

Access to Medicine Index 2018

METHODOLOGY REPORT

access to
medicine
index

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ACCESS TO MEDICINE FOUNDATION

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A good practice framework

There is no simple blueprint for making medicine accessible to all who need them. Often, the poorest people must tackle complex and changeable barriers before they can access the health products they need. Nevertheless, huge strides are being made on major global health challenges – eradicating guinea worm, bringing out new medicines for tuberculosis and hepatitis C, vaccinating a generation of girls against cervical cancer. There are indeed tools and solutions available that can take us a long way forward in improving access to medicine.

Our focus at the Access to Medicine Foundation is on the role of the pharmaceutical industry. My team and I present here the current framework for pharmaceutical industry good practice regarding access to medicine in low- and middle-income countries, in the form of the metrics for the 2018 Access to Medicine Index. They have been identified through our proven consensus-building model. We conducted a series of targeted stakeholder consultations to test and explore society's current expectations of pharmaceutical companies in 2017.

Our discussions resulted in a tightly focused methodology that efficiently identifies where companies have the greatest potential to make change. In priority areas, the Index analysis will also deepen. For example, in 2018, the Index R&D analysis will match company pipelines against the urgent R&D priorities set by WHO and others. The timely inclusion of cancer in the scope of the Index reflects the view that a transactional relationship is no longer enough. Companies must also engage in improving the continuum of care for cancer patients, and align with the growing prioritisation of cancer care in low and middle income countries.



During ten years of research, we have identified real progress from the pharmaceutical industry and best practices in many areas linked to access: in R&D for neglected diseases, in new business models that serve low-income populations, and in a variety of maturing access initiatives that are making real change. Yet in other areas, the pace of change remains slow, most notably in pricing.

In 2018, we will publish a new update in our Index research. We will be working in the meantime to show how this methodology report can be used to prioritise which actions companies should take. Pharmaceutical companies need willing and able partners to work with them to improve access and to continue the slow-burning move away from the traditional pharma business model. We invite global health teams working with and within companies, as well as investors, donors and governments, academics and NGOs to use this methodology when working to develop healthy markets and healthy populations.

A handwritten signature in blue ink that reads "Jayasree K. Iyer".

Jayasree K. Iyer
Executive Director
Access to Medicine Foundation

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Executive Summary

Globally, two billion people cannot access the medicine they need. Huge advances in global health are being made, and yet new challenges continue to emerge. Among the many stakeholders working to improve access, pharmaceutical companies have a critical role to play. In 2017, the Access to Medicine Foundation has built consensus on how pharmaceutical companies can address current global health priorities. This report describes the consensus-building process and how the latest cycle has shaped the methodology for the 2018 Access to Medicine Index. The refined methodology has a tighter focus on where companies have the largest potential for impacting access.

The Access to Medicine Index analyses 20 of the largest 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 in these countries. 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 a guide and an incentive for pharmaceutical companies working to do more for people who lack access to medicine.

In 2016, the Access to Medicine Index reported that pharmaceutical companies are getting more sophisticated in how they get essential products to poor people. However, good practice was found to be limited to a narrow range of products and countries, and many opportunities to expand good practice are yet to be acted upon.

The Index methodology is updated every two years to take account of new developments and emerging challenges in access to medicine. Each methodology review is informed by a wide-ranging multi-stakeholder dialogue coordinated by the Access to Medicine Foundation. For more than ten years, the Foundation has built stakeholder consensus on what we can expect from pharmaceutical companies.

Fine-grained review and consensus building

The Index research team began the 2017 review with a fine-grained evaluation of the 2016 indicators and data sets, checking the robustness and continuing relevance of each measure in turn. The outcomes led to adjustments to ana-

lytical scopes and the development of new measurements where needed. Throughout this process, the team debated a range of issues with governments, multilateral organisations, research institutions, non-governmental organisations (NGOs), investors, patient organisations, policy centers and pharmaceutical companies.

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 of independent experts, 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, WHO, governments, NGOs, patient organisations, the industry, academia and investors.

Analysis scopes in 2018

The 2018 Index will measure the same 20 companies as in 2016, as they remain the largest R&D-based pharmaceutical companies with the most relevant expertise and portfolios. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine. The majority have consistently qualified for inclusion since 2008. Their efforts to improve access to medicine will be assessed across 106 low- and middle-income countries and in relation to 77 high-burden diseases, conditions and pathogens.

69 indicators

The Index research team applied stricter standards than in 2015 for deciding when to retain, strengthen, merge or remove a metric. As a result, the methodology has a tighter focus on where action by pharmaceutical companies has the greatest potential for improving access to medicine. It provides a robust framework for efficiently tracking company performance. The 2017 methodology comprises 69 indicators: four are mergers of pre-existing ones and 15 have been removed. Five new indicators were developed in response to changes in global health priorities, including one that specifically recognises R&D targeting priority R&D gaps or needs, as identified by stakeholders such as WHO.

KEY CHANGES

• **Targeted analysis of priority R&D.** WHO and others have called for R&D to be urgently prioritised for specific diseases in order to address urgent public health issues. The 2018 Index will analyse how companies are responding through an assessment of R&D for priority diseases. More than half of the disease scope (45 out of 77) have an identified priority R&D gap or need, including for new diagnostic products, vaccines or medicines.

• **Cancer is now in scope.** Cancer incidence continues to rise in low- and middle-income countries. These countries shoulder a considerable proportion of the global cancer burden, and are increasingly prioritising cancer care in national health-care plans. In 2018, the Index will assess companies' actions to improve access to cancer control for the first time. Cancers that place a high burden on public health will be analysed in R&D, while cancer medicines on the latest WHO Model List of Essential Medicines (2017) qualify for analyses of pricing, patenting and donations practices.

• **Closer analysis of behaviours that facilitate access to medicine.** The Access to Medicine Index measures four aspects of pharmaceutical company behaviour – transparency, commitment, performance and innovation (referred to as Strategic Pillars). Their relative importance varies depending on the action in question, whether it is negotiating voluntary licenses, marketing activities or capacity building initiatives, for example. For the first time, this variation has been captured in the Index's analytical framework.

• **New metrics for capturing the quality and impact of access initiatives.** In 2018, the Index will take a deeper look at the quality of companies' capacity building initiatives, by comparing them against a framework of good practice standards developed by the Index research team. The Index will also expand its analysis of where and how companies monitor and measure the impact of their access-to-medicine activities.

Table 1. Analysis scopes for the 2018 Access to Medicine Index

COMPANY SCOPE

20 companies

- Selected based on a combination of market capitalisation and relevance of portfolio for access to medicine.

DISEASE SCOPE

77 diseases, conditions and pathogens

- 21 communicable diseases
- 14 non-communicable diseases
- 20 neglected tropical diseases
- 10 maternal & neonatal health conditions
- 12 priority pathogens

GEOGRAPHIC SCOPE

106 low and middle-income countries

- 31 low-income countries
- 52 lower-middle-income countries
- 23 upper-middle-income countries

PRODUCT TYPE SCOPE

8 types

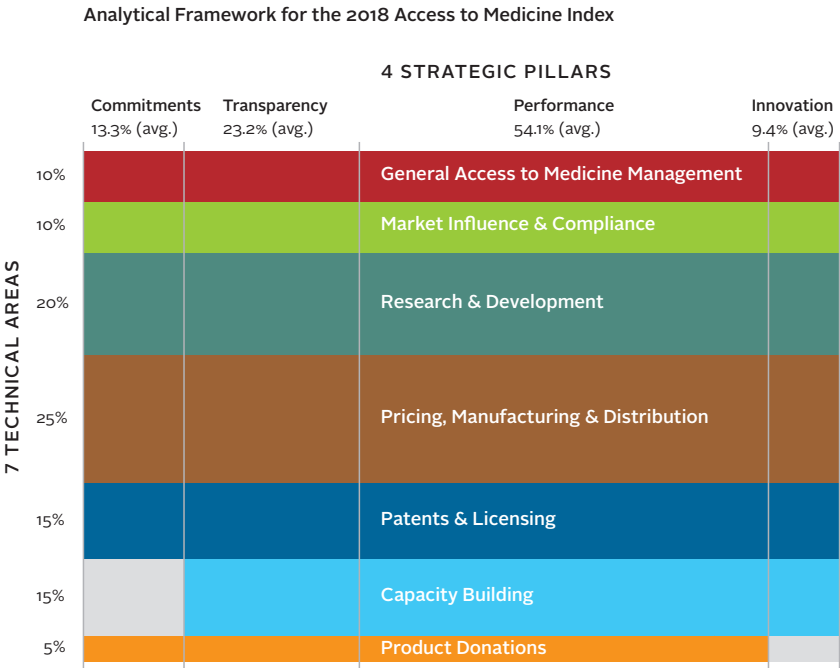
Medicines, microbicides, preventive vaccines, therapeutic vaccines, vector control products, platform technologies, diagnostics, contraceptive methods and devices.

Figure 1. Analytical Framework for the 2018 Access to Medicine Index

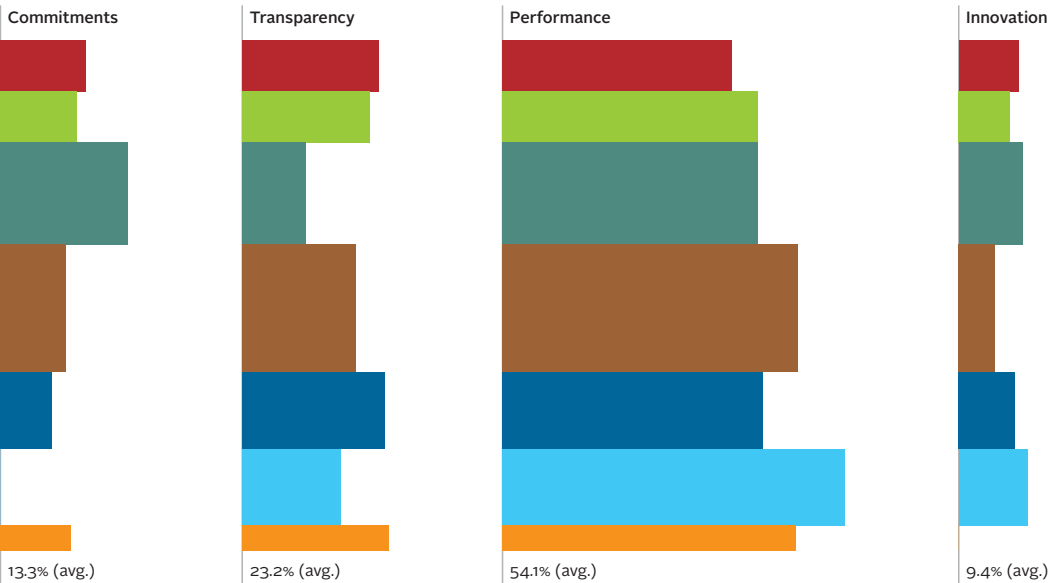
The 2018 Access to Medicine Index analyses company behaviour using a framework of 69 indicators organised in seven Technical Areas. The framework's four pillars correspond to four aspects of behaviour. For the first time in 2018, the weight of each pillar now varies between the Technical Areas, giving a more sensitive reflection of where these behaviours matter most.

In 2018, the target overall weights of the Strategic Pillars remain closely aligned with the weights agreed in 2015 by the Expert Review Committee. In 2015, these weights were: 15% for Commitments, 25% for Transparency, 50% for Performance and 10% for Innovation.

The new approach to weighting the Strategic Pillars has been developed by the Foundation research team and tested both with an external expert in ranking analytics and the Index's Expert Review Committee. Final weights of each Technical Area within the four pillars will be set during data analysis, once new indicators have been confirmed as robust and can be fully integrated into the 2018 Framework. Target weights are indicated in the figure below.



Strategic Pillar weights: the target distribution of pillar weights across Technical Areas in 2018



**The 2018 Access to
Medicine Index**
Methodology 2017

INTRODUCTION

Improving access to medicine in 2017

All people share the right to the highest attainable standard of health, as noted in the WHO Constitution. Yet access to medicine continues to be out of reach for an estimated two billion people worldwide. Huge advances are being made toward internationally agreed global health targets. Nevertheless, new and complex health challenges continue to emerge, demanding sustained commitment and deeper cooperation from many different sides, as well as wider adoption of proven solutions. Providing access depends on a complex range of factors and stakeholders.

Development aid for health has slipped since the first decade of this century as government budgets have tightened. Aid grew only 0.1% between 2015 and 2016, compared to growth rates of up to 11.4% annually between 2000 and 2010.¹ This slow-down is particularly concerning for low-income countries that rely heavily on aid to maintain the health of their populations.¹ Yet, in many cases this gap is not being filled by recipient governments. In many countries in sub-Saharan Africa and in low-income countries, government health expenditure as a percentage of GDP has also been in decline in recent years.²

While budget growth has slowed, crises and new trends have posed further challenges to global health. For example, the Ebola outbreak in 2014 led to over 11,000 deaths in West Africa.³ This was followed by the Zika outbreak in early 2015, which quickly spiked to almost 3,500 suspected and confirmed cases in Central America in early 2016.⁴ Antimicrobial resistance is growing and already causes more than 700,000 deaths each year worldwide.⁵ Rapid urbanisation, worsening diets, increasingly sedentary lifestyles and aging populations are contributing to a rise in non-communicable diseases (NCDs).⁶ Climate change is expected to cause a quarter of a million additional deaths per annum from malnutrition, malaria, diarrhoea and heat stress between 2030 and 2050.⁷

Geopolitical and societal factors are also influencing the shape of the global health landscape. The World Economic Forum has identified economic disparity and global governance failures, the decline of trust in institutions, and persisting gender inequalities as contributors to a fractured health landscape.⁸ Some see these global risks as factors in a move away

from globalisation,⁹ which could present a deeper crisis for global cooperation in areas such as health.

Progress is being made

Nevertheless, during the same period, progress toward global health targets has continued, demonstrating that effective approaches are being developed and applied. For example, child mortality dropped by almost 50% between 1990 and 2013. There has been a 48% decline in AIDS-related deaths since the peak of the HIV/AIDS epidemic in 2005,¹⁰ and more than half of all people living with HIV are accessing antiretroviral therapy.¹¹ In 2015, 71% of countries had an NCD plan addressing cancer, up from 50% in 2010.¹² In 2017, the WHO World Health Assembly, endorsed a set of measures to improve cancer control.¹³

Breakthroughs in R&D continue to bring new promise. Direct-acting antivirals mean country-by-country elimination of hepatitis C is a real possibility. Immunotherapy has become a clinically validated treatment for many cancers,¹⁴ with mortality from cancer dropping by 23% since 1991 in the United States.¹⁵ Recent advances in gene-editing technology hold further promise for cancer control.¹⁶

Cooperation to limit antimicrobial resistance (AMR) is also strengthening, with multiple initiatives starting up in recent years, such as the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) and the Global Antibiotic Research and Development Partnership (GARDP) in the field of R&D. Numerous pharmaceutical companies have signalled their readiness to play a part in addressing AMR by signing the Davos Declaration on Antibiotic Resistance and the Industry Roadmap for Progress on Combating Antimicrobial Resistance.^{17,18}

Critical role for pharmaceutical companies

In 2017, the need for all stakeholders to take action on access to medicine remains clear, with each having their own appropriate role and responsibilities. Pharmaceutical companies control unique products that can greatly alleviate disease burdens; they also have the expertise to meet the need for new and adapted innovative products; the power to address the affordability of those products; and the ability to strengthen

supply chains and support healthcare infrastructures. When pharmaceutical companies take positive action, it can have a profound effect on people's lives.

In 2016, the Access to Medicine Index reported that pharmaceutical companies are getting more sophisticated in how they get products to poor people, and are addressing global health priorities for example in R&D. However, good practice was found to be limited to a narrow range of products and countries, and many opportunities to expand good practice are yet to be acted upon.

The work of the Access to Medicine Foundation

The Access to Medicine Index analyses 20 of the top 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 people who still lack access to medicine.

Over the past decade, the Access to Medicine Foundation has developed a robust process for building consensus among a wide range of stakeholders on what society expects of pharmaceutical companies regarding access to medicine in low- and middle-income countries. These expectations are then translated into metrics that form the basis of the methodology for the Access to Medicine Index.

The Index methodology is updated every two years in line with developments in access to medicine following a wide-ranging multi-stakeholder dialogue coordinated by the Access to Medicine Foundation. The dialogue draws together the views of NGOs, governments, the industry and multi-lateral organisations, in order to build consensus on how and where pharmaceutical companies can and should be improving access to medicine.

How the Index has responded to global challenges

As a result, the Index methodology has evolved continually since the first Access to Medicine Index was published in 2008.



Over the past ten years, the Access to Medicine Index has identified increasing engagement by pharmaceutical companies in access to medicine.

For example, the disease scope has been adjusted in line with changing views on which diseases should be prioritised for improving access to medicine. In 2008, the Index focused mainly on Neglected Tropical Diseases (NTDs) as defined by WHO, expanding to include high-burden diseases including NCDs in 2010. The latest refinement in this direction is the inclusion of cancer in the 2018 Access to Medicine Index.

The geographic scope has also been refined, to ensure it covers countries where greater access to medicine is needed most. Many countries have moved into higher World Bank classifications over the lifespan of the Index: 72% of the world's poor now live in middle-income countries.¹⁹ To adapt to these demographic changes, the 2014 Index adopted measures of human development and inequality in its country inclusion framework, to bring some higher income countries with low levels of equality into the Index scope.

The 2018 Access to Medicine Index

In 2017 the Foundation has completed the 6th review of its methodology for the Access to Medicine Index. The 2018 Access to Medicine Index will measure the same 20 companies as in 2016. Considering their size, resources, pipelines, portfolios and global reach, these companies have a critical role to play in improving access to medicine. The refined methodology comprises 69 indicators, covers 106 countries and 77 diseases, conditions and pathogens. The Foundation will now begin the process of data collection, verification, scoring and analysis, before publishing the next Access to Medicine Index in late 2018. The Foundation will also use this latest methodology to provide guidance to pharmaceutical companies on where the priorities now lie, and how they match with the many solutions and practices identified in previous iterations of the Index.

REVIEWING THE METHODOLOGY

How the Index captures changes in the access-to-medicine landscape

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 aim is to confirm the global priorities regarding access to medicine and define how society expects pharmaceutical companies to contribute. The emphasis is on defining ambitious, but achievable actions for companies to take. For this latest review, the Foundation drew on more than a decade of experience in building consensus on where pharmaceutical companies can take action, before translating it into robust metrics. The result is the methodology for the 2018 Access to Medicine Index.

The process for the methodology review has been developed over six Index cycles. It includes a series of internal checks on indicators, data sets, measures of behaviour and on analytical approaches. This is followed by an external review, during which the consensus view is sought between a range of stakeholders on specific access topics and the role for pharmaceutical companies, as well as on the analytical scopes and the appropriate weights for the areas measured by the Index.

The primary principles of the Methodology Review are: (1) that all metrics are robust and data can efficiently and feasibly be collected; (2) that the Index is responsive to changing access needs; and (3) that all metrics are relevant to the appropriate role for pharmaceutical companies in improving access to medicine.

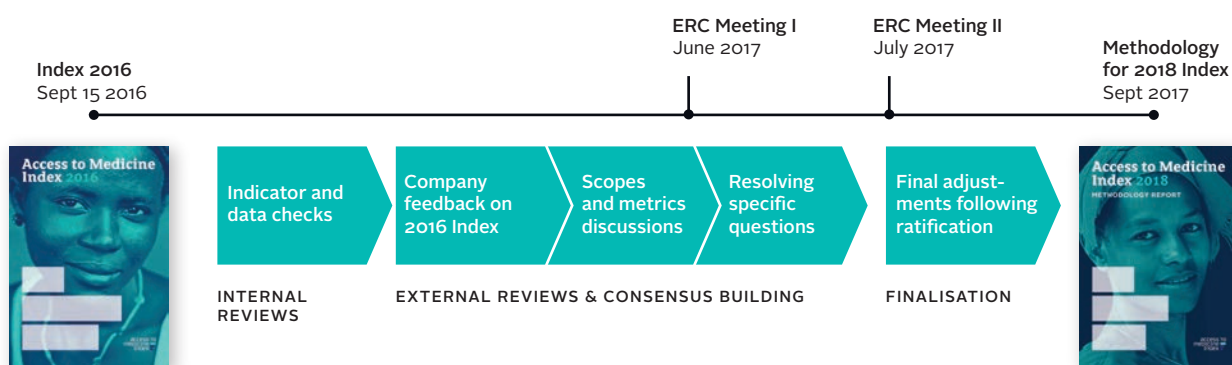
COMMITTEE CONSULTATIONS

Throughout each Methodology Review, formal committees support the Index team. Summaries of discussions and decisions are provided in the next section. Recommendations for specific areas of the Index are provided by Technical Subcommittees of specialists in different aspects of access to medicine. Strategic guidance is provided by the Expert Review Committee (ERC), an independent body of experts, including from WHO, governments, patient organisations, the industry, non-governmental organisations (NGOs), academia and investors. The ERC met twice to review proposals for the scope, structure and analytical approach of the 2018 Index and to ratify the final methodology.

Expert Review Committee in 2018

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Prashant Yadav	Harvard Medical School

Figure 2. 2017 Methodology Review for the 2018 Access to Medicine Index



*At time of ERC meetings

INTERNAL REVIEW OF INDICATORS AND DATA

The Foundation reviewed each of the indicators of the 2016 Access to Medicine Index for robustness, response quality and the potential for companies to improve access to medicine through a series of quantitative and qualitative analyses:

- **Distribution analyses.** Assessing the distribution of scores per indicator to check the spread of company behaviour in the 2016 Index. This indicates whether expectations of companies are fair (large clusters of low scores may indicate expectations may be too high) and the extent of room for improvement. Outcomes inform refinements to indicators and scoring guidelines.
- **Response rate analyses:** Assessing company response rates to each data point requested in the 2016 Index. This confirms whether questions are clear and whether companies can feasibly gather data per question; it can also indicate the relevance companies assign per question and/or their willingness to disclose information.
- **Correlation analyses:** Indicator-level assessments of score correlations, which help diagnose less relevant indicators, and can reveal or confirm positive or negative relationships between related areas of company behaviour.
- **Qualitative indicator review:** A battery of qualitative assessments of each indicator, including clarity of expectations and role for companies, continuing relevance to access to medicine, potential for longitudinal comparisons and the 'change-making' potential of each indicator.

These tests were used to identify where scoring guidelines could be tightened, detect and eliminate the risk of redundant measures, and pinpoint opportunities for enhancing data quality. In 2017, the Foundation applied stricter standards for deciding when to merge or remove a metric. These standards were linked to: the relevance of the measured behaviour to access to medicine; clarity regarding the industry's role; and the degree of consensus among stakeholders regarding how companies should behave. During the indicator review, topics were identified for discussion during the next phase of consensus building and stakeholder dialogue.

CONSENSUS BUILDING AND DIALOGUE

The Foundation has built stakeholder consensus on what we can expect from pharmaceutical companies for more than a decade. While disagreement persists in key areas, such as pricing and the management of intellectual property, overall the depth of consensus on the appropriate role for pharmaceutical companies has grown. In 2017, the Foundation's process of consensus building has once again underpinned methodological changes for the 2018 Access to Medicine Index. The Foundation strives to ensure that the consultation process is wide-ranging, independent, transparent and includes the engagement of key global health experts.

Review and engagement process

The stakeholder dialogue was targeted toward priority areas and topics identified by the Foundation's research team for discussion with experts. Topics were prioritised through: internal analyses of data and indicators, independent reviews of the Index research during the 2015-16 period of analysis, and a review of developments in access-to-medicine theory and practice. The Foundation team also engaged with the companies measured by the 2016 Index and its associated data-collection processes.

The Foundation's research team then reached out to a broad range of experts through a targeted stakeholder engagement exercise. Experts were identified from relevant organisations, through a review of the literature, and recommendations from other stakeholders. The research team engaged with experts and stakeholders from a wide range of backgrounds to ensure alternative viewpoints and technical expertise were incorporated. This included discussions with representatives of multilateral organisations, research institutions, NGOs, investors, and companies (see Appendix).

