Methodology Report 2013

for the 2014 Access to Medicine Index

access to medicine index

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Expert Review Committee
Hans Hogerzeil - Chair
Natacha Dimitrijevic
Marja Esveld
Regina Kamoga
Richard Laing
Dennis Ross-Degnan
Dilip Shah
Peter Shelby

Technical Subcommittees
Peter Beyer
Esteban Burrone
Jaime Espin
Jennifer Dent
Michele Forzley
Javier Guzman
Warren Kaplan
Jillian Kohler
Niranjan Konduri
Prashant Yadav

Additional contributors
Afshin Mehrpouya
Rachelle Harris
'Strategic Access to Medicine Workshop' participants, *May 2013, The Netherlands*
'Stakeholder Dialogue: Ensuring quality affordable medicine in developing countries' participants, *June 2013, Ghana*
'Investor Dialogue' participants, *September 2013, France*

access to medicine FOUNDATION

Access to Medicine Foundation
Scheepmakersdijk 5a
NL-2011 AS Haarlem
The Netherlands

For questions about this report, please contact Jayasree Iyer
E jiyer@atmindex.org or info@atmindex.org
T + 31 (0)23 53 39 187
W www.accesstomedicineindex.org

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for the 2014 Access to Medicine Index

Access to Medicine Foundation
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Introduction

As developers and manufacturers of life-saving products, the world's leading pharmaceutical companies play an important role in improving access to medicine for the world's poor. Through their own initiatives and in collaboration with other relevant stakeholders such as multi-lateral organisations, governments and the global health community, these companies are increasingly helping to address the access to medicine challenge.

In order to suitably capture the industry's progress in line with society's evolving expectations, the Access to Medicine Index methodology is systematically reviewed every two years. While maintaining as much consistency as possible for the purpose of trend analysis, the methodology is adjusted where needed. This report describes the methodology that will be used for the 2014 Access to Medicine Index, and highlights the refinements made since the previous report.

A word with the founder

Head of Research Jayasree Iyer talks to Wim Leereveld, Founder and CEO, about refining the methodology for the 2014 Access to Medicine Index.


'Maintaining consistency while reflecting evolving priorities'

Executive Summary

The methodology for the 2014 Access to Medicine Index remains largely the same as the methodology for the previous Index. The 2014 Index will use the same framework for analysis, which continues to be constructed along seven Technical Areas with indicators measured across four Strategic Pillars. The weights within the framework remain unchanged and most of the indicators remain the same, though the number of indicators has been reduced. The geographic scope and disease scope have been expanded.

How the methodology was updated

The Index is produced over a two-year cycle. In the first year, the Access to Medicine Foundation reviews the Index methodology on the basis of intensive expert stakeholder feedback and defines the methodology for the next Access to Medicine Index. An Expert Review Committee and Technical Subcommittees, which offer strategic guidance, stakeholder perspectives and technical expertise, are formally consulted during this process. In the second year, pharmaceutical company data is collected, analysed and published in the Access to Medicine Index report.

In 2013, the Index team began refining the methodology for the 2014 Index by conducting an extensive and rigorous quantitative and qualitative analysis of the methodology and data from past Indices. The Index team outlined key areas for methodological enhancement and in particular highlighted indicators to be retained for longitudinal trend analysis. The Index team then engaged with stakeholders to understand their multiple perspectives and to stay up-to-date on developments in the access to medicine landscape. Feedback was sought through an online survey, calls with individual companies, and three separate stakeholder meetings with pharmaceutical companies, investors, and experts in developing countries. Insights were incorporated into the review process and considered by the Technical Subcommittees and the Expert Review Committee.

What remains the same?

The 2014 Index uses the same framework for analysis as the 2012 Index, which allows for comparison and trend analysis. The framework continues to be constructed along the same seven Technical Areas, with indicators measured across the same four Strategic Pillars. The weights of these Technical Areas and Strategic Pillars for the 2014 Index also remain unchanged. Most of the indicators remain unchanged.

