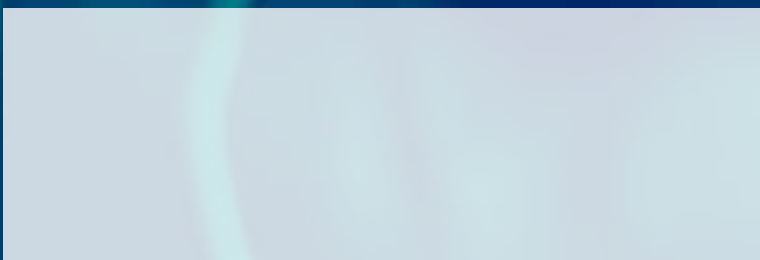
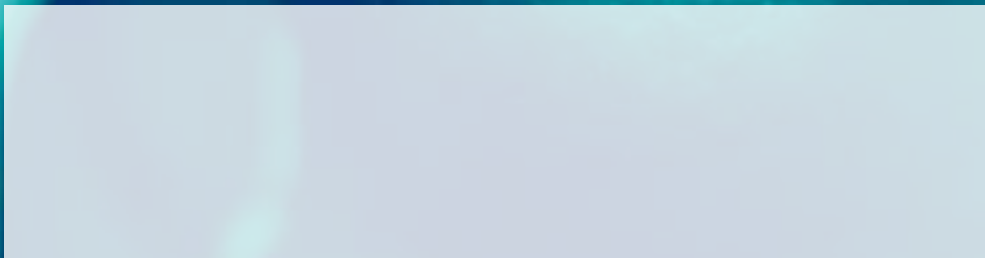
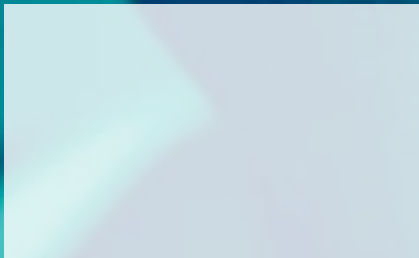


The 2016 Access to Medicine Index

# Methodology

## 2015



access TO  
medicine   
INDEX 

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The Access to Medicine Foundation would like to thank all of the representatives of the many different stakeholders in the access to medicine landscape who contributed their views to the development of this methodology. A full list of these individuals is provided on page 52.



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Introducing the methodology for the 2016 Access to Medicine Index

## A tool for matching action to agendas

**The Access to Medicine Index is a tool for spurring change for the 2 billion people who still lack access to medicine worldwide.** It works by stimulating and guiding pharmaceutical companies to develop sustainable access programmes, innovate and to work with other stakeholders to help solve the most troubling access problems.

I'm proud to present our latest methodology for the 2016 Access to Medicine Index. It was developed through careful review, together with experts from across the access-to-medicine ecosystem. We have spent the past months challenging theories and dogmas, analysing companies' past behaviour and putting the most critical areas of the Index under the magnifying glass. I would particularly like to thank our Technical Experts and the members of our Expert Review Committee for their strategic guidance during this process. The result is a bolder set of metrics, with a high emphasis on performance.

This methodology represents a call for action, driven by data. It identifies many areas where pharma companies still need to innovate and perform: such as in addressing the affordability of products, the investment and prioritisation of R&D, and the development of sustainable business models that include the poor.

Now is the time to start using this tool – for planning access activities, engaging with companies, for prioritising investments and to match action to agendas. Over the next year, we will be using it to benchmark company behaviour in the 2016 Access to Medicine Index. This Index will reveal how much progress we are making and where future opportunities for action lie.

Jayasree K Iyer,  
Executive Director  
Access to Medicine Foundation



**Without the cooperation and consensus of the biggest pharmaceutical companies, and all of their stakeholders, it is impossible to address today's global health challenges.** There are still so many people worldwide who cannot access the medicine they need. At the same time, I see that the will from all stakeholders to reach them is rapidly growing.

This is the fifth Methodology Report of the Access to Medicine Index. The methodology is more demanding, guiding and ambitious than ever before: performance is even more important now. At the end of 2016, it will result in the 5<sup>th</sup> Access to Medicine Index.















Compliments to Jayasree Iyer and her team for once again achieving stakeholder consensus and translating it into a practical method for measuring company performance. Researchers, academics, the global health community, and not least the pharmaceutical companies, will value the clear expectations on companies' access-to-medicine policies and practices represented in this report. Let us further develop this guidance and cooperate on its delivery.

On that note, I'm also very proud that Jay will lead the organisation as it takes the initial idea of ranking companies to the next level.

Wim Leereveld,  
Founder  
Access to Medicine Foundation

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## Executive Summary

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Globally, 2 billion people still cannot access the medicine they need. Among the many stakeholders working to improve this situation, pharmaceutical companies have a crucial role to play. For almost ten years now, the Access to Medicine Foundation has built stakeholder consensus on what we can expect from pharmaceutical companies. This report describes the key dilemmas, discussions and outcomes of the most recent phase of consensus building, and how they translate into the methodology for the next Access to Medicine Index. In 2015, the emphasis has shifted further towards measuring performance where it matters.

The Access to Medicine Index analyses the top 20 research-based pharmaceutical companies with products for high-burden diseases in low- and middle-income countries. The Index ranks these companies 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 both an incentive and a guide for pharmaceutical companies to do more for the two billion people worldwide who still lack access to medicine.

The Index is the product of a rigorous methodology for benchmarking companies' access-to-medicine performances against stakeholder expectations for company behaviour. This methodology is reviewed every two years with input from experts working across the access-to-medicine field. These reviews align the methodology with evolving global health priorities, while continually reinforcing and refining the Index metrics in key areas. This report describes the outcome of the latest review, and translates the methodology into a set of ambitious, yet achievable and clear expectations for pharmaceutical company behaviour in each area measured by the Access to Medicine Index.

### Critical review and consensus building

The Index team began the 2015 review with an extensive series of indicator-level qualitative and quantitative analyses, before developing proposals for new measurements of company behaviour where necessary. During this process, the team held individual and collective discussions with governments, investors, industry, universities, think tanks, policy centres, patient organisations and other research organisations. Discussions covered specific questions relating to pharmaceutical company policy and practice, as well as broader perspectives on the role for the industry regarding access.

With the assistance of its formal committees, the Index team balanced the viewpoints provided to identify workable ways forward. Strategic guidance was provided by the Foundation's Expert Review Committee (ERC), an independent body of experts from, among others, the WHO, governments, patient organisations, the industry, academia and investors.

### Key changes in 2015

In summary, the 2015 methodology will give greater emphasis to companies' performances over their commitments. It will have a deeper focus on how companies approach people with the highest access needs, including through pricing and R&D. Following minor adjustments, the analysis scopes remain largely unchanged. The 2015 methodology comprises 83 indicators.

#### Greater emphasis on performance

The weighting of the Performance Strategic Pillar has been increased to 50%: in the 2016 Index, companies' scores in the Performance pillar will account for half of their overall Index scores. The Commitment Pillar has been reduced to 15%. This change will incentivise more companies to make the shift from commitment-making to action-taking. This is the first change to the Pillars weighting since 2012.

**Measuring performance where it matters**

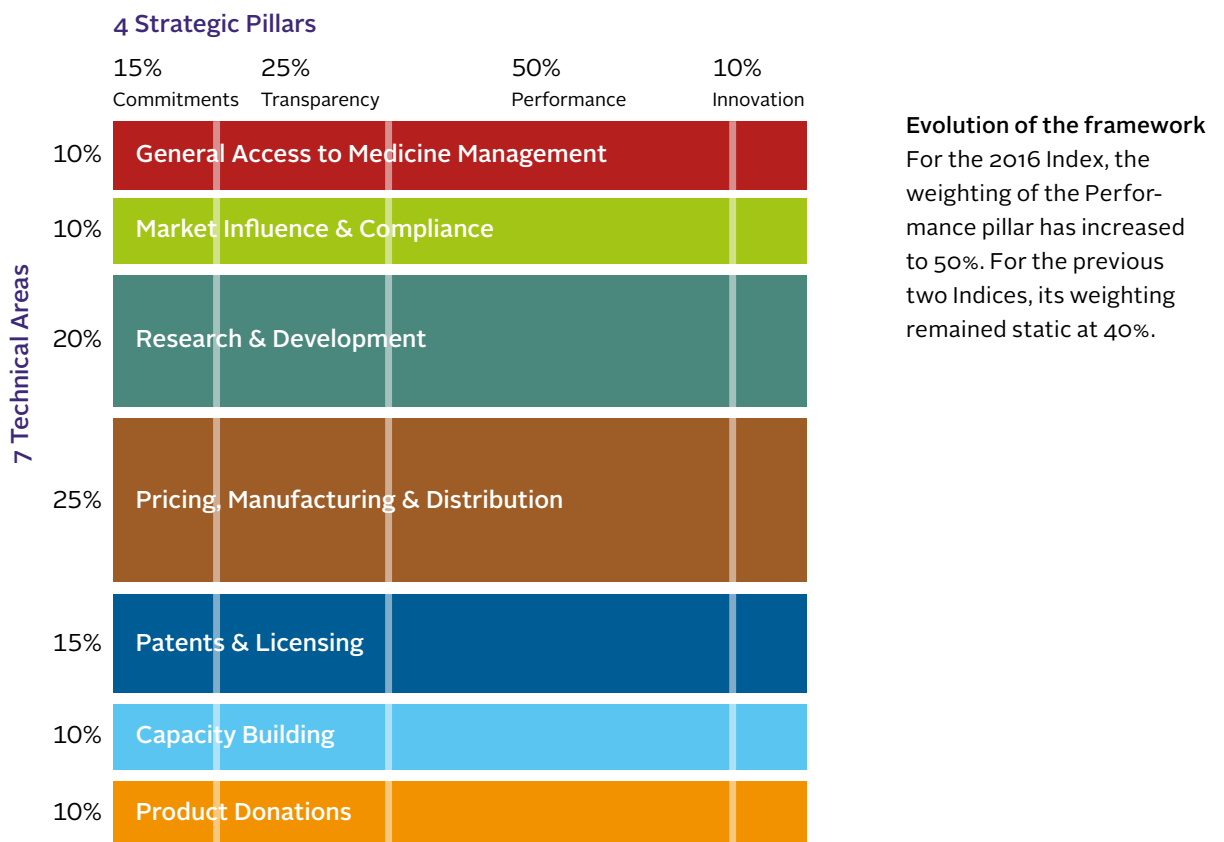
New measurements have been developed to uncover whether companies take action where the need is highest. For example:

**A new measurement of needs-based pricing:** The 2016 Index will map companies' pricing actions against disease burdens and inequality, assessing how companies customise pricing strategies according to socio-economic factors. This will allow for more rigorous benchmarking of company pricing behaviour and an analysis of how they differentiate strategies according to patients' needs and ability to pay.

**More recognition for R&D with no viable market:** Stakeholders generally agreed that the Index should especially recognise companies' efforts to engage in R&D for products with no real chance of significant profitability. In response, the Index methodology will give more credit to R&D projects that are demonstrably addressing high-need, non-commercial product gaps.

**A closer analysis of access strategies in middle-income countries:** Middle-income countries increasingly face high levels of socio-economic inequality. In response, the 2016 Index will look specifically at pricing actions in countries where both the burden of disease and inequality are comparatively high. In licensing, the 2016 Index will look more closely at whether and how companies license products for manufacture and distribution in middle-income countries.

**Figure 1 How we measure: analytical framework for the 2016 Access to Medicine Index**



### Analysis scopes in 2016

The 2016 Index will measure the same 20 companies as the 2014 Index, as they remain the largest R&D-based pharmaceutical companies with the most relevant expertise and portfolios. The geographic scope now totals 107 countries: a handful of countries have moved out of scope, as socio-economic conditions have improved, while others (Iran, Jamaica, Mexico, Panama and Peru) have moved into scope. The disease scope for the 2016 Index comprises 50 conditions and diseases. Since 2014, more up-to-date data on disease burdens have become available, bringing three additional non-communicable diseases into scope.

### 83 indicators

The 2015 methodology comprises 83 indicators: 6 are new and 9 are mergers of pre-existing indicators. 9 indicators from the previous methodology have been removed. Changes were made following statistical analyses, either to improve our measurements of company practice, to align with changes in global-health priorities, or to improve efficiencies in analysis and data capture.

**Table 1** What we measure; Analysis scopes for the 2016 Access to Medicine Index

<b>Company Scope</b>	<b>20 research-based pharmaceutical companies</b>
<b>Geographic Scope</b>	<b>107 countries</b>  82 World Bank-based (LIC and LMIC) 11 UN HDI-based (MHDC and LHDC) 13 UN IHDI-based (<0.6) 1 UN ECOSOC-based (LDC)
<b>Disease Scope</b>	<b>50 diseases</b>  10 Communicable diseases 14 Non-communicable diseases 17 Neglected tropical diseases 9 Maternal and neonatal health conditions, plus contraceptives
<b>Product Type Scope</b>	<b>8 types</b>  Medicines, Microbicides, Therapeutic Vaccines, Preventive Vaccines, Diagnostics, Vector Control Products, Contraceptive Methods & Devices, Platform Technologies



# Reviewing the Methodology

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## Approach to the Methodology Review

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Each Access to Medicine Index is the result of a two-year process known as the ‘Index cycle’, which begins with a targeted review of the Index methodology. The review draws on the Foundation’s decade of experience in researching and refining metrics for tracking pharmaceutical company performances regarding access to medicine.

The previous methodology review, for the 2014 Access to Medicine Index, was carried out in 2013 and assessed the methodology indicator by indicator. This resulted in a refinement of what the Index measures as well as how it measures. The 2015 Methodology Review has built on this. Following its proven process of assessment, consultation and ratification, the Index team has reviewed the methodology to align it with changes in access-to-medicine priorities and in how pharmaceutical companies can support greater access to healthcare.

### Design principles

The 2015 review was carried out in line with a set of core design principles:

- 1 Reflect changes in the access-to-medicine landscape and the role for pharmaceutical companies
- 2 Preserve the capacity for fine-grained comparison between companies’ performances
- 3 Maintain capacity for trend analysis between successive Indices
- 4 Ensure data can feasibly be collected by companies

### The review process

A process of both internal review and external engagement was carried out:

#### *Internal analyses*

As a first step, 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 2016, and where data quality could be enhanced.

#### *Consensus building and stakeholder dialogue*

The Foundation reached out to a broad range of experts through a targeted stakeholder engagement exercise. Many of these consultations were based around questions relating to specific indicators or measurements. Their insights have helped to ensure that the methodology is up-to-date and to build consensus regarding the appropriate role for pharmaceutical companies in addressing access to medicine. The Foundation team also reviewed the 2014 Index with the companies we measure.

#### *Committee consultations*

Throughout the methodology review, formal committees supported the Index team. Recommendations for specific sections of the Index were provided by Technical Sub-Committees: panels of specialists in different aspects of access to medicine. Strategic guidance was provided by the Expert Review Committee (ERC), an independent body of experts, including from the World Health Organization (WHO), governments, patient organisations, the industry, Non-Governmental Organisations (NGOs), academia and investors. The ERC met on three occasions throughout 2015, to review proposals for the scope, structure and analytical approach of the 2016 Access to Medicine Index. It also ratified the methodology prior to publication.

## Consensus building and stakeholder dialogue

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Through continued stakeholder dialogue, the Access to Medicine Foundation aims to build greater consensus on the appropriate role for pharmaceutical companies regarding access to medicine. Over its decade of dialogue, the Foundation has noted increasing industry engagement here, with pharmaceutical companies adopting new access-oriented practices, and greater collaboration with other stakeholders in the global health community. While disagreement remains, such developments are significant in what has often been a charged debate.

This process of consensus-building is used by the Foundation to underpin methodological changes for the next Access to Medicine Index, which will once again map company behaviour against stakeholder expectations. For these reasons the Index strives to ensure that the process is both open and wide-ranging.

### **Broad engagement**

The stakeholder dialogue in 2015 was focused around specific questions that required additional perspectives on how to strengthen individual measurements. For example: how could we more closely examine company approaches to affordability? How could we more effectively compare different donation programs? How could the Index reflect company engagement in R&D for products with little commercial value? How should companies be evaluated on the geographic scope of their licences? How can the alignment of access strategies with core business strategies be measured?