The Foundation used the views gathered to inform its proposals for modifications to the methodology. These proposals were discussed in detail with the Index's Technical Sub-Committees and ERC. 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.

REVIEWING THE METHODOLOGY

Key decisions and discussions

Discussions held during the methodology review were wide-ranging and rich. In many cases, there was alignment on the behaviours that the 2018 Access to Medicine Index should measure and how. In others, it was difficult to find consensus. In these cases, the Index team, with its Technical Subcommittees and Expert Review Committee, identified workable ways forward, balancing the evidence and viewpoints gathered. This section highlights discussions where the appropriate decision was contested, or where discussions led to new areas of measurement.

In this section:

► CANCER IN SCOPE

How can the Access to Medicine Index bring cancer into its scope?

► PRIORITY R&D

What are pharmaceutical companies doing to answer calls for urgently needed R&D?

► ACCESS PLANNING

Is it time for access planning to become standard practice during development?

► ASSESSING IMPACT

How should pharmaceutical companies assess the impact of access initiatives?

► DONATIONS

Can donation programmes provide sustainable access to medicine?

► CANCER IN SCOPE

HOW CAN THE ACCESS TO MEDICINE INDEX BRING CANCER INTO ITS SCOPE?

Cancer is one of the world's leading causes of death, and now accounts for 1 in 6 deaths worldwide.²⁰ Clearly, cancer is a priority global health issue. However, providing good cancer care is an almost uniquely complex challenge, requiring prevention, screening, diagnosis, referral, treatment and palliative care, among other steps. In poorer countries, the necessary infrastructure and resources for delivering this care are typically weak or limited. Although the majority of countries have a national cancer control plan (NCCP) in place, in poorer countries, the necessary infrastructure and resources for delivering cancer care are typically weak or limited. China, India and Brazil, for example, have relatively strong health systems that are better equipped for the management of cancer, while countries such as Kenya and South Africa do not yet meet basic infrastructure requirements for cancer treatment.²¹

Cancer has not previously been included in the scope of the Access to Medicine Index. When its inclusion was last discussed, in 2015, stakeholders expressed contrasting views: for example, that the need for greater action to improve cancer control had triggered WHO to add 16 cancer medicines to its Model List of Essential Medicines (WHO EML); that there is a need to stimulate companies to address the affordability of cancer medicines in countries with constrained finances; that companies can only play a limited role in improving cancer support systems; that the Index should instead prioritise diseases with a more critical need for access to treatment, including typical childhood killers with known and effective treatments on the market.

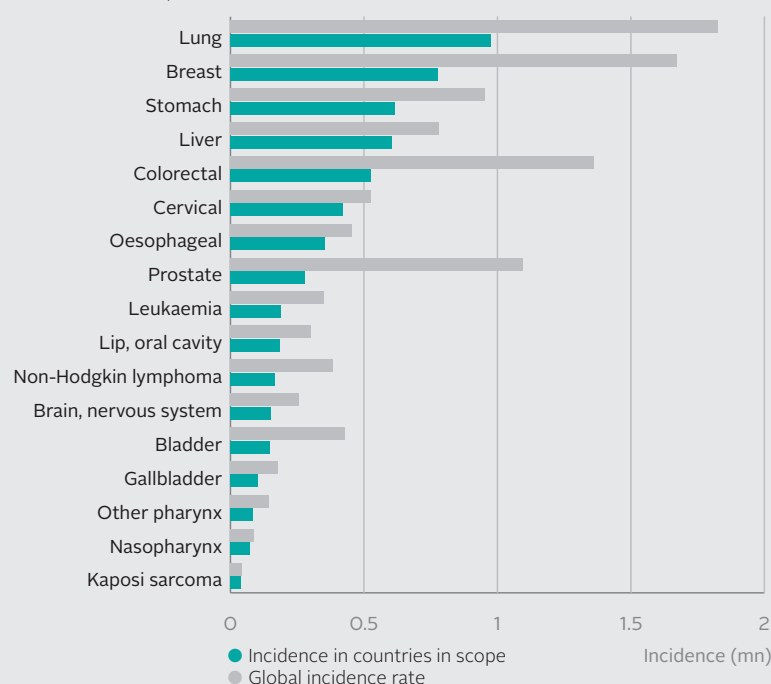
During the 2017 Methodology Review, the research team once again examined whether cancer should be brought into the Index scope,

comparing evidence gathered during the 2015 review, with new developments and viewpoints on cancer prioritisation and the opportunities for pharma companies.

Cancer incidence continues to rise in low- and middle-income countries, with such countries shouldering a large proportion of the burden (see figure 3).²² Three further medicines have been added to the WHO EML (in 2017).²³ In the same period, R&D activity for cancer treatment has expanded rapidly, and the global oncology market is now expected to grow by almost a third to USD 150 billion by 2020.²⁴

Figure 3. Cancers in scope for R&D: poorer countries shoulder large burdens

The 2018 Index will analyse company pipelines for 17 cancer types. These have been selected based on their incidence either globally or in countries in scope. For most of these cancer types, more than 50% of the incidence is in the 106 low- and middle-income countries in the scope of the Index.



At the 2017 WHO World Health Assembly, delegates agreed a resolution on cancer prevention and control, urging greater efforts to “promote the availability and affordability of quality, safe and effective medicines (for cancer), in particular, but not limited to, those on the WHO Model List of Essential Medicines (WHO EML).”²⁵

In 2017, the Access to Medicine Foundation carried out a first study of how pharmaceutical companies are addressing cancer control. It found that 16 companies were engaged in 129 diverse initiatives in low- and middle-income countries.²⁶ The range and volume of initiatives indicates that

pharmaceutical companies can build capacity at all levels of health services across the cancer continuum of care in low- and middle-income countries. Furthermore, the companies share an opportunity to increase access to affordable medicine. Together, these companies produce 34 of the 46 unique cancer medicines on the WHO EML (2015).

DECISION: CANCER IS IN SCOPE FOR THE 2018 INDEX

On reviewing new developments with stakeholders, and with strategic guidance from the Expert Review Committee, the Foundation decided to include cancer for the first time in the scope of the Access to Medicine Index in 2018. In its analysis, the Index will acknowledge where possible the context of national cancer care systems. The 2018 Index will examine 27 cancer types: 17 in the R&D Technical Area, and 19 in the Technical Areas relating to pricing, patenting and donations (see Appendix). Nine cancers are in both sets. In Capacity Building, the Index will include all initiatives related to cancer.

Bringing cancers into scope for R&D highlighted a significant omission in the global health landscape: an absence of prioritisation regarding cancer-care research needs in low- and middle-income countries. Therefore a proxy was needed; incidence was highlighted as the most robust indication of whether further R&D was needed to treat a particular cancer

type in low-resource settings. The cancers in scope for R&D are selected based on global incidence, on incidence in countries in the scope of the Index, and where the burden was disproportionately high in low- and middle-income countries

When it comes to registered products, an external prioritisation does exist. Cancers in scope for product deployment are selected based on whether there are relevant registered products on the WHO EML (2017), highlighted in the recent cancer resolution as those needing particular focus when considering availability and affordability. This focuses the analysis on a subset of cancer products identified by WHO as essential for the treatment of cancer.

The decision to include cancer in the 2018 Index scope is described in more detail in *Cancer Control 2017* (by the International Network for Cancer Treatment and Research).

► PRIORITY R&D

WHAT ARE PHARMACEUTICAL COMPANIES DOING TO ANSWER CALLS FOR URGENTLY NEEDED R&D?

There are many diseases without adequate or effective treatments available, or where the products are not sufficiently tailored to meet the needs of people living in low- and middle-income countries. Pharmaceutical companies have much to add in this space: addressing such 'product gaps' is a core expertise of the industry. However, there is a mismatch in incentives. Commercial incentives remain a primary driver for pharmaceutical R&D. The product gaps and research needs that matter more to people living in low- and middle-income countries and less to people in wealthier countries typically offer little or no commercial incentive to engage in pharmaceutical R&D.

Despite this, companies can and do engage in R&D with less commercial promise, for example through collaborative models such as Product Development Partnerships (PDPs), which can facilitate risk- and expertise-sharing. As a first analysis in this space, the 2016 Access to Medicine Index looked at whether pharmaceutical companies were addressing 'high-need, low-incentive' product gaps. It found that 31 out of 84 of the gaps analysed were being addressed by one or more companies, largely through partnerships, and through a combined total of 151 projects. This analysis compared companies' pipelines with priority product gaps identified by Policy Cures Research (G-FINDER) for diseases already included in the Index disease scope.²⁷

During the 2017 methodology review, the Foundation sought to expand this analysis to draw in a more comprehensive range of diseases where a pressing research need or product gap had been identified. In discussions with stakeholders, emerging infectious diseases such as Ebola and Zika were cited as diseases that were not within the Index scope, but where R&D was of critical value – and where companies have shown clear evidence of engagement.

Stakeholders were clear that companies could be expected to act and incentivised to do more in this low-incentive space.

Following these discussions, the Foundation identified and reviewed published, independently defined lists of priority product gaps and research needs. Such prioritisations can stimulate R&D by providing guidance and directing resources to where they are most needed. The Index offers an additional incentive in the form of recognition for R&D that targets these priorities. The Index team found R&D priority lists defined by global health stakeholders, such as WHO, for a range of Communicable Diseases, Neglected Tropical Diseases and Maternal & Neonatal Health Conditions. However, no priority list has yet been developed to identify R&D needs within the field of Non-Communicable Diseases (NCDs). On reaching out to stakeholders, it was recognised that very limited work has been done in this field. Stakeholders identified the absence of an external prioritisation list for NCDs as a significant concern that needed to be addressed by the global health community.

The prioritisation lists identified by the Index team define specific product gaps that are disproportionately needed by populations in low- and middle-income countries, as well as gaps linked to potential global health threats, such as emerging infectious diseases and pathogens that have developed antibiotic resistance. To address the lack of a prioritisation list for NCDs, stakeholders endorsed the Index team's proposition to include R&D projects for NCDs that demonstrably address a need specific to populations in low- and middle-income countries.

DECISION: EXPAND DISEASE SCOPE TO CAPTURE INDUSTRY RESPONSES TO R&D PRIORITIES CURRENTLY IDENTIFIED

The disease scope has been expanded to include all diseases, conditions and pathogens with an identified product gap on the five independently compiled lists of product gaps and R&D needs that are deemed priorities for public health. The aim is to provide a complete analysis of how the companies in scope are addressing such R&D priorities. This analysis will aid global health stakeholders in understanding where R&D is taking place, and recognise and encourage companies to address all priority gaps on these lists.

The five lists are:

- G-FINDER neglected diseases, products and technologies (2017);²⁷
- G-FINDER reproductive health areas, products and technologies (2014);²⁸
- WHO R&D Blueprint (2017);²⁹
- WHO Initiative for Vaccine Research gaps (2017)³⁰
- WHO pathogen priority list for R&D of new antibiotics (2017)³¹

► PLANNING FOR ACCESS

IS IT TIME FOR ACCESS PLANNING TO BECOME STANDARD PRACTICE DURING PRODUCT DEVELOPMENT?

Pharmaceutical companies start working on their market access strategies while products are still in development. Their aim is to secure strong market positions for new products, and they generally target markets with high potential profitability. It is less common for companies to also plan for access for populations in less profitable markets during development. These access plans aim to make successful innovations rapidly available for patients in low- and middle-income countries, and at affordable prices and support their rapid uptake.

During the methodology review, the Foundation's research team asked stakeholders to consider whether companies can be expected to step up their access-planning and integrate it more deeply into their businesses. Is it time for access planning to become standard practice during development?

In the 2016 Index, access provisions were expected only when they were part of collaborative research projects, usually with PDPs. During previous methodology reviews, the stakeholder view was that access planning was more likely in such partnerships than in projects conducted by companies in-house. The 2014 Index showed 39% of projects carried out in collaboration had plans for access in place, rising to 51% in the 2016 Index.

Views among stakeholders have since shifted; the consensus now is that companies should apply the lessons they have learned from access planning in PDPs and bring them in-house. Indeed, companies in many cases already do so. Looking only at late-stage R&D projects, the 2016 Index showed that 41% of projects conducted by companies in-house had associated access provisions. Importantly, expanding this expectation would capture companies' plans for more projects targeting NCDs. These projects typically happen in-house, rather than in collaboration. Given the increasing burden of NCDs in low-and middle income countries, the need for companies to also make new NCD products rapidly accessible is growing.

On the question of timing (i.e., when access planning should take place), stakeholders tended to agree that broad commitments – e.g., to ensure the affordability of the product on approval – can be made very early in development. However, they were also clear that, in most cases, it is not possible to develop detailed access provisions tailored to local contexts until at least phase II clinical development.

DECISION: BROADER MEASUREMENT OF ACCESS PROVISIONS

Stakeholders agreed that it was now time to broaden the focus of the Index's measurement of access provisions: that companies can now be expected to plan for access for all prospective products that are needed in low- and middle-income countries. Following this shift, the Index adjusted its measure to recognise all access provisions, whether for R&D carried out in partnership or in-house.

This means it will now look more comprehensively at access provisions for R&D projects targeting NCDs. Regarding timing, the 2018 Index will expect advance planning for access for projects from phase II. This provides a clearer expectation and point of focus for early consideration of access.

► ASSESSING IMPACT

HOW CAN THE INDEX MEASURE THE IMPACT OF ACCESS INITIATIVES?

The pressure to show that initiatives to improve access to medicine actually work is growing, particularly as pharmaceutical companies are expanding their engagement in access initiatives in low- and middle-income countries. Governments, NGOs, patient groups and communities increasingly expect to see a measureable impact. The companies themselves also seek a greater understanding of what works and what doesn't, to demonstrate and build on success and avoid repeating past failures.

The increasing focus on impact measuring started with the global development community, driven by several economic and political factors. For example, many funding agencies have reduced or retargeted their development budgets, while major donors have pushed hard for greater demonstration of 'value for money'. At the same time, there is a growing public perception that five decades of development assistance – in time, money and other resources – have not led to the hoped-for effects. This perception has put pressure on donors, and consequently other actors in international development such as NGOs, academia and the private sector, to do a better job of demonstrating clear, tangible results that can be understood by both their peers and the general public.

Several pharmaceutical companies have already started to announce, plan and carry out impact assessments of their access initiatives. For example, University College London recently carried out a study of Novo Nordisk's Base of the Pyramid projects. This initiative aims to facilitate access to diabetes care for people in work, but on low incomes, in certain low- and middle-income countries.³² Boston University has started a programme that aims to measure the impact of initiatives associated with Access Accelerated: an industry initiative to prevent NCDs and improve access to care in low- and lower-middle income countries.

Discussions held during the Foundation's 2017 Methodology Review confirmed that such moves are viewed as a step in the right direction. Stakeholders see value in pharmaceutical companies working with third parties and each other to develop and fine tune their approaches to impact measuring, as well as in sharing information about their results and successes. However, there is still no agreement among stakeholders on how to best define impact, or on the most appropriate models for assessing the impact of pharmaceutical companies' access initiatives. Stakeholders have also highlighted risks that stem from confusion between outcome and impact measurements.

Stakeholders argued for transparency regarding impact measurement, specifically in terms of companies sharing information about their approaches and whether they work, as well as the results of their evaluations, so that a wider community of actors can learn from them.

In 2016, the Index evaluated whether companies or their partners carry out impact assessments for donation programmes. When the measure was developed in 2015, these programmes were identified through stakeholder consultation as the most likely focus of impact measurement. A study from Boston University has since confirmed this position;³³ it found that 31 out of 47 published evaluations related to donation programmes. However, many stakeholders and pharmaceutical companies now expect more; impact assessments are now viewed as possible and potentially instructive in a variety of access initiatives, from inclusive business models, to health systems strengthening activities.

THE DECISION: INDEX TO LOOK FOR BROADER EFFORTS TO EVALUATE IMPACT

For the 2018 Index, companies' efforts to evaluate impact will also be measured in the Technical Areas of General Access to Medicine Management and Capacity Building, as well as in Product Donations. More specifically, the Index will recog-

nise those companies taking steps and making plans to measure impact, share information about the variety of ways they engage in this work, including with third parties, and credit those companies that take steps to publish the results.

► DONATIONS

CAN DONATION PROGRAMMES PROVIDE SUSTAINABLE ACCESS TO MEDICINE?

The donation of pharmaceutical products can help to ensure that the poorest populations – people with no ability to pay – are able to access the medicines they need. Donations continue to demonstrate particular value during humanitarian emergencies, when healthcare infrastructure is damaged and populations are especially vulnerable. Donations have become a core component of global efforts to eliminate, eradicate and control neglected tropical diseases, which predominantly affect the poorest populations across the world.

Recently, however, some have raised concerns regarding the long-term sustainability of product donations. For example, Médecins Sans Frontières recently rejected an offer of pneumococcal vaccine donations calling instead for the vaccine to be sold at a discounted price.³⁴ The organisation's rationale is that donation programmes are vulnerable to changing priorities within companies, while market-based approaches are more likely to last.³⁴ Other commentators have noted that donations can disrupt market incentives for generic competition,³⁵ and emphasised the importance of taking long-term sustainability into account when donating products, especially for those targeting chronic diseases.³⁶

During the 2017 Methodology Review, the Foundation found a growing consensus among stakeholders that sustainable

access to pharmaceuticals is better guaranteed through models such as equitable pricing or licensing than through donations. Such approaches emphasise affordability for payers and encourage low- and middle-income country governments to invest in their health systems. At the same time, equitable pricing and licensing can provide companies with a return on their investments as an incentive to remaining in a given market longer-term.

Stakeholders agree that donation programmes remain an appropriate approach for improving access to medicine in certain contexts, particularly for reaching the poorest and most vulnerable populations. There is also a critical difference between programmes that aim for disease eradication and those where eradication cannot be seen as a goal (i.e., programmes targeting chronic diseases). Where donations are deemed appropriate, the consensus view is that programmes must include assessments of how access can be sustainable in the long-term. This means companies working with governments to establish plans to ensure recipient populations can continue to access treatments for as long as they are needed, even after donation programmes end. Once again, sustainable approaches are especially pressing where patients suffer from chronic diseases.

THE DECISION: GREATER EMPHASIS ON SUSTAINABILITY PLANNING; REDUCED WEIGHT FOR PRODUCT DONATIONS OVERALL

Following these discussions, the research team carried out a close examination of the Product Donations Technical Area with the sustainability of access in mind. This led to a reduction in the overall weight of the Technical Area, from 10% to 5% of companies' final Index score.

The Index will also apply a more stringent standard regarding the quality of donation programmes; companies are now expected to ensure donations programmes are designed and

implemented in a sustainable manner, with a view to the long-term needs of the populations they serve. Finally, the Index will differentiate between programmes targeting communicable diseases and those targeting NCDs, recognising that NCD programmes cannot aim for disease eradication and/or elimination.

What the Index measures

The Access to Medicine Index assesses company policies and behaviour regarding specific diseases and product types and in a specific geographic scope. The following pages set out the rationale for these analytical scopes and how they have been defined.

In this section:

COMPANY SCOPE

20 companies

- Selected based on a combination of market capitalisation and relevance of portfolio for access to medicine.

DISEASE SCOPE

77 diseases, conditions and pathogens

- 21 Communicable Diseases
- 14 Non-Communicable Diseases
- 20 Neglected Tropical Diseases
- 10 Maternal & Neonatal Health Conditions
- 12 Priority Pathogens

GEOGRAPHIC SCOPE

106 Low and middle-income countries

- 31 Low-Income Countries (LICs)
- 52 Lower-Middle-Income countries (LMICs)
- 23 Upper-Middle-Income Countries (UMICs)

PRODUCT TYPE SCOPE

Medicines, microbicides, preventive vaccines, therapeutic vaccines, vector control products, platform technologies, diagnostics, contraceptive methods and devices.

WHAT WE MEASURE

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.

For the 2018 Index, 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. Companies qualify

for analysis based on their market capitalisation and the relevance of their product portfolios and pipelines.

In 2016, the Index once again reported that the pharmaceutical industry was making progress, although with action unevenly spread across the areas measured. The 20 companies were found to have 850 products on the market for high-burden diseases, and were developing a further 420 products.

Table 2. Companies included in the 2018 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 Stock Exchange	ABBV US	ABBV.N	USA	101.76	25.638
Astellas Pharma Inc.	4503	Tokyo Stock Exchange	4503 JT	4503.T	JPN	29.98	12.148
AstraZeneca plc	AZN	London Stock Exchange	AZN LN	AZN.L	GBR	69.3	23.002
Bayer AG	BAYN	Frankfurt Stock Exchange	BAYN GY	BAYGn.DE	DEU	86.46	49.273
Boehringer Ingelheim GmbH	n/a	n/a	n/a	n/a	DEU	n/a	16.698
Bristol-Myers Squibb Co.	BMJ	New York Stock Exchange	BMJ US	BMJ.N	USA	97.67	19.427
Daiichi Sankyo Co. Ltd.	4568	Tokyo Stock Exchange	4568 JT	4568.T	JPN	14.54	8.455
Eisai Co. Ltd.	4523	Tokyo Stock Exchange	4523 JT	4523.T	JPN	17.06	4.62
Eli Lilly & Co.	LLY	New York Stock Exchange	LLY US	LLY.N	USA	81.2	21.222
Gilead Sciences Inc.	GILD	NASDAQ	GILD US	GILD.O	USA	94.34	30.39
GlaxoSmithKline plc	GSK	London Stock Exchange	GSK LN	GSK.L	GBR	94.68	34.307
Johnson & Johnson	JNJ	New York Stock Exchange	JNJ US	JNJ.N	USA	313.43	71.89
Merck & Co. Inc.	MRK	New York Stock Exchange	MRK US	MRK.N	USA	162.31	39.807
Merck KGaA	MRK	Frankfurt Stock Exchange	MRK GY	MRCG.DE	DEU	45.47	15.828
Novartis AG	NOVN	SIX Swiss Exchange	NOVN VX	NOVN.VX	CHE	191.38	48.52
Novo Nordisk A/S	NOVO B	Copenhagen Stock Exchange	NOVOB DC	NOVOB.CO	DNK	92.13	15.841
Pfizer Inc.	PFE	New York Stock Exchange	PFE US	PFE.N	USA	197.1	52.82
Roche Holding AG	ROG	SIX Swiss Exchange	ROG VX	ROG.VX	CHE	198.09	49.626
Sanofi	SAN	EURONEXT Paris	SAN FP	SASY.PA	FRA	104.7	35.632
Takeda Pharmaceutical Co. Ltd.	4502	Tokyo Stock Exchange	4502 JT	4502.T	JPN	32.76	14.843

*Market cap on 31 December 2016, from Bloomberg terminal

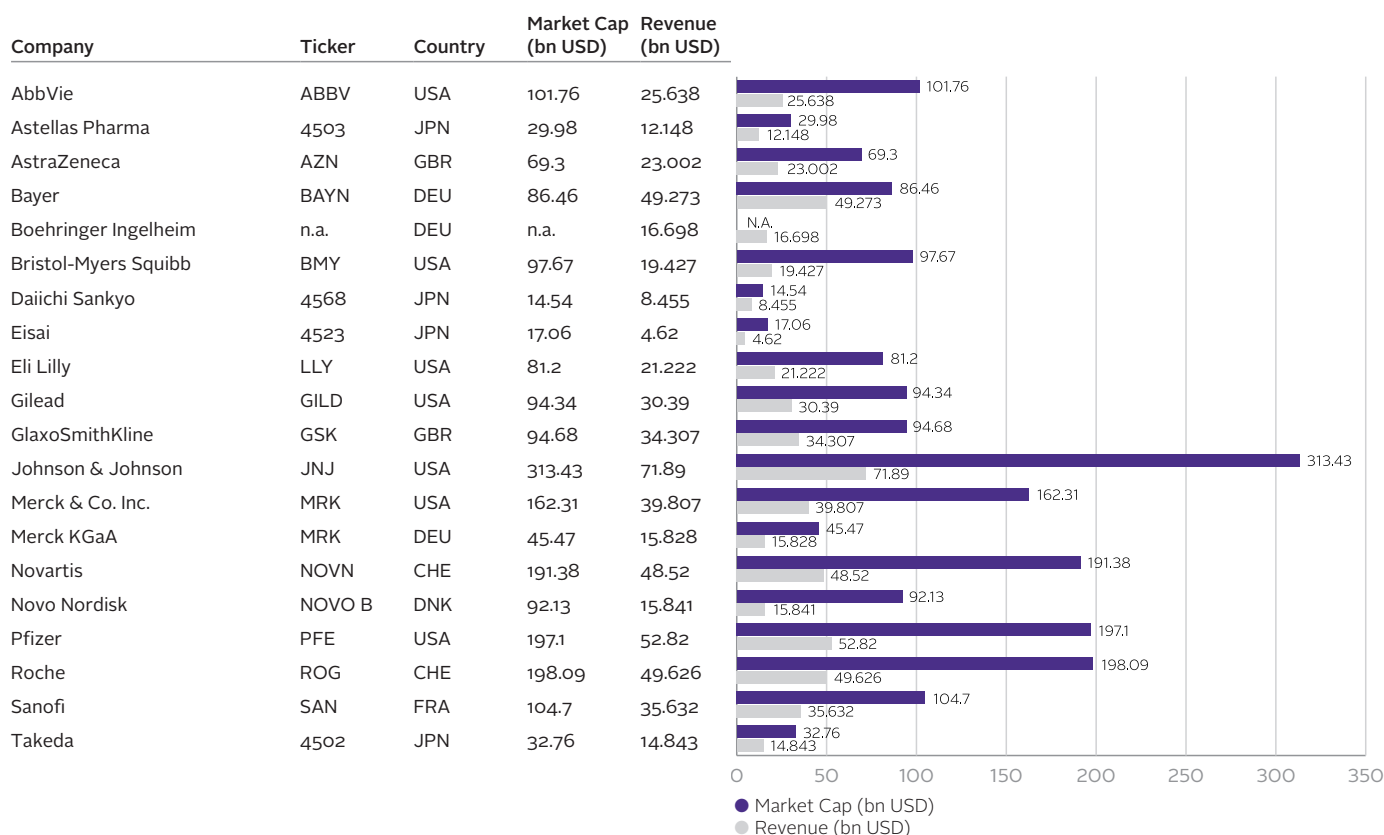
**Exchange rates on 31 December 2016, from oanda.com

Scope in 2017-2018

The 2018 Index will again measure the same 20 companies included in the 2016 Index, facilitating trend analysis and comparability between Indices. The majority of these companies have consistently qualified for inclusion since 2008, meaning the Index has tracked their performance for ten years. Other large companies, for example Amgen, Celgene, Otsuka have an important role to play in access to medicine. They are encouraged to use the Methodology when considering access approaches for their products.