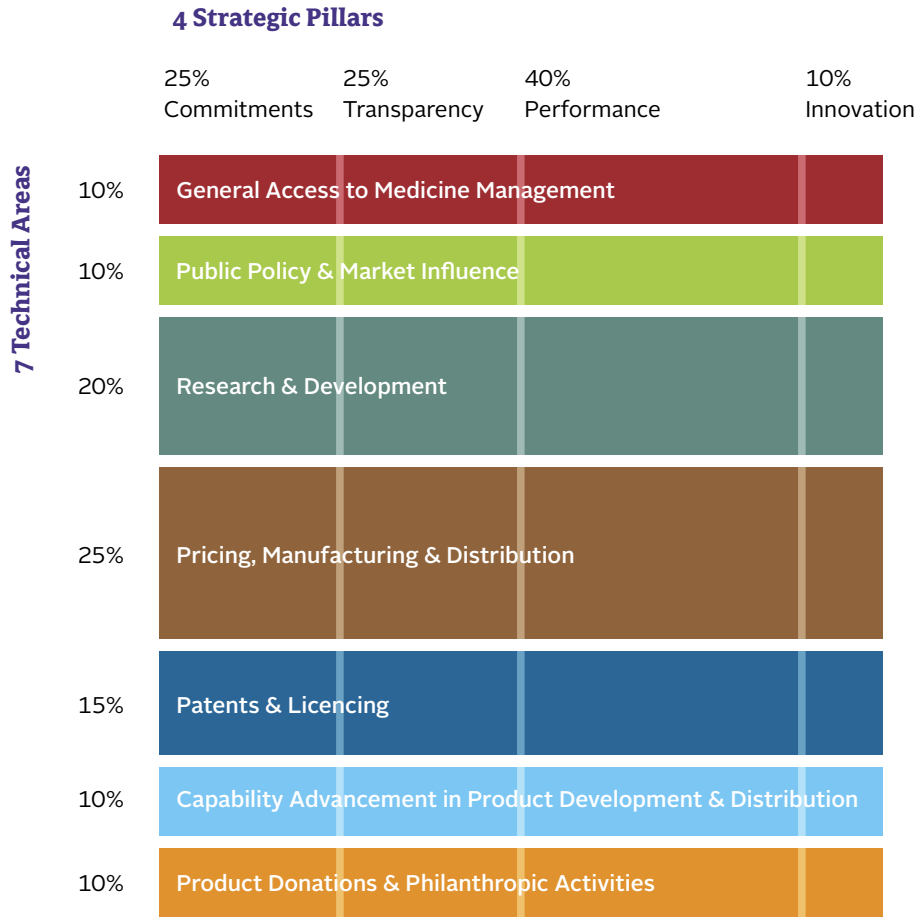
What has changed?

Several strategic changes have been made in order to stay up-to-date with developments in the pharmaceutical industry and the access to medicine landscape. A selection of these changes is outlined below.

Tailoring to local needs: In 2014 the analysis will be broadened to include an assessment of the extent to which companies tailor their access strategies to local expectations, needs and conditions. The 2014 Index will also place greater emphasis on how companies target local public health needs as part of their overall access strategy, their R&D strategy, pricing strategies and capability advancement initiatives.

Inequality as a third selection criterion for country scope: Widespread inequality of human development within countries often inhibits access to medicine for the poorest population segments. Therefore the Index has added the UN Inequality-Adjusted Human Development Index as third criterion for determining its geographic scope. This means that four higher-income countries with large numbers of people living in poverty (Brazil, Colombia, Ecuador and Venezuela) have been added to the geographic scope.

Figure 1 **How we measure**



More meaningful measurements of affordability: The focus of the pricing analysis will be shifted towards affordability rather than comparison of tiered pricing programmes. The Index will now capture all forms of equitable pricing strategies where companies include socio-economic needs and affordability in determining commercial prices in countries covered by the Index. It will also assess the rationale behind companies' equitable pricing strategies and seek disclosure of volume of sales to the poorest segments of the population.

Tracking breaches worldwide: The 2014 Index will include an assessment of company breaches of codes of conduct or laws on ethical marketing, lobbying, corruption, bribery or anti-competitive behaviour that occur anywhere in the world, not only in countries included in the Index. The reason for this change is that company policies and practices outside the Index geographic scope can affect access to medicine in countries covered by the Index.