To help resolve such questions, the Index team gathered views from a wide range of stakeholders: including multilateral organisations, research institutions, NGOs, investors and companies (see the appendix for a full list of named respondents). A meeting was held at the WHO, and further engagements were conducted via teleconference and by email. Views were balanced against each other and woven into methodology proposals discussed in detail with our Technical Sub-Committees and Expert Review Committee (ERC).

### **Discussions and decisions**

The recommendations and strategic guidance provided by the ERC in particular helped to identify ways forward where disagreement or uncertainty existed in areas of measurement. An overview of some of the key discussions and decisions that arose during the methodology review are presented in the next section.

## Key discussions and decisions

Discussions held during the 2015 Methodology Review were wide-ranging and rich. While in many cases there was alignment on the appropriate elements of company access activities to measure and how they could be evaluated, in other areas it was difficult to reach consensus. In these cases the Index team, with the assistance and oversight of both Technical Sub-Committees and the Expert Review Committee, identified workable ways forward, balancing both evidence identified and viewpoints provided.

The following pages highlight selected discussions on key issues and the final decisions reached. Discussions represented here are where the appropriate way forward was hotly contested, or where new areas of measurement were defined responding to stakeholder feedback on their importance.

### DISCUSSION

## How do pharmaceutical companies manage access strategies in middle-income countries?

Since 2013, the United Nations Development Programme (UNDP) has reclassified eight countries as having high human development, rather than medium human development,<sup>1</sup> and the World Bank has moved 10 countries up from lower to higher income groups.<sup>2</sup> Such countries represent a significant future opportunity for the pharmaceutical industry. McKinsey recently reported that emerging markets (many of which are within the scope of the Index) now spend USD85 billion more on pharmaceutical products than Germany, France, Italy, the UK and Spain combined.<sup>3</sup>

Greater national wealth and higher levels of development do not always indicate greater equality, and this inequality is tied closely to a lack of access to medicine for the poorer populations within these countries. Middle-income countries bear 70% of the total global disease burden,<sup>4</sup> and represent 75% of all people on living less than a dollar a day.<sup>5</sup> A clear message was received from stakeholders that companies must be able to demonstrate how they target the needs (particularly through pricing and licensing strategies) of the very poor segments of these increasingly wealthy territories.

### **Decision: Strengthen the Index's analysis of how companies target poor populations in middle-income countries**

In 2016, there are several important shifts in the Index methodology that are designed to capture if and how companies are applying access-to-medicine strategies in middle-income country markets. Most notably:

#### **1. Pricing**

When measuring pricing strategies, we will newly prioritise companies' focus on countries where the burden of disease and inequality are comparatively high, as is often the case in middle-income countries. By also including low-income countries in this analysis, we will be able to compare and contrast how companies approach markets that are at different stages of development.

#### **2. Licensing**

Measures in licensing will look more closely at whether companies are prepared to license their products for manufacture and distribution in more lucrative markets (middle-income countries), and how they achieve this, for example, by agreeing tiered royalties for different country groupings.

## Should access to cancer treatments be a focus for the Access to Medicine Index?

Cancer is a significant issue for the global poor. More than half of the 14 million people diagnosed with cancer in 2012 live in less-developed regions.<sup>6</sup> Plus, the cancer burden in these countries is predicted to increase as socio-economic development continues:<sup>7</sup> one third of all cancers are at least partly caused by lifestyle factors more commonly associated with higher-income countries.<sup>8</sup>

In 2015, the WHO added 16 new cancer drugs to the Essential Medicines List (EML),<sup>9</sup> including several that are comparatively new and can present affordability issues. The addition of these products to the list has raised fresh questions about how countries with constrained finances will manage the increased expense to health budgets, should they elect to add these drugs to national medicines lists. It has also prompted observers to ask which strategies companies can deploy to support greater access.

Given that some cancer drugs are high-priced, that access to them is limited, and that the burden of cancer in low-income and middle-income countries is increasing, some stakeholders argued for the inclusion of at least a subset of cancer conditions within the disease scope of the 2016 Index.

Contrasting this view, other stakeholders noted that issues with access to cancer treatment in low- and middle-income countries are not limited to a lack of access to new products. Lower-income countries are less likely to have the support systems in place that are needed for effective treatment, and in fact may be more likely to suffer from stock-outs of the older, generic medicines needed. It was also argued that the Index should continue to give priority to other diseases, ones with higher disease burdens, ones considered neglected, and typical childhood killers.

### **Decision: Cancer drugs will not be included in the scope of the 2016 Index**

Balancing these views, and largely given the comparatively high burden of other diseases, no cancer type will be yet be included in the disease scope of the 2016 Access to Medicine Index (see page 25).

However, given the increasing burden of cancer in low- and middle-income countries, coupled with the policy shifts noted at the World Health Organization, the Index team has decided to gather information from companies with marketed and pipeline cancer drugs regarding their efforts to make these medicines affordable and available in countries within the Index scope. This data will not be used in the analysis and scoring process for the 2016 Access to Medicine Index. It will instead be used to conduct an initial exploration of pharmaceutical company activity in access to cancer medicines.

## How can pharmaceutical companies target pricing strategies toward need?

When new products enter the market, debate often arises around whether it has been priced affordably. Yet, what 'affordable' means is often unclear. Affordability matters at two levels – for patients and for health systems, beginning with public sector budgets. In the end, it depends on who is paying and the constraints they face. There is much debate among stakeholders as to how companies can ensure pharmaceutical products are affordable. As a result, how the Index evaluates company pricing strategies has also evolved over time. In 2012, the Index measured the extent to which companies engaged in differential (tiered) pricing. In 2014 the Index progressed to examining whether companies took 'ability to pay' into account when designing pricing strategies.

The 2014 approach yielded new insights. For example, companies considered affordability in their pricing strategies for one-third of all relevant marketed products. Yet the 2014 Index also found that company pricing practices are incredibly diverse. Further, while companies may take socio-economic factors into account when setting pricing practices, they frequently group countries together according to aggregative measures, such as World Bank-defined income level.

Stakeholders have strongly voiced the view that the national income level of a country or group of countries is insufficient for establishing whether a company has fully considered the ability of the population to pay. It was felt that companies should take account of differences between countries' disease burdens, their levels of inequality, their healthcare financing systems, and the ability of different groups to pay, as well as other constraints and variables. The development of a suitable model for evaluating whether pricing strategies are needs-based was required.

### Decision: A measurement of 'needs-based' pricing

The 2016 Index will newly analyse how companies consider socio-economic factors (in addition to income level) in forming their pricing strategies, in order to evaluate the extent to which companies are customising strategies according to the needs and constraints of the population groups they are targeting.

When assessing pricing based on need, the 2016 Index will evaluate companies' equitable pricing strategies only in a defined sub-set of Index-defined 'priority countries'.<sup>\*</sup> This sub-set has been derived from an analysis of disease burden, inequality and income-level, and is specific to each disease within the Index scope. This is not a measure of demand nor of how many patients need any given product. Company practice in this group of countries will serve as a proxy for determining whether companies take high-need countries into account when developing pricing strategies.

This framework will allow for comparability between companies in different disease areas and will set a first, objective baseline for measuring how companies are approaching needs-based pricing. Using priority countries as a proxy for countries in need will allow for more rigorous benchmarking of company behaviour in pricing and an analysis of how they differentiate strategies in different countries.

<sup>\*</sup>'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.

## How can the Index best capture companies' efforts to minimise corruption and bribery?

Companies have a clear responsibility to be acutely aware of where they are most at risk of corruption and bribery across their business, and to put in place processes to both monitor and mitigate this risk.

The 2014 Access to Medicine Index found that almost all companies measured had been the subject of legal decisions and settlements related to unethical behaviour. This was despite all companies having some kind of code of conduct in place that complies with industry standards defining ethical behaviour. There is clearly a gap between companies' stated intentions in this area and their actions.

During the methodology review, stakeholders argued that the 2016 Index should measure how companies actively mitigate the risk of misconduct occurring across the entire breadth of their activities. Different suggestions included capturing how companies identify risk and monitor compliance with behavioural standards, and how ethical behaviour is incentivised.

### **Decision: Investigating risk mitigation**

The 2016 Index will investigate how companies maintain global oversight of business areas where unethical marketing, corruption and bribery occur; how they identify and manage risk; what follow-up actions they take in the event of misconduct; and how they ensure sales targets do not incentivise aberrant behaviour. Some stakeholders also felt that a closer reflection of the relative seriousness of unethical behaviour, and its impact on patients, should be developed.

### **Decision: categorising breaches**

In 2016, the Index will stratify different kinds of breaches, identify where they occurred, and whether they carried a civil or criminal penalty or fell within the remit of industry-regulated watchdogs. Proxies for impact on patients will be identified where possible, for example, an analysis of the scale of fines within the U.S. has been suggested as a proxy for the scale of the impact on patients and the public purse.

## What are pharmaceutical companies doing to engage in R&D for diseases with no viable market?

Incentives for investing in pharmaceutical R&D are largely tied to the market's ability to pay for the resulting products. So where diseases disproportionately affect populations with weak purchasing power (and where companies generally have a limited chance of recouping expenditures), product gaps and needs can go unaddressed. Further disincentives to engaging in 'non-commercial' R&D can include a lack of clearly defined public-health related R&D priorities; and regulatory barriers, including a lack of harmonisation.

In recognition of this, alternative incentive models have been developed, including 'push' mechanisms that help reduce R&D expenditure, such as research subsidies, public-private partnerships, and tax benefits; as well as 'pull' incentives that aim to reward R&D outcomes, such as advanced market commitments, price arrangements, and regulatory measures. Stakeholders generally agreed that the Index should recognise companies' efforts to engage in R&D for products where the market is limited or absent. Such activities should be targeted toward need and toward known product gaps.

### **Decision: The 2016 Index will reward companies that engage in non-commercial R&D**

R&D projects that are demonstrably addressing high-need, non-commercial product gaps will be given extra credit in the scoring process. Following stakeholder suggestions, these product gaps will be drawn from a gap analysis conducted by Policy Cures (G-FINDER).<sup>10,11</sup>



# What we measure

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## 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.

In 2014, the companies measured by the Index reported 700 products on the market for high-burden diseases, and were developing a further 327 products. The size, geographic reach and capacity of these companies to develop, manufacture and distribute needed health products means they play an important role in supporting access to medicine. The Index looks to them to ensure they target product development to need, and ensure the availability and affordability of the products they bring to market.

Companies included in the Index scope are those with the highest market capitalisation and the most relevant product portfolios and pipelines with respect to the diseases and countries covered by the Index. For 2015, the company scope has been reviewed to take account of changes in product portfolios, revenue and market capitalisation as well as other industry changes, such as mergers, acquisitions and divestments.

**Table 2 Companies included in the 2016 Access to Medicine Index - 20 companies**

Company	Ticker	Stock Exchange	Bloomberg	Reuters	Country	Market cap (bn USD)*	Revenue (bn USD)**
AbbVie Inc.	ABBV	New York	ABBV:US	ABBV.N	USA	94.39	19.96
Astellas Pharma Inc.	4503	Tokyo	4503:JP	4503.T	JPN	35.32	11.35
AstraZeneca plc	AZN	London	AZN:LN	AZN.L	GBR	85.44	42.98
Bayer AG	BAYN	Frankfurt	BAYN:GR	BAYGn.DE	DEU	117.15	56.07
Boehringer Ingelheim GmbH	n/a	n/a	n/a	n/a	DEU	-	17.68
Bristol-Myers Squibb Co.	BMJ	New York	BMJ:US	BMJ.N	USA	99.28	15.88
Daiichi Sankyo Co. Ltd.	4568	Tokyo	4568:JP	4568.T	JPN	11.03	8.37
Eisai Co. Ltd.	4523	Tokyo	4523:JP	4523.T	JPN	15.47	4.99
Eli Lilly & Co.	LLY	New York	LLY:US	LLY.N	USA	75.97	19.62
Gilead Sciences Inc.	GILD	NASDAQ	GILD:US	GILD.O	USA	155.81	24.89
GlaxoSmithKline plc	GSK	London	GSK:US	GSK.L	GBR	113.27	37.89
Johnson & Johnson	JNJ	New York	JNJ:US	JNJ.N	USA	279.80	74.33
Merck & Co. Inc.	MRK	New York	MRK:US	MRK.N	USA	167.63	42.24
Merck KGaA	MRK	Frankfurt	MRK:GR	MRCG.DE	DEU	43.32	14.99
Novartis AG	NOVN	SIX Swiss Exchange	NOVN:VX	NOVN.VX	CHE	245.07	58.00
Novo Nordisk A/S	NOVO B	Copenhagen	NOVOB:DC	NOVOb.CO	DNK	17.85	15.81
Pfizer Inc.	PFZE	New York	PFE:US	PFE.N	USA	216.67	49.61
Roche Holding AG	RO; ROG	SIX Swiss Exchange	RO:SW;ROG	ROG.VX	CHE	231.16	51.88
Sanofi	SAN	EURONEXT Paris	SAN:FP	SASY.PA	FRA	132.68	44.83
Takeda Pharmaceutical Co. Ltd.	4502	Tokyo	4502:JP	4502.T	JPN	40.29	16.18

\*Market cap from Bloomberg & Yahoo Finance 19 Feb 2015 (Exchange rate from www.oanda.com 19 Feb 2015)

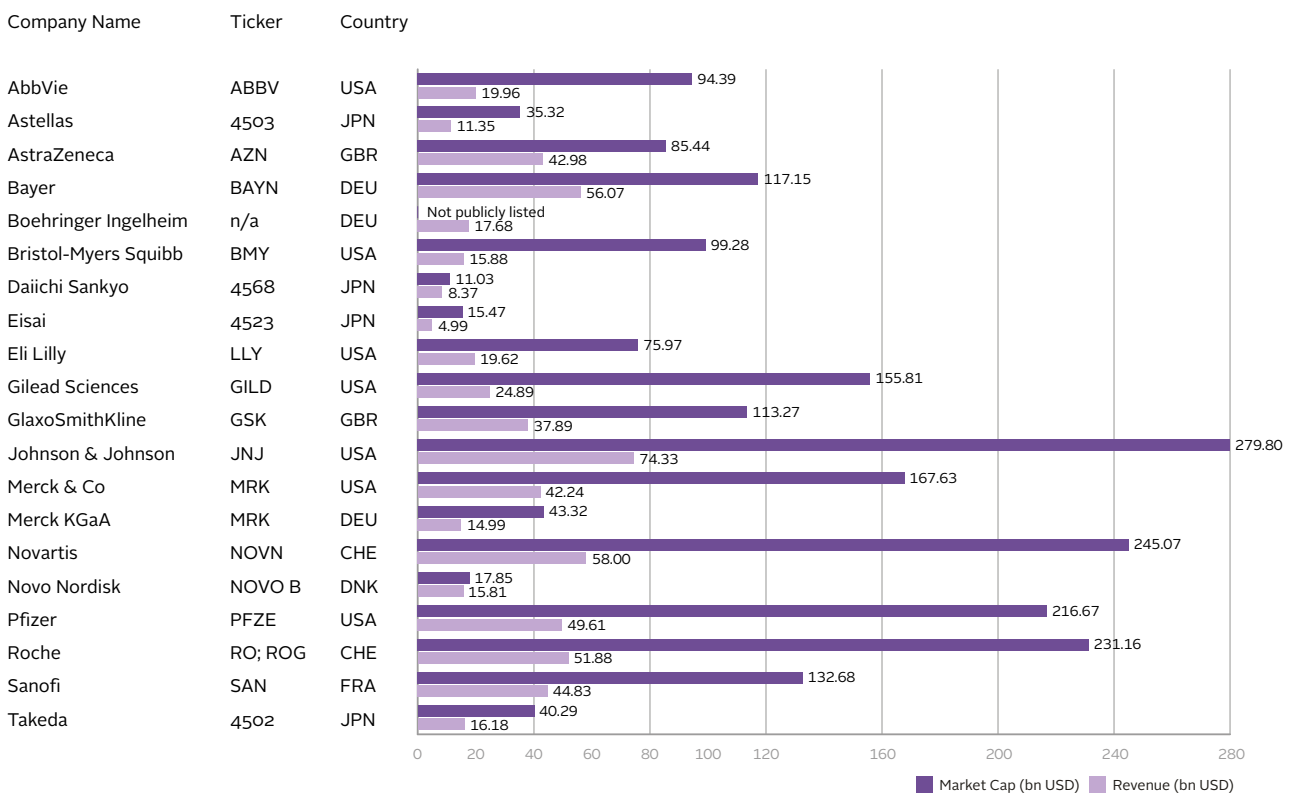
\*\*Revenue = ttm (trailing twelve months); meaning the time-frame of the past 12 months from Annual reports 2014; for Japanese companies fiscal years from their reports in March 2015 (Exchange rate from www.oanda.com 1 Apr 2014 - 31 Mar 2015 for Japanese companies and 1 Jan- 31 Dec 2014 for others)

**Scope in 2015-2016**

The 2016 Index will again measure the same 20 companies included in the 2014 Index, facilitating trend analysis and comparability between Indices. The Index has measured these companies for 10 years, meaning their performance can be tracked over time.