Pharmaceutical companies that exclusively produce generic medicines remain excluded from the Index in 2018. The Access to Medicine Foundation recognises that these companies play a significant role in access to medicine, particularly in low- and middle-income countries. Generic medicines marketed by the 20 research-based companies or any of their generic medicine subsidiaries in which they have more than 50% ownership are included.

Figure 4. Market cap & revenue of companies listed in the 2018 Access to Medicine Index



WHAT WE MEASURE

Disease Scope

The Access to Medicine Index assesses pharmaceutical company action in relation to a defined set of diseases, identified as the most critical priorities regarding access to medicine. The Foundation has defined this list using data on disease burdens, incidence and independent prioritisations to pinpoint where greater access to medicine is most needed.

Following the 2017 Methodology Review, the disease scope for the 2018 Access to Medicine Index comprises 77 diseases, conditions and pathogens. In a change from previous years, part of the disease scope is analysed in only one area of the Index; 10 diseases and 12 pathogens are relevant only to the R&D Technical Area (see figure 5a). All remaining diseases and conditions (55) are in scope for all seven Technical Areas.

Defining the disease scope

Diseases are brought into scope, for example, because they impose a high global disease burden despite the existence of effective treatments, or disproportionately affect poorer populations. To identify such diseases, the Foundation uses a screening protocol (see figure 7). This is based primarily on the relevance of pharmaceutical intervention, global and/or country-level disease burdens and the prioritisation

of the disease by organisations such as WHO for improving access to medicine. The disease scope for 2018 has been updated with reference to the most recent WHO Global Health Estimates (2015 DALY Updates), which also provided country-level DALY data.³⁷ As in previous Indices, the Index uses ICD-10 codes where possible to define diseases.³⁸ ICD-10 codes relevant to the 2018 Index are listed in the Appendices.

KEY CHANGES

Cancer is now in scope. There are 27 cancer types are in scope: 17 cancers with high disease burdens are in scope for R&D, while 19 cancers with relevant products on the WHO Model List of Essential Medicines (2017)²² are in scope for the Technical Areas relating to pricing, patenting and donations. Nine cancers are in both sets. (see Appendix).

Analysis of priority R&D expands. The Index is expanding its analysis of R&D that targets specific, high-priority product gaps. The gaps themselves have been identified and published externally on five independent priority lists (see figure 5b and Appendix on R&D Priorities). Over half of the diseases in scope (45 out of 77) have an identified priority product gap.

Figure 5. Breaking down the 2018 disease scope

In a change from previous iterations of the Index, not all diseases, conditions and pathogens in scope are analysed in all areas of the Access to Medicine Index. A group of 22 diseases and pathogens are only analysed in the R&D Technical Area (see figure 5a). These have been identified as an R&D priority for global health, yet do not meet other criteria for inclusion. In total, 45 out of 77 diseases are on independent R&D priority lists (see figure 5b).

Figure 5a. Diseases and pathogens only in scope for R&D

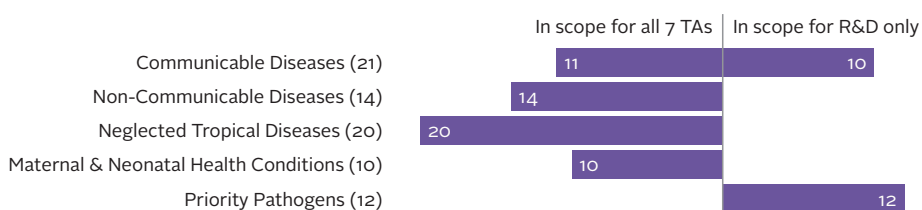
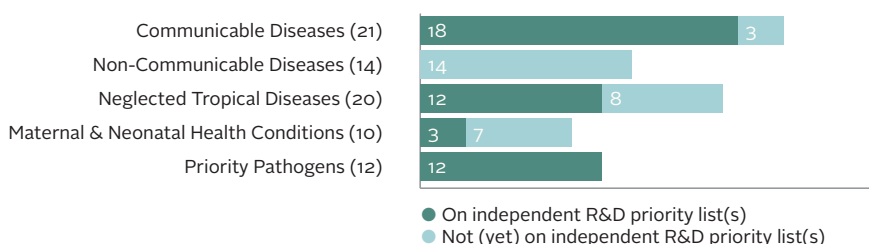


Figure 5b. Diseases and pathogens on independent R&D priority lists



DISEASE SCOPE

21 Communicable Diseases

The 2018 Index includes the ten Communicable Diseases (CDs) with the highest DALY burdens in countries in scope.³⁷ Tetanus has been retained, although it is 11th by DALY burden, as 99% of all cases are in the countries in scope and an effective preventative vaccine is available. For the 2018 Index, viral hepatitis (B and C) has been reclassified from the Non-Communicable Disease (NCDs) category to the CD category. For 2018, syphilis has been clustered with four additional sexually transmitted infections (STIs): chlamydia, genital herpes, gonorrhoea and trichomoniasis. This category includes 10 diseases added in 2018 due to the identification of priority product gaps for R&D.

14 Non-Communicable Diseases

The 2018 Index includes the ten NCDs with the highest DALY burdens in countries in scope.³⁷ An exception to this approach is cancer: cancer types are included if they (a) have high burdens of disease or (b) have relevant medicines on the WHO List of Essential Medicine. Epilepsy has been retained, although it is 11th by DALY burden, as it is one of the most common neurological diseases globally, and 80% of this burden is located in low- and middle-income countries. Approximately 75% of patients in these countries cannot access the medicine they need.³⁹ As in 2016, bipolar affective disorder and schizophrenia have been retained following stakeholder emphasis on the high need for access to treatment for these conditions.⁴⁰ Viral hepatitis (B and C) has been moved into the CD category (formerly included as cirrhosis of the liver).

20 Neglected Tropical Diseases

The 2018 Index once again covers all WHO-classified Neglected Tropical Diseases (NTDs).⁴¹ NTDs are particularly prevalent in poor regions of low-income countries, especially rural areas. In line with updates to the WHO list of NTDs, the 2018 Index includes three additional NTDs: (1) mycetoma, chromoblastomycosis and other deep mycoses; (2) scabies and other ectoparasites; and (3) snakebite envenoming. All NTDs are included irrespective of DALY burden.

10 Maternal and Neonatal Health Conditions (including contraceptives)

As in 2014 and 2016, the Index continues to include contraceptives and the nine most prevalent Maternal and Neonatal Health Conditions (MNHs), in continuing recognition of the importance of protecting mothers and neonates.⁴²

12 Priority pathogens

In a change from previous iterations, the 2018 scope includes the 12 pathogens on the 2017 WHO priority pathogens list. These pathogens are deemed a priority for efforts to curb antimicrobial resistance through the development of new and effective antibiotics. These pathogens are in scope for the R&D Technical Area only.

Footnotes on p.27.

Figure 6. Low- and middle-income countries shoulder the bulk of disease burdens

These four charts give an indication of how the diseases and conditions in scope disproportionately affect people living in low- and middle-income countries – even for non-communicable diseases, such as heart disease and cancer. Behind these numbers are millions of people who cannot rely on access to affordable, quality medicine.

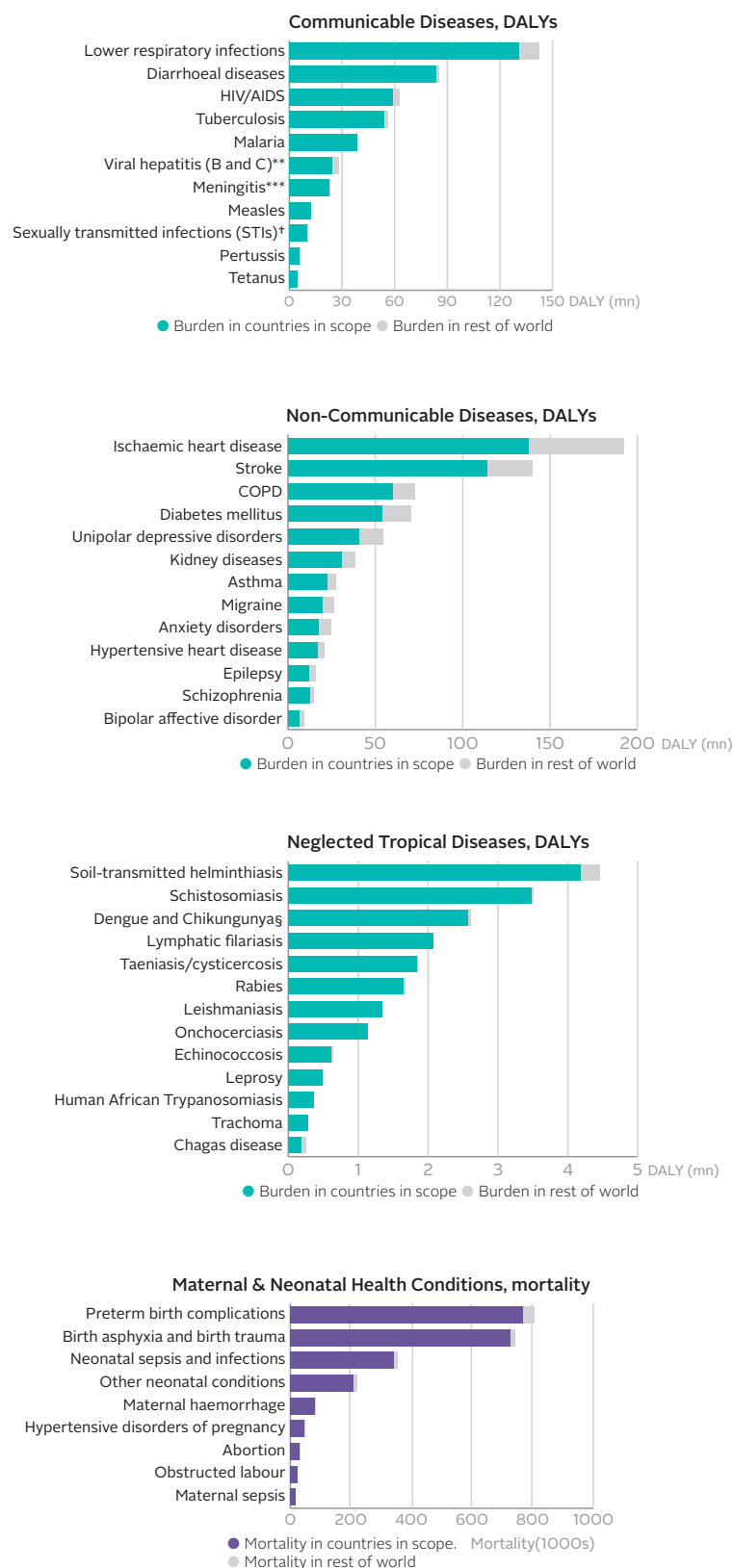
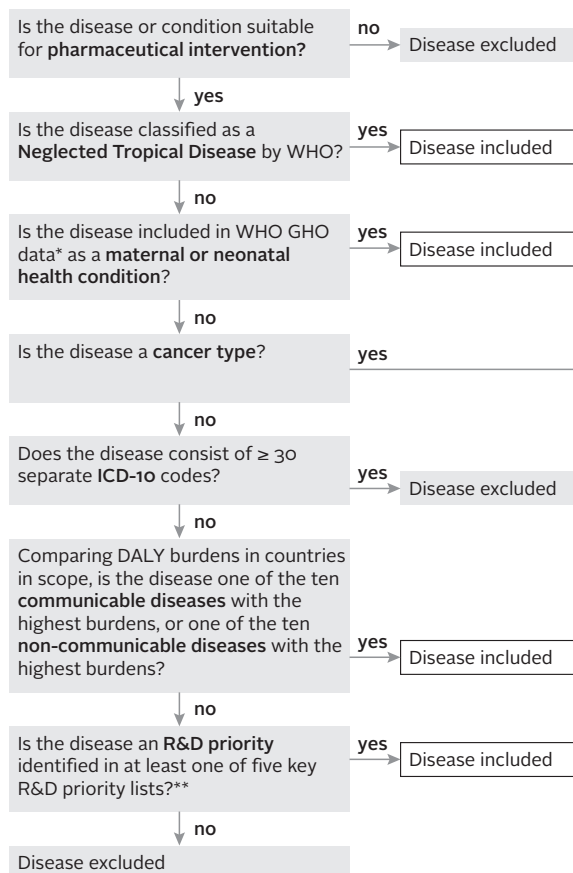


Figure 7. Defining the disease scope – screening protocol

The Access to Medicine Index analyses company practice in relation to a defined set of diseases identified as priorities for improving access to medicine. They are identified using the screening protocol shown here.

Which diseases qualify for inclusion?



Cancer inclusion criteria

Different criteria apply for including cancers in (a) R&D analyses AND/OR (b) in Product Deployment analyses.

For R&D analyses: Included if cancer falls into one or more of the groups below:

- 1) The ten cancer types with the highest global incidence rates.
- 2) The ten cancer types with the highest incidence rates in countries in scope.
- 3) The ten cancer types with the highest proportion of sufferers living in countries in scope.

For Product Deployment analyses: Included if the cancer has one or more relevant products on the WHO EML. Only these products will be analysed. Product Deployment refers to pricing, patents and licensing, and donations.

Exceptions: Epilepsy, bipolar affective disorder, schizophrenia, tetanus. All four were in scope in 2016 and have been retained due to, e.g., the continuing need for better access to treatment.

*As listed in the WHO methods and data sources for global burden of disease estimates 2000-2011

**R&D priority lists: Policy Cures Research G-FINDER neglected disease and reproductive health areas; WHO R&D Blueprint; WHO Initiative for Vaccine Research gaps; WHO priority pathogen list.

Table 3. List of diseases, conditions and pathogens included in the 2018 Access to Medicine Index – 77

	In scope for R&D (Designated R&D priority*)	In scope for all Technical Areas		In scope for R&D (Designated R&D priority*)	In scope for all Technical Areas
Communicable Diseases			Neglected Tropical Diseases		
Arenaviral haemorrhagic fevers (incl. Lassa fever)		●	Buruli ulcer	●	●
Crimean Congo Haemorrhagic Fever (CCHF)		●	Chagas disease	●	●
Diarrhoeal diseases	●	●	Dengue and chikungunya	●	●
Filoviral diseases (Ebola and Marburg)		●	Dracunculiasis	●	
Henipaviral diseases (including Nipah virus)		●	Echinococcosis	●	
HIV/AIDS	●	●	Food-borne trematodiasis	●	
Leptospirosis		●	Human African Trypanosomiasis	●	●
Lower respiratory infections	●	●	Leishmaniasis	●	●
Malaria	●	●	Leprosy	●	●
Measles	●		Lymphatic filariasis	●	●
Meningitis**	●	●	Mycetoma, chromoblastomycosis and other deep mycoses	●	
Middle East Respiratory Syndrome coronavirus (MERS-CoV)		●	Onchocerciasis	●	●
Pertussis	●		Rabies	●	
Rheumatic fever		●	Scabies and other ectoparasites	●	
Rift Valley Fever (RVF)		●	Schistosomiasis	●	●
Severe Fever with Thrombocytopenia Syndrome (SFTS)		●	Snakebite envenoming	●	
Sexually transmitted infections (STIs)***	●	●	Soil-transmitted helminthiasis	●	●
Tetanus	●		Taeniasis/cysticercosis	●	●
Tuberculosis	●	●	Trachoma	●	●
Viral hepatitis (B and C)†	●	●	Yaws	●	
Zika		●			
Non-Communicable Diseases			Maternal & Neonatal Health Conditions		
Anxiety disorders	●		Abortion	●	
Asthma	●		Birth asphyxia and birth trauma	●	
Bipolar affective disorder	●		Contraceptive methods	●	●
Cancer‡	●		Hypertensive disorders of pregnancy	●	
Chronic obstructive pulmonary disease (COPD)	●		Maternal haemorrhage	●	●
Diabetes mellitus	●		Maternal sepsis	●	●
Epilepsy	●		Neonatal sepsis and infections	●	
Hypertensive heart disease	●		Obstructed labour	●	
Ischaemic heart disease	●		Other neonatal conditions	●	
Kidney diseases	●		Preterm birth complications	●	
Migraine	●				
Schizophrenia	●				
Stroke	●				
Unipolar depressive disorders	●				
			Priority Pathogens		
			<i>Acinetobacter baumannii</i> (carbapenem-resistant)		●
			<i>Campylobacter</i> (fluoroquinolone-resistant)		●
			<i>Enterobacteriaceae</i> (carbapenem-resistant, 3rd generation cephalosporin-resistant)		●
			<i>Enterococcus faecium</i> (vancomycin-resistant)		●
			<i>Haemophilus influenza</i> (ampicillin-resistant)		●
			<i>Helicobacter pylori</i> (clarithromycin-resistant)		●
			<i>Neisseria gonorrhoeae</i> (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)		●
			<i>Pseudomonas aeruginosa</i> (carbapenem-resistant)		●
			<i>Salmonella</i> (spp., fluoroquinolone-resistant)		●
			<i>Shigella</i> (spp., fluoroquinolone-resistant)		●
			<i>Staphylococcus aureus</i> (methicillin-resistant, vancomycin intermediate and resistant)		●
			<i>Streptococcus pneumoniae</i> (penicillin-non-susceptible)		●

● Newly in scope for the 2018 Index
Exclusions: none in 2018

* Diseases, conditions and pathogens indicated as R&D priorities on identified lists published by WHO and Policy Cures Research.

** Projects targeting cryptococcal meningitis are included for the analysis of specified R&D priorities.

*** Includes chlamydia, genital herpes, gonorrhoea, syphilis, trichomoniasis. See R&D Priorities Appendix for details of specific R&D priorities.

† Includes acute hepatitis (B and C) and cirrhosis caused by hepatitis (B and C). See R&D Priorities Appendix for details of specific R&D priorities.

‡ Includes 27 cancer types. See Cancer Inclusion Appendix for more details.

WHAT WE MEASURE

Geographic Scope

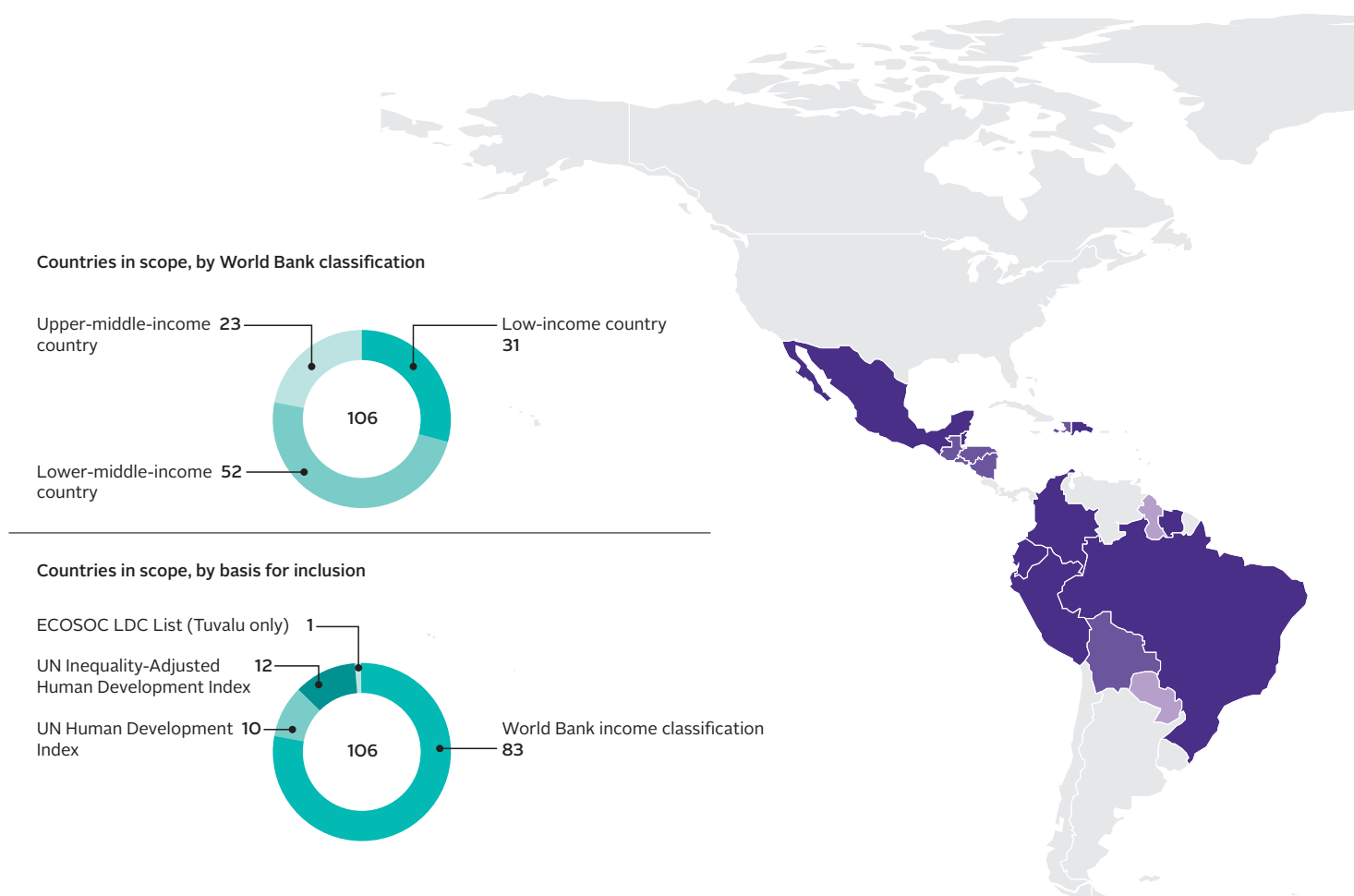
The Access to Medicine Index measures pharmaceutical companies' actions in countries where better access to medicine is most needed. This set of countries is referred to as the Index's geographic scope.