Refining some indicators and removing redundancies: Based on quantitative analysis, stakeholder consultations and internal review, the indicators have undergone some minor refinements. In order to increase their robustness and take into account relevant new developments, several indicators have been added, combined, replaced or removed. Overall, the number of indicators decreased from 101 to 95 and some have been earmarked for longitudinal trend analysis.

Refinements to what we measure

Companies: The company scope for the 2014 Index was only changed to reflect splits, mergers or a change in the relevance of companies' products to the disease scope. The 2014 Index measures 21 companies, with the addition of AbbVie since the 2012 Index.

Countries: The addition of the development inequality criteria resulted in the inclusion of more countries in Latin America in 2014. Some other minor adjustments were made, bringing the total number of countries to 106.

Diseases: The disease scope has expanded from 33 to 47 conditions (plus birth control), largely based on new information on the global burden of disease. Chlamydia, schizophrenia and bipolar affective disorder have been added and all 17 WHO-classified neglected tropical diseases are now included, as are more maternal and neonatal conditions. Coverage of cirrhosis of the liver has been broadened to include chronic viral hepatitis.

Product types: The product type scope remains unchanged from the 2012 Index, covering medicines, microbicides, therapeutic and preventive vaccines, diagnostics, vector control products and platform technologies.

Table 1 **What we measure**

Company Scope	21 research-based pharmaceutical companies		
Geographic Scope	106 countries	84	World Bank-based (LIC and LMIC)
		18	UN HDI-based (LDC and MHDC)
		4	IHDI-based (HHDC)
Disease Scope	47 diseases	10	Highest burden communicable diseases
		12	Highest burden non-communicable diseases
		17	Neglected tropical diseases
		8	Maternal and neonatal health conditions (plus birth control)
Product Type Scope	Medicines, vaccines, diagnostics, vector control products, microbicides and platform technologies		

What we measure

The Access to Medicine Index measures pharmaceutical companies' policies and practices in improving access to medicine across a specific range of countries, diseases and product types.

Company Scope

The Index assesses the world's top research-based pharmaceutical companies with respect to their efforts in access to medicine. The size, resources and global reach of these companies give them unique opportunities to improve access to medicine through innovative strategies, technologies and initiatives in markets throughout the world.

The companies included are those with the highest market capitalisation and product portfolios most relevant to the countries and diseases covered by the Index. The company scope is updated each publication cycle to accommodate changes in product portfolios and market capitalisation – a commonly used indicator of net worth – as well as industry changes such as mergers, acquisitions and internal splits.

Table 2 **List of companies included in the 2014 Access to Medicine Index - 21 companies**