Pharmaceutical companies that exclusively produce generic medicines remain excluded from the Index in 2016. 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.

**Figure 2 Market cap & revenue of companies listed in the 2016 Access to Medicine Index**



## Geographic Scope

The Access to Medicine Index measures pharmaceutical companies' efforts in countries where access to medicine is most needed. This set of countries is referred to as the Index's geographic scope.

As in 2014, the geographic scope for the 2016 Access to Medicine Index is defined using three criteria: (1) countries' levels of income (gross national income (GNI) per capita); (2) their levels of development; (3) and the scope and scale of inequality in each country. These assessments are based on data from the World Bank, the United Nations Development Programme (UNDP), and the United Nations Economic and Social Council (ECOSOC).

### Changes In 2015

The geographic scope for the 2016 Access to Medicine Index comprises 107 countries.

Several additional countries in the Americas have been included (Jamaica, Mexico, Panama and Peru), as well as Iran. Countries removed from the scope include Jordan, Venezuela and

### Defining the country scope

**Step 1:** All countries defined by the World Bank as low income or lower middle-income<sup>12</sup> are included. For the 2016 Index, this step accounts for the lion's share of the geographic scope, bringing 82 countries into scope.

**Step 2:** All countries defined by the UNDP as either low or medium human development<sup>13</sup> are included. This ensures that several central measures of human development (life expectancy, education, and standard of living) are taken into account. This resulted in a further 11 inclusions.

**Step 3:** All countries that receive a score of less than 0.6 on the UN Inequality-Adjusted Human Development Index<sup>14</sup> are included. This measure takes account of how health, education and income are distributed within each country. This resulted in 13 inclusions, among them the five new additions: Iran, Jamaica, Mexico, Panama and Peru. New exclusions on this basis for 2016 were Fiji, Jordan, Tonga and Venezuela. Data was not available for Tonga.

**Step 4:** The final step is to include all Least Developed Countries (LDCs), as defined by ECOSOC.<sup>15</sup> This brings Tuvalu into scope. Although Tuvalu is classed by the World Bank as being an upper-middle income country, it is also an LDC.

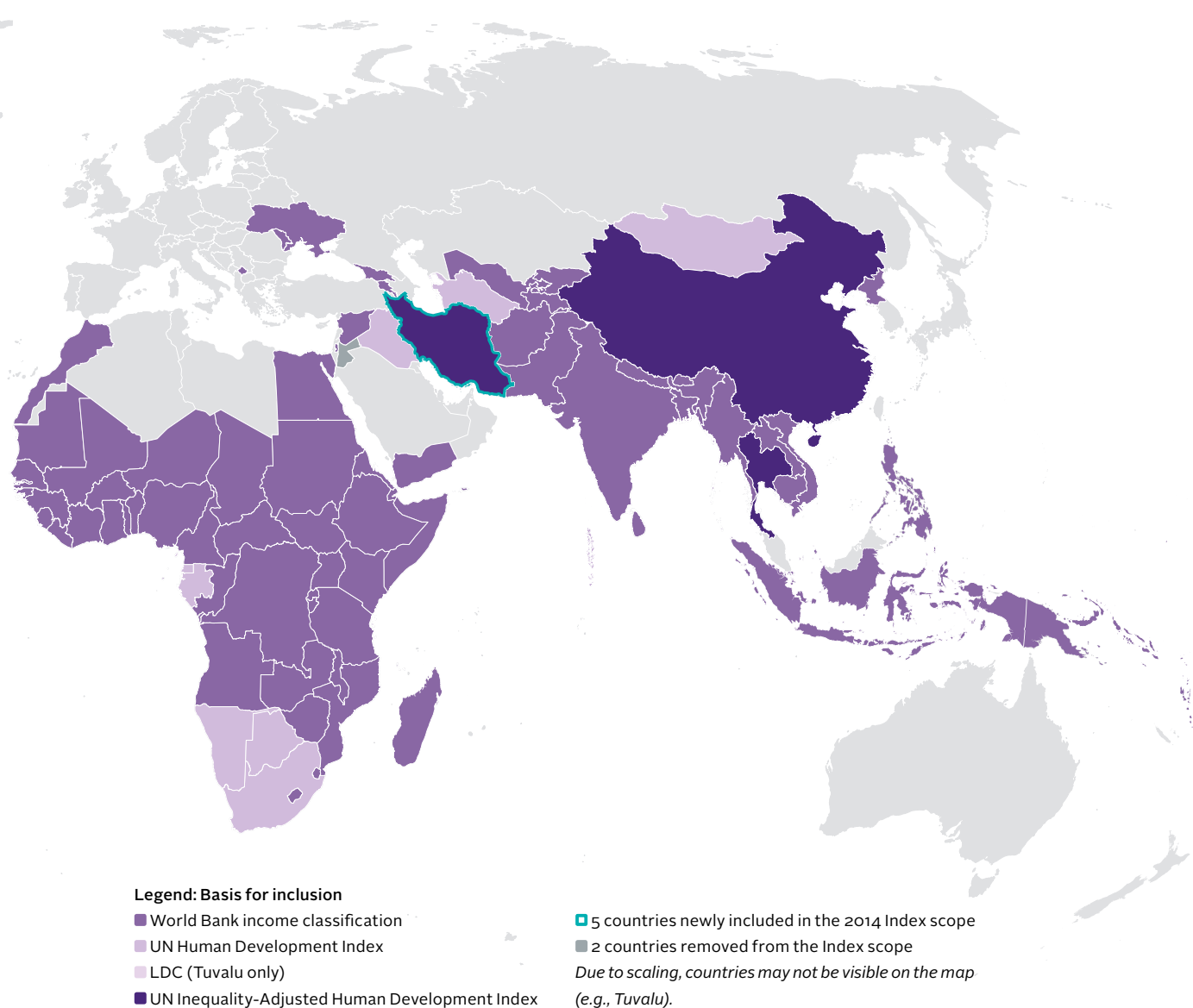


Fiji, as improving socio-economic conditions have moved these countries out of the Index scope. Tonga was excluded due to a lack of available data.

Although 102 of the countries in scope remain unchanged, since 2013, some of these have increased in national income and/or development levels (according to either the World Bank, or UNDP). This is undoubtedly to be welcomed. However, as noted on page 12, greater wealth and higher levels of development do not always indicate greater equality, nor greater access to medicine.

In order to ensure that the 2016 Index captures larger countries with significant pharmaceutical industry activity and high burdens of disease, poverty and inequality, the cut-off point for country inclusion using the inequality-adjusted Human Development Index was adjusted to 0.6 (on a scale of 0 to 1).

**Figure 3 Map of countries included in the 2016 Access to Medicine Index - 107 countries**



**Table 3 List of countries included in the 2016 Access to Medicine Index - 107 countries**

Country	Classification				
<b>East Asia &amp; Pacific</b>		<b>Middle East &amp; North Africa</b>		Nigeria	LMIC
Cambodia	LIC	Djibouti	LMIC	Rwanda	LIC
China	HiHDI	Egypt, Arab Rep.	LMIC	São Tomé and Príncipe	LMIC
Indonesia	LMIC	Iran, Islamic Rep.	HiHDI	Senegal	LMIC
Kiribati	LMIC	Iraq	MHDC	Sierra Leone	LIC
Korea, Dem.Rep.	LIC	Morocco	LMIC	Somalia	LIC
Lao PDR	LMIC	Palestine, State of	LMIC	South Africa	MHDC
Micronesia, Fed. Sts.	LMIC	Syrian Arab Rep.	LMIC	South Sudan	LIC
Mongolia	MHDC	Yemen, Rep.	LMIC	Sudan	LMIC
Myanmar	LMIC	<b>South Asia</b>		Swaziland	LMIC
Papua New Guinea	LMIC	Afghanistan	LIC	Tanzania, United Rep.	LIC
Philippines	LMIC	Bangladesh	LMIC	Togo	LIC
Samoa	LMIC	Bhutan	LMIC	Uganda	LIC
Solomon Islands	LMIC	India	LMIC	Zambia	LMIC
Thailand	HiHDI	Maldives	MHDC	Zimbabwe	LIC
Timor-Leste	LMIC	Nepal	LIC	Countries removed since 2014 Index	
Tuvalu	LDC	Pakistan	LMIC		
Vanuatu	LMIC	Sri Lanka	LMIC	Fiji	MHDC
Vietnam	LMIC	<b>Sub-Saharan Africa</b>		Tonga	MHDC
<b>Europe &amp; Central Asia</b>		Angola	LHDC	Jordan	MHDC
Armenia	LMIC	Benin	LIC	Venezuela, RB	HiHDI
Georgia	LMIC	Botswana	MHDC		
Kosovo	LMIC	Burkina Faso	LIC		
Kyrgyz Rep.	LMIC	Burundi	LIC		
Moldova	LMIC	Cameroon	LMIC		
Tajikistan	LMIC	Cape Verde	LMIC		
Turkmenistan	MHDC	Central African Rep.	LIC		
Ukraine	LMIC	Chad	LIC		
Uzbekistan	LMIC	Comoros	LIC		
<b>Latin America &amp; Caribbean</b>		Congo, Dem. Rep.	LIC		
Belize	HiHDI	Congo, Rep.	LMIC		
Bolivia	LMIC	Côte d'Ivoire	LMIC		
Brazil	HiHDI	Equatorial Guinea	MHDC		
Colombia	HiHDI	Eritrea	LIC		
Dominican Rep.	HiHDI	Ethiopia	LIC		
Ecuador	HiHDI	Gabon	MHDC		
El Salvador	LMIC	Gambia, The	LIC		
Guatemala	LMIC	Ghana	LMIC		
Guyana	LMIC	Guinea	LIC		
Haiti	LIC	Guinea-Bissau	LIC		
Honduras	LMIC	Kenya	LMIC		
Jamaica	HiHDI	Lesotho	LMIC		
Mexico	HiHDI	Liberia	LIC		
Nicaragua	LMIC	Madagascar	LIC		
Panama	HiHDI	Malawi	LIC		
Paraguay	MHDC	Mali	LIC		
Peru	HiHDI	Mauritania	LMIC		
Suriname	HiHDI	Mozambique	LIC		
		Namibia	MHDC		
		Niger	LIC		

## Disease Scope

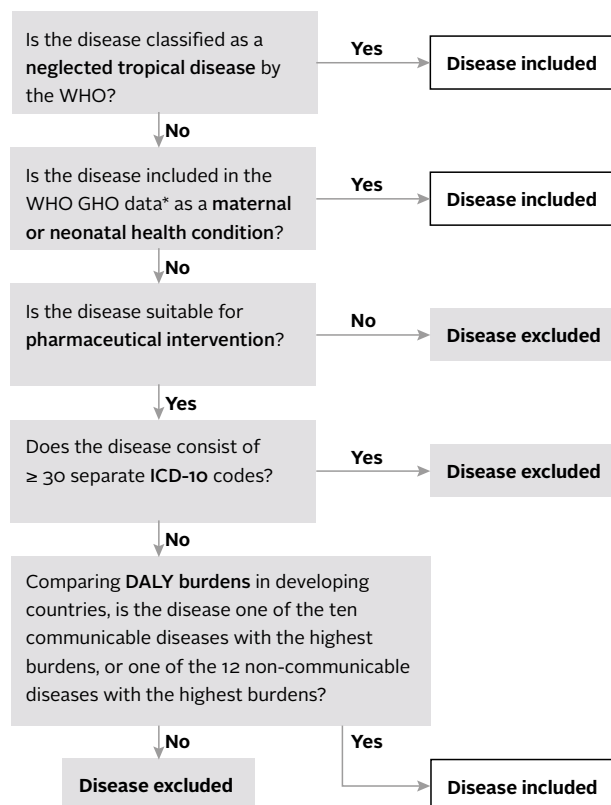
The Access to Medicine Index measures pharmaceutical companies' efforts to address diseases that have the greatest burdens in low-income and lower-middle income countries and the greatest need in terms of access to medicine. The disease scope is divided into four categories: communicable diseases, non-communicable diseases (NCDs), neglected tropical diseases (NTDs), and maternal and neonatal health conditions.

In 2016, the disease scope has expanded from 47 to 50 conditions and diseases. Depending on the disease category, diseases are included based on their burdens of disability-adjusted life years (DALYs), other WHO classifications and the relevance of pharmaceutical interventions. The selection includes those diseases most relevant to countries in scope, and ensures the 2016 Index is comparable with previous Indices. Diseases are defined using the WHO International Classifications of Diseases (ICD-10) codes.<sup>16</sup> These identify both primary diseases and secondary diseases that result from the progression of a primary disease. ICD-10 codes covered in the 2016 Index are listed in the Appendices.

### Changes in 2015

For 2016, the WHO Global Health Observatory 2012 DALY estimates<sup>17</sup> have been used to establish the disease scope for communicable and non-communicable diseases. This is both the most recent available data, and also more accurately reflects disease burdens in countries within the scope of Index: it includes estimated burdens in low-income and lower-middle income countries, as well as global burdens.

Figure 4 Defining the disease scope





**\*WHO GHO Data**

WHO Global Health Observatory 2012 DALY Estimates (all ages, both sexes, LICs, LMICs)

**Table 4 List of diseases included in the 2016 Access to Medicine Index - 50 diseases**Total DALYs (LICs & LMICs)  
unless indicated otherwise

<p><b>Communicable diseases (10)</b></p> <p>The 2016 Index covers the ten communicable diseases with the highest DALY burdens in low-income and lower-middle income countries. This includes lower respiratory infections, HIV/AIDS, tuberculosis and malaria.</p> <p>Exclusions: Chlamydia</p>	<p>Lower respiratory infections 121,068,536</p> <p>Diarrhoeal diseases 89,536,536</p> <p>HIV/AIDS 68,614,932</p> <p>Malaria 52,991,412</p> <p>Tuberculosis 36,403,940</p> <p>Meningitis 26,674,319</p> <p>Measles 11,194,628</p> <p>Syphilis 6,403,176</p> <p>Pertussis 5,657,488</p> <p>Tetanus 5,384,352</p>
<p><b>Non-communicable diseases (14)</b></p> <p>The 2016 Index covers the 12 non-communicable diseases with the highest DALY burdens in low-income and lower-middle income countries. Two mental health disorders (bipolar affective disorder and schizophrenia)<sup>18</sup> were retained following stakeholder emphasis on the high need for access to treatments for these conditions. It is estimated that between 76% and 85% of people with severe mental disorders receive no treatment for their disorder in low-income and middle-income countries. As in 2014, chronic hepatitis is included under cirrhosis of the liver. All cancers remain excluded from the Index disease scope. In 2016, cerebrovascular disease is referred to as stroke; nephritis and nephrosis is referred to as kidney diseases.</p> <p>Exclusions: Osteoarthritis</p>	<p>Ischaemic heart disease 70,459,863</p> <p>Stroke* 56,454,095</p> <p>Chronic Obstructive Pulmonary disease (COPD) 52,471,475</p> <p>Unipolar depressive disorders 35,521,719</p> <p>Diabetes mellitus 26,915,498</p> <p>Cirrhosis of the liver** 22,422,505</p> <p>Kidney diseases*** 18,128,559</p> <p>Asthma 16,223,415</p> <p>Epilepsy 14,347,659</p> <p>Anxiety disorders 13,175,172</p> <p>Migraine 10,150,681</p> <p>Hypertensive heart disease 10,113,460</p> <p>Bipolar affective disorder 5,920,895</p> <p>Schizophrenia 5,133,445</p>
<p><b>Neglected tropical diseases (17)</b></p> <p>The 2016 Index covers all 17 WHO-classified neglected tropical diseases (NTDs).<sup>19</sup> NTDs are particularly prevalent in poor regions of low-income countries, especially rural areas. New to the 2016 disease scope is chikungunya, which has been newly classified by the WHO and listed alongside dengue fever (both are vector-borne, with similar symptoms, though are distinct diseases). All NTDs are included irrespective of DALY burden, recognising both that the market has failed to adequately address them, and their particular relevance in poorer regions, where cases may go undiagnosed, untreated and unreported.</p>	<p>Schistosomiasis 3,700,597</p> <p>Soil transmitted helminthiasis**** 3,360,656</p> <p>Leishmaniasis 3,196,523</p> <p>Lymphatic filariasis 2,810,555</p> <p>Rabies 2,083,208</p> <p>Food-borne trematodiasis 1,875,000†</p> <p>Human African trypanosomiasis 1,248,941</p> <p>Dengue and chikungunya 1,238,610‡</p> <p>Onchocerciasis 593,762</p> <p>Taeniasis/cysticercosis 503,000†</p> <p>Trachoma 214,395</p> <p>Leprosy 199,424</p> <p>Echinococcosis 144,000†</p> <p>Chagas disease 44,408</p> <p>Buruli ulcer N/A</p> <p>Yaws N/A</p> <p>Dracunculiasis N/A</p>
<p><b>Maternal and neonatal health conditions (9, plus contraceptives)</b></p> <p>The 2016 Index includes the nine most prevalent maternal and neonatal health conditions, in continuing recognition of the importance of protecting mothers and neonates. It also covers contraceptives. These are the same nine conditions covered in the 2014 Index.</p>	<p>Maternal haemorrhage 3,289,000†</p> <p>Hypertensive disorders of pregnancy 2,797,000†</p> <p>Abortion 2,138,000†</p> <p>Obstructed labour 1,792,000†</p> <p>Maternal sepsis 1,309,000†</p> <p>Preterm birth complications 91,782,664</p> <p>Birth asphyxia and birth trauma 63,824,424</p> <p>Neonatal sepsis and infections 36,107,007‡</p> <p>Other neonatal conditions 10,896,418</p> <p>Contraceptive methods N/A</p>

 Diseases/conditions added to the 2016 Index Disease Scope.