As in 2014 and 2016, the geographic scope for the 2018 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).

Although the methodology for determining the geographic scope remains unchanged, some countries have moved into or out of the scope based on the most updated data.

Three countries have moved out of scope for 2018: Georgia, Jamaica and Panama. Georgia is now classified as an Upper-Middle-Income Country (UMIC) and both Jamaica and Panama's level of inequality have improved. Two other countries have moved into scope: Tonga and Tunisia. Both of these countries are now classified as lower-middle-income countries (LMICs) based on 2017 data from the World Bank. The new total of countries in the scope of the Index is 106.

Figure 8. Countries included in the 2018 Access to Medicine Index - 106 Countries



HOW THE SCOPE IS DEFINED

Step 1:

Include all countries classified as low income or lower middle-income countries based upon the latest available World Bank data (2017).⁴³ For the 2018 Index, this brings 83 countries into scope, including two new inclusions - Tonga and Tunisia. Georgia was excluded from the 2018 Index based on this criterion.

Step 2:

Include all countries defined by the UNDP as either low or medium human development using Human Development Index (HDI) data.⁴⁴ This adds an additional 10 countries to the 2018 Index scope.

Step 3:

Include all high development countries with an inequality-adjusted HDI ratio (HiHDI) of less than 0.6, as defined by the UN Inequality-Adjusted Human Development Index.⁴⁴ This change captures those higher-income countries with significant levels of inequality. This resulted in 12 more inclusions in the Index scope: among these countries is China. Although there is no updated data available for China, it was included in this step based on HiHDI data from 2013. Jamaica and Panama were excluded for the 2018 Index based on this criteria.

Step 4:

The final step is to include all the Least Developed Countries (LDC) as defined by ECOSOC.⁴⁵ This step brings one more country into scope: Tuvalu. Although classified as a UMIC by the World Bank, it is also classified as an LDC.

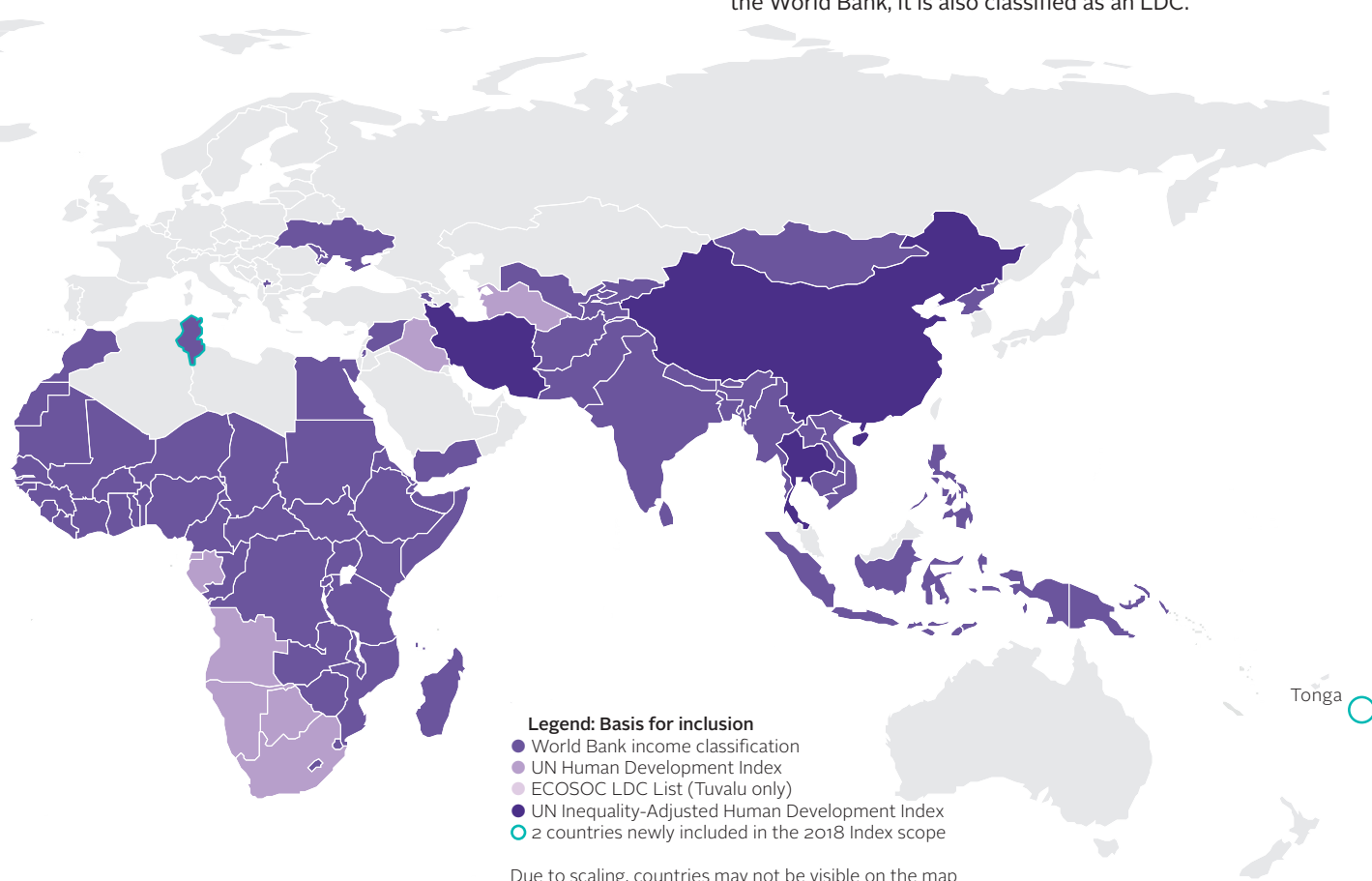


Table 4. List of countries included in the 2018 Access to Medicine Index – 106 countries

East Asia & Pacific		Middle East & North Africa		Malawi	LIC
Cambodia	LMIC	Djibouti	LMIC	Mali	LIC
China	HiHDI	Egypt, Arab Rep.	LMIC	Mauritania	LMIC
Indonesia	LMIC	Iran	HiHDI	Mozambique	LIC
Kiribati	LMIC	Iraq	MHDC	Namibia	MHDC
Korea, Dem. People's Rep.	LIC	Morocco	LMIC	Niger	LIC
Lao PDR	LMIC	Palestine, State of/		Nigeria	LMIC
Micronesia, Fed. Sts.	LMIC	West Bank Gaza	LMIC	Rwanda	LIC
Mongolia	LMIC	Syrian Arab Republic	LMIC	São Tomé and Príncipe	LMIC
Myanmar	LMIC	Tunisia	LMIC	Senegal	LIC
Papua New Guinea	LMIC	Yemen, Rep.	LMIC	Sierra Leone	LIC
Philippines	LMIC			Somalia	LIC
Samoa	LMIC	South Asia		South Africa	MHDC
Solomon Islands	LMIC	Afghanistan	LIC	South Sudan	LIC
Thailand	HiHDI	Bangladesh	LMIC	Sudan	LMIC
Timor-Leste	LMIC	Bhutan	LMIC	Swaziland	LMIC
Tonga	LMIC	India	LMIC	Tanzania	LIC
Tuvalu	LDC	Maldives	HiHDI	Togo	LIC
Vanuatu	LMIC	Nepal	LIC	Uganda	LIC
Vietnam	LMIC	Pakistan	LMIC	Zambia	LMIC
		Sri Lanka	LMIC	Zimbabwe	LIC
Europe & Central Asia		Sub-Saharan Africa		Countries removed since 2016 Index	
Armenia	LMIC	Angola	LHDC	Georgia	
Kosovo	LMIC	Benin	LIC	Jamaica	
Kyrgyz Republic	LMIC	Botswana	MHDC	Panama	
Moldova	LMIC	Burkina Faso	LIC		
Tajikistan	LMIC	Burundi	LIC		
Turkmenistan	MHDC	Cabo Verde	LMIC		
Ukraine	LMIC	Cameroon	LMIC		
Uzbekistan	LMIC	Central African Republic	LIC		
Latin America & Caribbean		Chad	LIC		
Belize	HiHDI	Comoros	LIC	LIC	Low-income country
Bolivia	LMIC	Congo, Dem. Rep.	LIC		World Bank income classifications
Brazil	HiHDI	Congo, Rep.	LMIC	LMIC	Lower middle-income country
Colombia	HiHDI	Côte d'Ivoire	LMIC		World Bank income classifications
Dominican Republic	HiHDI	Equatorial Guinea	MHDC	LDC	Least Developed Country
Ecuador	HiHDI	Eritrea	LIC		UN Human Development Index
El Salvador	LMIC	Ethiopia	LIC	LHDC	Low Human Development Country
Guatemala	LMIC	Gabon	MHDC		UN Human Development Index
Guyana	MHDC	Gambia, The	LIC	MHDC	Medium Human Development Country
Haiti	LIC	Ghana	LMIC		UN Human Development Index
Honduras	LMIC	Guinea	LIC	HiHDI	High Human Development Country
Mexico	HiHDI	Guinea-Bissau	LIC		with high inequality
Nicaragua	LMIC	Kenya	LMIC		UN Inequality-Adjusted Human
Paraguay	MHDC	Lesotho	LMIC		Development Index
Peru	HiHDI	Liberia	LIC		
Suriname	HiHDI	Madagascar	LIC		

● Newly in scope for the 2018 Index

WHAT WE MEASURE

Product Type Scope

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

In 2018, the Index continues to use the same eight product types within the product scope. These product types correspond with those in the 2016 G-Finder report and the 2014 G-Finder Reproductive Health report.^{27,28}

Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

Microbicides

These include topical microbicides specifically intended to prevent HIV.

Therapeutic Vaccines

This covers vaccines intended to treat infection.

Preventive Vaccines

This covers vaccines intended to prevent infection.

Diagnostics

This covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable, easier to use in the field).

Vector Control Products

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides intended for global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors associated with transmitting Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Contraceptive Methods & Devices

This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used to control contraception (e.g., condoms or diaphragms). It also includes combination products that deliver medicines (e.g., hormone-delivery contraceptive rings).

Platform Technologies

Only products that are specifically directed at meeting the needs of people living in the countries covered by the Index are included. These comprise, for example, general diagnostic platforms, adjuvants, immunomodulators and delivery technologies and devices. Implants and platform technologies for reproductive health are also included in this category.

How the Index measures

The 2018 Access to Medicine Index assesses company behaviour using an analytical framework of 69 indicators organised in seven Technical Areas. The following pages set out how this framework is constructed, what each Technical Area measures and the rationale for each indicator.

In this section:

ANALYTICAL FRAMEWORK

- How the framework is constructed
- Strategic Pillar weights and approach

TECHNICAL AREAS

- Expectations for company behaviour
- Key changes for 2018

INDICATORS

- Indicators per Technical Area
- Rationales for each indicator

ANALYTICAL FRAMEWORK

The analytical framework: revealing the actions that matter most for access

The 2018 Access to Medicine Index is based on an analytical framework of seven Technical Areas, each covering an area of corporate activity. Per area, companies' policies and practices are measured by indicators that correspond to priority areas of action for pharmaceutical companies. They have been developed through ten years of methodology development, with the aim of defining a set of ambitious yet achievable expectations of pharmaceutical company behaviour.

The Framework is further divided into four Strategic Pillars: Commitments, Transparency, Performance and Innovation. In 2017, the Foundation adjusted its approach for determining pillar weights – these weights, per pillar, can now vary between the Technical Areas. As a result, the framework is now more finely tuned to stakeholders' expectations of company behaviour in each of the actions measured. Performance remains the heaviest weighted pillar in all Technical Areas.

Seven Technical Areas

The seven Technical Areas have been confirmed by stakeholders as those areas where pharmaceutical companies have core responsibilities as well as the ability to influence access to medicine in low- and middle-income countries. Each area is assigned a weight according to its importance for improving access to medicine. These weights were reviewed for the 2018 Access to Medicine Index and two adjustments were made: (1) the weight of Product Donations has decreased from 10% to 5%, to reflect a continuing shift of expectations away from philanthropy and toward market-based access initiatives, which are seen as more sustainable; and (2) the weight of Capacity Building has increased from 10% to 15%, to recognise the benefit such activities can bring when locally appropriate and responsibly managed.

69 indicators

There are 69 indicators in the Framework in 2018. This is 14 fewer than in 2015, as the Index team have tightened the methodology's focus on those areas where companies have the greatest potential for improving access to medicine. Some indicators are new, and others have been refined, either to tailor the metric more closely to stakeholders' expectations of company behaviour or to improve data capture, comparison between companies and other analyses. Some indica-

tors have been removed or merged, depending on either the relevance of the measured behaviour to access to medicine, the level of clarity regarding the industry's role, or the degree of consensus among stakeholders regarding how companies should behave. Indicators are listed on page 43.

Four Strategic Pillars

Within each Technical Area, indicators are linked to four Strategic Pillars: Commitments, Transparency, Performance and Innovation. The pillars provide a series of lenses for examining these dimensions of company behaviour across the Technical Areas. They enable the Index to compare how these behaviours differ depending on the area of activity in question, whether it is in Research & Development, Capacity Building or pricing.

Commitments

The Index measures commitments in terms of companies' positions, strategies, policies and codes of conduct related to access to medicine. Commitments are the first step to improving access to medicine: they make clear what the company values, its aims, and how it aims to achieve them.

Transparency

These indicators focus on whether companies disclose information regarding initiatives and activities that impact upon access to medicine. Transparency is key for accountability and promotes the sharing of practices and approaches.

Performance

This pillar measures companies' actions to promote access to medicine, and carries the highest weight. Its indicators measure how and where companies put access-related policies and priorities into action, for example, by addressing product gaps through R&D, implementing equitable pricing strategies or licensing products on access-oriented terms.

Innovation

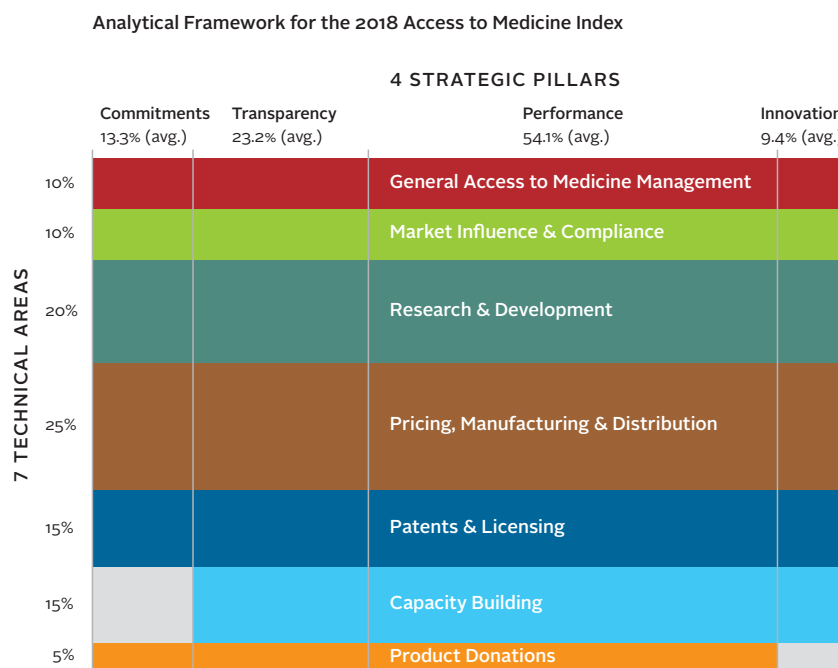
This pillar captures how companies create or employ new and unique means of advancing industry practice. As the pharmaceutical industry penetrates new markets, there are opportunities to develop innovative approaches that respond to local needs, and make access to medicine more sustainable.

Figure 1. Analytical Framework for the 2018 Access to Medicine Index

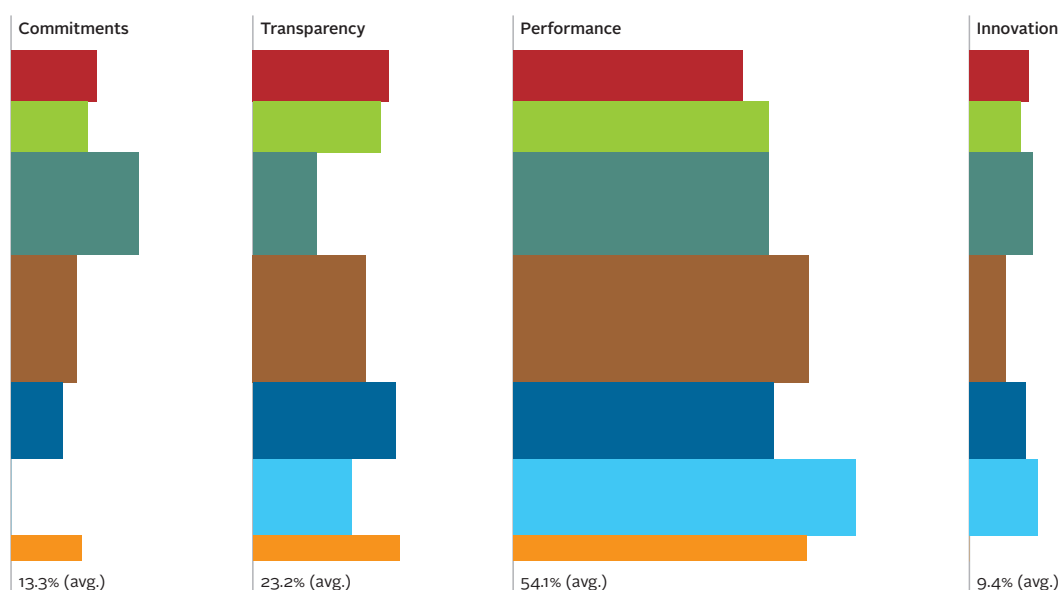
The 2018 Access to Medicine Index analyses company behaviour using a framework of 69 indicators organised in seven Technical Areas. The framework's four pillars correspond to four aspects of behaviour. For the first time in 2018, the weight of each pillar now varies between the Technical Areas, giving a more sensitive reflection of where these behaviours matter most.

In 2018, the target overall weights of the Strategic Pillars remain closely aligned with the weights agreed in 2015 by the Expert Review Committee. In 2015, these weights were: 15% for Commitments, 25% for Transparency, 50% for Performance and 10% for Innovation.

The new approach to weighting the Strategic Pillars has been developed by the Foundation research team and tested both with an external expert in ranking analytics and the Index's Expert Review Committee. Final weights of each Technical Area within the four pillars will be set during data analysis, once new indicators have been confirmed as robust and can be fully integrated into the 2018 Framework. Target weights are indicated in the figure below.



Strategic Pillar weights: the target distribution of pillar weights across Technical Areas in 2018



TECHNICAL AREAS

A GENERAL ACCESS TO MEDICINE MANAGEMENT

10%

This Technical Area looks at how companies govern, plan for and manage the achievement of access-linked objectives. It looks at access-to-medicine strategies, examining the rationale behind them, whether they align with business strategies, how targets and objectives are structured, and how progress is tracked and measured. It captures innovative business models that aim to improve access. Stakeholder engagement is also analysed, including an assessment of how stakeholders' views are incorporated into strategy planning, and whether companies are transparent about stakeholder engagement activities.

Key changes in 2018

In 2018, the Index will map whether companies assess the impact of access activities, including whether they plan to conduct and publish impact studies linked to innovative business models. In addition, the Index will examine whether access-linked incentive schemes also include long-term incentives for employees.

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Access-to-medicine strategy

Indicator(s)

Companies are expected to develop and implement a clear, long-term strategy for improving access to medicine. First steps include identifying specific objectives relating to access. Companies are then expected to underpin their access objectives with a business rationale, and align them with overarching corporate strategies and processes. This can help ensure the longevity of access-to-medicine strategies.

A.I.2

Managing for access-to-medicine outcomes

To ensure access strategies are successfully implemented, good management policies and practices need to be established. Companies are expected to assign board-level responsibility for access to medicine and establish long-term access-related incentives for employees as part of their performance management policies. By monitoring and measuring the outcomes and impact of access-to-medicine activities, companies can generate the necessary information to ensure progress is being made. Companies should track progress against defined goals, conduct impact assessments of access activities and make results publicly available.

A.I.1, A.II.1, A.III.1, A.III.3

Stakeholder engagement

Companies are expected to engage with a wide range of stakeholders when developing and implementing access strategies. This allows for dialogue and knowledge-sharing and helps companies understand and target the needs of the populations their activities aim to support. Companies are expected to have clear systems in place for enabling extensive dialogue between both global and local stakeholders, and processes for incorporating this shared knowledge within access strategies. All information relating to stakeholder selection, engagement strategies, activities and outcomes should be publicly disclosed, ensuring transparency and accountability.

A.II.2, A.III.2

Innovation

Companies are expected to develop financially sustainable business models that explicitly aim to increase access to medicine in low- and middle-income countries. Innovative approaches to stakeholder management, governance and management systems are also expected by the Index. Innovations are more likely to lead to a successful outcome if they have a long-term vision and goal, financial commitment, clear objectives and support from senior level.

A.IV.1, A.IV.2

For indicators and their full rationales, see p.43.

TECHNICAL AREAS

B MARKET INFLUENCE & COMPLIANCE

10%

This Technical Area looks at the interaction between companies and other organisations such as governments, patient groups, healthcare professionals and think tanks, and how these links may affect access to medicine. It also examines companies' internal processes, looking for how they mitigate the risk of breaches of industry codes and national laws concerning marketing and corruption from occurring. In addition, this Technical Area reviews evidence of such breaches where they have occurred in countries within the scope of the Index.

Key changes in 2018

The Index will analyse how companies govern compliance and the nature of their internal control frameworks (standardised processes that aim to ensure adherence to laws and minimise the risk of misconduct). In 2016, the Index analysed breaches of ethical marketing and anti-corruption laws and codes wherever they occurred globally; in 2018, these measures will focus on breaches occurring in countries within the scope of the Index.

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Ethical marketing and anti-corruption

Indicator(s)

Corrupt behaviour and unethical marketing can have direct consequences on access to medicine, including misdirecting national health budgets and promoting the irrational use of medicines. Companies can limit the occurrence of misconduct by setting the right tone from the top, rigorously monitoring and enforcing stringent standards of behaviour across their business and third-party organisations, by changing their sales incentive structures, and ensuring remedial action is taken in the event of misconduct. Companies are expected to have detailed codes of conduct for marketing practices and preventing corruption that are aligned with internationally recognised standards. Companies are also expected to have mechanisms in place that enforce these codes for both employees and third parties. Clear policies are essential on making payments to third-party organisations, and companies are expected to be transparent with regards to these payments, particularly in countries within the Index scope. Companies should assign board-level responsibility for ethics and anti-corruption policies.

B.I.1, B.I.2, B.II.3

Responsible lobbying

When companies seek to influence government policies in access to medicine, they are expected to do this responsibly. Transparency is essential for enabling public scrutiny of a company's influence. Therefore, companies are expected to take a public stance on a wide range of access-to-medicine issues, and be transparent about where they seek to actively influence policy and how they intend to this. Companies are also expected to publish all their memberships and political contributions they have made, and have clear policies in place for governing external engagement and preventing conflicts of interest.

B.II.1, B.II.2

Compliance

Companies are expected to show zero tolerance toward deliberate acts of unethical behaviour and corruption. Companies are expected to take ownership for ensuring good conduct at the highest levels and enforce rigorous standards of behaviour across their operations. Proportionate action must be taken when unethical behaviour occurs, including when third-party contractors are involved. Companies are expected to have strong internal control frameworks in place, which include rigorous monitoring processes and auditing mechanisms, fraud-specific risk assessments and clear segregation of duties. Companies are expected to be free of negative rulings and/or settlements with regard unethical behaviour and corruption, in countries within the Index scope.