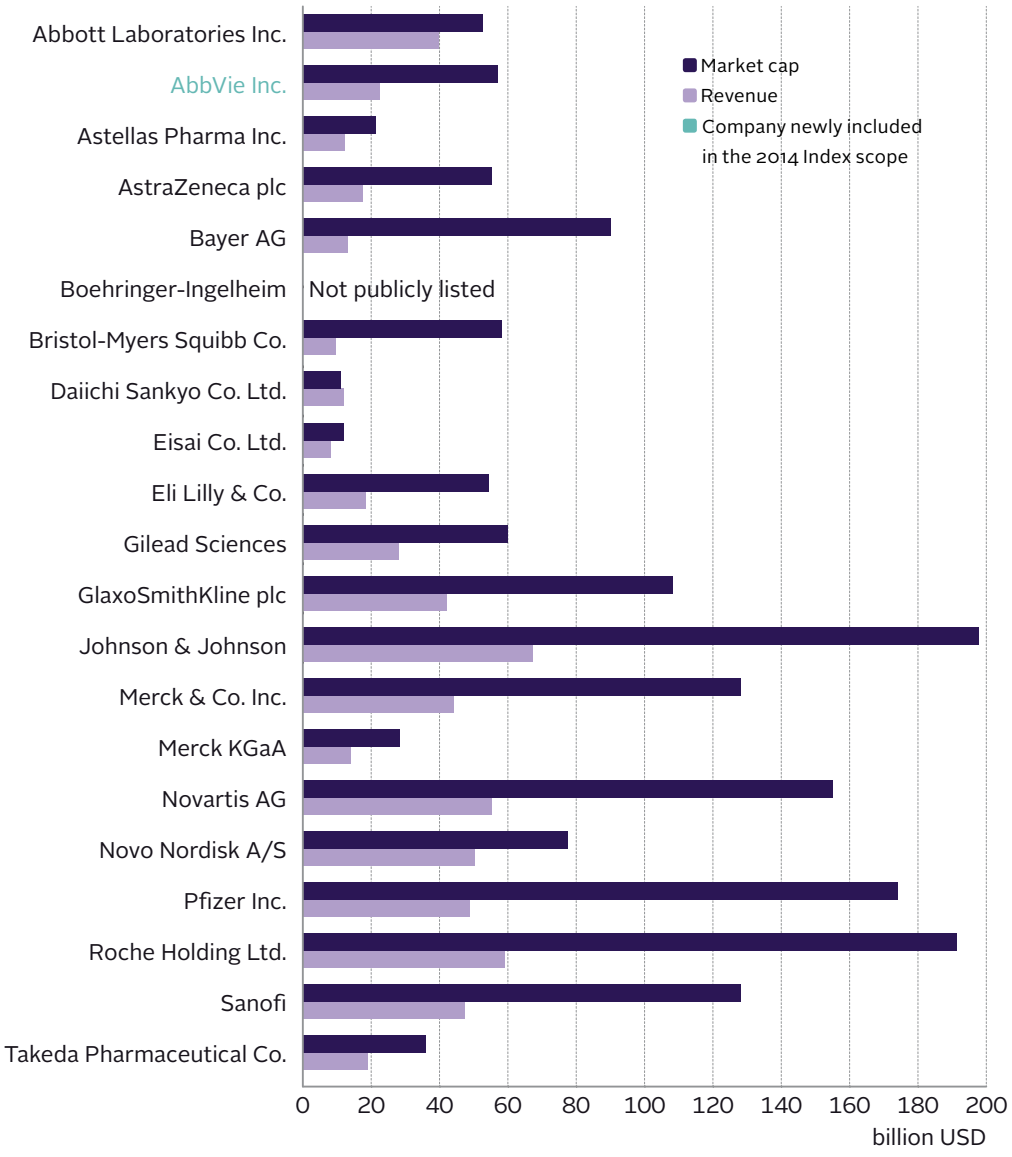
Ticker	Company	Country	Market cap (billion, USD)[1]	Revenue (billion, USD)[2]
ABT-N	**Abbott Laboratories Inc.**	USA	52.699	39.874
ABBV-N	AbbVie Inc.	USA	57.040	22.603
4503-TO	**Astellas Pharma Inc.**	JPN	21.314	12.275
AZN-LN	**AstraZeneca plc**	GBR	55.133	17.621
BAY-FF	**Bayer AG**	DEU	90.108	13.231
Not publicly listed	**Boehringer-Ingelheim**	DEU	Not publicly listed	
BMY-N	**Bristol-Myers Squibb Co.**	USA	58.248	9.703
4568-TO	**Daiichi Sankyo Co. Ltd.**	JPN	10.979	11.886
4523-TO	**Eisai Co. Ltd.**	JPN	11.819	8.205
LLY-N	**Eli Lilly & Co.**	USA	54.332	18.380
GILD-O	**Gilead Sciences**	USA	59.848	27.987
GSK-LN	**GlaxoSmithKline plc**	GBR	108.168	42.119
JNJ-N	**Johnson & Johnson**	USA	197.868	67.224
MRK-N	**Merck & Co. Inc.**	USA	128.298	44.154
MRK-FF	**Merck KGaA**	DEU	28.216	14.116
NOVN-VX	**Novartis AG**	CHE	155.222	55.375
NOVO'B-KO	**Novo Nordisk A/S**	DNK	77.479	50.235
PFE-N	**Pfizer Inc.**	USA	174.144	48.777
ROG-VX	**Roche Holding Ltd.**	USA	191.280	58.986
SAN-FR	**Sanofi**	FRA	128.048	47.347
4502-TO	**Takeda Pharmaceutical Co.**	JPN	35.886	19.108

■ Company newly included in the 2014 Index scope

The 2014 Index measures 21 companies, with the addition of AbbVie since the 2012 Index. In January 2013, AbbVie split off from Abbott Laboratories to become a separate, independent biopharmaceutical company comprising Abbott's former proprietary pharmaceutical business. Since the split-off, both AbbVie and Abbott meet the criteria for inclusion in the 2014 Index. The remaining 19 companies from the 2012 Index continued to meet these criteria and were therefore retained.