 Data source: Murray et al<sup>20</sup>

\* In 2014, listed as cerebrovascular disease.

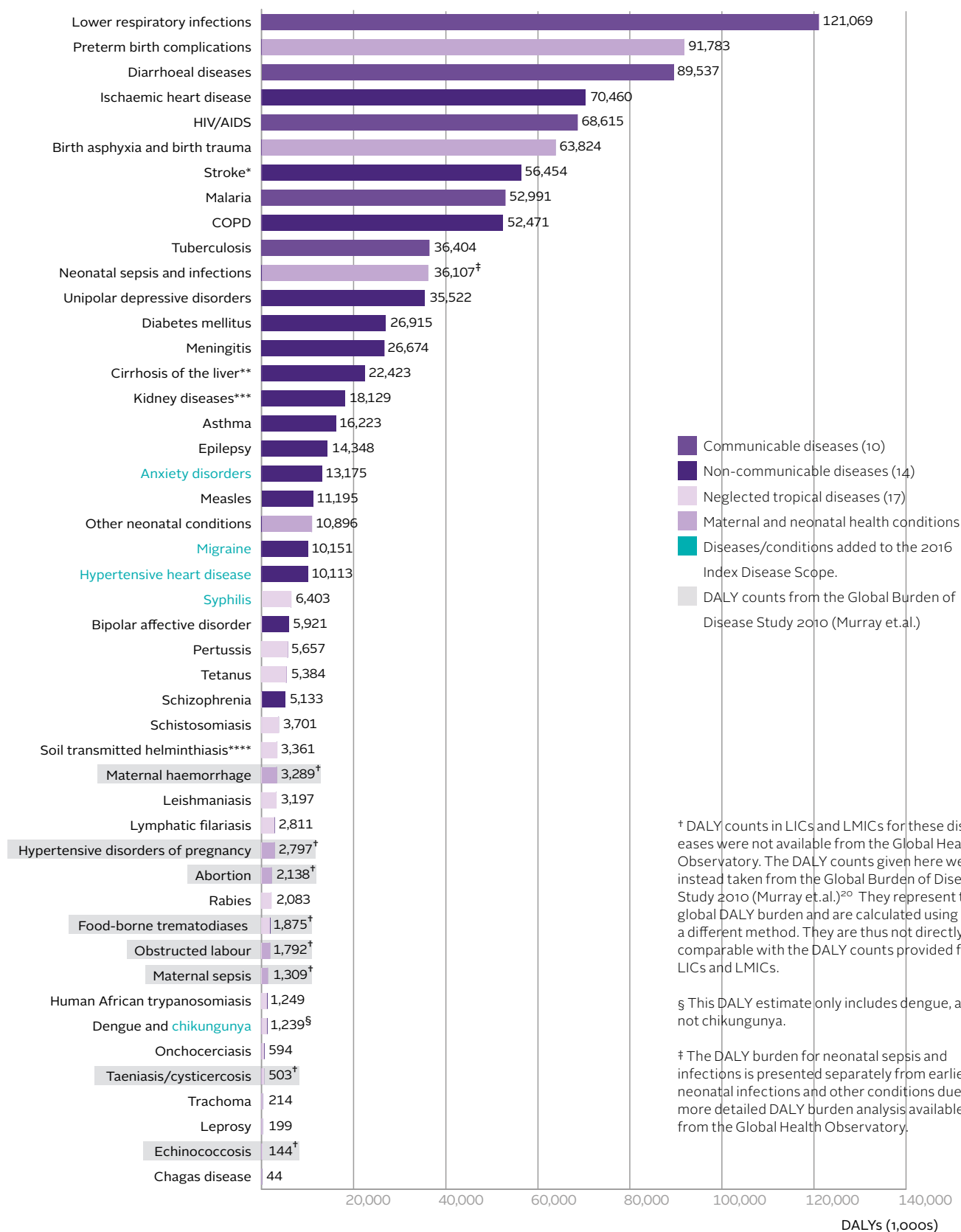
\*\* Includes chronic hepatitis

\*\*\* In 2014, listed as nephritis and nephrosis

\*\*\*\* Referred to in ICD-10 as intestinal nematode infections



**Figure 5 DALYs of diseases in the 2016 Access to Medicine Index**



† DALY counts in LICs and LMICs for these diseases were not available from the Global Health Observatory. The DALY counts given here were instead taken from the Global Burden of Disease Study 2010 (Murray et.al.)<sup>20</sup> They represent the global DALY burden and are calculated using a different method. They are thus not directly comparable with the DALY counts provided for LICs and LMICs.

§ This DALY estimate only includes dengue, and not chikungunya.

† The DALY burden for neonatal sepsis and infections is presented separately from earlier neonatal infections and other conditions due to more detailed DALY burden analysis available from the Global Health Observatory.

Conditions for which DALY data were not available (Buruli ulcer, Yaws, and Dracunculiasis), or not applicable (Contraceptives), are not presented in this figure.

## Product Type Scope

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This scope is deliberately broad in order to capture the wide-ranging product types available to support prevention, diagnosis and treatment of relevant conditions and diseases in the countries covered by the Access to Medicine Index.

In 2016, the Index continues to align the product scope with the categories provided in the 2014 G-Finder report.<sup>21</sup> For the 2016 Index, we have also drawn on the 2014 G-Finder Reproductive Health report.<sup>22</sup> This adds to our ability to evaluate and analyse the area of Maternal & Neonatal Health conditions, which continues to receive increasing international attention.

### Changes in 2015

Contraceptive Methods & Devices are now presented as a separate category. The Platform Technologies category now includes technologies for reproductive health.

<b>Medicines</b>	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.
<b>Microbicides</b>	These include topical microbicides specifically intended to prevent HIV.
<b>Therapeutic Vaccines</b>	This covers vaccines intended to treat infection.
<b>Preventive Vaccines</b>	This covers vaccines intended to prevent infection. A forthcoming Access to Vaccines Index will provide a dedicated analysis of relevant companies' efforts to improve access to preventive vaccines.
<b>Diagnostics</b>	This covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable and/or easier to use in the field).
<b>Vector Control Products</b>	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.
<b>Contraceptive Methods &amp; Devices</b>	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 and similar).
<b>Platform Technologies</b>	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 now included in this category.

# How we measure

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## Analytical framework: weights, measures and strategic pillars

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The 2016 Access to Medicine Index uses the same overarching framework for analysis as previous indices, updated to align with changes in the access-to-medicine landscape and stakeholder consensus on the appropriate role for pharmaceutical companies.

### Seven Technical Areas

The framework is constructed along seven Technical Areas. Stakeholders have identified these as areas where companies have the ability to influence access to medicine in low- and middle-income countries. Each one has been assigned a weight that corresponds to the shared perception of the importance of each area for improving access to medicine. These weightings were reviewed in 2015 and remain unchanged. Compared to the 2014 Access to Medicine Index, philanthropy will now be measured under the Capacity Building Technical Area, and anti-competitive behaviour will be measured under Patents & Licensing.

The names of the following Technical Areas have changed since the previous Index:

- Market Influence & Compliance (previously Public Policy & Market Influence)
- Capacity Building (previously Capability Advancement in Product Development and Distribution)
- Product Donations (previously Product Donations & Philanthropy)

### Four Strategic Pillars

Each Technical Area is assessed along four strategic pillars: Commitments, Transparency, Performance, and Innovation. The strategic pillars are organised to capture different 'stages' of company action to improve access to medicine, from commitment to performance and innovation, supported by transparency. For the 2016 Index, the weights of two strategic pillars have been shifted, moving emphasis away from commitment and towards performance. The commitments pillar in 2016 will be weighted 15% (down from 25%) and the performance pillar will be weighted 50% (up from 40%).

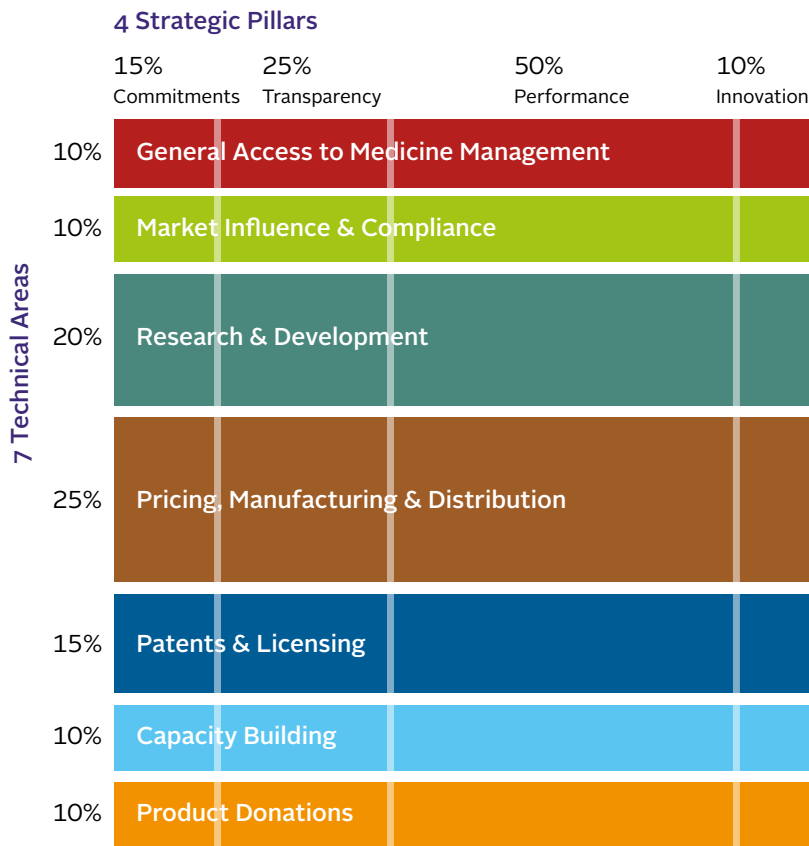
After four successive indices that show incremental improvements in the industry's performance, it is timely to emphasise that commitments must be strongly backed up with action. This responds to stakeholder views, both from companies and the broader global health community, that a greater premium needs to be placed on 'doing'.

### 83 Indicators

Company efforts in each Technical Area are measured through indicators, each related in turn to one of the four strategic pillars. The Index is a relative ranking, where companies are compared with each other rather than against an absolute, ideal state. The highest attainable scores for each indicator do not reflect an ideal characteristic of industry behaviour, but a culmination of stakeholder views of what can be reasonably expected of companies.


The 2016 Index has 83 indicators, down from 95 in 2014. Some are new, and others have been refined, either to improve our measurements of company practice, or to improve efficiencies in analysis and data capture. Certain indicators have been removed. Other indicators have changed in order to clarify the wording. For a complete list of indicators, see pages 39-50.


**Figure 1 Framework of analysis for 2016**





**Evolution of the framework**

For the 2016 Index, the weighting of the Performance pillar has increased to 50%. For the previous two Indices, its weighting remained static at 40%.

- 

**I Commitments (15%)**  
 In this pillar, the Index measures companies' values, strategies, policies, and codes of conduct for improving performance related to access to medicine. Companies receive more credit for commitments that are publicly available in reports, statements or other verifiable sources. Commitments are the first step to improving access to medicine: they define what the company values and aims to achieve.
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**II Transparency (25%)**  
 In this pillar, indicators focus on whether companies disclose information regarding access-to-medicine initiatives and activities that impact upon access to medicine. Transparency regarding policies and practices (whether positive or negative) allow companies to be held accountable for their approach, and helps to support public confidence. Companies will receive credit for sharing information requested of them, with public transparency valued most highly.
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**III Performance (50%)**  
 The Performance pillar measures what companies actually do to promote access to medicine across the seven Technical Areas, and as such, receives the most weight. It shows where companies put access-related policies and priorities into action, for example, by addressing product gaps through R&D, engaging in equitable pricing strategies, or licensing their products on access-oriented terms. The weighting of this pillar has increased for the 2016 Index.
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**IV Innovation (10%)**  
 In this pillar, the Index captures how companies create or employ new and unique means to advance industry practice regarding access to medicine. As the pharmaceutical industry looks for ways to enter new markets, there are opportunities to develop innovative strategies and models that respond to local needs, and make access to medicine more sustainable.

## A General Access to Medicine Management

This Technical Area investigates how companies integrate access-to-medicine issues within their corporate strategies, governance structures and management systems. It analyses how companies engage with stakeholders, consider their stakeholders when making plans and are transparent about stakeholder engagement activities. The Index also examines the strategic rationale behind companies' access strategies.

Assigning board-level responsibility for access to medicine increases the chances that targets will be met and progress tracked. Similarly, integrating access strategies with overall business strategies increases their chances of sustainability. Through engagement with local stakeholders, companies can better incorporate local needs and perspectives within their access strategies, increasing the likelihood of uptake and success. Investing in innovation can lead companies to develop and embed improved methods for meeting the needs of the poor.

**2016**

The 2016 Index will look more closely at how companies align access strategy with corporate strategy. It will also examine the extent to which they publicly share stakeholder engagement strategies on access, and explore how they select and engage with stakeholders. The innovation analysis in this area will expand in 2016, to include stakeholder engagement, governance and management structure.

### Expectations for company behaviour

#### Access-to-medicine strategy

Implementing a clear, long-term access strategy is crucial to tangibly improving access to medicine. First steps include identifying specific objectives relating to access to medicine. Leading companies will underpin their access objectives with a strong business rationale, and align them with overall corporate strategies and processes.

#### Managing for access-to-medicine outcomes

To ensure access-strategies are translated into positive outcomes, companies can incorporate access-related incentives and objectives in performance management processes for their staff and assign board-level responsibility for access to medicine. Better performers will also establish governance and incentive systems that support access to medicine, and provide more complete, public access to this information.

#### Stakeholder engagement

Strategic stakeholder engagement allows for dialogue and knowledge sharing, and helps companies understand more about risks and opportunities while developing access-to-medicine initiatives that are targeted to local needs. Transparency about how stakeholders are selected and how their views are incorporated enhances accountability. Companies are encouraged to join discussions that can bring positive changes in their operations with regards to the needs of the poor. Better performing companies will have systems in place for increasing dialogue with global and local stakeholders and for incorporating stakeholder perspectives into their access strategies. They will publicly disclose information about their stakeholder engagement strategies, engagement activities and outcomes related to access to medicine.