B.I.3, B.II.4, B.III.1, B.III.2, B.III.3

Innovation

Innovative activities and initiatives that seek to tackle unethical behaviour and minimise the risk of non-compliance in countries are welcome, particularly in countries where regulations are weak. The Index will look for evidence of the development and implementation of new transparent approaches to prevent corruption, bribery and unethical marketing, new ways of engaging responsibly with external organisations, and of incentivising staff and contractors to behave responsibly.

B.IV.1

For indicators and their full rationales, see p.44.

TECHNICAL AREAS

C RESEARCH AND DEVELOPMENT

20%

This Technical Area analyses in-house and collaborative R&D activity that aims to develop or adapt products for the diseases, conditions and pathogens within the Index scope. It also examines whether companies put plans in place during development to accelerate access to successful products for people living in low- and middle-income countries. It investigates companies' codes of conduct governing clinical trials, as well as the oversight and enforcement of these codes, evidence of non-compliance, and how post-trial access to medicines in development is considered.

Key changes in 2018

The 2018 Index will give additional recognition to R&D that addresses specific priorities identified by global health stakeholders such as WHO. This change has led to a broader disease scope for R&D than for other Technical Areas (see Disease Scope and Appendix). Plans to support access to medicine ('access provisions') will be evaluated for both in-house and collaborative projects and expected from clinical phase II onwards. Greater focus will be placed on how companies consider post-trial access to investigational products.

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Product development

Companies are expected to ensure their R&D strategies take account of the health priorities of countries within the Index scope, are supported by sufficient resources and include access-relevant targets. In following these strategies, companies are expected to develop and adapt products that address public health needs and that are suitable for people living in countries within the Index scope. Leading companies will dedicate greater proportions of their pipelines to high-need diseases and target priority R&D gaps.

Indicator(s)

C.I.1, C.II.1, C.III.1, C.III.2, C.III.3, C.III.4, C.III.5

Planning for access

Planning for access helps ensure public health needs are taken into consideration during product development. As a result, such planning can help people gain more rapid access to new products at more affordable prices following market entry. Such plans are referred to by the Index as 'access provisions'. The establishment of a structured process to develop access plans can help ensure access provisions become a standard practice. Companies are expected to have provisions in place for pipeline projects from (at least) phase II clinical trials. This expectation holds for R&D projects carried out in-house and in collaboration.

C.I.2, C.III.6

Clinical trial conduct

Strict adherence to globally agreed clinical trial standards helps ensure the ethical treatment of clinical trial participants. Enforcement mechanisms for ethical clinical trial conduct are weaker in low- and middle-income countries, raising the expectation that companies publicly commit to adhering to globally agreed standards for all trials. In turn, companies must ensure clinical trials are conducted ethically and to high standards in practice; they are expected to adhere to Good Clinical Practice guidelines and comply with the Declaration of Helsinki. A breach of codes of conduct will be interpreted by the Index as an indication that clinical trials are being poorly managed. Companies are expected to have transparent policies in place to ensure post-trial access to treatments tested in clinical trials in Index countries.

C.I.3, C.I.4, C.III.7

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. To qualify as 'innovative', R&D models must explicitly target the needs of patients living in countries relevant to the Index.

C.IV.1

For indicators and their full rationales, see p.46.

TECHNICAL AREAS

D PRICING, MANUFACTURING & DISTRIBUTION

25%

This Technical Area looks at how companies register products for sale in countries in scope, how they set prices that take affordability into account, and whether their manufacturing and distribution practices help ensure high-quality products are available to and used appropriately by those in need.

Key changes in 2018

A new indicator has been introduced that will assess companies' efforts to ensure populations in need have access to a sufficient supply of products. The Index will also inspect whether companies take public health needs into account when making commitments to file for marketing approval. A further change looks at whether companies' equitable pricing commitments are made public, and if they apply to future products.

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Filing for marketing approval/registration

Indicator(s)

In order for products to become available to populations in need, they must first be approved for sale by the country's regulatory authority. How companies commit to product registration and then file for registration in practice influences which countries will be able to access much-needed products. Companies are expected to have disease-specific, time-bound targets for filing to register new products in countries where there is a need. These targets should be informed by public health needs. Companies are expected to rapidly file a comparatively large proportion of their products in countries where they are needed. Companies are then expected to publicly disclose the registration status of their products.

D.I.2, D.II.3, D.III.4

Equitable pricing strategies

Affordability is a key driver for access in many low- and middle-income countries. Companies are expected to make commitments and develop strategies to price their products equitably within and between countries, in order to ensure prices are affordable. When setting prices – whether at the level of whole countries, or for populations within a country – companies are expected to take account of the ability of the purchaser to pay for the product. This can be achieved by considering multiple socio-economic factors when setting prices. Companies are expected to apply equitable pricing strategies to a comparatively large proportion of their products, and in a comparatively large proportion of countries where disease burdens and inequalities are high (referred to as priority countries - see Appendix). Companies must provide proof of implementing their strategies by providing price and sales data for their products.

D.I.1, D.II.1, D.II.2, D.III.1, D.III.2, D.III.3

Manufacturing & distribution

Responsible manufacturing and distribution practices are necessary to ensure high-quality products are available to and used appropriately by those in need. Companies are expected to adapt product packaging according to local needs in order to facilitate rational use by practitioners and patients. Companies are also expected to support the sufficient and timely supply of their products, particularly to low-income countries and hard-to-reach populations, by making efforts to understand product distribution and demand behaviour in countries. To carry out effective drug recalls, when required, companies are expected to implement stringent drug-recall standards, policies and procedures, and to track their products throughout the supply chain.

D.III.5, D.III.6, D.III.7

Innovation

Companies are encouraged to develop innovative pricing models (including financing mechanisms) and manufacturing and distribution models, with the aim of facilitating the sufficient supply of products at affordable prices. Companies are expected to provide evidence of resources invested and progress made towards increasing affordability and availability of their products.

D.IV.1

For indicators and their full rationales, see p.49.

TECHNICAL AREAS

E PATENTS & LICENSING

15%

This Technical Area looks at how companies manage their intellectual property to support the supply and affordability of pharmaceuticals in countries in the scope of the Index. It looks at how companies manage the impact of patent monopolies on medicines' availability and affordability through: (a) the public disclosure of both patent statuses and filing/enforcement policies, and (b) steps that support market entry by generic medicine manufacturers through access-oriented licensing arrangements. It will also examine whether companies have refrained from anti-competitive activities.

Key changes in 2018

The 2018 Index will deepen its evaluation of patent disclosures made in countries in scope. Specifically, it will look at whether companies consistently and clearly disclose patent-status information to stakeholders. The Index will look for additional provisions when examining the quality of the terms of licences and non-assert declarations: whether companies offer waivers on data exclusivity and if they consider the public health impact of agreed licences. Agreements to licence out intellectual property on access-oriented terms to accelerate R&D will now be measured in this Technical Area (previously measured in Research & Development).

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Patenting strategy

Indicator(s)

Companies are expected to publicly commit to either not patenting, to abandoning existing patents, or to not enforcing patents in the broadest range of countries in scope. Companies are also expected to publicly disclose the patent status of products in all countries to a consistent and clear standard, through the publication of key details indicating whether, where and under what conditions a patent is in place. These activities can support the entry of generic pharmaceutical manufacturers into new markets. Supporting generic entry stimulates greater competition between manufacturers. In turn, this can place downward pressure on pharmaceutical prices, improving affordability and supporting supply for those in need.

E.I.1, E.II.2

Licensing

Companies are expected to engage in licensing where opportunities exist, in order to promote access to patented products via generic manufacture. Companies are expected to reach licensing agreements on newly registered products (or those still in development) on terms that specifically promote access to their products, and to ensure these agreements are disclosed publicly. The agreements should include a broad geographic scope including middle-income countries, in recognition of the need to supply new medicines cost-effectively to poor populations in these comparatively wealthier countries. Companies are also expected to license out their intellectual property, including more valuable assets, on access-oriented terms to external researchers in order to accelerate R&D.

E.II.3, E.III.1, E.III.2, E.III.3, E.III.4

Competition

All companies, including those without registered patents in countries in scope, can take steps to support a competitive marketplace for pharmaceuticals. Companies are expected to show zero tolerance of anti-competitive behaviour, including price collusion and making payments aimed at delaying competitors from entering markets. 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.

E.III.6

Trade policy

Companies are expected to publicly and specifically endorse the full range of flexibilities set out in the Doha Declaration on the TRIPS Agreement and Public Health that aim to protect public health. Companies are expected to not engage in lobbying or litigation intended to restrict these flexibilities, for example, by challenging the criteria countries set to determine a product's patentability or the legitimacy of compulsory licences.

E.II.1, E.III.5

Innovation

Companies are encouraged to seek, develop and engage in new, progressive mechanisms for managing intellectual property that support access to medicine. This can include examples of novel forms of transparency, external engagement and licensing in new areas. Methods for improving access to newly approved medicines with long patent terms remaining would be of particular significance.

E.IV.1

For indicators and their full rationales, see p.51.

TECHNICAL AREAS

F CAPACITY BUILDING

15%

This Technical Area captures how companies are building the capacities of health and pharmaceutical systems in low- and middle-income countries. It covers five distinct areas where companies can contribute knowledge and expertise: R&D; local manufacturing capacity; supply chain management; pharmacovigilance systems; and health system strengthening. These five areas cover some of the most significant local

barriers to access to medicine in countries within the scope of the Index.

Key changes in 2018

In 2018, the Index will take a deeper look at the quality of companies' capacity building initiatives by evaluating them against a newly developed framework of good practice standards (see Appendix).

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

R&D capacity building

Indicator(s)

Companies have the expertise and ability to support the development of a skilled R&D sector in low and middle-income countries. Engagement efforts aimed at building local R&D capacity support the development of research skills that can enable local researchers to address relevant health needs and priorities. Companies are expected to collaborate with local universities or public sector research organisations to identify and address local skills gaps or infrastructure needs relating to R&D. Companies' initiatives should ideally also aim to have a long-term impact on local R&D capacity and align with the goals of the research institution.

F.III.2

Manufacturing capacity building

Manufacturing medicines locally can lead to reduced costs and improved supply, but quality must be guaranteed. When companies work with third-party manufacturers in low- and middle-income countries, they are expected to ensure local staff have the skills and technology necessary to meet the requirements of good manufacturing practices (GMP). Companies are also encouraged to engage with other manufacturers and universities to build capacity in quality manufacturing beyond their own products. Such initiatives must target skills gaps, aim for long-term impact, be guided by clear goals and objectives and include measurement of outcomes.

F.III.1

Supply chain capacity building

Inefficiencies and weaknesses along supply chains – whether in the procurement process, delivery logistics, storage or other stages – can impact the accessibility, availability and quality of medicines. Companies are expected to engage with relevant, local partners to identify bottlenecks and improve capacity for good supply chain management. To reduce the public health dangers of substandard or falsified (SF) medicines, companies are expected to systematically report cases to national authorities and WHO Rapid Alert.

F.II.2, F.III.3

Pharmacovigilance capacity building

Many countries lack efficient systems for detecting, evaluating and responding to safety issues regarding medicines and vaccines. To help fill this gap, companies are expected to share safety data with national authorities and update efficacy and safety labels to ensure patient safety. These steps are of particular importance in countries where regulation and pharmacovigilance systems are weak or non-existent. Companies are also encouraged to engage with third-party partners to strengthen national pharmacovigilance systems through training, secondments or consulting, while managing conflicts of interest.

F.II.1, F.III.4

Health system strengthening

Robust health systems must be in place in order for products to be deployed, prescribed and administered efficiently. This includes infrastructure, trained health professionals, diagnostic capacity, data-management systems, and more. Large pharmaceutical companies have the expertise and the capacity to strengthen local health systems, provided initiatives are carried out with appropriate partners. Companies' initiatives are expected to address local needs, have processes in place to avoid conflicts of interest, have clear goals and objectives, measure outcomes and/or impact, and aim for sustainable models and long-term impact.

F.III.5

Innovation in capacity building

The Index looks for innovative approaches to building local capacity in all of the five subthemes. Innovative initiatives must aim to deliver lasting improvements through novel approaches. Initiatives are expected to meet good practice standards (see Appendix) and measure progress and impact to be considered innovative.

F.IV.1

For indicators and their full rationales, see p.52.

TECHNICAL AREAS

G PRODUCT DONATIONS

5%

This Technical Area looks at companies' product donation programmes in countries within the scope of the Index. It looks at the scale of companies' donation programmes, and at how companies work with partner organisations to ensure programmes are of high quality, sustainable, that they respond directly to need and that they support capacity of recipient communities to receive the product.

Key changes in 2018

The weight of this Technical Area has been reduced from 10% to 5% of the Index, recognising the growing consensus among stakeholders that, most often, sustainable access is better guaranteed through models such as equitable pricing or licensing than through donations. The Index will place increased focus on whether companies ensure their donation programmes are sustainable, paying particular attention to the distinct requirements of communicable and non-communicable diseases. The Index will analyse companies' approaches to making ad hoc donations (e.g., in response to emergencies), including whether these donations align with international guidelines and respond clearly to need.

KEY THEMES AND EXPECTATIONS FOR COMPANY BEHAVIOUR

Scale and reach

Indicator(s)

Globally, donation programmes continue to play an important role in controlling, eliminating and eradicating some diseases that affect 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 health care systems are weak. Companies are expected to expand their programmes to more countries and beneficiaries, with the reach of donation programmes depending on the course of treatment (e.g., short versus long term). Companies are expected to publicly disclose all details relating to the scale of their programmes.

G.II.1, G.III.2

Quality and sustainability

Companies are expected to ensure the sustainability of their donation programmes: i.e., that recipients can continue to access the donated product for as long as needed. This can include strong commitments to achieving eradication, control or elimination, or to plan for the management of the programme to transition to other parties once the company's involvement ends. This can be particularly important where eradication, control or elimination is not possible, and patients require lifelong treatment, for example for donation programmes targeting non-communicable diseases. Companies can help ensure sustainability by incorporating capacity building activities into their programmes, for example by supporting improved screening and diagnosis. Companies (or partners) are expected to monitor the outcomes and impact of their donation programmes and to publicly disclose the results.

G.I.1, G.II.1 G.III.1

Ad hoc donations

When making ad hoc donations, such as in response to humanitarian emergencies, companies are expected to be positioned to respond rapidly, to ensure that these contributions respond to an expressed need, and to align with WHO Guidelines for Medicine Donations or equivalent standards.

G.I.1

For indicators and their full rationales, see p.54.

INDICATORS

A GENERAL ACCESS TO MEDICINE MANAGEMENT		10%
2018 indicator	Change since 2016	Indicator rationale
A.I Commitments		
A.I.1 Governance: Management structures The company has a governance system that includes direct board-level responsibility and accountability for its access-to-medicine initiatives.	Retained No change	Assigning responsibility for access at the highest level of a company increases the chance that access-related objectives are formulated, given attention, remain on track and are achieved.
A.I.2 Access-to-medicine strategy The company sets objectives to improve access to medicine, and aligns its access-to-medicine strategy with its core business.	Retained No change	An access-to-medicine strategy aligned with corporate strategies indicates that a company considers access to be relevant for its long-term sustainability and growth.
A.II Transparency		
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.	Retained No change	Public reporting of such information informs external stakeholders of companies' activities and progress and enables accountability.
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.	Modified Disclosure of stakeholder engagement activities limited to three examples.	Public disclosure of such information enables accountability, e.g., regarding whether engagement informs company policy, and provides assurance as to its depth, breadth and quality.
A.III Performance		
A.III.1 Managing for access-to-medicine outcomes: Performance management system The company has a performance management system to monitor and measure the outcomes and impact of its access-to-medicine activities across its global operations.	Modified Indicator now also covers whether performance management systems incorporate impact measurements.	Measuring and monitoring outcomes and impact ensures progress is tracked and enables it to be evaluated, making success more likely.
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. The company has a system in place to incorporate local and other external perspectives on access to medicine in the development and implementation of its access strategies.	Merged with A.III.4 This indicator has been merged with A.III.4 (Stakeholder engagement: Local perspectives) to cover all aspects of stakeholder engagement strategies and processes.	Stakeholder engagement ensures companies can take account of different perspectives to inform its access-related activities. Engaging with local stakeholders in particular helps ensure activities target local needs.

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 within the Index scope, for diseases within the scope of the Index.

Modified

This indicator now also assesses whether incentives relate to long-term goals. Incentives for senior management are no longer differentiated from those for other employees.

Access-related incentives encourage employees to work towards achieving access-related goals and objectives.

A.IV Innovation

A.IV.1 Innovation in business models

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

Retained (minor change)

This indicator has been changed slightly to newly assess whether or not companies have planned to evaluate the impact of these models after roll-out.

Innovative business models that aim to identify and unlock market inefficiencies in low- and middle-income countries can create opportunities for business and patients alike. This will support the integration of access activities with regular business activities.

A.IV.2 Innovation in governance and stakeholder engagement

The company has developed innovative (unique in the sector) approaches to its access governance, its performance management systems and/or its stakeholder engagement.

Retained

No change

Innovative approaches to access governance and stakeholder engagement can improve the way companies work on access through, e.g. new ways of involving stakeholders, or testing new methods for measuring social impact.

B MARKET INFLUENCE & COMPLIANCE

10%

2018 indicator

Change since 2016

Indicator rationale

B.I Commitments

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 practice.

Retained

No change

Enforcing such a code of conduct provides guidance to employees and third parties, minimising the risk of unethical marketing practices occurring. Such practices can have direct negative consequences for access through, e.g. encouraging inappropriate use of medicines and wastage of scarce resources.

B.I.2 Governance of anti-corruption

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

Retained

No change

Corruption can divert scarce resources from health budgets, impact prices and the availability of medicines. Proactively fighting corruption promotes ethical behaviour, which ultimately favours access to medicine.

B.I.3 Governance of compliance

The company has a governance structure in place that manages compliance. This includes the following components: a) direct board level responsibility for compliance; and b) a compliance committee with board level representation which meets regularly.

New

This is a new indicator to assess the governance system within companies for compliance.

The governance structure is critical to the robustness of a company's compliance system, in turn supporting minimisation of the risk of misconduct. Strong senior advocacy of compliance provides 'tone from the top' about the seriousness of non-compliance.

B.II Transparency

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.	Retained No change	Transparency allows stakeholders to understand the company's position on issues relating to access, and where companies may influence access-to-medicine policy. This helps to hold companies accountable.
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.	Retained This indicator has been changed slightly to remove the expectation for an exhaustive list of organisations to be disclosed to the Index, placing greater emphasis on what is disclosed publicly.	Public disclosure of such information shows how companies work towards influencing access to medicine issues at the policy level. Transparency on these policy positions ensures accountability.
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 healthcare professionals and opinion leaders).	Retained No change	Public disclosure of marketing activities provides accountability regarding interactions with health care professionals, with the aim of (for e.g.,) curbing inappropriate incentives that can lead to irrational prescribing.
B.II.4	Ethical marketing and corruption: Disclosure of breaches The company publicly discloses information regarding breaches in countries within the scope of the Index of internationally recognised codes of conduct, laws and regulations that govern ethical marketing and corruption in the last two years.	Modified This indicator has been modified to limit the scope of breaches assessed to only those occurring within the country scope of the Index.	Public disclosure of such information demonstrates accountability on the part of companies, including to stakeholders their actions may have affected. Accountability minimises risks deriving from unethical behaviour that may influence access to medicine.

B.III Performance

B.III.1	Ethical marketing and anti-corruption: Incidence of breaches The company has not been the subject of settled cases for corrupt practice or incidents of unethical marketing practice in countries within the scope of the Index during the past two years.	Modified This indicator has been modified to limit the scope of breaches assessed to only those occurring within the country scope of the Index.	Such civil, criminal and regulatory infractions give an indication of the quality of a company's compliance systems and culture regarding ethical behaviour, which can limit access to medicine through (for e.g.) diversion of resources from health budgets.
B.III.2	Ethical marketing and anti-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 or anti-corruption. The company provides evidence of follow-up actions taken to mitigate the risk of future breaches.	Retained No change	Companies' enforcement procedures and follow-up actions show how they react to misconduct and whether they are serious about minimising unethical behaviour, which can limit access to medicine.

B.III.3 Compliance: Internal control framework

The company demonstrates that it has a robust internal control framework, which includes the following components: a) fraud-specific risk assessment; b) a monitoring system for compliance (other than auditing); c) auditing and review mechanisms, which involve the use of both internal and external resources, and apply to all third parties and all countries where it has operations, based on risk assessment; d) procedures for segregation of duties between: management tasks and authorisation tasks, custody of assets and verification tasks, and accounting tasks and payment tasks.

Modified

This indicator has been modified to incorporate multiple elements of an internal control framework, alongside existing measures of auditing and review mechanisms.

These frameworks reduce the risk of non-compliance by monitoring and tracking all compliance with laws and regulations, including focused monitoring on procedures with an enhanced risk of non-compliance, supported with clear guidance.

B.IV Innovation

B.IV.1 Innovation in market influence and compliance

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

Retained

No change

Innovation to improve ethical business performance can help address the fact that regulatory frameworks in low- and middle-income countries are weaker, with a corresponding need for companies to rely more on robust internal systems to minimise the risk of non-compliance.

C RESEARCH & DEVELOPMENT

20%

2018 indicator

Change since 2016

Indicator rationale

C.I Commitments

C.I.1 Product development: R&D commitment and strategy

The company commits to conduct R&D of products for diseases within the scope of the Index with the goal of improving access to medicine in countries within scope. It operationalises its commitments with an R&D strategy that takes public health needs into account and has a system for setting targets and evaluating progress over time.

Modified

This indicator has been modified to increase focus on R&D strategies that take public health needs into account.

Companies' R&D commitments and strategies can significantly influence how its R&D activities respond to health needs identified globally or locally. R&D commitments and strategies should take public health needs into account in a structured way, and be sustainable in the long-term.

C.I.2 Planning for access: Structured process

The company has a process through which equitable access is planned for products successfully developed in-house and through R&D partnerships.

Modified

This indicator has been modified to evaluate processes for establishing access provisions for both in-house and collaborative projects.

Establishing a structured process to develop access plans for product candidates for both in-house and collaborative R&D increases the likelihood that a company will develop long-term access provisions as early in development as possible.

C.I.3 Clinical trial conduct: Policies and compliance systems	Merged with C.III.9	
The company commits to and has processes to ensure compliance with standards of quality assurance, control and ethics when conducting clinical trials in countries within the Index scope. These standards are consistent with codes such as Good Clinical Practice (GCP), and the Declaration of Helsinki, regardless of whether the trials are conducted in-house or through a third-party, e.g., contract research organisation (CRO).	This indicator has been merged with C.III.9. The requirement for Good Participatory Practice (GPP) has been removed, as this did not apply equally across all companies.	Such commitments and processes help ensure the safe and ethical treatment of trial participants. Certain principles unique to the Declaration of Helsinki are of particular relevance to access in low- and middle-income countries, e.g. the principle that trial participants receiving a placebo must be provided with the best available standard of care.
C.I.4 Clinical trial conduct: Post-trial access	New	
The company publicly commits to ensure post-trial access to treatments tested through clinical trials in countries within the scope of the Index.	This is a new indicator which measures companies' commitments concerning post-trial access.	Commitment to this principle helps ensure that access to investigational products can continue once the trial has ended (post-trial access) for trial participants and for the general population in which the trial was held (once the product has been registered). Public disclosure of this commitment enables accountability.

C.II Transparency

C.II.1 Disclosure of resources dedicated to R&D	Modified	
The company publicly discloses the resources dedicated to its R&D activities conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.	This indicator has been modified to expect that companies publicly disclose data on R&D investments at the disease and/or project level for all of their relevant R&D projects.	Public disclosure of R&D investments enables accountability regarding companies' long-term commitments to R&D for diseases which significantly impact low- and middle-income countries.