Pharmaceutical companies that exclusively produce generic medicines are still excluded from the Index in 2014. However, the Access to Medicine Foundation recognises that these companies play a significant role in access to medicine, particularly in low- and middle-income countries, and is exploring the feasibility of a separate Index for generics companies. Generic medicines marketed by the 21 research-based companies or any of their (generics) subsidiaries in which they have more than 50% ownership are included.

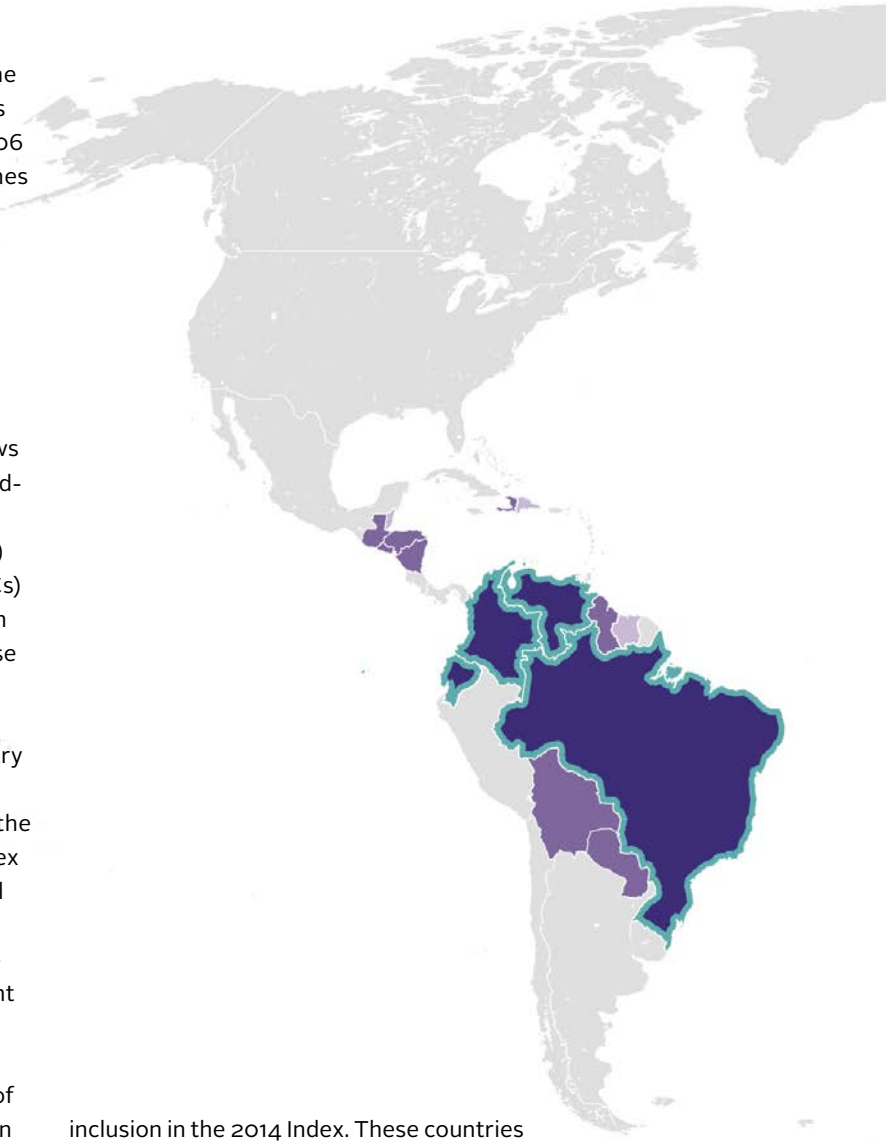
Figure 2 **Market cap & revenue of companies included in the 2014 Acces to Medicine Index**



Geographic Scope

The Index measures pharmaceutical companies' efforts in countries where access to medicine is most needed based on levels of income, development and, for the first time in 2014, socio-economic equality.