**Innovation**

Companies are encouraged to develop innovative business models and to adopt new governance and management approaches. Frontrunners will develop original, financially sustainable business models that demonstrably improve the health, social and economic status of the people they serve, and explicitly aim to increase access to medicine. They will also develop innovative approaches to stakeholder engagement, governance and management systems. Innovation often has a long-term investment horizon, a clear vision and goals, and senior-level support.

## B Market Influence & Compliance

This Technical Area looks at how companies interact with (or finance) external organisations, such as governments, patient groups, and think tanks, and where these links may affect access to medicine by influencing policy. It also examines evidence of breaches of ethical marketing codes, corruption and bribery, and how companies mitigate the risks of breaches occurring.

Companies can take various actions to limit the chances of misconduct occurring, for example by rigorously monitoring and enforcing stringent standards of behaviour across their businesses, by changing their incentive structures, and by taking remedial action in the event of failure. Companies can build confidence in their approach to influencing policy by disclosing their policy positions, the financial nature of their external relationships, and how they are governed.

**2016**

The 2016 Index will now treat instances of unethical behaviour differently according to whether they are: criminal convictions, civil settlements, or breaches of codes of conduct (in relation to ethical marketing, corruption and bribery). The Index will examine more deeply how companies self-regulate behaviour, looking at how sales behaviour is incentivised, evidence of auditing procedures, and if remedial action is taken in the event of failures. Analyses of anti-competitive behaviour are now included in Patents & Licensing.

### Expectations for company behaviour

**Market influence**

Companies are expected to demonstrate that they do not seek to influence government policy in ways that would limit access to medicine. Companies performing strongly will share their public stances on a wider range of access to medicine issues, and will be more explicit about how they actively seek to influence policy. They will be more open about their memberships and political contributions, and will be able to show that they have clear policies for the governance of external engagement. Companies lagging behind will remain more reluctant to share information, and as a result, fail to instil the public with confidence about the appropriateness of their activities and their policy stances.

**Compliance**

Companies are expected to show zero tolerance for unethical behaviour and non-compliance. Leading companies will take greater ownership at the highest levels and enforce more rigorous standards of behaviour across their operations, including third party contractors. Positive steps will include rigorous monitoring of compliance with anti-corruption and ethical marketing policies, and taking decisive action in the event of failure. Leading companies will be more open about marketing in countries covered by the Index, and will show reform of employee incentives to minimise the risk of unethical marketing behaviour. Companies will

lag behind when they remain closed; are reluctant to share information about marketing strategies; show little evidence of monitoring and enforcement against breaches; and are subject to a comparably high number of legal decisions and settlements concerning unethical behaviour. For 2016, evidence of breaches occurring anywhere in the world will continue to be included for analysis.

### **Innovation**

Since the first Access to Medicine Index was published in 2008, performance in Market Influence & Compliance has typically been low. There is room for innovative action. The Index is looking for evidence of companies trialling more transparent zero-tolerance approaches to corruption, bribery and unethical marketing, and of finding new ways of engaging responsibly with external organisations, and of motivating their staff and contractors to behave responsibly.

## **C Research & Development**

This Technical Area analyses in-house and collaborative R&D efforts aimed at developing new or adapted products for diseases within the Index scope. It also examines whether companies put steps in place during development to accelerate and facilitate access to products for people living in low- and middle-income countries on market entry.

The Index also investigates companies' clinical trial codes of conduct, evidence of oversight and enforcement mechanisms for these codes, and whether there is evidence of breaches of clinical trial conduct in countries within the Index scope. Finally, it examines the transparency of data surrounding companies' clinical trials, such as the publication of trial results (whether positive or negative) and the sharing of patient-level clinical trial data with trusted external parties.

### **2016**

The 2016 Index will place more emphasis on R&D for products where the market is limited or absent. Early-stage discovery projects from all disease categories are now included for analysis (for an overview of inclusion criteria, see Appendix 2). Pipelines will be assessed relative to company size, rather than, as in 2014, the company's overall pipeline size. The period of analysis for breaches of clinical trial conduct is now two years, rather than five, bringing it in line with the overall period of analysis of the Index.

### **Expectations for company behaviour**

#### **Product development**

Companies are expected to develop and adapt products for high-need diseases that are suitable for people in countries in scope. R&D activities should be guided by a strategy that takes health priorities in these countries into account, supported by meaningful targets and sufficient resources. At a minimum, companies are expected to develop at least some new products for diseases in scope, while considering their future accessibility. Leading companies will dedicate the greatest proportion of their pipelines to high-need diseases, and systematically plan for the future accessibility and suitability of products under development.

#### **Collaborations and Intellectual Property (IP) sharing**

Companies are expected to have a policy of including access-oriented principles in development contracts, and to publicly disclose the licensing details of research collaborations. To accelerate early drug-discovery and development, companies can open up compound



libraries to external researchers and engage in partnerships with a broad range of organisations under access-orientated terms and conditions.

#### **Clinical trial conduct & transparency**

Companies are responsible for ensuring that clinical trials are conducted ethically and to high standards. At a minimum, companies are expected to adhere to Good Clinical Practice guidelines, and comply with the Declaration of Helsinki. When engaging in HIV prevention trials, companies are also expected to include Good Participatory Practice Guidelines in codes of conduct. They are also expected to monitor and audit compliance of all trials, including outsourced ones, taking disciplinary action where relevant. Other positive steps include registering trials in a public registry; timely publication of results regardless of outcomes; and a mechanism for sharing all patient-level clinical trial data. Better performing companies will be more active and transparent in these matters, and have stronger policies for selecting outsourcing partners.

#### **Innovation**

The Index looks for innovative, sustainable or open R&D models that facilitate efforts to develop or adapt products for high-burden diseases in low- and middle-income countries. These innovative R&D models must explicitly target the needs of patients living in countries relevant to the Index.

## **D Pricing, Manufacturing & Distribution**

This Technical Area centres on how companies take affordability and other socio-economic factors into account when developing pricing strategies, and how their manufacturing and distribution practices ensure products are available, affordable and used appropriately, and that their quality is not compromised.

By considering patients' and governments' ability-to-pay as well as other relevant socio-economic factors, companies can try to ensure access to medicine is not restricted through affordability issues. By quickly filing for the registration of products in high-need countries, companies can ensure products are available to the populations who need them. Adapting brochures and packaging to reflect local needs (such as language, literacy levels and demographics) can help ensure products are used appropriately. With effective drug recall systems, companies can ensure compromised products are removed from the market as quickly and efficiently as possible.

### **2016**

**The Index will analyse how companies take different socio-economic factors into account when developing pricing strategies, in order to to evaluate the extent to which companies customise strategies according to the needs and constraints of the population groups they target. Further, the 2016 Index will examine whether companies' equitable pricing strategies target countries the Index has prioritised for pricing analysis.\* This approach will facilitate the comparison of companies' practices in different disease areas and countries.**

\*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.

## Expectations for company behaviour

### Equitable pricing strategies

Leading companies will take socio-economic factors into account when setting prices, to differentiate both between countries and within different national population segments. They will apply equitable pricing strategies to a larger proportion of the products they market that address diseases within the scope of the Index, and in a larger proportion of countries where disease burden and inequality are particularly high. Proof of strategy implementation will be provided in the form of examples of corresponding price and sales data.

### Accountability for sales agents' pricing practices

Pricing mark-ups can have a significant effect on final prices and product affordability. At a minimum, companies are expected to mitigate their potential effects by providing sales agents with general pricing guidelines. Leading companies will also have processes and mechanisms for training sales agents, monitoring mark-ups and auditing sales agents' pricing practices. They will apply these guidelines to third-party distributors, wholesalers and retailers.

### Filing for registration/marketing approval

Companies are expected to quickly file for the registration of products in relevant countries, taking need into account. At a minimum, companies will have filed to register at least some relevant products in this way, while leading companies will have filed to register a relatively large proportion of relevant products in more countries in need. They will also have disease-specific, time-bound targets for filing for the registration of new products in all countries where there is a need. They will publicly disclose the criteria they use in decision-making processes and the registration status of most of their products.

### Drug recall systems

Companies are expected to have at least general guidelines for drug recalls and disclose basic information on all recalls that have occurred. Leading companies will both have and implement stringent drug-recall standards, policies and procedures. To facilitate recalls, they will also track their products. To raise awareness of potential risk, they will publicly disclose where, when and why a drug recall has taken place.

### Brochure & packaging adaptation to facilitate rational use

As a first step, companies will provide evidence of adapting packaging to address at least some specific local populations' needs. Leading companies will implement such adaptations more broadly, to help ensure patients understand their treatment, and receive the appropriate medicine in the proper dose, for an adequate period of time.

### Innovation

Companies are encouraged to develop innovative business models related to pricing, and innovative practices related to manufacturing and distribution, with the aim of increasing affordability and availability of their products in countries within the Index scope. Leading companies will also provide evidence that these strategies have been successfully implemented by describing resources invested and progress made towards increasing affordability and availability of their products.

## E Patents & Licensing

This Technical Area looks at how companies support a healthy, competitive market for pharmaceuticals. This includes managing the impact of patent monopolies on medicines prices (e.g., by taking steps that support both the market entry of generic medicine manufacturers, and the activities of drug procurement agencies), and by refraining from anti-competitive activity.

Research-based pharmaceutical manufacturers can assist generic medicine manufacturers to enter new markets by either not patenting, not enforcing patents, or by agreeing pro-access licensing terms. In turn, this stimulates greater production and competition, and places more sustainable, downwards pressure on medicine prices. When companies extend patents unfairly, or pay generic medicine manufacturers to stay out of certain markets, competition can be stifled. This can lead to higher prices and compromise access for those in need.

### 2016

The 2016 Index will now assess all aspects of competition-related behaviour in this Technical Area (previously this was split between two Technical Areas). This will enable the 2016 Index to present a more joined-up narrative about how companies support a competitive market for medicines. The 2016 Index will also stratify licensing behaviour by countries' economic classifications, in recognition of the pressing need to find more ways of providing affordable medicines in middle-income countries.

### Expectations for company behaviour

#### Patenting Strategy

To support healthy, competitive markets, leading companies will publish patent statuses, publicly agree not to patent, not to enforce patents, and to abandon existing patents in the broadest range of countries, and publicly agree to waive rights to data exclusivity. Poorer performers will fail to clearly disclose patent statuses, will file patents in Least-Developed Countries and will seek to extend and defend patents unfairly.

#### Licensing

The Index looks at whether companies will seek to engage in licensing where opportunities exist, and whether they agree pro-access licensing terms for a wide range of countries (including middle-income countries). Leading companies will license out newly registered or products still in development on transparent, access-friendly terms. They will also include more middle-income countries within their licences, recognising the need to supply new medicines cost-effectively in these jurisdictions.

#### Competition

All companies, including those without patents in place in countries in scope can take steps to support a competitive marketplace of pharmaceuticals. Companies are expected to publicly state support for competition, support this statement with behaviour which stimulates competition, and show zero tolerance for anti-competitive behaviour: avoiding price collusion, and not making payments aimed at delaying competitors from entering markets.

#### Trade Policy

Companies are expected to publicly and specifically endorse the full range of flexibilities in the Doha Declaration on TRIPS and Public Health aimed at protecting public health. Leading companies will not engage in lobbying activities intended to restrict these flexibilities, or hinder access to affordable medicines through other mechanisms related to trade policy.

Companies will fall behind if they fail to acknowledge the Doha Declaration, or misrepresent the flexibilities contained. Companies will also perform poorly for litigating against countries for their application of TRIPS flexibilities, or for challenging patentability criteria or the legitimacy of compulsory licences.

#### **Innovation**

The Index looks for new, progressive mechanisms for managing patent rights in ways that support access to medicine. This can include striking examples of transparency, external engagement and licensing. Of particular value are methods for improving access to very new medicines that have long patent terms remaining.

## **F Capacity Building**

This Technical Area seeks to capture the long-term, systematic engagement of companies with local stakeholders to build local capacities for providing healthcare. It examines how companies contribute to the strengthening of local research, development, production and distribution systems, and how they support the skills and knowledge of people needed to keep these systems functioning. It also looks at how companies help build national systems for monitoring product safety once products reach the market.

Some of the most significant barriers to access to medicine relate to gaps in local healthcare infrastructure, skills gaps amongst the local workforce, poorly functioning supply chains, and weak quality assurance systems. Large multinational pharmaceutical companies have the know-how, the reach, and the strategic incentive to address these local barriers to access. Capacity building activities can be implemented where conflicts of interest are absent, and can be implemented through partnerships and collaboration in areas where an identified need or gaps exists.

**2016**

Philanthropic activities to increase access to medicine will now be analysed here, rather than in the Product Donations chapter: these monetary contributions are often directed at activities that build local capacities. In 2016, this chapter will also measure companies' transparency regarding post-marketing safety surveillance data and the reporting of suspected falsified or substandard medicines. Timely reporting of these kinds of data, especially where regulatory systems are weak, can reduce the risk to public health.

### **Expectations for company behaviour**

#### **Capacity building in R&D**

Companies are encouraged to create and maintain collaborations with public sector research organisations in order to build local research and development capacity in countries within the Index scope. The Index looks for long-term engagement and encourages assessment of local labour market gaps.

#### **Capacity building in manufacturing**

When engaging in local production, companies are expected to ensure that local staff have the required skills to meet the highest quality standards. Local capacity in manufacturing can be improved by technology transfer, or through training local, in-house and third-party manufacturers to comply with globally accepted standards. The Index assesses how often companies engage in such training activities.

**Capacity building in supply chain management**

Poorly-functioning supply chains can create barriers to access, such as stock-outs or the introduction of falsified medicines. Companies can support supply chains by providing training and engaging with government, regulators, distributors and other organisations. To reduce the public health dangers of suspected falsified or substandard medicines, companies should systematically report issues to national authorities and WHO Rapid Alert.

**Capacity building in pharmacovigilance**

Many countries lack efficient systems to detect, evaluate and respond to safety issues regarding medicines and vaccines. Companies are encouraged to collaborate with local authorities to help strengthen national pharmacovigilance systems, for example through training, secondments or consulting. Companies are expected to keep labels up to date with the latest efficacy and safety information, and are also expected to make safety data available to regulators, and to publicly disclose post-marketing safety surveillance data.

**Initiatives to build other capacities**

Beyond improvements to the pharmaceutical value chain, companies can also help remove barriers to access to medicine through initiatives that support diagnosis and treatment or by helping to improve treatment-seeking behaviour. The Index assesses where and how often companies engage in such capacity building initiatives, how potential for conflicts of interest are addressed, how local needs are addressed and whether companies track impact.

**Sustainable philanthropy**

In resource-limited settings, companies can improve access to medicine through philanthropy (i.e., monetary support). This can be targeted towards disease prevention, improving healthcare infrastructure or general patient education. The Index looks for evidence of sustainable philanthropy, evidenced by long-term investment in activities that have a clearly defined strategy aligned with global health priorities and national objectives.

**Innovation**

Innovative approaches in local capacity building can improve affordability, quality and overall access to medicine for diseases and countries within the scope of the Index. The Index looks for innovation that measures progress and impact.

## G Product Donations

This Technical Area looks at companies' product donation programmes in countries within the scope of the Index. It examines how companies partner with external organisations such as governments and local NGOs in order to ensure much-needed medicine reaches patients living in the intended communities.

Globally, donation programmes play an important role in controlling, eliminating and eradicating diseases affecting people living in poverty. For millions of people, donations represent their only chance of gaining access to the medicines they need – particularly during humanitarian crises or if they live in regions where healthcare systems do not function. By implementing consistent strategies for monitoring the impact and outcome of donation programmes, companies can improve the delivery of products and significantly enhance their responses to local needs.

**2016**

Previously, this Technical Area included philanthropic activity. This will now be analysed under Capacity Building to better enable linked activities to be analysed together. In 2016, Product Donations will also explore in more detail how companies engage in partnerships with international organisations and local stakeholders to ensure the quality of product donation programmes. It will also gather insight into the number of units donated and analyse the public disclosure of impact assessments and evaluations.

## Expectations for company behaviour

### Product donation delivery & implementation

Where they have appropriate products, companies are encouraged to design and implement donation programmes that target the highest burden diseases, including non-communicable diseases. Companies are expected to commit to aligning with national and international agreements on health priorities. They are also expected to disclose the type, volume and destination of their donated products. Better performers will have long-term, detailed strategies for donation programs that maximise impact on public health.