C.III Performance

C.III.1 Resources dedicated to R&D	Modified	
The financial R&D investment dedicated to diseases within the scope of the Index out of the company's total revenue.	This indicator has been modified to measure R&D investments for diseases in scope as a proportion of company revenue.	Investment in R&D for diseases that are the highest priority in countries in scope supports the development and entry of innovative and adapted products in the future.
C.III.2 R&D pipeline	Merged with C.III.3	
The size of the R&D pipeline within the scope of the Index, including innovative and adaptive R&D, and in-house and collaborative R&D.	This indicator has been merged with C.III.3 from Index 2016. It now evaluates all projects targeting diseases in scope i.e., innovative and adaptive projects are evaluated under one indicator.	R&D of innovative and adapted products is critical to ensure the future availability of needed products. Considering the high attrition rate in pharmaceutical R&D, larger R&D pipelines indicate a greater chance that investigational products will make it to the market.
C.III.3 High-priority R&D	New	
The share of the company's R&D pipeline within the Index scope targeting specific needs of populations in countries in the Index scope.	Measures the proportion of the pipeline that targets specific needs in countries in scope, based on whether projects target R&D gaps defined in key priority lists developed by global health stakeholders.	R&D to develop products that specifically addresses the public health needs of low- and middle-income countries can ensure the development of these products even when commercial incentives are lacking or insufficient.

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

The share of the company's research pipeline (both innovative and adaptive) within the Index scope that is being developed in partnership.

Retained

No change

Collaborative R&D facilitates risk- and expertise-sharing which can accelerate R&D, and ensure engagement from the pharmaceutical industry as commercial incentives may not provide such opportunities.

C.III.5 Product development: Movement through the pipeline

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

Retained

No change

A product's movement along the pipeline from one stage to another can be an indication of how efficient a company's R&D activities are (while acknowledging expected R&D failures), and how quickly new high-need products may be available.

C.III.6 Planning for access: Project-specific plans

The company provides evidence that its R&D projects (both in-house and collaborative) are supported by commitments and strategies to improve access to products that target diseases relevant to the Index in countries within the scope of the Index.

Modified

This indicator has been modified to also include in-house projects, and to assess companies on access provisions from phase II and onwards (without ruling out the possibility for companies to consider access provisions even earlier in the process).

Planning for access helps ensure that public health needs are considered during product development and can facilitate rapid access to affordable products after market entry. Planning can include registration plans, equitable pricing strategies, supply commitments and patent waivers.

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.

Retained

No change

Breaches of clinical trial codes of conduct are an indication of poor management of in-house and outsourced trials conducted in populations in countries in scope. The safe and ethical treatment of trial participants is critical both during and after clinical trials.

C.IV Innovation**C.IV.1 Innovation in R&D**

The company has adopted innovative (unique in the sector), sustainable or open business models to further the global R&D agenda for the development of products for diseases relevant to the Index.

Retained

No change

Innovative R&D models that target product development gaps and issues relevant to populations in countries in scope can lead to improvements in the rate, quality and quantity of products that emerge from R&D pipelines and are needed in low- and middle income countries

D PRICING, MANUFACTURING, & DISTRIBUTION

25%

2018 indicator

Change since 2016

Indicator rationale

D.I Commitments

D.I.1 Commitment to equitable pricing

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

Modified

This indicator has been modified with a new expectation for the commitment to be public, and to also apply to future products.

Such commitments help ensure companies consider affordability when setting prices for all products (current and future) targeting diseases which are the highest priority in countries in scope. Public disclosure is important to hold a company accountable to perform on its commitments.

D.I.2 Filing for marketing approval/registration targets

The company commits to filing for marketing approval or product registration within a specific timeframe in sub-Saharan Africa and low-income countries for products for diseases within the scope of the Index, considering public health need.

Modified

This indicator has been modified to capture the expectation that a company's registration targets are informed by a public health rationale.

Committing to file to register products rapidly and, ensuring these commitments take public health need into account, helps ensure people in countries with less commercially attractive markets can also access much-needed new products.

D.II Transparency

D.II.1 Equitable pricing strategies: Volume of sales disclosure

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

Retained

No change

Volume of sales data provides important evidence that a company's equitable pricing strategies are being applied in practice.

D.II.2 Equitable pricing strategies: Price disclosure

The company discloses ex-manufacturer prices for products covered under equitable pricing programmes within the scope of the Index.

Retained

No change

Price data provides important evidence that a company's equitable pricing strategies are being applied in practice.

D.II.3 Public disclosure of registration status

The company publicly discloses the status of marketing approvals for products in scope in countries in scope.

Modified

This indicator has been modified to no longer expect disclosure of criteria used in registration decision-making process.

Transparency here facilitates global health stakeholders both to identify where products are not yet registered but needed, ultimately supporting registration and supply of products to all countries in need.

D.III Performance

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

The company's equitable pricing strategies cover a significant percentage of the company's products that target diseases within the scope of the Index and a significant percentage of 'priority countries'.

Retained

No change

The broader application of equitable pricing strategies across a company's portfolio, applied to a wider range of countries means more patients in need are likely to have access to affordable products. See Appendix II for lists of 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.	Retained No change	These factors indicate whether the prices a company sets are likely to be responsive to ability-to-pay in the countries covered by the relevant pricing strategies.
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.	Retained No change	These factors are an indication of whether the prices a company sets are likely to be responsive to ability-to-pay within population segments in countries covered by the relevant pricing strategies.
D.III.4	Filing for marketing approval/registration: Needs-based The company has filed to register its newest products targeting diseases within the Index scope in countries in need within scope.	Retained No change	Filing to register is a critical step in ensuring that patients in countries within the scope of the Index have rapid access to new products.
D.III.5	Drug recall system 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.	Retained No change	To protect patients from risks associated with product quality, product recalls must be carried out effectively and to stringent standards in low- and middle-income countries.
D.III.6	Brochure and packaging adaptation: Rationale use 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.	Retained No change	When companies adapt brochure and packaging information to the needs of specific populations (e.g., through translations or use of pictures), they increase the likelihood people will understand how to use medicines appropriately and rationally.
D.III.7	Aligning supply and demand The company makes efforts to understand product distribution and demand behaviour in countries in the scope of the Index beyond first product hand-off, and takes informed action to ensure products are made available in sufficient quantities in a timely manner.	New This indicator measures whether a company makes pro-active efforts to align supply with demand in countries in scope. Emphasis will be placed on efforts to ensure sufficient supply to low-income countries in the scope of the Index, and poorer and rural populations.	Recognising that companies may have limited influence on and responsibility for health systems, such efforts can allow companies to better assess product flow through the supply chain and create proactive planning processes. This can help ensure product integrity, improve production timelines and prevent stock-outs.

D.IV Innovation

D.IV.1	Innovation in Pricing, Manufacturing and Distribution The company has introduced innovative approaches (unique in the sector) to equitable pricing, manufacturing and distribution that help with sustainable delivery of products for diseases within the Index scope to individuals in the countries relevant to the Index. If the approach focuses on equitable pricing, it targets those who face the highest financial barriers to access.	Merged with D.IV.2 This indicator has been merged with D.IV.2 to include innovative manufacturing and distribution practices in drug recalls, registration, brochure and packaging adaptations and supply.	Innovations in these areas can support affordability, availability and accessibility of medicine, e.g., by matching prices to the ability to pay, by increasing rational use or by limiting stock-outs.
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*Socioeconomic factors include disease burden/prevalence, level of inequality, type of healthcare system, public financing systems, types of supply chains within a country, the country's regulatory system, patient education/awareness and cost-analysis.

E PATENTS & LICENSING

15%

2018 indicator

Change since 2016

Indicator rationale

E.I Commitments

E.I.1 Patent filing and enforcement

The company publicly commits to not filing for or enforcing patents related to diseases within the Index scope in Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

Retained

This text has been updated to clarify the expectation that the commitment must be publicly disclosed.

Transparency about where patents are filed or will be enforced gives greater certainty to international drug procurers and generic medicine manufacturers when planning the manufacture and/or supply of generic products.

E.II Transparency

E.II.1 Endorsement of TRIPS flexibilities

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.

Retained

No change

Public support for this declaration shows that a company supports the international consensus for the need to safeguard access to medicine from the potential impact of market exclusivity conferred by patents.

E.II.2 Patent disclosure

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

Modified

This indicator has been modified to further assess the quality of patent disclosure.

Transparency is part of the social contract underlying patents. Standardised transparency of Standardised transparency of patent status can support procurement agencies and generic manufacturers in making informed decisions about which products to supply to a given market.

E.II.3 Disclosure of licensing practice

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

Retained

No change

Transparency regarding licences enables scrutiny of the quality of these agreements. Where licences include pro-access terms, transparency facilitates the uptake of similar terms in other licence agreements.

E.III Performance

E.III.1 Licensing: scale

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

Retained

No change

Non-exclusive voluntary licensing can increase the market for (and potential access to) patented pharmaceuticals by facilitating generic entry and market competition, leading to more affordable pricing and increased supply.

E.III.2 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.

Moved from R&D C.III.8

This indicator has been moved from R&D, as it is a measure of the IP approach of the company.

Sharing intellectual property on terms conducive to access can accelerate R&D to make new products available to populations in need in low- and middle-income countries. Sharing more valuable assets, such as those more likely to accelerate a product onto the market, can maximise this potential.

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.

Modified

This indicator has been modified to include consideration of impact and waivers on data exclusivity.

Such terms provide generic medicine manufacturers with additional flexibility (for e.g., in the manufacturing or distribution processes) which in turn supports them in maximising affordability and supply.

E.III.4 Licensing: Geographic scope

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

Retained

No change

A broader geographic scope means more countries can benefit from increased access to products captured under the licence, e.g., through increased affordability and supply.

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.

Retained

No change

Where intellectual property strategies are not employed in this way (e.g., companies pressure governments not to adopt TRIPS flexibilities), it can have a negative impact on access to medicine in those countries.

E.III.6 Anti-competitive behaviour: No-IP

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

Modified

This indicator has been modified to limit the scope of breaches assessed to only those occurring within the country scope of the Index.

Anti-competitive behaviour, such as price collusion, or pay-for-delay, can strengthen monopoly power and, e.g., lead to increased prices.

E.IV Innovation

E.IV.1 Innovation in Patents & Licensing

The company has adopted innovative (unique in sector) programmes aimed at managing the exclusivity conferred by patent protection to support competition for products relevant to the Index, in countries within the Index scope.

Retained

No change

Innovations that support competition can lead to increased markets, improved affordability and supply, and lead other industry members to engage in similar activities.

F CAPACITY BUILDING

15%

2018 indicator

Change since 2016

Indicator rationale

F.II Transparency

F.II.1 Pharmacovigilance: Sharing safety data

The company shares post-marketing surveillance data with relevant authorities beyond legal requirements and updates product safety and/or efficacy labels (regardless of product lifecycle stage) in countries within the scope of the Index.

Modified

This indicator has been modified to remove the requirement to publicly disclose PSURs because the benefit to access to medicine and patient safety was unclear.

Such actions help to minimise the potential for harm to patients by providing up-to-date information about the safety of medicines, focused on where regulatory capacity may be weaker.

F.II.2	Supply chain management: Reporting falsified and substandard medicines The company has a policy/protocol for reporting substandard and falsified (SF) medicines in countries within the scope of the Index that specifies time-frames for reporting to relevant stakeholders (i.e., national regulatory authorities and WHO Rapid Alert).	Retained This indicator's text has been changed slightly for the purpose of clarity.	Imposing and enforcing strict policies with time-frames for reporting helps to ensure authorities can take swifter action to remove SF medicines from distribution.
<hr/>			
F.III	Performance		
F.III.1	Capacity building in manufacturing The company undertakes manufacturing capacity building initiatives with local manufacturers aimed at achieving international Good Manufacturing Practice (GMP). These initiatives meet good practice standards* in countries within the scope of the Index.	Modified This indicator has been modified to measure company performance in manufacturing capacity building in a more qualitative way. Further, in-house manufacturing capacity building is excluded for the 2018 Index.	Local production can support access to, and the reliable supply of medicines. Focusing on building GMP capacity ensures locally produced medicines also meet quality standards.
F.III.2	Capacity building in R&D The company undertakes R&D capacity building initiatives in partnership with local universities and public sector research organisations that meet good practice standards in countries within the scope of the Index with the aim of increasing local capacity for health research (including clinical trial capacity) and product development.	Modified This indicator has been modified to measure company performance in R&D capacity building in a more qualitative way.	Local R&D capacity can help drive the emergence of a pharmaceutical and health research sector better positioned to prioritise and to research local health issues, and to develop products which respond to them.
F.III.3	Capacity building in supply chain management The company undertakes supply chain capacity building initiatives in countries within the scope of the Index in partnership with local stakeholders (e.g., ministries of health, procurement, logistics and distribution agencies) that meet good practice standards with the aim of improving the affordability, accessibility and quality of products.	Modified This indicator has been modified to measure company performance in supply chain management capacity building in a more qualitative way.	Poorly-functioning supply chains can create barriers to access, such as stock-outs or the introduction of falsified medicines. Strengthening gaps in the supply chain can remove these barriers.
F.III.4	Capacity building in pharmacovigilance The company undertakes pharmacovigilance capacity building initiatives with reputable partners that meet good practice standards* with the aim of developing and strengthening national pharmacovigilance systems in countries within the scope of the Index.	Modified This indicator has been modified to measure company performance in pharmacovigilance capacity building in a more qualitative way.	Strong pharmacovigilance systems are needed in all countries to effectively monitor and report on the safety of products.
F.III.5	Health system strengthening The company undertakes health system strengthening initiatives related to access to medicine in partnerships with local stakeholders (where there is no conflict of interest) that meet good practice standards* in countries within the scope of the Index.	Modified This indicator has been modified to measure company performance in other capacity building in a more qualitative way. Further the title of this indicator has been changed to health system strengthening, to emphasise the importance of strong health systems in ensuring access to medicines.	While health systems are the primary responsibility of governments, companies can provide support. Well-functioning health systems promote better diagnosis, disease surveillance, and overall treatment. They are critical for sustainable access to medicine.

*See Appendix

F.IV Innovation

F.IV.1 Innovation in Capacity Building

The company has developed or adopted innovative (i.e., unique in sector) approaches to building capacity related to access to medicine through partnerships with relevant stakeholders in countries within the scope of the Index.

Retained

This indicator has been changed slightly to provide more clarity and guidance on the definition of innovation in this area.

Innovation here can lead to effective new strategies and models that sustainably respond to local needs for specific capacities.

G PRODUCTION DONATIONS

5%

There are no indicators in the Innovation Strategic Pillar in this Technical Area.

2018 indicator	Change since 2016	Indicator rationale
G.I Commitments		
G.I.1 Sustainability of donation programmes	New	
The company engages in long-term, sustainable donation programmes, taking into account the need to make transitional plans for programmes where eradication, control and elimination is not possible. When making ad-hoc donations the company ensures that they are carried out in alignment with international guidelines, and are made in response to an expressed need.	This indicator is new and it measures a company's long-term commitment to donation programmes and whether the company ensures transition planning is in place to ensure sustainable access.	Donation programmes can be an important route to access to medicine for the poorest populations. Once programmes are established, companies have a responsibility to consider their long-term sustainability, to ensure people do not lose access once programmes come to an end. When donations are made ad hoc, being ready respond to need ensures that people receive appropriate products rapidly.
G.II Transparency		
G.II.1 Transparency in product donation management	Retained	
The company publicly discloses the scale of the programme (financial value, units donated, beneficiaries), impact assessments and outcome measures (regardless of who conducted these) of its structured donation programmes in countries within the scope of the Index.	No change	Transparency here ensures a company's actions can be matched to their commitments (e.g., the eradication of a particular disease).
G.III Performance		
G.III.1 Quality of product donations	Retained	
The company and/or its partner(s) monitors the outcomes and impact of its structured donation programmes, and engages in capacity building activities to support the quality of the initiative.	No change	Monitoring outcomes and impact enables companies to evaluate and improve ongoing programmes. Capacity building elements (e.g., training, diagnosis) enhance the effectiveness of programmes.
G.III.2 Scale of product donations	Modified	
The number of countries and the number of beneficiaries reached through all of the company's structured donation programmes during the period of analysis.	This indicator has been modified so that similar donation programmes are compared (i.e. NTD programmes compared with other NTD programmes and NCD programmes with other NCD programmes).	Good quality donation programmes (long-term, needs-based) can expand their coverage to include more people who have no other means to access the products they need.

Appendices

- I. Contributors to this report
- II. Priority countries for pricing and registration
– 2018 update
- III. Cancers in scope for the 2018 Access to
Medicine Index
- IV. Good practice standards framework for the capacity
building analysis
- V. Priority diseases and pathogens for R&D analysis
- VI. ICD-10 coverage & (cancers only) WHO EML relevance
- VII. References
- VIII. Definitions and acronyms

APPENDIX I. CONTRIBUTORS TO THIS REPORT

Throughout the methodology review, formal committees supported the Index research team. 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. Recommendations on specific topics of the Index were provided by Technical Subcommittees: panels of specialists in

different aspects of access to medicine. Other experts from a variety of organisations (academic, industry, non-governmental, multilateral, investors) supported the development of the Methodology for the 2018 Access to Medicine Index 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 report is not intended to imply endorsement of the Access to Medicine Index, its final methodology, the analysis or the results. Final decisions regarding the content of the Technical Areas and indicators are ultimately made by the Access to Medicine Foundation. Contributors engaged in a personal capacity and their views may not necessarily reflect the views of all members of the stakeholder groups or the organisations they represent.

APPENDIX II. PRIORITY COUNTRIES FOR PRICING AND REGISTRATION – 2018 UPDATE

For each disease in the scope of the 2018 Index, the Index has a defined list of 'priority countries'. These defined lists of countries are used for certain indicators in the Technical Area Pricing, Manufacturing & Distribution. They are those countries that have been identified as having one of the highest burdens for the disease in question, based on WHO data (2012), or IHME

data (2015), adjusted for multi-dimensional inequality (UNDP, 2012). 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.

Table 5. Priority countries

This table shows the priority countries identified for each disease – dots denote priority country status. Individual priority country lists exist for viral hepatitis (B and C) and the sexually transmitted infections included in the scope of the 2018 Index (syphilis, chlamydia, gonorrhoea, trichomoniasis and genital herpes). Countries in the scope of the 2018 Index that have not been designated as priority countries for any disease are not included in this table.

For certain neglected tropical diseases and maternal and neonatal health conditions, where DALY data was not available, other criteria were used. Other criteria were also used to identify priority countries for cancer, to ensure alignment with the inclusion of cancer in the 2018 Index. Where DALY data was not used, Kosovo and Tuvalu are no longer listed as priority countries, unless identified based on the alternative criteria noted below.

Disease	Afghanistan	Angola	Bangladesh	Benin	Bolivia	Brazil	Burkina Faso	Burundi	Cambodia	Cameroon	Central African Rep.	Chad	China	Colombia	Comoros	Congo, Dem. Rep.	Congo, Rep.	Côte d'Ivoire	Ecuador	Egypt, Arab Rep.	El Salvador	Equatorial Guinea	Ethiopia	Gabon	Ghana	Guatemala	Guinea	Haiti	Honduras	India	Indonesia
Non-communicable																															
Anxiety disorders	•	•				•							•			•						•								•	
Asthma		•											•			•														•	
Bipolar affective disorder						•							•			•							•							•	
Cancer (all except Kaposi Sarcoma)		•				•							•							•										•	
Cancer (Kaposi sarcoma)																							•							•	
Chronic obstructive pulmonary disease		•											•			•							•							•	
Diabetes mellitus	•					•							•			•							•							•	
Epilepsy													•			•							•							•	
Hypertensive heart disease	•					•							•			•							•							•	
Ischaemic heart disease	•					•							•			•							•							•	
Kidney diseases			•										•			•														•	
Migraine	•	•				•	•						•			•							•							•	
Schizophrenia						•							•			•							•							•	
Stroke	•					•							•			•							•							•	
Unipolar depressive disorders	•					•							•			•							•							•	
Communicable																															
Chlamydia														•		•							•							•	
Diarrhoeal diseases	•	•										•				•							•							•	
Genital herpes						•							•			•							•							•	
Gonorrhoea	•															•					•		•							•	
HIV/AIDS																							•							•	
Lower respiratory infections	•															•							•							•	
Malaria	•	•					•					•				•							•							•	
Measles	•															•							•							•	
Meningitis	•	•										•				•							•							•	
Pertussis	•															•							•							•	
Syphilis	•	•										•				•							•							•	
Tetanus	•	•										•				•							•							•	
Trichomoniasis						•							•			•							•							•	
Tuberculosis	•	•														•							•							•	
Viral hepatitis B			•									•	•			•							•				•			•	
Viral hepatitis C	•															•				•			•							•	
Neglected tropical																															
Buruli ulcer	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
Chagas disease					•	•								•							•					•				•	
Chikungunya			•				•	•	•	•	•	•			•	•						•				•				•	
Dengue					•			•								•							•				•			•	
Dracunculiasis	•											•				•	•						•	•						•	
Human African Trypanosomiasis										•	•					•							•			•				•	
Leishmaniasis		•														•							•							•	
Leprosy					•								•	•		•							•							•	
Lymphatic filariasis																		•												•	
Mycetoma, chromoblastomycosis and other deep mycoses																														•	
Onchocerciasis										•	•	•				•							•							•	
Rabies	•											•				•							•							•	
Scabies and other ectoparasites					•								•			•							•							•	
Schistosomiasis																•							•							•	
Snakebite envenoming	•	•												•		•							•		•					•	
Soil-transmitted helminthiasis			•											•		•							•							•	
Trachoma						•								•									•							•	
Yaws				•						•	•					•	•	•	•	•				•						•	
Maternal & neonatal																															
Abortion													•			•							•							•	
Birth asphyxia and birth trauma	•												•			•							•							•	
Contraceptive methods						•					•	•				•							•				•			•	
Hypertensive disorders of pregnancy	•	•														•							•							•	
Maternal haemorrhage	•															•							•							•	
Maternal sepsis		•														•							•							•	
Neonatal sepsis and infections	•	•														•							•							•	
Obstructed labour	•	•											•			•							•							•	
Other neonatal conditions	•	•												•		•							•							•	
Prematurity and low birth weight	•	•											•			•							•							•	

Table 6. Exceptions that have been included in the priority country table, as specific countries could be identified (WHO data unless otherwise noted).

Disease	Variable used to determine priority countries
Buruli ulcer	Countries with new reported cases of Buruli ulcer in 2013 and/or 2014; countries with no data in 2013 or 2014; actively reporting countries; and previously reported countries, cross-checked with WHO Weekly Epidemiological Record, 2004.
Cancer	Countries with the highest incidence of cancer (GLOBOCAN, 2012), adjusted for multi-dimensional inequality (UNDP, 2015); plus countries with no data. A separate priority country list was identified for Kaposi sarcoma, due to its disproportionately high burden in low-income countries. However, for both lists, no additional adjustment was made to ensure the inclusion of low-income countries, due to potential barriers in capacity for regulatory approval and safe and effective administration of cancer products in these countries.
Chikungunya	Countries with documented, endemic or epidemic chikungunya.
Contraceptive methods	Based on DALYs for maternal conditions; plus top 5 countries by unmet need for family planning.
Dracunculiasis	Endemic countries and countries not yet certified free of dracunculiasis (with no recent history or in pre-certification phase).
Mycetoma, chromoblastomycosis and other deep mycoses	Countries with the highest number of cases and highest average prevalence (van de Sande, 2013).
Prematurity and low birth weight	Based on DALYs for preterm birth complications, but compared with list of 10 countries that account for 60% of the world's preterm births by rank-in-numbers.
Snakebite envenoming	Countries with the highest number of cases and deaths (Kasturiratne <i>et al.</i> , 2008).
Soil-transmitted helminthiasis	Countries with 20 million or more children (preschool-age children and school-age children) requiring preventive chemotherapy for soil-transmitted helminthiasis; countries with no data.
Yaws	Currently endemic countries, and countries with interrupted transmission.

Exceptions that have not been included in the priority country table, as specific countries could not be identified.

Disease	Priority countries
Echinococcosis	All countries in scope
Foodborne trematodiasis	All countries in scope
Taeniasis/cysticercosis	All endemic countries in scope

APPENDIX III. CANCERS IN SCOPE FOR THE 2018 ACCESS TO MEDICINE INDEX

Cancer is included in the Index disease scope for the first time in 2018. Cancer types have been selected for the Index disease scope using two approaches: (a) cancer types based on high incidence both globally and in countries in the scope of the Index, with incidence being seen as an indication of where further R&D needs to be incentivised; and (b) cancer types based on the products registered on the 2017 WHO Model List of Essential Medicines (EML). There are 27 cancer types in scope: 17 are in scope for the R&D Technical Area, and 19 are in scope for the Technical Areas relating to pricing, patenting and donations. Nine cancers types are in both sets.