The addition of the development equality criteria has resulted in the expansion of the Index geographic scope to more countries in Latin America. The 2014 Index covers 106 countries, with the addition of five new ones – Brazil, Colombia, Ecuador, South Sudan and Venezuela – and the removal of two – Algeria and Marshall Islands.



Since 2012, the Index has used the latest available World Bank country classifications[3] as the base criteria for defining its geographic scope. This classification allows for the identification of economically disadvantaged populations at the country level and brings all low-income countries (LICs) and lower-middle income countries (LMICs) into the Index country scope. South Sudan has been added for the 2014 Index because it was newly classified as a LIC in 2013.

The level of social development in a country is also an important indicator of a population's access to medicine. The Index uses the most recent UN Human Development Index (HDI)[4], which aggregates important social markers of life expectancy, education and income levels per capita, to capture countries that have lower levels of development despite higher levels of income.

In recognition that widespread inequality of human development within countries often inhibits access to medicine for the poorest population segments, the Index has this year added the UN Inequality-Adjusted Human Development Index (IHDI)[5] as a third tool for determining its geographic scope. The IHDI corrects the HDI score for inequality within a country, taking in to account such factors as the Gini coefficient of income distribution to yield a new inequality-adjusted human development score. Using the IHDI, four high human development countries (HHDC) – Brazil, Colombia, Ecuador and Venezuela – that did not fall under the World Bank LIC or LMIC classification qualified for inclusion in the 2014 Index. These countries are included regardless of their World Bank or HDI classification because they scored below 0.55 on the IHDI. This cut-off was set in order to capture countries with the greatest disparities.

Algeria is no longer covered by the Index because it is now considered a high human development country with little social inequality and the Marshall Islands are no longer covered because the World Bank now classifies it as an upper-middle-income country and because it likewise has a low level of social inequality.