### Quality & impact in product donations

Companies are expected to collaborate with reputable partners such as the WHO, local NGOs and/or national governments to carry out donation programmes in accordance with sustainable, long-term strategies, in alignment with local needs and priorities. Better performing companies will follow the WHO Guidelines for Medicine Donations (Revised 2010) and/or other international guidelines. For all donation programmes, companies are encouraged to integrate mechanisms for continuous outcome reporting and assessing health impacts, together with their partners, and to make these reports publicly available where possible and appropriate.

### Innovation

Companies are encouraged to seek new, more effective and efficient strategies to improve their donation programmes. Better performing companies will trial innovative and impactful approaches for initiating and implementing product donation programmes, enabling them to – for example – better address local challenges and involve local stakeholders. Companies are encouraged to look for more effective approaches for scaling-up and expanding successful product donations to reach more people and to facilitate better patient outcomes.

# Indicators

## Indicator-level changes

A list of all 83 indicators that will be used to assess companies in the 2016 Access to Medicine Index is available in the following pages. Indicators were retained, changed or deleted based on the following guidelines.

Indicators were retained when:

- The specific data available was of sufficient quality, and
- They remained relevant to access to medicine.

Indicators were considered for change when:

- Average company scores were unevenly high or low, as compared to actual high or low activity in companies, signifying opportunities to increase the standard or address low scores by enhancing indicators;
- Their relevance to access to medicine had changed; or
- They could be combined with other indicators to simplify data collection.

## A General Access to Medicine Management

2016 indicator

Change/rationale (excl. language clarifications)

### A.I Commitments (15%)

#### A.I.1 Governance: Management structures

The company has a governance system that includes direct board-level responsibility and accountability for access-to-medicine initiatives for countries within the Index scope.

#### A.I.2 Access-to-medicine strategy

The company sets objectives to improve access to medicine, and aligns their access-to-medicine strategy with their core business.

New

To measure whether companies set access-to-medicine objectives, and align their access-to-medicine strategy with their core business.

### A.II Transparency (25%)

#### A.II.1 Managing for access-to-medicine outcomes: Public reporting

The company publicly reports on its commitments, objectives, targets and performance information related to improving access to medicine.

Indicator merger

To combine two 2014 indicators (A.II.1; A.II.2) related to the objectives and performance of access-to-medicine activities.

#### A.II.2 Stakeholder engagement: Public reporting

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.

New

To capture public disclosure of companies' stakeholder engagement activities related to access to medicine.

### A.III Performance (50%)

#### A.III.1 Managing for access-to-medicine outcomes: Performance management system

The company has a performance management system to implement, monitor and measure the outcomes of its access-to-medicine activities in countries within the Index scope.

#### A.III.2 Stakeholder engagement

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.

Indicator move

From commitment pillar to performance pillar

#### A.III.3 Governance: Performance management & incentives

The company has internal incentive structures to reward the effective delivery of initiatives that improve access to medicine in countries relevant to the Index, for diseases within the scope of the Index.

#### A.III.4 Stakeholder engagement: Local perspectives

The company has a system in place to incorporate external and local perspectives on access-to-medicine needs in the development and implementation of access strategies.



**A.IV Innovation (10%)****A.IV.1 Innovation in business models**

The company has contributed to the development of innovative business models that meet the needs of patients in countries within the Index scope.

**A.IV.2 Innovation in governance and stakeholder engagement**

The company has adopted innovative approaches to managing for governance, management systems and/or stakeholder engagement.

**New**

To measure innovation in governance and stakeholder engagement.

**B Market Influence & Compliance**

2016 indicator

Change/rationale (excl. language clarifications)

**B.I Commitments (15%)****B.I.1 Governance of ethical marketing**

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 practices.

**Modification**

To incorporate measurement of incentive structures for sales agents

**B.I.2 Governance of corruption & bribery**

The company commits to proactively engaging in fighting corruption through its internal policies, oversight of third parties, external commitments and memberships.

**Modification**

To incorporate more stringent measurement of oversight of third parties

**B.II Transparency (25%)****B.II.1 Market influence: Policy positions**

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.

**B.II.2 Market influence: Memberships**

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.

**Indicator merger**

To combine two 2014 lobbying disclosure indicators (B.II.2; B.II.3). Also modified to place new emphasis on public disclosure, and disclosure of policy for responsible external engagement.

**B.II.3 Disclosure of marketing strategy and practice**

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 health-care professionals and opinion leaders).

**B.II.4 Ethical Marketing & Corruption: Disclosure of breaches**

The company publicly discloses information regarding global breaches of internationally recognised codes of conduct, laws and regulations that govern ethical marketing, bribery and corruption in the last two years.

**Modification**

To emphasise public disclosure

### B.III Performance (50%)

#### B.III.1 Ethical Marketing & Corruption: Incidence of breaches

The company has not been the subject of settled cases for corrupt practice, bribery or incidences of unethical marketing practice during the past two years.

#### Modification

To stratify breaches according to whether they are civil, criminal or code of practice breaches.

#### B.III.2 Ethical Marketing & Corruption: Enforcement

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, bribery or corruption. The company provides evidence of follow-up action taken to mitigate risk of future breaches.

#### Modification

To place greater emphasis on follow-up action

#### B.III.3 Ethical Marketing & Corruption: Monitoring

The company demonstrates that they have a regular, rigorous audit procedure to ensure the application of their codes of conduct/policies for managing ethical marketing, corruption and bribery, using auditing resources both internal and external to the company, which extends to all countries relevant to the Index in which the company operates, and to all third parties with whom the company is engaged.

#### New

To capture the extent and rigour of monitoring of compliance with corruption and marketing codes

### B.IV Innovation (10%)

#### B.IV.1 Innovation in Market Influence & Compliance

The company has adopted an innovative approach to improving ethical business performance within countries within the scope of the Index in ethical marketing, lobbying, or bribery and corruption.

## C Research & Development

2016 indicator

Change/rationale (excl. language clarifications)

### C.I Commitments (15%)

#### C.I.1 Product development: Innovative and adaptive R&D

The company commits to carrying out research focusing on the development of both innovative products and adaptive formulations of its existing products for diseases within the scope of the Index with the goal of improving access to medicine in countries within scope.

#### C.I.2 Collaborative R&D: Ensuring equitable access

The company commits to ensuring equitable access to products successfully developed through R&D partnerships.

#### C.I.3 Clinical trial conduct: Commitment to standards

The company commits to complying with standards of quality assurance and 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), Good Participatory Practice Guidelines (GPP), 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).

#### Modification

To capture evidence of compliance with Good Participatory Practice Guidelines (GPP) from companies with relevant HIV/AIDS R&D

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## C.II Transparency (25%)

### C.II.1 Disclosure of resources dedicated to R&D

The company 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.

### C.II.2 Collaborative R&D: Disclosure of licensing detail

The company discloses licensing details pertaining to its research collaborations related to diseases within the scope of the Index (with regard to intellectual property rights, access provisions etc.).

### C.II.3 Disclosure of clinical trial data

The company discloses information regarding the results of all of its clinical trials conducted in countries relevant to the Index, regardless of the outcome and whether the trial was conducted in-house or through a third-party (e.g., contract research organisation (CRO)).

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## C.III Performance (50%)

### C.III.1 Resources dedicated to R&D

The portion of financial R&D investment dedicated to diseases of relevance to the Index out of the company's total R&D expenditures.

### C.III.2 Share of pipeline: New molecules

The share of the research pipeline reflecting relevant 'new molecules' for diseases within the scope of the Index including in-house and collaborative research, corrected for company size.

#### Modification

The share of the research pipeline will be corrected for company size.

### C.III.3 Share of pipeline: Adapted products

The share of the research pipeline and registered products reflecting relevant adapted products or new technologies specific to a disease within the scope of the Index and with an unmet need in a country within the scope of the Index, including in-house and collaborative research, corrected for company size.

#### Modification

The share of the research pipeline will be corrected for company size.

### C.III.4 Collaborative R&D: Share of pipeline

The share of R&D partnerships in which the company has been involved, with the aim of developing products or formulations for diseases within the scope of the Index that specifically target access issues in countries relevant to the Index, adjusted for the number of relevant products in the company's relevant research pipeline.

#### Modification

Measure will be corrected with the share of the relevant pipeline developed in collaboration rather than the overall pipeline.

### C.III.5 Product development: movement through the pipeline

The number of candidates relating to diseases within the scope of the Index moving through R&D life cycle from early research phases to more advanced phases.

### C.III.6 Collaborative R&D: Terms and conditions

The company provides evidence that the terms and conditions of its research collaborations are conducive to improving access to products that target diseases relevant to the Index in countries within the scope of the Index.

**C.III.7 Clinical trial conduct: Breaches**

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.

**Modification**

To reduce period of analysis from five to two years (in-line with overall period of analysis).

**C.III.8 IP sharing**

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.

**C.III.9 Clinical trial conduct: Compliance with standards**

The company provides evidence of ensuring compliance with GCP and the Declaration of Helsinki when conducting trials in countries within the scope of the Index, regardless of whether the trial was conducted in-house or through a third-party (e.g., contract research organisation (CRO)).

**C.IV Innovation (10%)****C.IV.1 Innovation in R&D**

The company has adopted innovative (i.e., 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.

**D Pricing, Manufacturing & Distribution**

2016 indicator

Change/rationale (excl. language clarifications)

**D.I Commitments (15%)****D.I.1 Commitment to equitable pricing**

The company commits to implementing equitable pricing strategies for its products aimed at diseases relevant to the Index, in countries within the scope of the Index.

**Indicator merger**

To combine two 2014 indicators (D.I.1; D.I.2) and create a single commitment indicator

**D.I.2 Accountability for sales agents' pricing practices**

The company adopts clear policies to guide, monitor and audit the pricing practices of its local sales agents with the aim of improving affordability and accessibility of its products.

**D.I.3 Filing for marketing approval/registration targets**

The company has targets for 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.

## D.II Transparency (25%)

### D.II.1 Equitable pricing strategies: volume of sales disclosure

The company discloses the volume of its sales for products covered under equitable pricing programmes within the scope of the Index.\*

\*Data analysis will be centred on 'priority countries.' 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.

#### Modification

To base analysis on strategies targeted towards priority countries

### D.II.2 Equitable pricing strategies: Price disclosure

The company discloses target prices for products covered under equitable pricing programmes within the scope of the Index.\*

\*Data analysis will be centred on 'priority countries.' 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.

#### Modification

To remove disclosure of pricing strategies as a measurement factor and base analysis on strategies targeted towards priority countries

### D.II.3 Public disclosure of registration criteria and status

The company publicly discloses both the criteria used in its registration (i.e., marketing approval) decision-making process and the status of marketing approvals.

#### Modification

To emphasise public disclosure

### D.II.4 Public disclosure of drug recalls

The company publicly discloses information about drug recalls and breaches it has been involved in related to drug quality issues in the countries within the Index scope.

## D.III Performance (50%)

### D.III.1 Equitable pricing strategies: Market and product scope

The company's equitable pricing programmes cover a significant percentage of the company's products relating to diseases within the scope of the Index and a significant percentage of relevant priority countries.

#### Modification

To base analysis only on products that target priority countries

### D.III.2 Equitable pricing strategies: Inter-country

The company takes into consideration needs-based affordability and other relevant socioeconomic factors when making inter-country pricing decisions.\*

\*Data gathered from priority country strategies will inform this analysis.

#### Modification

To focus on socioeconomic factors in addition to affordability

### D.III.3 Equitable pricing strategies: Intra-country

The company takes into consideration needs-based affordability and other relevant socioeconomic factors when making intra-country pricing decisions.\*

\*Data gathered from priority country strategies will inform this analysis.

#### New

To separate analysis of inter- and intra-country pricing strategies

### D.III.4 Filing for marketing approval/registration: Needs-based

The company has attempted to file for registration/ marketing approval for its products for diseases relevant to the Index in countries relevant to the Index in need.

#### Modification

To evaluate registration performance based on incidence of filing for registration rather than approved registration.

<b>D.III.5</b>	<b>Drug recall system</b> The company has in place policies, 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.	<b>Modification</b> To analyse drug recall systems (policies, procedures, resources) and remove compliance with WHO GMP as a benchmark
<b>D.III.6</b>	<b>Brochure and packaging adaptation: Rational use</b> The company provides evidence of needs-based brochure and packaging adaptation to facilitate rational use, beyond adaptations required by local regulatory requirements, for its products destined for countries within the scope of the Index.	<b>Indicator move</b> From commitment to performance pillar

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<b>D.IV Innovation (10%)</b>		
<b>D.IV.1</b>	<b>Innovation in equitable pricing</b> The company has introduced innovative approaches (i.e., unique in the sector) to equitable pricing that help with sustainable delivery of products for diseases relevant to the Index to individuals in the countries relevant to the Index who face the highest financial barriers to access.	
<b>D.IV.2</b>	<b>Innovation in manufacturing &amp; distribution</b> The company has introduced innovative approaches (i.e., unique in the sector) to manufacturing and distribution of products for diseases relevant to the Index which may help with sustainable delivery of such products to countries relevant to the Index.	

## E Patents & Licensing

2016 indicator

Change/rationale (excl. language clarifications)

### E.I Commitments (15%)

<b>E.I.1</b>	<b>Competition: Patent filing</b> The company commits to not filing for or enforcing patents related to diseases within the scope of the Index in Least Developed Countries, low income and lower-middle income countries.	
<b>E.I.2</b>	<b>Commitment to competition</b> The company publicly endorses competition on the pharmaceutical market and commits to not engaging in anti-competitive practice. This is evidenced by both a public commitment to engaging in proactive activities that foster competition (e.g., licensing, patent abandonment, waivers of data exclusivity) and an absence of anti-competitive behaviour.	<b>Indicator merger</b> To combine two 2014 competition-related commitment indicators (E.I.2; B.I.1)

### E.II Transparency (25%)

<b>E.II.1</b>	<b>Trade Policy: Endorsement of TRIPS flexibilities</b> 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.	<b>Modification</b> To emphasise public disclosure
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**E.II.2 Competition: Patent disclosure**

The company publicly discloses the patent status of its products for diseases relevant to the Index, in countries within the Index scope.

**E.II.3 Disclosure of licensing practice**

The company publicly discloses detailed information about the voluntary licensing and non-assert agreements it is engaged in, for products relevant to the Index, in countries within the Index scope.

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**E.III Performance (50%)****E.III.1 Licensing: Scale**

The company actively engages in issuing multiple voluntary licences and/or non-assert declarations for products relevant to the Index, in countries within the Index scope.

**E.III.2 Licensing: Patent pools**

The company supports patent pools such as the Medicines Patent Pool for manufacture and distribution of relevant products, and for development of combination therapies for products relevant to the Index, in countries within the Index scope.

**E.III.3 Access-oriented licensing**

The company includes access-oriented terms and conditions within the voluntary licences and non-assert declarations it agrees for products relevant to the Index, in countries within the Index scope.

**Modification**

To include flexible technology transfer terms and pre-registration licensing as possible examples of access-oriented licensing clauses

**E.III.4 Licensing: Geographic scope**

The company includes a broad range of countries within the geographic scope of their licences, including middle-income countries with comparatively high burdens of disease.

**New**

To gauge the geographic scope of licences

**E.III.5 Anti-competitive behaviour: Trade policy**

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 intellectual property standards as it pertains to public health, confirmed by the Doha Declaration.

**Indicator merger**

To combine two 2014 indicators concerning IP-related anti-competitive practice (B.III.4, E.III.5)

**E.III.6 Anti-competitive behaviour: Non-IP**

There is evidence that the company has engaged in anti-competitive behaviour outside of its intellectual property strategy that impacts access to medicine.

**Indicator move**

From Market Influence & Compliance (formerly B.III.2)

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**E.IV Innovation (10%)****E.IV.1 Innovation in patents & licensing**

The company has adopted innovative (i.e., 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.

## F Capacity Building

2016 indicator

Change/rationale (excl. language clarifications)

### F.I Commitments (15%)

#### F.I.1 Manufacturing: Assessing training needs

The company has a policy in place for the assessment and provision of training needs aimed at reaching or maintaining the highest quality standards both for in-house and third-party manufacturers in countries within the scope of the Index.