Defining the cancer scope for R&D Technical Area

The 2018 Access to Medicine Index will examine 17 cancer types in the R&D Technical Area (see table 7). These cancers have been brought into scope for having either the highest burden by incidence globally, or the highest incidence and/or percentage of global burden in countries in scope of the Index, based on data from GLOBOCAN (2012).²²

Which R&D projects will be analysed will depend on their clinical trial stage. Projects that target any cancer types up to and including those in Phase I clinical trials will be included. For Phase II projects and onwards, projects will only be included if they target one of the 17 prioritised cancer types.

Defining the cancer scope for analysis of product deployment

The Access to Medicine Index measures pharmaceutical companies' efforts to address availability and affordability during product deployment, as covered in the Pricing, Manufacturing & Distribution, Patents & Licensing and Product Donations Technical Areas. The scope of analysis in these Technical Areas will comprise of 31 cancer types with relevant registered products on the 2017 WHO EML and WHO List of Essential Medicine for Children (EMLc) as shown in table 8 (50 products).

As in the methodology for the 2016 Index, products for the management of pain and supportive treatments (for e.g. anti-emetics) will not be included.

Table 7. Cancer types in scope and basis for inclusion for the R&D Technical Area

There are three criteria for including cancer types in the 2018 Index R&D analysis. Each cancer type had to meet one or more criteria to qualify. The table shows the 17 cancer types included, indicates which criteria they met and provides the corresponding data.

Cancer types in scope (17)	Inclusion criteria		
	Ten cancer types with: Highest global incidence rates	Ten cancer types with: Highest Incidence in countries in scope	Ten cancer types where: Countries in scope account for highest % of global incidence
Bladder	429,793		
Brain, nervous system			59%
Breast	1,671,149	776,202	
Cervical	527,624	419,829	80%
Colorectal	1,360,602	528,152	
Gallbladder			57%
Head and neck: Lip, oral cavity		185,884	62%
Head and neck: Nasopharynx			83%
Head and neck: Other pharynx			59%
Kaposi sarcoma			90%
Leukaemia		190,975	
Liver	782,451	606,369	77%
Lung	1,824,701	974,521	
Lymphoma: Non-Hodgkin lymphoma	385,741		
Oesophageal	455,784	355,421	78%
Prostate	1,094,916	279,388	
Stomach	951,594	617,516	65%

Table 8 Cancer types in scope and basis for inclusion for product deployment analyses

ATMI cancer type	Indication as described on WHO EML/EMLc	WHO EML*	WHO EMLc**	Number of medicines on WHO EML	Products on WHO EML/EMLc
Breast	Early-stage breast cancer	●		10	carboplatin, cyclophosphamide, docetaxel, doxorubicin, fluorouracil, methotrexate, paclitaxel, anastrozole□, leuporelin□, tamoxifen
	Early-stage HER2 positive breast cancer	●		1	trastuzumab
	Metastatic breast cancer	●		8	capecitabine, cyclophosphamide, docetaxel, doxorubicin, paclitaxel, vinorelbine, anastrozole□, tamoxifen
	Metastatic HER2 positive breast cancer	●		1	trastuzumab
Cervical	Cervical cancer	●	●	2	cisplatin***, HPV vaccine†
Colorectal	Early-stage colon cancer	●		4	calcium folinate, capecitabine, fluorouracil, oxaliplatin
	Early-stage rectal cancer	●		3	calcium folinate, capecitabine, fluorouracil
	Metastatic colorectal cancer	●		5	calcium folinate, capecitabine, fluorouracil, irinotecan, oxaliplatin
Gastrointestinal stromal tumour‡	Gastrointestinal stromal tumour	●		1	imatinib
General ‡	Refer to EML/EMLc for information on specification			4	allopurinol, filgrastim, procabazine, zoledronic acids
Gestational neoplasia‡	Gestational trophoblastic neoplasia	●		6	calcium folinate, cyclophosphamide, dactinomycin, etoposide, methotrexate, vincristine
Head and neck: Nasopharynx	Nasopharyngeal cancer	●		4	carboplatin, cisplatin***, fluorouracil, paclitaxel
Head and neck: other‡	Head and neck cancer	●		1	cisplatin***
Kaposi sarcoma	Kaposi sarcoma	●		5	bleomycin, doxorubicin, paclitaxel, vinblastine, vincristine
Kidney	Wilms tumour	●	●	3	dactinomycin, doxorubicin, vincristine
Leukaemia	Acute lymphoblastic leukaemia	●	●	14	asparaginase, cyclophosphamide, cytarabine, daunorubicin, doxorubicin, etoposide, mercaptopurine, methotrexate, tioguanine, vincristine, dexamethasone, hydrocortisone, methylprednisolone, prednisolone□
	Acute myelogenous leukaemia	●		2	cytarabine, daunorubicin
	Acute promyelocytic leukaemia	●		5	all-trans retinoic acid, cytarabine, daunorubicin, mercaptopurine, methotrexate
	Chronic lymphocytic leukaemia	●		6	bendamustine, chlorambucil, cyclophosphamide, fludarabine, rituximab, prednisolone□
	Chronic myeloid leukaemia	●		4	dasatinib , hydroxycarbamide, imatinib, nilotinib
Lung	Non-small cell lung cancer	●		6	carboplatin, cisplatin, etoposide, gemcitabine, paclitaxel, vinorelbine
Lymphoma: Hodgkin lymphoma	Hodgkin lymphoma	●	●	8	bleomycin¶, cyclophosphamide, dacarbazine¶, doxorubicin¶, etoposide, vinblastine¶, vincristine, prednisolone
Lymphoma: Non-Hodgkin lymphoma	Burkitt lymphoma	●	●	7	calcium folinate, cyclophosphamide, cytarabine, doxorubicin, etoposide, vincristine, prednisolone□
	Diffuse large B-cell lymphoma	●		5	cyclophosphamide, doxorubicin, rituximab, vincristine, prednisolone□
	Follicular lymphoma	●		6	bendamustine, cyclophosphamide, doxorubicin, rituximab, vincristine, prednisolone□
Ovarian	Epithelial ovarian cancer	●		3	carboplatin, gemcitabine, paclitaxel
	Ovarian germ cell tumours	●	●	7	bleomycin, cisplatin, etoposide, ifosfamide, mesna, paclitaxel, vinblastine
Prostate	Metastatic prostate cancer	●		3	docetaxel, bicalutamide□, leuporelin□
Testicular	Testicular germ cell tumours	●	●	6	bleomycin, cisplatin, etoposide, ifosfamide, mesna, vinblastine
Retinoblastoma‡	Retinoblastoma	●	●	3	carboplatin, etoposide, vincristine
Sarcomas‡	Ewing sarcoma, osteosarcoma and rhabdomyosarcoma	●	●	11	calcium folinate, carboplatin, dislatin, cyclophosphamide, dactinomycin, doxorubicin, etoposide, ifosfamide, mesna, methotrexate, vincristine

Data and cancer type nomenclature follows GLOBOCAN 2012, with the exception of those marked ‡. Data is missing from this set for Kiribati, Kosovo, Sao Tomé And Príncipe, Tongo and Tuvalu.

Regarding cancer, product deployment analyses will only look at relevant products on the WHO Model List of Essential Medicines (2017) (WHO EML) or on the WHO EML for Children. Product Deployment analyses cover the Technical Areas of Pricing, Manufacturing & Distribution, Patents & Licensing and Product Donations. For products for other diseases in scope, this restriction does not apply.

The list uses the data and nomenclature by GLOBOCAN 2012 for naming the cancer types. Exceptions to this marked with ‡.

□ Square box: The WHO EML incorporates square box symbols (□) to indicate similar clinical performance within a pharmacological class. A medicine which is not specifically mentioned on the EML but is part of same class for the same indication as a listed squarebox market medicine, will be evaluated as if on the WHO EML

* EML: WHO Model List of Essential Medicines (2017)

** EMLc: WHO Model List of Essential Medicines for Children (2017)

*** Indicated as a radio-sensitiser in adults only

† For the prevention of cervical cancer

‡ Exceptions to the data and nomenclature by GLOBOCAN 2012. Listed on the 2017 WHO EML.

§ Malignancy-related bone disease

|| Indicated for imatinib-resistant chronic myeloid leukaemia

¶ Indicated for Hodgkin-lymphoma in adults only

APPENDIX IV. THE GOOD PRACTICE STANDARDS FRAMEWORK FOR CAPACITY BUILDING

The 2018 Access to Medicine Index has developed a Good Practice Standards Framework to qualitatively analyse capacity building initiatives within the Capacity Building Technical Area. The framework is tailored for each subtheme in the Technical Area and is comprised of six standards:

Good Practice Standards for initiatives:

1. Addresses local needs, priorities, and/or skills gap;
2. Guided by clear, measurable goals or objectives;
3. Aims for long-term impact and sustainability;
4. Carried out in partnership with relevant stakeholders;
5. Includes regular monitoring, evaluation and public sharing of approaches, progress and learnings;
6. Has good governance structures in place (including for mitigating or preventing conflicts of interest).

A breakdown of how this framework is used to evaluate the five subthemes listed in the Capacity Building Technical Area is shown in Table 9.

The Good Practice Standards Framework has been developed to convey stakeholder expectations for good practice in capacity building in each of the five subthemes. Some of the Good Practice Standards are considered an inclusion criteria for analysis in the Index while others will be used to guide the qualitative analysis. This table provides a guide to the criteria by which submitted company initiatives are included for analysis in the Index and the criteria by which they are analysed and scored on, per subtheme.

Table 9. Inclusion and scoring criteria for capacity building initiatives

		R&D Capacity Building	Manufacturing Capacity Building	Supply Chain Capacity Building	Pharmacovigilance Capacity Building	Health System Strengthening	Corresponding element of the Good Practice Standards Framework
Inclusion criteria	Active during the period of analysis	●	●	●	●	●	
	Active in Index country/countries	●	●	●	●	●	
	Done in partnership	●*		●	●	●	2
	Addresses local needs or skills gaps	●	●	●	●	●	3
	Processes in place to mitigate or prevent conflict of interest					●	1
Good practice standard for scoring	Does the partnership have good governance structures in place?	●			●**		1
	Does the initiative have clearly defined goals and/or objectives?	●	●	●	●	●	6
	Does the initiative measure and report outcomes?	●	●	●	●	●	5
	Does the initiative measure impact and report/plan to report results?					●	5
	Does the initiative aim for long-term impact and sustainability?	●	●	●	●	●	4

*R&D capacity building must be carried out in partnership with a local university or research institution in a country in the scope of the Index.

**Pharmacovigilance capacity building initiatives should have processes in place to mitigate or prevent conflict of interest.

APPENDIX V. PRIORITY DISEASES AND PATHOGENS FOR R&D ANALYSIS

Table 10. Priority diseases and pathogens analysed in the Research & Development Technical Area

The 2018 Access to Medicine Index has placed further emphasis on R&D for projects that address specific priority product gaps. The table below provides an overview of the criteria and priority lists used to identify diseases with R&D priority gaps. The diseases in scope for R&D include 45 (out of 77) diseases with an identified priority product gap.

Some diseases are included in more than one priority list. Pathogens have been brought into the disease scope for the 2018 Index for the first time. These have been identified by WHO on its pathogen priority list: as priority R&D targets for new and effective antibiotics active against the pathogens themselves and the diseases they cause. This WHO pathogen priority list does not define specific products needed.

ATMI Disease	Specific disease target	Medicines	Vaccines (Preventive)	Vaccines (Therapeutic)	Diagnostics	Microbicides	Vector Control Products	Devices (for reproductive health only)	Policy Cures Research G-FINDER neglected diseases	Policy Cures Research G-FINDER reproductive health areas	WHO R&D Blueprint	WHO Initiative for Vaccine Research gaps	WHO Pathogen Priority List	Also analysed in other TAS
Arenaviral haemorrhagic fevers	Lassa Fever													
Buruli ulcer														
Chagas disease														
Contraceptive methods	Reproductive health products ¹													
Criean Congo Haemorrhagic Fever (CCHF)														
Dengue														
Diarrhoeal diseases	Cholera													
	Cryptosporidiosis													
	Enterotoxigenic E.coli (ETEC)													
	Giardiasis [Iambliasis]													
	Shigellosis													
	Rotaviral enteritis													
	Enterococcal E.coli (EAgEC)													
	Typhoid and paratyphoid fever (S. typhi, S. paratyphi A)													
	Non-typhoidal S. enterica (NTS)													
Filoviral diseases	Ebola													
	Marburg													
Henipaviral diseases	Nipah													
HIV/AIDS														
Human African trypanosomiasis														
Leishmaniasis														
Leprosy														
Leptospirosis														
Lower respiratory infections	S. pneumonia													
	Severe Acute Respiratory Syndrome (SARS)													
	Influenza													
	Respiratory syncytial virus (RSV)													
Lymphatic filariasis														
Malaria														
Maternal haemorrhage	Postpartum haemorrhage													
Maternal sepsis	Group B Streptococcus													
Meningitis	N. meningitidis													
	S. pneumoniae													
	Cryptococcal meningitis													
Middle East Respiratory Syndrome coronavirus (MERS-CoV)														
Onchocerciasis														
Rheumatic fever														
Rift Valley Fever (RVF)														
Schistosomiasis														
Severe Fever with Thrombocytopenia Syndrome (SFTS)														
Sexually transmitted infections (STIs)	Syphilis (incl. congenital syphilis)													
Soil-transmitted helminthiasis	Hookworm diseases													
	Strongyloidiasis													
	Trichuriasis													
	Ascariasis													
Taeniasis/cysticercosis														
Trachoma														
Tuberculosis														
Viral hepatitis (B and C)	Hepatitis C (genotypes)													
Zika														

● Gap identified

● Specific gap

Definition: High-priority product gap identified for the disease, condition or pathogen on one or more of the R&D Priority Lists.

Definition: Specific product gap identified, e.g., for a new route of administration to be developed, or serotypes to be targeted.

Table 11. Priority pathogens

12 pathogens have been brought into the disease scope for the 2018 Index R&D analysis. These have been identified by the WHO pathogen priority list. Pathogens on this list are deemed by WHO as priority R&D targets for new and effective antibiotics active against the pathogens themselves and the diseases they cause. This WHO pathogen priority list does not define specific products needed.

Pathogens	Policy Cures Research G-FINDER neglected diseases	Policy Cures Research G-FINDER reproductive health areas	WHO R&D Blueprint	WHO Initiative for Vaccine Research gaps	WHO Pathogen Priority List	Also analysed in other TAs
<i>Acinetobacter baumannii</i> (carbapenem-resistant)					●	
<i>Campylobacter</i> (fluoroquinolone-resistant)					●	
<i>Enterobacteriaceae</i> (carbapenem-resistant, 3 rd generation cephalosporin-resistant)	●				●	●
<i>Enterococcus faecium</i> (vancomycin-resistant)					●	
<i>Haemophilus influenza</i> (ampicillin-resistant)					●	●
<i>Helicobacter pylori</i> (clarithromycin-resistant)					●	
<i>Neisseria gonorrhoeae</i> (3 rd generation cephalosporin-resistant, fluoroquinolone-resistant)					●	●
<i>Pseudomonas aeruginosa</i> (carbapenem-resistant)					●	
<i>Salmonella</i> (spp., fluoroquinolone-resistant)	●				●	●
<i>Shigella</i> (spp., fluoroquinolone-resistant)	●				●	●
<i>Staphylococcus aureus</i> (methicillin-resistant, vancomycin intermediate and resistant)					●	
<i>Streptococcus pneumonia</i> (penicillin-non-susceptible)	●				●	●

● Specific gap

Definition: Specific product gap identified, e.g., for a new route of administration to be developed, or serotypes to be targeted.

General notes

Additional to the above diseases and specific targets, the priority lists also include non-specific diseases (multiple or other) which are not further defined.

In some cases of duplicates (an R&D gap has been identified on more than one list) one list may define specific restriction for this gap. The ATMI will consider projects targeting either the general gap or restricted gap equally.

APPENDIX VI. ICD-10 COVERAGE & (CANCERS ONLY) WHO EML RELEVANCE

Communicable Diseases

	Disease	DALYs (countries in scope)	ICD-10 codes	ICD-10 name
1	Lower respiratory infections	131.150.237	J09 J10 J11 J12 J13 J14 J15 J16 J17 J18 J20 J21 J22 P23 U04	Influenza due to identified zoonotic or pandemic influenza virus Influenza due to identified seasonal influenza virus Influenza, virus not identified Viral pneumonia, not elsewhere classified Pneumonia due to Streptococcus pneumoniae Pneumonia due to Haemophilus influenzae Bacterial pneumonia, not elsewhere classified Pneumonia due to other infectious organisms, not elsewhere classified Pneumonia in diseases classified elsewhere Pneumonia, organism unspecified Acute bronchitis Acute bronchiolitis Unspecified acute lower respiratory infection Congenital pneumonia Severe acute respiratory syndrome [SARS]
2	Diarrhoeal diseases	83.764.595	A00 A01 A03 A04 A06 A07 A08 A09	Cholera Typhoid and paratyphoid fevers Shigellosis Other bacterial intestinal infections Amoebiasis Other protozoal intestinal diseases Viral and other specified intestinal infections Other gastroenteritis and colitis of infectious and unspecified origin
3	HIV/AIDS	59.213.043	B20 B21 B22 B23 B24	Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases Human immunodeficiency virus [HIV] disease resulting in malignant neoplasms Human immunodeficiency virus [HIV] disease resulting in other specified diseases Human immunodeficiency virus [HIV] disease resulting in other conditions Unspecified human immunodeficiency virus [HIV] disease
4	Tuberculosis	54.332.361	A15 A16 A17 A18 A19 B90	Respiratory tuberculosis, bacteriologically and histologically confirmed Respiratory tuberculosis, not confirmed bacteriologically or histologically Tuberculosis of nervous system Tuberculosis of other organs Miliary tuberculosis Sequelae of tuberculosis
5	Malaria	38.491.119	B50 B51 B52	Plasmodium falciparum malaria Plasmodium vivax malaria Plasmodium malariae malaria

			B53	Other parasitologically confirmed malaria
			B54	Unspecified malaria
			P37.3	Congenital falciparum malaria
			P37.4	Other congenital malaria
6	Viral hepatitis (B and C)	24.703.328	B16	Acute hepatitis B
			B17.0	Acute delta-(super)infection of hepatitis B carrier
			B17.1	Acute Hepatitis C
			B17.8	Other specified acute viral hepatitis
			B17.9	Acute viral hepatitis, unspecified
			B18.0	Chronic viral hepatitis B with delta-agent
			B18.1	Chronic viral hepatitis B without delta-agent
			B18.2	Chronic viral hepatitis C
			B18.9	Chronic viral hepatitis, unspecified
			B19	Unspecified viral hepatitis
			K74	Fibrosis and cirrhosis of liver
7	Meningitis	22.781.461	A39	Meningococcal infection
			G00	Bacterial meningitis, not elsewhere classified
			G03	Meningitis due to other and unspecified causes
8	Measles	12.264.045	B05	Measles
9	Sexually transmitted infections (STIs)	10.092.695	A50	Congenital syphilis
			A51	Early syphilis
			A52	Late syphilis
			A53	Other and unspecified syphilis
			A54	Gonococcal infection
			A55	Chlamydial lymphogranuloma (venereum)
			A56	Other sexually transmitted chlamydial diseases
			A59	Trichomoniasis
			A60	Anogenital herpesviral [herpes simplex] infection
10	Pertussis	5.950.007	A37	Pertussis
11	Tetanus	4.662.932	A33	Tetanus neonatorum
			A34	Obstetrical tetanus
			A35	Other tetanus

Non-Communicable Diseases

	Disease	DALYs (countries in scope)	ICD-10 codes	ICD-10 name
1	Ischaemic heart disease	137.803.915	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	Stroke	113.999.836	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	Chronic obstructive pulmonary disorder (COPD)	59.841.914	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	Diabetes mellitus	53.660.514	E10	Type 1 diabetes mellitus (minus E10.2)
			E11	Type 2 diabetes mellitus (minus E11.2)
			E12	Malnutrition-related diabetes mellitus (minus E12.2)
			E13	Other specified diabetes mellitus (minus E13.2)
			E14	Unspecified diabetes mellitus (minus E14.2)
5	Unipolar depressive disorders	40.359.896	F32	Depressive episode
			F33	Recurrent depressive disorder
			F34.1	Dysthymia
6	Kidney diseases	30.361.404	No0	Acute nephritic syndrome
			No1	Rapidly progressive nephritic syndrome
			No2	Recurrent and persistent haematuria
			No3	Chronic nephritic syndrome
			No4	Nephrotic syndrome
			No5	Unspecified nephritic syndrome
			No6	Isolated proteinuria with specified morphological lesion
			No7	Hereditary nephropathy, not elsewhere classified
			No8	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
			E10.2	Type 1 diabetes mellitus with renal complications
			E11.2	Type 2 diabetes mellitus with renal complications
			E12.2	Malnutrition-related diabetes mellitus with renal complications
			E13.2	Other specified diabetes mellitus with renal complications
			E14.2	Unspecified diabetes mellitus with renal complications
7	Asthma	22.489.628	J45	Asthma
			J46	Status asthmaticus
8	Migraine	19.608.650	G43	Migraine
9	Anxiety disorder	17.637.255	F40	Phobic anxiety disorders
			F41	Other anxiety disorders
			F42	Obsessive-compulsive disorder
			F43	Reaction to severe stress, and adjustment disorders
			F44	Dissociative [conversion] disorders
10	Hypertensive heart disease	17.053.619	I10	Essential (primary) hypertension
			I11	Hypertensive heart disease
			I12	Hypertensive renal disease
			I13	Hypertensive heart and renal disease
			I15	Secondary hypertension
11	Epilepsy	12.610.507	G40	Epilepsy
			G41	Status epilepticus

12	Schizophrenia	11.707.269	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
13	Bipolar affective disorder	6.542.313	F29	Unspecified nonorganic psychosis
			F30	Manic episode
14	Cancer	Presented seperately	F31	Bipolar affective disorder

Neglected Tropical Diseases

	Disease	DALYs(countries in scope)	ICD-10 codes	ICD-10 name
1	Soil-transmitted helminthiasis	4.179.035	B76	Hookworm diseases
			B77	Ascariasis
			B78	Strongyloidiasis
			B79	Trichuriasis
			B80	Enterobiasis
			B81	Other intestinal helminthiasis, not elsewhere classified
2	Schistosomiasis	3.478.062	B65	Schistosomiasis [bilharziasis]
3	Dengue and Chikunkunya	2.575.517	A92.0	Chikungunya virus disease
			A97	Dengue
4	Lymphatic filariasis	2.069.423	B74.0	Filariasis due to Wuchereria bancrofti
			B74.1	Filariasis due to Brugia malayi
			B74.2	Filariasis due to Brugia timori
5	Taeniasis/cysticercosis	1.846.098	B68	Taeniasis
			B69	Cysticercosis
6	Rabies	1.654.232	A82	Rabies
7	Leishmaniasis	1.346.249	B55	Leishmaniasis
8	Onchocerciasis	1.135.571	B73	Onchocerciasis
9	Echinococcosis	607.742	B67	Echinococcosis
10	Leprosy	484.820	A30	Leprosy [Hansen disease]
11	Human African trypanosomiasis	371.657	B56	African trypanosomiasis
12	Trachoma	275.741	A71	Trachoma
13	Chagas disease	191.781	B57	Chagas disease
14	Food-borne trematodiasis	n/a	B66.0	Opisthorchiasis
			B66.1	Clonorchiasis
			B66.3	Fascioliasis
			B66.4	Paragonimiasis
15	Buruli Ulcer	n/a	A31.1	Cutaneous mycobacterial infection
16	Yaws	n/a	A66	Yaws
17	Dracunculiasis	n/a	B72	Dracunculiasis
18	Mycetoma, chromoblastomycosis and other deep mycoses	n/a	B43	Chromomycosis and phaeomycotic abscess
			B47	Mycetoma
			B48	Other mycoses, not elsewhere classified
19	Scabies and other ectoparasites	n/a	B86	Scabies
20	Snakebite envenoming	n/a	T63.0	Snake venom