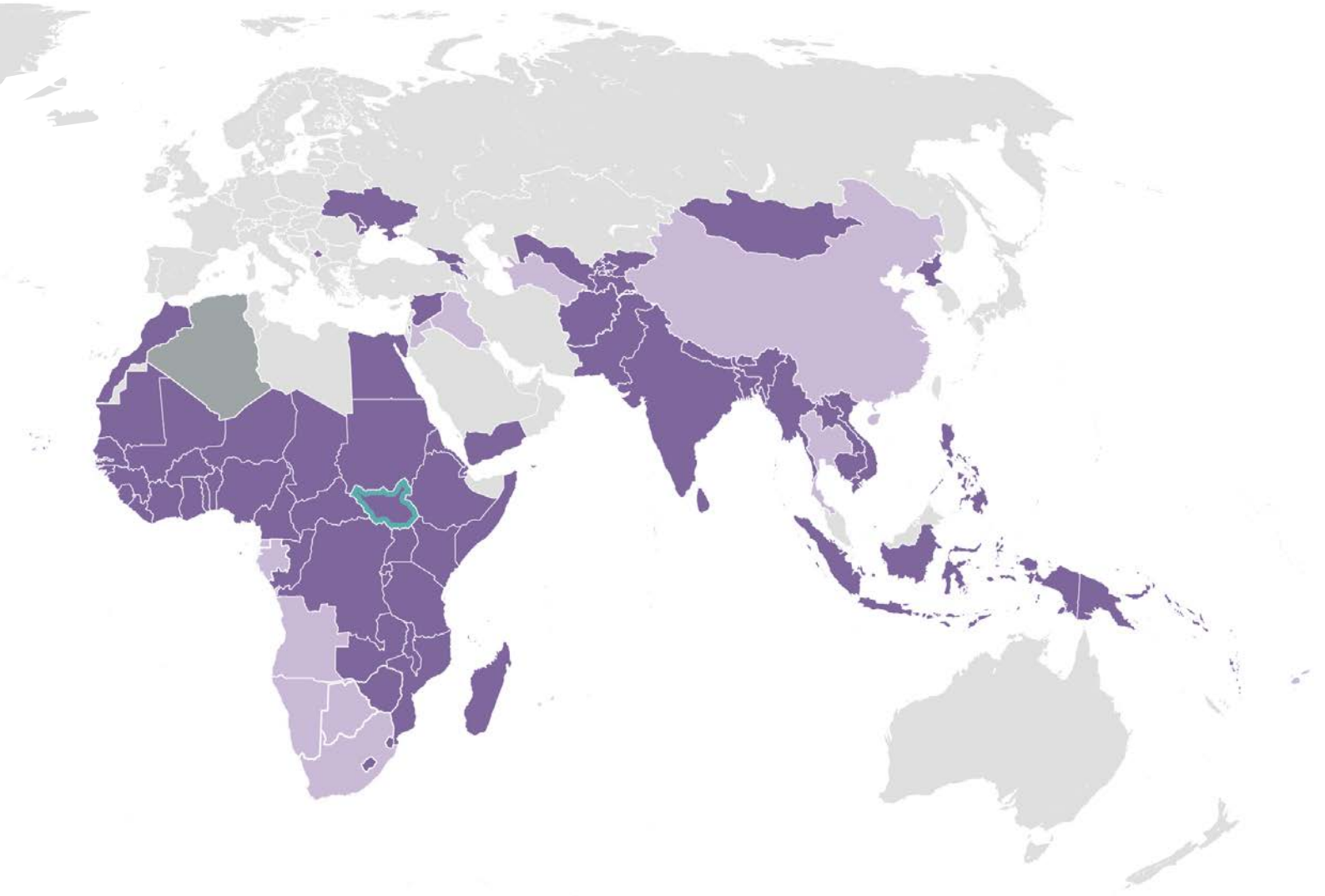


Figure 3 **Map of countries included in the 2014 Access to Medicine Index**

- World Bank income classification
- UN Human Development Index
- UN Inequality-Adjusted Human Development Index

- 5 Countries newly included in the 2014 Index scope
- 2 Countries removed from the Index scope

Due to scaling, countries may not be visible on the map.

Table 3 **List of countries included in the 2014 Access to Medicine Index – 106 countries**

Country	Classification
East Asia & Pacific	
Cambodia	LIC*
China	MHDC
Fiji	MHDC
Indonesia	LMIC
Kiribati	LMIC
Korea, Dem. Rep.	LIC
Lao PDR	LMIC*
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LIC*
Papua New Guinea	LMIC
Philippines	LMIC
Samoa	LMIC*
Solomon Islands	LMIC*
Thailand	MHDC
Timor-Leste	LMIC
Tonga	MHDC
Tuvalu	LDC
Vanuatu	LMIC*
Vietnam	LMIC
Europe & Central Asia	
Armenia	LMIC
Georgia	LMIC
Kosovo	LMIC
Kyrgyz Rep.	LIC
Moldova	LMIC
Tajikistan	LIC
Turkmenistan	MHDC
Ukraine	LMIC
Uzbekistan	LMIC
Latin America & Caribbean	
Belize	MHDC
Bolivia	LMIC
Brazil	HiHDI
Colombia	HiHDI
Dominican Rep.	MHDC
Ecuador	HiHDI
El Salvador	LMIC
Guatemala	LMIC
Guyana	LMIC
Haiti	LIC*
Honduras	LMIC
Nicaragua	LMIC
Paraguay	LMIC
Suriname	MHDC
Venezuela, RB	HiHDI

Country	Classification
Middle East & North Africa	
Djibouti	LMIC*
Egypt, Arab Rep.	LMIC
Iraq	MHDC
Jordan	MHDC
Morocco	LMIC
Syrian Arab Rep.	LMIC
West Bank and Gaza	LMIC
Yemen, Rep.	LMIC
South Asia	
Afghanistan	LIC
Bangladesh	LIC*
Bhutan	LMIC
India	LMIC
Maldives	MHDC
Nepal	LIC*
Pakistan	LMIC
Sri Lanka	LMIC
Sub-Saharan Africa	
Angola	LHDC*
Benin	LIC*
Botswana	MHDC
Burkina Faso	LIC*
Burundi	LIC*
Cameroon	LMIC
Cape Verde	LMIC
Central African Rep.	LIC*
Chad	LIC*
Comoros	LIC
Congo, Dem. Rep.	LIC*
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	MHDC
Eritrea	LIC
Ethiopia	LIC
Gabon	MHDC
Gambia, The	LIC*
Ghana	LMIC
Guinea	LIC*
Guinea-Bissau	LIC*
Kenya	LIC
Lesotho	LMIC*
Liberia	LIC
Madagascar	LIC*
Malawi	LIC*
Mali	LIC*
Mauritania	LMIC*