#### Modification

To shift focus to human resources rather than quality management systems and GMP guidelines.

#### F.I.2 Sustainable philanthropy

The company commits to and explains its rationale (including how it targets local public health needs) for investing in health infrastructure-related philanthropic projects outside of the pharmaceutical value chain, including their relevance to long-term sustainable access to medicine in countries within the scope of the Index.

#### Indicator move

From Product Donations (formerly G.I.3)

### F.II Transparency (25%)

#### F.II.1 Pharmacovigilance: Sharing safety data

The company publicly discloses post-marketing surveillance data and provides evidence of product stewardship in countries within the scope of the Index.

#### Modification

To capture whether companies publicly disclose safety data and ensure that product safety and efficacy information is updated in countries with weak regulatory systems.

#### F.II.2 Supply chain management: Reporting falsified and substandard medicines

The company has a policy in place that describes how and when to report any suspect falsified and/or substandard medicines and vaccines it encounters in countries within the scope of the Index to relevant authorities (i.e., national regulatory authorities and WHO Rapid Alert). The timescale for reporting follows local laws and regulations, or in the absence of these, prescribes reporting within seven days of discovery.

#### New

To capture company policies for reporting suspect falsified and/or substandard medicines

#### F.II.3 Capacity building in R&D: Addressing local needs

The company discloses details of its partnerships/collaborations with public sector research institutes or universities in countries relevant to the Index evidencing how they aim to create local research capacity and product development for diseases within the scope of the Index.

#### F.II.4 Supply chain management: Transparency across supply chains

The company discloses details of how it is transparent with other stakeholders to improve supply chain efficiency, with the goals of: preventing product diversion; preventing stock-outs; addressing information gaps; addressing the trade in falsified medicine; improving demand forecasting; and improving drug regulation.



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### **F.III Performance (50%)**

#### **F.III.1 Capacity building in manufacturing**

The company assists local manufacturers and/or in-house manufacturing facilities in countries within the scope of the Index to achieve international good manufacturing standards\* through training or technology transfer.\*

\*Such as WHO or International Conference on Harmonisation (ICH) Good Manufacturing Practices (GMP) or equally recognised national certifications.

#### **F.III.2 Capacity building in R&D**

The company participates in local partnerships with public sector research institutes or universities in countries relevant to the Index with the aim of increasing local capacity for health research (including clinical trial capacity) and product development.

#### **F.III.3 Capacity building in supply chain management**

The company is engaged in programmes/partnerships with governments (e.g. Ministry of Health, procurement, logistics and distribution agencies) and other distributors in countries within the scope of the Index to develop locally appropriate supply chain capacities with the aim of improving the affordability, accessibility and quality of products that target diseases relevant to the Index.

#### **F.III.4 Capacity building in pharmacovigilance**

The company is actively engaged in developing and implementing national pharmacovigilance-related programmes in the countries within scope of the Index.

#### **F.III.5 Initiatives to build other capacities**

The company carries out initiatives outside the pharmaceutical value chain (where there is no conflict of interest) with the potential to improve the capacity of organisations in countries relevant to the Index to address access to medicine in those countries.

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### **F.IV Innovation (10%)**

#### **F.IV.1 Innovation in capacity building**

The company has introduced innovative (i.e., unique in sector) approaches to capacity building, working with organisations in countries relevant to the Index to improve the quality and accessibility of products for diseases within scope of the Index.

## G Product Donations

2016 indicator

Change/rationale (excl. language clarifications)

### G.I Commitments (15%)

#### G.I.1 Consistency in product donation policies

The company aligns with the WHO Guidelines for Medicine Donations (Revised 2010) or to equivalent standards in all its product donation activities, and commits to administration to patients in the intended communities.

#### Indicator merger

To combine two 2014 indicators (G.I.1; G.I.2)

#### G.I.2 Commitment in product donation implementation

The company commits to ensuring that donation programmes are supported with strategies that align with national public health objectives (and the WHO Guidelines for Medicine Donations (Revised 2010))

#### Modification

To place clearer emphasis on supporting national public health objectives

### G.II Transparency (25%)

#### G.II.1 Quality in product donation management

The company publicly discloses the financial value and evaluation(s) (regardless of who conducted these) of its structured donation programmes in the countries within the scope of the Index.

#### Modification

To shift focus to public disclosure of impact assessments and financials.

#### G.II.2 Transparency in product donation delivery and implementation

The company discloses detailed information about the type, volume and destination of products that are part of its ad hoc donation programmes donated in the countries within the scope of the Index.

### G.III Performance (50%)

#### G.III.1 Quality in product donation monitoring

The company and/or its partner(s) monitor outcomes and the impact of structured donation programmes.

#### Modification

To include partners' activities.

#### G.III.2 Scale of product donation

The number of units donated through structured donation programmes to countries within the scope of the Index, both during the period of analysis and from the start of the programme (adjusted for company size).

#### Modification

To shift focus from financial value of programmes to a measure of the magnitude of donation programmes.

#### G.III.3 Focus of product donation delivery

The scale and scope of donated products to the countries within the scope of the Index.

### G.IV Innovation (10%)

#### G.IV.1 Innovation in product donation management

The company has introduced innovative (i.e., unique in the sector), sustainable and impactful approaches to managing product donations, which may result in the programme's increased effectiveness and efficiency.

# Appendices

## Contributors to this report

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Throughout the methodology review, formal committees supported the Index team. Recommendations for specific sections of the Index were provided by Technical Sub-Committees: panels of specialists in different aspects of access to medicine. Strategic guidance was provided by the Expert Review Committee (ERC), a panel of independent experts from the WHO, governments, patient organisations, the industry, NGOs, academia and investors, among others.

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### Other Contributors

In addition to reviewing the 2014 Index with the companies we measure, the Access to Medicine Foundation contacted experts from a variety of organisations (academic, industry, non-governmental, multilateral, investors) to support the development of the 2015 Index Methodology with multiple viewpoints. We gratefully acknowledge all contributions. The following individuals agreed for their names to be publicly acknowledged:

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Acknowledgement in this appendix is not intended to imply endorsement of the Access to Medicine Index, its final methodology, the analysis or results. Final decisions regarding the content of the Technical Areas and indicators are ultimately made by the Access to Medicine Foundation.

## Overview of inclusion criteria for analysis: R&D projects

The Index limits its analysis to products targeted at needs in countries within the Index scope. The table below provides an overview of the criteria used to determine whether individual R&D projects submitted by the companies are to be included in the analysis. In a change from the previous Index, all early-stage projects (i.e., projects in discovery or pre-clinical stages or phase I of clinical development) are accepted for analysis. For diseases in two categories (Non-Communicable Diseases and Maternal & Neonatal Health Conditions), late-stage projects (i.e., projects in phases II or III of clinical development) have to be shown to have access provisions in place in order to qualify for analysis.

As soon as a product that meets a high unmet need gains approval from regulatory agencies, it should efficiently be made available to the people who need it. By putting measures (or ‘access provisions’) in place during the later stages of development (after the product’s profile is well-defined), companies can significantly accelerate the speed at which new products become available in sufficient quantities at an affordable price.

Access provisions can take many forms, including patent waivers, voluntary licensing, supply commitments, registration targets, or equitable pricing strategies.

**Table 5 Inclusion criteria for analysis: R&D projects**

<i>Disease category</i>	Innovative R&D (to develop new products)		Adaptive R&D (addressing characteristics of existing products)
	Early-stage projects	Late-stage projects	All stages
<b>Non-communicable diseases</b>	●	●	●
<b>Communicable diseases</b>	●	●	●
<b>Neglected Tropical Diseases</b>	●	●	●
<b>Maternal &amp; Neonatal Health conditions</b>	●	●	●

■ R&D projects for diseases in scope are included. For adaptive products, companies need to show how the adaptation targets a need in resource-limited settings.

■ R&D projects for diseases in scope are only included where evidence of access provisions has been provided (access provisions are measures put in place to ensure future affordability and availability).

## ICD-10 Coverage

### Communicable Diseases

	DALYs (in LICs + LMICs)	Index Disease	ICD-10 Classification
1	121,068,536	<b>Lower respiratory infections</b>	J09 – Influenza due to certain identified influenza virus J10 - Influenza due to other identified influenza virus J11 - Influenza, virus not identified J12 - Viral pneumonia, not elsewhere classified J13 - Pneumonia due to Streptococcus pneumoniae J14 - Pneumonia due to Haemophilus influenzae J15 - Bacterial pneumonia, not elsewhere classified J16 - Pneumonia due to other infectious organisms, not elsewhere classified J17 - Pneumonia in diseases classified elsewhere J18 - Pneumonia, organism unspecified J20 - Acute bronchitis J21 - Acute bronchiolitis J22 - Unspecified acute lower respiratory infection P23 – Congenital pneumonia U04 – Severe acute respiratory syndrome [SARS]
2	89,536,536	<b>Diarrhoeal diseases</b>	A00 - Cholera A01 - Typhoid and paratyphoid fevers A03 - Shigellosis A04 - Other bacterial intestinal infections A06 - Amoebiasis A07 - Other protozoal intestinal diseases A08 - Viral and other specified intestinal infections A09 - Other gastroenteritis and colitis of infectious and unspecified origin
3	68,614,932	<b>HIV/AIDS</b>	B20 - Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases B21 - Human immunodeficiency virus [HIV] disease resulting in malignant neoplasms B22 - Human immunodeficiency virus [HIV] disease resulting in other specified diseases B23 - Human immunodeficiency virus [HIV] disease resulting in other conditions B24 - Unspecified human immunodeficiency virus [HIV] disease
4	52,991,412	<b>Malaria</b>	B50 - Plasmodium falciparum malaria B51 - Plasmodium vivax malaria B52 - Plasmodium malariae malaria B53 - Other parasitologically confirmed malaria B54 - Unspecified malaria P37.3 – Congenital falciparum malaria P37.4 – Other congenital malaria
5	36,403,940	<b>Tuberculosis</b>	A15 - Respiratory tuberculosis, bacteriologically and histologically confirmed A16 - Respiratory tuberculosis, not confirmed bacteriologically or histologically A17 - Tuberculosis of nervous system A18 - Tuberculosis of other organs A19 - Miliary tuberculosis B90 – Sequelae of tuberculosis

6	26,674,319	<b>Meningitis</b>	A39 - Meningococcal infection G00 - Bacterial meningitis, not elsewhere classified G03 - Meningitis due to other and unspecified causes
7	11,194,628	<b>Measles</b>	B05 - Measles
8	6,403,176	<b>Syphilis</b>	A50 - Congenital syphilis A51 - Early syphilis A52 - Late syphilis A53 - Other and unspecified syphilis
9	5,657,488	<b>Pertussis</b>	A37 - Whooping cough
10	5,384,352	<b>Tetanus</b>	A33 - Tetanus neonatorum A34 - Obstetrical tetanus A35 - Other tetanus

**Non- Communicable Diseases**

	DALYs (in LICs + LMICs)	Index Disease	ICD-10 Classification
1	70,459,863	<b>Ischaemic heart disease</b>	I20 - Angina pectoris I21 - Acute myocardial infarction I22 - Subsequent myocardial infarction I23 - Certain current complications following acute myocardial infarction I24 - Other acute ischaemic heart diseases I25 - Chronic ischaemic heart disease
2	56,454,095	<b>Stroke</b>	I60 - Subarachnoid haemorrhage I61 - Intracerebral haemorrhage I62 - Other nontraumatic intracranial haemorrhage I63 - Cerebral infarction I64 - Stroke, not specified as haemorrhage or infarction I65 - Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction I66 - Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction I67 - Other cerebrovascular diseases I68 - Cerebrovascular disorders in diseases classified elsewhere I69 - Sequelae of cerebrovascular disease
3	52,471,475	<b>Chronic obstructive pulmonary disease</b>	J40 - Bronchitis, not specified as acute or chronic J41 - Simple and mucopurulent chronic bronchitis J42 - Unspecified chronic bronchitis J43 - Emphysema J44 - Other chronic obstructive pulmonary disease
4	35,521,719	<b>Unipolar depressive disorders</b>	F32 - Depressive episode F33 - Recurrent depressive disorder F34.1 - Dysthymia
5	26,915,498	<b>Diabetes mellitus</b>	E10 - Type 1 diabetes mellitus E11 - Type 2 diabetes mellitus E12 - Malnutrition-related diabetes mellitus E13 - Other specified diabetes mellitus E14 - Unspecified diabetes mellitus
6	22,422,505	<b>Cirrhosis of the liver</b>	K70 - Alcoholic liver disease K74 - Fibrosis and cirrhosis of liver

	DALYs (in LICs + LMICs)	Index Disease	ICD-10 Classification
7	18,128,559	<b>Kidney diseases</b>	N00 - Acute nephritic syndrome N01 - Rapidly progressive nephritic syndrome N02 - Recurrent and persistent haematuria N03 - Chronic nephritic syndrome N04 - Nephrotic syndrome N05 - Unspecified nephritic syndrome N06 - Isolated proteinuria with specified morphological lesion N07 - Hereditary nephropathy, not elsewhere classified N08 - Glomerular disorders in diseases classified elsewhere N10 - Acute tubulo-interstitial nephritis N11 - Chronic tubulo-interstitial nephritis N12 - Tubulo-interstitial nephritis, not specified as acute or chronic N13 - Obstructive and reflux uropathy N14 - Drug- and heavy-metal-induced tubulo-interstitial and tubular conditions N15 - Other renal tubulo-interstitial diseases N16 - Renal tubulo-interstitial disorders in diseases classified elsewhere N17 - Acute renal failure N18 - Chronic kidney disease N19 - Unspecified kidney failure
8	16,223,415	<b>Asthma</b>	J45 - Asthma J46 - Status asthmaticus
9	14,347,659	<b>Epilepsy</b>	G40 - Epilepsy G41 - Status epilepticus
10 (new)	13,175,172	<b>Anxiety disorders</b>	F40 - Phobic anxiety disorders F41 - Other anxiety disorders F42 - Obsessive-compulsive disorder F43 - Reaction to severe stress, and adjustment disorders F44 - Dissociative [conversion] disorders
11 (new)	10,150,681	<b>Migraine</b>	G43 - Migraine
12 (new)	10,113,460	<b>Hypertensive heart disease</b>	I10 - Essential (primary) hypertension I11 - Hypertensive heart disease I12 - Hypertensive renal disease I13 - Hypertensive heart and renal disease I15 - Secondary hypertension
13	5,920,895	<b>Bipolar affective disorder</b>	F30 - Manic episode F31 - Bipolar affective disorder
14	5,133,445	<b>Schizophrenia</b>	F20 - Schizophrenia F21 - Schizotypal disorder F22 - Persistent delusional disorders F23 - Acute and transient psychotic disorders F24 - Induced delusional disorder F25 - Schizoaffective disorders F28 - Other nonorganic psychotic disorders F29 - Unspecified nonorganic psychosis



### Neglected Tropical Diseases

	DALYs (in LIC + LMICs)	Index Disease	Name ICD-10 Classifications
1	3,700,597	<b>Schistosomiasis</b>	B65 - Schistosomiasis [bilharziasis]
2	3,360,656	<b>Intestinal nematode infections</b>	B76 - Hookworm diseases B77 - Ascariasis B78 - Strongyloidiasis
3	3,196,523	<b>Leishmaniasis</b>	B55 - Leishmaniasis
4	2,810,555	<b>Lymphatic filariasis</b>	B74.0 - Filariasis due to <i>Wuchereria bancrofti</i> B74.1 - Filariasis due to <i>Brugia malayi</i> B74.2 - Filariasis due to <i>Brugia timori</i>
5	2,083,208	<b>Rabies</b>	A82 - Rabies
6	1,875,000*	<b>Food-borne trematodiasis</b>	B66.0 - Opisthorchiasis B66.1 - Clonorchiasis B66.3 - Fascioliasis B66.4 - Paragonimiasis
7	1,248,941	<b>Human African trypanosomiasis</b>	B56 - African trypanosomiasis
8	1,238,610**	<b>Dengue and chikungunya</b>	A90 - Dengue fever [classical dengue] A91 - Dengue haemorrhagic fever A92.0 – Chikungunya virus disease
9	593,762	<b>Onchocerciasis</b>	B73 - Onchocerciasis
10	503,000*	<b>Cysticercosis</b>	B69 - Cysticercosis
11	214,395	<b>Trachoma</b>	A71 - Trachoma
12	199,424	<b>Leprosy</b>	A30 - Leprosy [Hansen disease]
13	144,000*	<b>Echinococcosis</b>	B67 - Echinococcosis
14	44,404	<b>Chagas disease</b>	B57 - Chagas disease
15	NA	<b>Buruli ulcer</b>	A31.1 - Cutaneous mycobacterial infection
16	NA	<b>Yaws</b>	A66 - Yaws
17	NA	<b>Dracunculiasis</b>	B72 - Dracunculiasis

\* DALY counts in LICs and MICs for these diseases were not available from the Global Health Observatory. The DALY counts given here were instead taken from the Global Burden of Disease Study 2010 (Murray et al.)<sup>20</sup> They represent the global DALY burden and are calculated using a different method. They are thus not directly comparable with the DALY counts provided for LICs and LMICs and MICs.