Maternal and Neonatal Health Conditions

	Disease	ICD-10 codes	ICD-10 name
Maternal Conditions			
1	Maternal Haemorrhage	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	Hypertensive disorders of pregnancy	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	Abortion	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	Obstructed Labour	O64	Obstructed labour due to malposition and malpresentation of fetus
		O65	Obstructed labour due to maternal pelvic abnormality
		O66	Other obstructed labour
5	Maternal Sepsis	O85	Puerperal sepsis
		O86	Other puerperal infections
6	Contraceptive methods and devices	NA	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 Conditions			
1	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	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
		P14	Birth injury to peripheral nervous system
		P15	Other birth injuries

		P20	Intrauterine hypoxia
		P21	Birth asphyxia
		P24	Neonatal aspiration syndromes
		P25	Interstitial emphysema and related conditions originating in the perinatal period
		P26	Pulmonary haemorrhage originating in the perinatal period
		P29	Cardiovascular disorders originating in the perinatal period
3	Neonatal sepsis and infections	P35	Congenital viral diseases
		P36	Bacterial sepsis of newborn
		P37.0	Congenital tuberculosis
		P37.1	Congenital toxoplasmosis
		P37.2	Neonatal (disseminated) listeriosis
		P37.5	Neonatal candidiasis
		P37.8	Other specified congenital infectious and parasitic diseases
		P37.9	Congenital infectious and parasitic disease, unspecified
		P38	Omphalitis of newborn with or without mild haemorrhage
		P39	Other infections specific to the perinatal period
4	Other neonatal conditions	P00	Fetus and newborn affected by maternal conditions that may be unrelated to present pregnancy
		P01	Fetus and newborn affected by maternal complications of pregnancy
		P02	Fetus and newborn affected by complications of placenta, cord and membranes
		P04	Fetus and newborn affected by noxious influences transmitted via placenta or breast milk
		P08	Disorders related to long gestation and high birth weight
		P50	Fetal blood loss
		P51	Umbilical haemorrhage of newborn
		P52	Intracranial nontraumatic haemorrhage of fetus and newborn
		P53	Haemorrhagic disease of fetus and newborn
		P54	Other neonatal haemorrhages
		P55	Haemolytic disease of fetus and newborn
		P56	Hydrops fetalis due to haemolytic disease
		P57	Kernicterus
		P58	Neonatal jaundice due to other excessive haemolysis
		P59	Neonatal jaundice from other and unspecified causes
		P60	Disseminated intravascular coagulation of fetus and newborn
		P61	Other perinatal haematological disorders
		P70	Transitory disorders of carbohydrate metabolism specific to fetus and newborn
		P71	Transitory neonatal disorders of calcium and magnesium metabolism
		P72	Other transitory neonatal endocrine disorders
		P74	Other transitory neonatal electrolyte and metabolic disturbances
		P75	Meconium ileus in cystic fibrosis
		P76	Other intestinal obstruction of newborn
		P77	Necrotizing enterocolitis of fetus and newborn
		P78	Other perinatal digestive system disorders
		P80	Hypothermia of newborn
		P81	Other disturbances of temperature regulation of newborn
		P83	Other conditions of integument specific to fetus and newborn
		P90	Convulsions of newborn
		P91	Other disturbances of cerebral status of newborn
		P92	Feeding problems of newborn
		P93	Reactions and intoxications due to drugs administered to fetus and newborn
		P94	Disorders of muscle tone of newborn
		P95	Fetal death of unspecified cause
		P96	Other conditions originating in the perinatal period

Cancer: Included for Research & Development analysis

	Cancer type	Incidence (global)	ICD-10 codes	ICD-10 name
1	Lung	1.824.701	C33 C34	Malignant neoplasm of trachea Malignant neoplasm of bronchus and lung
2	Breast	1.671.149	C50	Malignant neoplasm of breast
3	Colorectal	1.360.602	C18 C19 C20 C21	Malignant neoplasm of colon Malignant neoplasm of rectosigmoid junction Malignant neoplasm of rectum Malignant neoplasm of anus and anal canal
4	Prostate	1.094.916	C61	Malignant neoplasm of prostate
5	Stomach	951.594	C16	Malignant neoplasm of stomach
6	Liver	782.451	C22	Malignant neoplasm of liver and intrahepatic bile ducts
7	Cervical	527.624	C53	Malignant neoplasm of cervix uteri
8	Oesophagael	455.784	C15	Malignant neoplasm of oesophagus
9	Bladder	429.793	C67	Malignant neoplasm of bladder
10	Lymphoma: Non-Hodgkin lymphoma	385.741	C82 C83 C84 C85 C96	Follicular lymphoma Non-follicular lymphoma Mature T/NK-cell lymphomas Other and unspecified types of non-Hodgkin lymphoma Other and unspecified malignant neoplasms of lymphoid, haematopoietic and related tissue
11	Leukaemia	351.965	C91 C92 C93 C94 C95	Lymphoid leukaemia Myeloid leukaemia Monocytic leukaemia Other leukaemias of specified cell type Leukaemia of unspecified cell type
12	Head and neck: Lip, oral cavity	300.373	C00 C01 C02 C03 C04 C05 C06 C07 C08	Malignant neoplasm of lip Malignant neoplasm of base of tongue Malignant neoplasm of other and unspecified parts of tongue Malignant neoplasm of gum Malignant neoplasm of floor of mouth Malignant neoplasm of palate Malignant neoplasm of other and unspecified parts of mouth Malignant neoplasm of parotid gland Malignant neoplasm of other and unspecified major salivary glands
13	Brain, nervous system	256.213	C70 C71 C72	Malignant neoplasm of meninges Malignant neoplasm of brain Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system
14	Gallbladder	178.101	C23 C24	Malignant neoplasm of gallbladder Malignant neoplasm of other and unspecified parts of biliary tract
15	Head and neck: Other pharynx	142.387	C09 C10 C12 C13 C14	Malignant neoplasm of tonsil Malignant neoplasm of oropharynx Malignant neoplasm of piriform sinus Malignant neoplasm of hypopharynx Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx
16	Head and neck: Nasopharynx	86.691	C11	Malignant neoplasm of nasopharynx
17	Kaposi sarcoma	44.247	C46	Kaposi sarcoma

Cancer: Included for Product Deployment analysis (based on relevance to WHO EML)

	Medicine defined by the WHO EML	Dosage form(s) defined by the WHO EML	Specific cancer target(s) defined by the WHO EML	ATMI Cancer type
8.2	Cytotoxic and adjuvant medicines			
1	all-trans retinoid acid (ATRA)	Capsule: 10 mg	Acute promyelocytic leukaemia	Leukaemia
2	allopurinol	Tablet: 100 mg; 300 mg	n/a	General
3	asparaginase	Powder for injection: 10 000 IU in vial	Acute lymphoblastic leukaemia	Leukaemia
4	bendamustine	Injection: 45 mg/0.5 mL; 180 mg/2 mL	Chronic lymphocytic leukaemia Follicular lymphoma	Leukaemia Lymphoma: Non-Hodgkin lymphoma
5	bleomycin	Powder for injection: 15 mg (as sulfate) in vial	Hodgkin lymphoma Kaposi sarcoma Ovarian germ cell tumour Testicular germ cell tumour	Lymphoma: Hodgkin lymphoma Kaposi sarcoma Ovarian Testicular
6	calcium folinate	Injection: 3 mg/ mL in 10- mL ampoule Tablet: 15 mg	Early stage colon cancer Early stage rectal cancer Gestational trophoblastic neoplasia Metastatic colorectal cancer Osteosarcoma Burkitt lymphoma	Colorectal Colorectal Gestational neoplasia Colorectal Sarcomas Lymphoma: Non-Hodgkin lymphoma
7	capecitabine	Tablet: 150 mg; 500 mg	Early stage colon cancer Early stage rectal cancer Metastatic breast cancer Metastatic colorectal cancer	Colorectal Colorectal Breast Colorectal
8	carboplatin	Injection: 50 mg/5 mL; 150 mg/15 mL; 450 mg/45 mL; 600 mg/60mL	Early stage breast cancer Epithelial ovarian cancer Nasopharyngeal cancer Non-small cell lung cancer Osteosarcoma Retinoblastoma	Breast Ovarian Head and neck: nasopharynx Lung Sarcomas Retinoblastoma
9	chlorambucil	Tablet: 2 mg	Chronic lymphocytic leukaemia.	Leukaemia
10	cisplatin	Injection: 50 mg/50 mL; 100 mg/100 mL	Cervical cancer (as a radio-sensitiser) Head and neck cancer (as a radio-sensitiser) Nasopharyngeal cancer (as a radio-sensitiser) Non-small cell lung cancer Osteosarcoma Ovarian germ cell tumour Testicular germ cell tumour	Cervical Head and neck: other Head and neck: nasopharynx Lung Sarcomas Ovarian Testicular
11	cyclophosphamide	Powder for injection: 500 mg in vial Tablet: 25 mg	Chronic lymphocytic leukaemia Diffuse large B-cell lymphoma Early stage breast cancer	Leukaemia Lymphoma: Non-Hodgkin Lymphoma Breast

			Gestational trophoblastic neoplasia	Gestational neoplasia
			Hodgkin lymphoma	Lymphoma: Hodgkin Lymphoma
			Follicular lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Rhabdomyosarcoma	Sarcomas
			Ewing sarcoma	Sarcomas
			Acute lymphoblastic leukaemia	Leukaemia
			Burkitt lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Metastatic breast cancer	Breast
12	cytarabine	Powder for injection: 100 mg in vial	Acute myelogenous leukaemia	Leukaemia
			Acute lymphoblastic leukaemia	Leukaemia
			Acute promyelocytic leukaemia	Leukaemia
			Burkitt lymphoma	Lymphoma: Non-Hodgkin Lymphoma
13	dacarbazine	Powder for injection: 100 mg in vial	Hodgkin lymphoma	Lymphoma: Hodgkin Lymphoma
14	dactinomycin	Powder for injection: 500 micrograms in vial	Gestational trophoblastic neoplasia	Gestational neoplasia
			Rhabdomyosarcoma	Sarcomas
			Wilms tumour	Kidney
15	dasatinib	Tablet: 20 mg; 50 mg; 70 mg; 80 mg; 100 mg; 140 mg	Imatinib-resistant chronic myeloid leukaemia	Leukaemia
16	daunorubicin	Powder for injection: 50 mg (hydrochloride) in vial	Acute lymphoblastic leukaemia	Leukaemia
			Acute myelogenous leukaemia	Leukaemia
			Acute promyelocytic leukaemia	Leukaemia
17	docetaxel	Injection: 20 mg/ mL; 40 mg/ mL	Early stage breast cancer	Breast
			Metastatic breast cancer	Breast
			Metastatic prostate cancer	Prostate
18	doxorubicin	Powder for injection: 10 mg; 50 mg (hydrochloride) in vial	Diffuse large B-cell lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Early stage breast cancer	Breast
			Hodgkin lymphoma	Lymphoma: Hodgkin Lymphoma
			Kaposi sarcoma	Kaposi sarcoma
			Follicular lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Metastatic breast cancer	Breast
			Osteosarcoma	Sarcomas
			Ewing sarcoma	Sarcomas
			Acute lymphoblastic leukaemia	Leukaemia
			Wilms tumour	Kidney
			Burkitt lymphoma	Lymphoma: Non-Hodgkin lymphoma
19	etoposide	Capsule: 100 mg Injection: 20 mg/ mL in 5- mL ampoule	Testicular germ cell tumour	Testicular
			Gestational trophoblastic neoplasia	Gestational neoplasia
			Hodgkin lymphoma	Lymphoma: Hodgkin Lymphoma
			Non-small cell lung cancer	Lung
			Ovarian germ cell tumour	Ovarian
			Retinoblastoma	Retinoblastoma
			Ewing sarcoma	Sarcomas

			Acute lymphoblastic leukaemia Burkitt lymphoma	Leukaemia Lymphoma: Non-Hodgkin Lymphoma
20	filgrastim	Injection: 120 micrograms/0.2 mL; 300 micrograms/0.5 mL; 480 micrograms/0.8 mL in pre-filled syringe 300 micrograms/mL in 1- mL vial, 480 mg/1.6 mL in 1.6- mL vial	Primary prophylaxis in patients at high risk for developing febrile neutropenia associated with myelotoxic chemotherapy. Secondary prophylaxis for patients who have experienced neutropenia following prior myelotoxic chemotherapy. To facilitate administration of dose dense chemotherapy regimens	General General General
21	fludarabine	Powder for injection: 50 mg (phosphate) in vial Tablet: 10 mg	Chronic lymphocytic leukaemia	Leukaemia
22	fluorouracil	Injection: 50 mg/ mL in 5- mL ampoule	Early stage breast cancer Early stage colon cancer Early stage rectal cancer Metastatic colorectal cancer Nasopharyngeal cancer	Breast Colorectal Colorectal Colorectal Head and neck: nasopharynx
23	gemcitabine	Powder for injection: 200 mg in vial, 1 g in vial	Epithelial ovarian cancer Non-small cell lung cancer	Ovarian Lung
24	hydroxycarbamide	Solid oral dosage form: 200 mg; 250 mg; 300 mg; 400 mg; 500 mg; 1g	Chronic myeloid leukaemia	Leukaemia
25	ifosfamide	Powder for injection: 500 mg vial; 1-g vial; 2-g vial	Testicular germ cell tumour Ovarian germ cell tumour Osteosarcoma Rhabdomyosarcoma Ewing sarcoma	Testicular Ovarian Sarcomas Sarcomas Sarcomas
26	imatinib	Tablet: 100 mg; 400 mg	Chronic myeloid leukaemia Gastrointestinal stromal tumour	Leukaemia Gastrointestinal stromal tumour
27	irinotecan	Injection: 40 mg/2 mL in 2- mL vial; 100 mg/5 mL in 5- mL vial; 500 mg/25 mL in 25- mL vial	Metastatic colorectal cancer	Colorectal
28	mercaptopurine	Tablet: 50 mg	Acute lymphoblastic leukaemia Acute promyelocytic leukaemia	Leukaemia Leukaemia
29	mesna	Injection: 100 mg/ mL in 4- mL and 10- mL ampoules Tablet: 400 mg; 600 mg	Testicular germ cell tumour Ovarian germ cell tumour Osteosarcoma Rhabdomyosarcoma Ewing sarcoma	Testicular Ovarian Sarcomas Sarcomas Sarcomas
30	methotrexate	Powder for injection: 50 mg (as sodium salt) in vial Tablet: 2.5 mg (as sodium salt)	Early stage breast cancer Gestational trophoblastic neoplasia Osteosarcoma	Breast Gestational neoplasia Sarcomas

			Acute lymphoblastic leukaemia	Leukaemia
			Acute promyelocytic leukaemia	Leukaemia
31	nilotinib	Capsule: 150 mg; 200 mg	Imatinib-resistant chronic myeloid leukaemia	Leukaemia
32	oxaliplatin	Injection: 50 mg/10 mL in 10-mL vial; 100 mg/20 mL in 20-mL vial; 200 mg/40 mL in 40-mL vial	Early stage colon cancer	Colorectal
		Powder for injection: 50 mg, 100 mg in vial	Metastatic colorectal cancer	Colorectal
33	paclitaxel	Powder for injection: 6 mg/mL	Epithelial ovarian cancer	Ovarian
			Early stage breast cancer	Breast
			Metastatic breast cancer	Breast
			Kaposi sarcoma	Kaposi sarcoma
			Nasopharyngeal cancer	Head and neck: nasopharynx
			Non-small cell lung cancer	Lung
			Ovarian germ cell tumour	Ovarian
34	procarbazine	Capsule: 50 mg (as hydrochloride)	n/a	General
35	rituximab	Injection: 100 mg/10 mL in 10-mL vial; 500 mg/50 mL in 50-mL vial	Diffuse large B-cell lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Chronic lymphocytic leukaemia	Leukaemia
			Follicular lymphoma	Lymphoma: Non-Hodgkin Lymphoma
36	tioguanine	Solid oral dosage form: 40 mg.	Acute lymphoblastic leukaemia	Leukaemia
37	trastuzumab	Powder for injection: 60 mg; 150 mg; 440 mg in vial	Early stage HER2 positive breast cancer	Breast
			Metastatic HER2 positive breast cancer	Breast
38	vinblastine	Powder for injection: 10 mg (sulfate) in vial	Hodgkin lymphoma	Lymphoma: Hodgkin Lymphoma
			Kaposi sarcoma	Kaposi sarcoma
			Testicular germ cell tumour	Testicular
			Ovarian germ cell tumour	Ovarian
39	vincristine	Powder for injection: 1 mg; 5 mg (sulfate) in vial	Diffuse large B-cell lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Gestational trophoblastic neoplasia	Gestational neoplasia
			Hodgkin lymphoma	Lymphoma: Hodgkin Lymphoma
			Kaposi sarcoma	Kaposi sarcoma
			Follicular lymphoma	Lymphoma: Non-Hodgkin Lymphoma
			Retinoblastoma	Retinoblastoma
			Rhabdomyosarcoma	Sarcomas
			Ewing sarcoma	Sarcomas
			Acute lymphoblastic leukaemia	Leukaemia
			Wilms tumour	Kidney
			Burkitt lymphoma	Lymphoma: Non-Hodgkin Lymphoma
40	vinorelbine	Injection: 10 mg/mL in 1- mL vial; 50 mg/5 mL in 5- mL vial	Non-small cell lung cancer	Lung
			Metastatic breast cancer	Breast
41	zoledronic acid	Concentrate solution for infusion: 4 mg/5 mL in 5- mL vial		General

		Solution for infusion: 4 mg/100 mL in 100- mL bottle		
8.3	Hormones and antihormones			
1	anastrozole	Tablet: 1 mg	Early stage breast cancer Metastatic breast cancer	Breast Breast
2	bicalutamide	Tablet: 50 mg	Metastatic prostate cancer.	Prostate
3	dexamethasone	Injection: 4 mg/ mL in 1- mL ampoule (as disodium phos- phate salt) Oral liquid: 2 mg/5 mL	Acute lymphoblastic leukaemia	Leukaemia
4	leuporelin	Injection: 7.5 mg; 22.5 mg in pre-filled syringe	Early stage breast cancer Metastatic prostate cancer	Breast Prostate
5	hydrocortisone	Powder for injection: 100 mg (as sodium succinate) in vial	Acute lymphoblastic leukaemia	Leukaemia
6	methylprednisolone	Injection: 40 mg/ mL (as sodium succinate) in 1- mL sin- gle-dose vial and 5- mL multi-dose vials; 80 mg/ mL (as sodium succinate) in 1- mL single-dose vial	Acute lymphoblastic leukamia	Leukaemia
7	prednisolone	Oral liquid: 5 mg/ mL Tablet: 5 mg; 25 mg	Chronic lymphocytic leukaemia Diffuse large B-cell lymphoma Hodgkin lymphoma Follicular lymphoma Acute lymphoblastic leukaemia Burkitt lymphoma	Leukaemia Lymphoma: Non-Hodgkin Lymphoma Lymphoma: Hodgkin Lymphoma Lymphoma: Non-Hodgkin Lymphoma Leukaemia Lymphoma: Non-Hodgkin Lymphoma
8	tamoxifen	Tablet: 10 mg; 20 mg (as citrate)	Early stage breast cancer Metastatic breast cancer	Breast Breast
19.3	Vaccines			
1	HPV vaccine		For prevention of cervical cancer	Cervical

APPENDIX VII. REFERENCES

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APPENDIX VIII. DEFINITIONS AND ACRONYMS

AMR	Antimicrobial Resistance
CD	Communicable Disease
COPD	Chronic Obstructive Pulmonary Disease
DALY	Disability Adjusted Life Year
ECOSOC	United Nations Economic and Social Council
EML	Essential Medicines List
EMLc	Essential Medicines List for Children
ERC	Expert Review Committee
GDP	Gross Domestic Product
GHO	Global Health Observatory
GMP	Good Manufacturing Practice
GNI	Gross National Income
HDI	Human Development Index
HiHDI	High Human Development Country with high inequality
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
ICD-10	WHO International Classifications of Diseases
IP	Intellectual property
LDC	Least Developed Country
LHDC	Low Human Development Country
LIC	Low-income country
LMIC	Lower-middle-income country
MHDC	Medium Human Development Country
MNH	Maternal and Neonatal Health
NCD	Noncommunicable Disease
NCCP	National Cancer Control Plan
NGO	Non-Governmental Organisation
NTD	Neglected Tropical Disease
PDP	Product Development Partnerships
PSUR	Period Safety Update Reports
R&D	Research & Development
SF	Substandard or Falsified Medicine
STI	Sexually Transmitted Infection
TRIPS	Trade Related Aspects of Intellectual Property Rights
UMIC	Upper-middle-income country
UNDP	United Nations Development Programme
WHO	World Health Organization

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

Access provisions

[Working definition, used for analysis] Provisions to ensure that public health needs are taken into consideration during the R&D phase. Access provisions can be included in R&D partnership agreements and/or developed in-house. They facilitate availability, accessibility and affordability for patients in countries within the scope of the Index (e.g., equitable pricing strategies, sufficient supply commitments, non-exclusivity in specified territories, waiving patent rights, royalty-free provisions).

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

[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.

Affordability

[Working definition, used for analysis] A measure of the payer's ability to pay for a product (whether or not they are the end user). The Index takes this into account when assessing pricing strategies for relevant products. Pharmaceutical companies use many different criteria to assess affordability.

Conflict of interest

A conflict of interest is the conflict that arises when the commercial interests of a company are potentially at odds with the interests of the partnership, the partner (i.e. local stakeholders), or the health and well-being of the population the partnership intends to help.

Equitable pricing strategy

[Working definition, used for analysis] A targeted pricing strategy which aims at improving access to medicine for those in need by taking affordability for individuals and healthcare systems into account in a manner that is locally appropriate.

Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source. [Definition from WHO, 2017]

Good governance structures

[Working definition, used for analysis] Good governance structures for partnerships include three components: 1) the structures put in place which establish clear roles, responsibilities, and decision making structures among the partners; 2) the systems of communications whereby information is regularly conveyed to all concerned; and 3) the transparency of processes, decisions, and outcomes of the partnership.

Good practice standards

A set of six standards that encompass good practice in capacity building initiatives. These standards form a framework used for the assessment of company capacity building initiatives. The standards include: working in partnership, having good governance structures in place, address-

ing local needs, having clear goals and objectives, measuring outcomes and/or impact, and aiming for sustainability and long-term impact.

Impact

'Impact' in the context of access initiatives, is the long-term result of a company's activities on the communities it intends to support. Impact is beyond the direct control of a given project or initiative however, as it involves other factors influenced by other actors and/or the context in which activities are executed. There is no shared or formally agreed definition of what constitutes impact.

Internal control framework

An internal control framework is a series of processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour of the company's employees and, if applicable, its company's third parties.

Inter-country equitable pricing

[Working definition, used for analysis] Where companies determine their pricing strategy at the country level and take into account affordability for countries in need.

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.

Performance management system

Formal and informal mechanisms, tools, processes and networks used by organisations to manage and reward performance in line with corporate and functional strategies and goals. This includes performance measurement, i.e. collecting, analysing and reporting information regarding the performance of an individual, group or organisation in order to track progress towards set goals.

Period of analysis

[Working definition, used for analysis] For the 2018 Index, the time period for which data will be analysed covers company activities which must be ongoing between June 2016 and the end of May 2018, as this the cycle of the Index. Projects that have ended before 1st June 2016 are not included.

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 often includes five low-income countries (World Bank defined) in order to ensure the Index evaluates pricing strategies directed towards poorer countries.

R&D priorities

R&D priorities are intended to define the most urgent pharmaceutical research needed to address global health risks for which no or limited products are available. It is often a need for new products with limited commercial incentive. The specific priority gaps or needs presented in this publication are identified by the global health community.

Substandard medical products

Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both. [Definition from WHO, 2017]

Structured donation programmes

[Working definition, used for analysis] A gift of products for which a defined strategy exists as to the type, volume and destination of donated products. Structured donation programmes are long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate or eradicate a disease.

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