patients, healthcare professionals/students and opinion leaders in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.

Falsified medicine

Medical products that deliberately/fraudulently misrepresent their identity, composition or source. [Definition from WHO, 2017]

Good governance structures

[Working definition, used for analysis]

Good governance structures for partnerships include three components: 1) the structures put in place which establish clear roles, responsibilities and decision-making structures among the partners; 2) the systems of communications whereby information is regularly conveyed to all concerned; and 3) the transparency of processes, decisions and outcomes of the partnership.

Good practice standards

A set of six standards that encompass good practice in capacity building initiatives. These standards form a framework used for the assessment of company capacity building initiatives. The standards include: working in partnership, having good governance structures in place, addressing local needs, having clear goals and objectives, measuring outcomes and/or impact and aiming for sustainability and long-term impact.

Impact

'Impact', in the context of access initiatives, is the long-term result of a company's activities on the communities it intends to support. Impact is beyond the direct control of a given project or initiative, however, as it involves other factors influenced by other actors and/or the context in

which activities are executed. There is no shared or formally agreed definition of what constitutes impact.

Innovative product R&D

[Working definition, used for analysis]

The development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides.

Inter-country equitable pricing

[Working definition, used for analysis]

Where companies determine their pricing strategy at the country level and take into account affordability for countries in need.

Internal control framework

An internal control framework is a series of processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour of the company's employees and, if applicable, third parties the company formally engages with.

These processes include:

- fraud-specific risk assessment to proactively identify vulnerabilities for fraud and actual cases;
- auditing and review mechanisms conducted by external, independent specialists, applying to third parties in all countries the company is operating;
- a live monitoring system for compliance, other than financial auditing, to continuously monitor activities to detect discrepancies;
- procedures to segregate duties, i.e. the process of having more than one person required to complete a task which may be susceptible to fraud and/or error. e.g. this can include a separation between: management tasks and authorisation tasks; custody of assets and verification tasks; and accounting tasks and payment tasks.

Intra-country equitable pricing

[Working definition, used for analysis]

Where companies determine pricing tiers within a country based on the socioeconomic profiles of different population segments, taking into account affordability for populations in need.

Outcome measures

Evaluating measures that are related to operationalisation of a donation programme. This includes quality control along the entire supply chain from manufacturing site to recipients and from recipients to the end-user. Reporting or monitoring are common procedures for evaluating outcome measures. Outcomes can be measured by the company or provided by recipients of the donated products.

Performance management system

Formal and informal mechanisms, tools, processes and networks used by organisations to manage and reward performance in-line with corporate and functional strategies and goals. This includes performance measurement, i.e. collecting, analysing and reporting information regarding the performance of an individual, group or organisation in order to track progress towards set goals.

Period of analysis

[Working definition, used for analysis]

For the 2018 Index, the time period for which data will be analysed covers company activities which must be ongoing between 1 June 2016 and 31 May 2018, as this is the cycle of the Index. Projects that have ended before 1 June 2016 are not included.

Priority R&D

R&D that addresses product gaps that are needed by people living in low- and middle-income countries due to ineffective, maladaptive or nonexistent products for certain diseases in the scope of the Index. These product gaps are defined as being those listed in a series of five priority lists developed by WHO and Policy Cures Research, an independent research group.

Substandard medical products

Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both. [Definition from WHO, 2017]

Structured donation programmes

[Working definition, used for analysis]

A gift of products for which a defined strategy exists as to the type, volume and destination of donated products. Structured donation programmes are long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate or eradicate a disease.

APPENDIX XV

Figures in this report

APPENDIX XVI

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