\*\* This DALY estimate only includes dengue, and not chikungunya.

## Maternal Conditions

	DALYs (global)	Index Disease	Name ICD-10 Classifications
1	3,289,000*	<b>Maternal Haemorrhage</b>	O44 - Placenta praevia O45 - Premature separation of placenta [abruptio placentae] O46 - Antepartum haemorrhage, not elsewhere classified O67 - Labour and delivery complicated by intrapartum haemorrhage, not elsewhere classified O72 - Postpartum haemorrhage
2	2,797,000 *	<b>Hypertensive disorders of pregnancy</b>	O10 - Pre-existing hypertension complicating pregnancy, childbirth and the puerperium O11 - Pre-eclampsia superimposed on chronic hypertension O12 - Gestational [pregnancy-induced] oedema and proteinuria without hypertension O13 - Gestational [pregnancy-induced] hypertension O14 - Pre-eclampsia O15 - Eclampsia O16 - Unspecified maternal hypertension
3	2,138,000*	<b>Abortion</b>	O00 - Ectopic pregnancy O01 - Hydatidiform mole O02 - Other abnormal products of conception O03 - Spontaneous abortion O04 - Medical abortion O05 - Other abortion O06 - Unspecified abortion O07 - Failed attempted abortion
4	1,792,000 *	<b>Obstructed Labour</b>	O64 - Obstructed labour due to malposition and malpresentation of fetus O65 - Obstructed labour due to maternal pelvic abnormality O66 - Other obstructed labour
5	1,309,000*	<b>Maternal Sepsis</b>	O85 - Puerperal sepsis O86 - Other puerperal infections
6	NA	<b>Contraceptive methods and devices</b>	Combined hormonal contraceptives, progestogen-only contraceptives, emergency contraceptive pills, intrauterine devices (IUD), copper emergency IUD, barrier methods (condoms, rings, spermicide, diaphragm with spermicide, cervical cap), Platform technologies (adjuvants and immunomodulators, general diagnostic platforms, delivery technologies and devices, implants and technologies for reproductive health)

## Neonatal Health

	DALYs (in LIC + LMICs)	Index Disease	Name ICD-10 Classifications
1	91,782,664	Preterm birth complications	P05 - Slow fetal growth and fetal malnutrition P07 - Disorders related to short gestation and low birth weight, not elsewhere classified P22 - Respiratory distress of newborn P27 - Chronic respiratory disease originating in the perinatal period P28 - Other respiratory conditions originating in the perinatal period
2	63,824,424	Birth asphyxia and birth trauma	P03 - Fetus and newborn affected by other complications of labour and delivery P10 - Intracranial laceration and haemorrhage due to birth injury P11 - Other birth injuries to central nervous system P12 - Birth injury to scalp P13 - Birth injury to skeleton

\* DALY counts in LICs and MICs for these diseases were not available from the Global Health Observatory. The DALY counts given here were instead taken from the Global Burden of Disease Study 2010 (Murray et.al.)<sup>20</sup> They represent the global DALY burden and are calculated using a different method. They are thus not directly comparable with the DALY counts provided for LICs and LMICs and MICs.

			<ul style="list-style-type: none"> <li>P14 - Birth injury to peripheral nervous system</li> <li>P15 - Other birth injuries</li> <li>P20 - Intrauterine hypoxia</li> <li>P21 - Birth asphyxia</li> <li>P24 - Neonatal aspiration syndromes</li> <li>P25 - Interstitial emphysema and related conditions originating in the perinatal period</li> <li>P26 - Pulmonary haemorrhage originating in the perinatal period</li> <li>P29 - Cardiovascular disorders originating in the perinatal period</li> </ul>
3	36,107,007	Neonatal sepsis and infections	<ul style="list-style-type: none"> <li>P35 - Congenital viral diseases</li> <li>P36 - Bacterial sepsis of newborn</li> <li>P37.0 – Congenital tuberculosis</li> <li>P37.1 – Congenital toxoplasmosis</li> <li>P37.2 – Neonatal (disseminated) listeriosis</li> <li>P37.5 – Neonatal candidiasis</li> <li>P37.8 – Other specified congenital infectious and parasitic diseases</li> <li>P37.9 - Congenital infectious and parasitic disease, unspecified</li> <li>P38 - Omphalitis of newborn with or without mild haemorrhage</li> <li>P39 - Other infections specific to the perinatal period</li> </ul>
4	10,896,418	Other neonatal conditions	<ul style="list-style-type: none"> <li>P00 - Fetus and newborn affected by maternal conditions that may be unrelated to present pregnancy</li> <li>P01 - Fetus and newborn affected by maternal complications of pregnancy</li> <li>P02 - Fetus and newborn affected by complications of placenta, cord and membranes</li> <li>P04 - Fetus and newborn affected by noxious influences transmitted via placenta or breast milk</li> <li>P08 - Disorders related to long gestation and high birth weight</li> <li>P50 - Fetal blood loss</li> <li>P51 - Umbilical haemorrhage of newborn</li> <li>P52 - Intracranial nontraumatic haemorrhage of fetus and newborn</li> <li>P53 - Haemorrhagic disease of fetus and newborn</li> <li>P54 - Other neonatal haemorrhages</li> <li>P55 - Haemolytic disease of fetus and newborn</li> <li>P56 - Hydrops fetalis due to haemolytic disease</li> <li>P57 - Kernicterus</li> <li>P58 - Neonatal jaundice due to other excessive haemolysis</li> <li>P59 - Neonatal jaundice from other and unspecified causes</li> <li>P60 - Disseminated intravascular coagulation of fetus and newborn</li> <li>P61 - Other perinatal haematological disorders</li> <li>P70 - Transitory disorders of carbohydrate metabolism specific to fetus and newborn</li> <li>P71 - Transitory neonatal disorders of calcium and magnesium metabolism</li> <li>P72 - Other transitory neonatal endocrine disorders</li> <li>P74 - Other transitory neonatal electrolyte and metabolic disturbances</li> <li>P75 - Meconium ileus in cystic fibrosis</li> <li>P76 - Other intestinal obstruction of newborn</li> <li>P77 - Necrotizing enterocolitis of fetus and newborn</li> <li>P78 - Other perinatal digestive system disorders</li> <li>P80 - Hypothermia of newborn</li> <li>P81 - Other disturbances of temperature regulation of newborn</li> <li>P83 - Other conditions of integument specific to fetus and newborn</li> <li>P90 - Convulsions of newborn</li> <li>P91 - Other disturbances of cerebral status of newborn</li> <li>P92 - Feeding problems of newborn</li> <li>P93 - Reactions and intoxications due to drugs administered to fetus and newborn</li> <li>P94 - Disorders of muscle tone of newborn</li> <li>P95 - Fetal death of unspecified cause</li> <li>P96 - Other conditions originating in the perinatal period</li> </ul>

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## Definitions

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For the sources used in determining these definitions, please contact the Access to Medicine Foundation.

### Access provisions

*[Working definition, used for analysis]*

Access measures put in place during product development to help ensure that public health needs are taken into consideration and to facilitate rapid access to affordable products after market entry. Examples of access provisions include non-exclusivity in field/territories, price caps, pricing strategies, licensing strategies, supply guarantee, waiving patent rights, royalty-free provisions or registration targets.

### 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 research/products

*[Working definition, used for analysis]*

Adapting an existing/registered New Chemical Entities (NCEs), Non Biological Entities (NBEs), or other relevant medicine, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides to address an unmet need in the countries within the Index 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.

### Anti-competitive practice

Any practice by a company or group of companies that has, is intended to have, or is likely to have, the effect of restricting, distorting or preventing competition in order to maintain or increase their market position and/or profits. Anti-competitive behaviour leads to disadvantage or detriment of competitors, customers and suppliers such that higher prices, reduced output, less consumer choice, loss of economic efficiency and misallocation of resources (or combinations thereof). It can include, for example, price-fixing or pay-for-delay.

### Audit

An internal or external examination of an organisation's accounts, processes, functions and performance to produce an independent and credible assessment of their compliance with applicable laws, regulations and auditing requirements.

### Breaches

Acts that are in violation/disregard of or non-compliant with laws, rules, guidelines or codes

### Conflict of interest

A situation where a professional or a company has a vested interest that creates a risk that professional judgement or actions will be unduly influenced. The interests at stake could be, for example, money, status, knowledge or reputation.

### Disability Adjusted Life Years (DALY)

A summary measure which combines time lost through premature death and time lived in states of less than optimal health, loosely referred to as "disability"

### Drug recall

Actions taken by a company or medicines regulatory authority to remove from the market products or batches of products that are found to be either defective or potentially harmful. Recalls include those due to both packaging and quality or safety issues.

### Equitable pricing

*[Working definition, used for analysis]*

A targeted pricing strategy which aims at improving access to medicine for those in need by taking affordability of individuals and healthcare systems into account in a manner that is locally appropriate.

### Ethical clinical trial conduct

Policies and procedures that are in place to ensure ethical clinical trial standards for all trials, including in-house and outsourced trials (e.g. ICH-GCP, Declaration of Helsinki, Good Participatory Practice Guidelines). The Index uses clinical trial codes of conduct, selection criteria for CROs, and oversight and enforcement mechanisms, such as monitoring/auditing and disciplinary action procedures, to compare clinical trial standards of companies.

### 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

A product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Falsification can apply to both branded and generic products. Substandard batches, quality defects or non-compliance with Good Manufacturing Practices/ Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with falsification. Medical products (whether generic or branded) that are not authorised for marketing in a given country but are authorised elsewhere are not considered falsified.

**Impact assessment**

Evaluating the effects that a policy, programme or activity has on the health of a population, and the distribution of those effects within the population. This includes the effect on patient outcomes, epidemiology, healthcare infrastructure and other effects that relate to public health. It can include also wider socio-economic impacts. A company or a third party can perform it.

**Innovative research**

*[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 pricing strategy at the country level and take into account affordability for countries in need.

**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.

**IP sharing partnerships**

*[Working definition, used for analysis]*

The sharing of intellectual property (e.g., compound libraries, patented compounds, processes or technologies) by a company to an external party (e.g., WIPO Re:Search, DNDi, MMV, TB Drug Accelerator) that use the IP for R&D targeting diseases within scope of the Index.

**Licensing agreement**

A contract in which the patent holder allows the contracting party (the licensee) to use the patent, either against a payment of royalties or free of charge for a defined period of time.

**Lobbying**

Any activity carried out to influence a government or institution's policies and decisions in favour of a specific cause or outcome. Even when allowed by law, these acts can become distortive if disproportionate levels of influence exist.

**Microbicides**

Microbicides are compounds that can be applied topically (inside the vagina or rectum) to prevent HIV transmission.

**National pharmacovigilance systems**

National pharmacovigilance systems include nationwide systems or projects to establish and support a database of adverse drug reactions with the purpose of informing regulatory decision making, improving the rational and safe use of medical drugs, assessing and communicating of the risks and benefits of drugs on the market, and educating of patients. A comprehensive national pharmacovigilance system should include efficient surveillance, effective communication methods and collaboration with relevant stakeholders.

**Non-assert declaration**

A legally binding commitment that contains an explicit set of conditions, including permitted actions and designated territories, for which the patent owner commits not to enforce patent rights. This allows for a generic version of a patent protected product to be produced.

**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.

**Outside the pharmaceutical value chain**

*[Working definition, used for analysis]*

Activities beyond the scope of the company's normal operations and distribution channels. These include raising awareness and advocacy efforts to strengthen disease prevention or health promotion, improving healthcare infrastructure and training healthcare professionals.

**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.

**Performance measures**

Indicators used to assess progress towards set targets and outcomes

**Period of analysis**

*[Working definition, used for analysis]*

For the 2016 Index, the time period for which data will be analysed covers company activities which must be ongoing between June 2014 and the end of May 2016, as this is the cycle of the Index. Projects that have ended before June 1st 2014 are not included.

**Platform technologies**

Platform technologies include adjuvants, immunomodulators, delivery technologies and devices and general diagnostic platforms. These technologies must aim to be suitable for use in resource-limited settings.

**Priority countries**

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.

**Pro-access**

*[Working definition, used for analysis]*

An adjective to ensure positive provisions that address public health needs. A pro-access licence will have explicit terms embedded within it that ensure timely medicine development and market registration, safe and acceptable products delivered to populations who need them.

**Product donation programmes**

*[Working definition, used for analysis]*

Gifts of products (medicines and vaccines only) that are on-going during the period of analysis. These are subdivided into structured donation programmes and ad-hoc donation programmes.

### **Product stewardship**

The updating of a company's product labels when new evidence regarding efficacy and/or safety emerges. Emphasis here is on company behaviour in markets with absence of adequate pharmacovigilance legislation and enforcement.

### **Rational use**

The scientifically sound use of medicines. Rational use requires that patients receive the appropriate medicine, in the proper dose, for an adequate period of time, and at a cost which is affordable to them and their community.

### **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.

### **Sustainable philanthropy**

*[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.

### **Tiered pricing**

A pricing scheme where a company adapts product prices based on the purchasing power of consumers in different geographic or socioeconomic segments. Tiered pricing takes into account affordability of medicines and other products for low-income segments, and is therefore a form of equitable pricing.

### **TRIPS Flexibilities**

In the context of public health, these typically refer to the flexibilities within the TRIPS Agreement confirmed by Doha Declaration (2001) that allow WTO members to implement TRIPS in a "manner supportive of WTO members' right to protect public health..." and to use the measures within TRIPS for this purpose. For example, countries may permit manufacturers to use a patented invention to obtain marketing approval before the expiry of the patent and without the permission of the patent owner. Other flexibilities include defining patentability criteria, parallel importation, and special exemptions for the Least Developed Countries.

### **Vector Control Products**

Vector control products 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 that transmit Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

### **Voluntary licence**

A contract through which the patent-holder (the licensor) voluntarily permits a contracting party (the licensee) for the manufacture and distribution of a product. A non-exclusive voluntary licence is when the licence can be agreed with multiple licensees.

## Acronyms

ATM	Access to Medicine	IP	Intellectual Property
COPD	Chronic Obstructive Pulmonary Disease	LDC	Least Developed Country
CROs	Clinical Research Organisations	LIC	Low-Income Country
CSR	Corporate Social Responsibility	LMIC	Lower-Middle Income Country
DALY	Disability-Adjusted Life Year	MHDC	Medium Human Development Country
DNDi	Drugs for Neglected Diseases initiative	MMV	Medicines for Malaria Venture
ECOSOC	United Nations Economic and Social Council	NBEs	Non Biological Entities
EML	Essential Medicines List	NCDs	Non-Communicable Diseases
ERC	Expert Review Committee	NCEs	New Chemical Entities
GCP	Good Clinical Practice	NGO	Non-Governmental Organisation
GDP	Good Distribution Practice	NTDs	Neglected Tropical Diseases
GHO	Global Health Observatory	TTM	Trailing Twelve Months
GMP	Good Manufacturing Practice	TRIPS	Trade Related Aspects of Intellectual Property Rights
GNI	Gross National Income	UMIC	Upper-Middle Income Country
HDI	Human Development Index	UNDP	United Nations Development Programme
HiHDI	High Human Development Country with High Inequality	TB	Tuberculosis
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome	WHA	World Health Assembly
IARC	International Agency for Research on Cancer	WHO	World Health Organization
ICD-10	WHO International Classifications of Diseases	WIPO	World Intellectual Property Organization
ICH	International Conference on Harmonisation	WTO	World Trade Organization
ICH-GCP	International Conference on Harmonisation guideline for Good Clinical Practice		

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