Country	Classification
Mozambique	LIC*
Namibia	MHDC
Niger	LIC*
Nigeria	LMIC
Rwanda	LIC*
São Tomé and Principe	LMIC
Senegal	LMIC*
Sierra Leone	LIC*
Somalia	LIC
South Africa	MHDC
South Sudan	LIC
Sudan	LMIC
Swaziland	LMIC
Tanzania	LIC*
Togo	LIC*
Uganda	LIC*
Zambia	LMIC*
Zimbabwe	LIC
Countries removed since 2012 Index	
Algeria	HHDC
Marshall Islands	UMIC

LIC: Low-income Country
World Bank income classification

LMIC: Lower-middle-income Country
World Bank income classification

LDC: Least Developed Country
UN Human Development Index

MHDC: Medium Human Development Country
UN Human Development Index

HiHDI: High Human Development Country with high inequality
UN Inequality-Adjusted Human Development Index

* LDC with WTO membership[6]

5 Countries newly included countries in the 2014 Index scope

2 Countries removed from the Index scope

Disease Scope

The Index measures pharmaceutical company activities that address diseases that have the greatest global burden and the greatest need in terms of access to medicine. The Index disease scope covers four main categories: communicable diseases, non-communicable diseases, neglected tropical diseases (NTDs) and maternal and neonatal health conditions.

For the 2014 Index, the disease scope has expanded from 33 to 47 conditions, largely to remain up-to-date with important epidemiological trends as reported by the World Health Organization (WHO).[7] As in previous Indices, diseases are included based on their global burden of disability-adjusted life years (DALYs), other WHO classifications, and the relevance of pharmaceutical interventions.

Index diseases are defined according to the WHO International Classification of Diseases (ICD-10) codes.[8] The ICD-10 identifies both primary and secondary diseases, which result from the progression of a primary disease. Primary diseases and related secondary diseases covered in the 2014 Index are listed in Appendix 2: ICD-10 Codes.

Communicable diseases

Inclusion of communicable diseases is based on disability-adjusted life years (DALYs) and relevance of pharmaceutical intervention, according to data from the 2008 update of the WHO Global Burden of Disease.[7] The ten communicable diseases in the scope have the highest global burden of DALYs. Chlamydia is the only addition to the list of communicable diseases included in the 2014 Index, which otherwise remains the same as in the 2012 Index.

Non-communicable diseases

As with communicable diseases, the inclusion of non-communicable diseases is based on disability-adjusted life years (DALYs) according to the 2008 update of the WHO Global Burden of Disease[7] and the relevance of pharmaceutical interventions. All non-communicable diseases from the 2012 Index remain in the scope, enabling comparability and trend analysis over time. In addition, coverage of cirrhosis of the liver has been broadened to include chronic viral hepatitis, as it can develop into cirrhosis of the liver. Two other conditions – schizophrenia and bipolar affective disorder – also have been added, in recognition of the increasing mental health burden in low- and middle-income countries according to the 2008 WHO Global Burden of Disease update[7] and the Global Burden of Disease 2010 study[9]. For the 2014 Index, all cancers remain excluded from the disease scope, as the disaggregated DALY burden for individual forms of cancer did not meet the criteria for inclusion (burden of 13,000 DALYs per 100,000).

Neglected tropical diseases

Neglected tropical diseases (NTDs) are considered neglected partly because the market has failed to adequately address them. They are particularly relevant in poor regions of developing countries, especially in rural areas where many cases go undiagnosed, untreated and unreported. NTDs are therefore included in the Index based on WHO disease classification from the Global Burden of Disease 2010[10] study rather than solely on global DALYs per disease. For the 2014 Index, the scope has been expanded to include food-borne trematodiases (which include fascioliasis), echinococcosis, rabies and cysticercosis, so that all 17 WHO-classified NTDs are now covered. Global DALYs per disease are shown where available.

Maternal and neonatal health conditions

In recognition of the importance of protecting maternal and neonatal health from conception through childbirth, the Index measures the most prevalent maternal and neonatal health conditions. The 2012 Index included a limited number of ICD-10 codes in this category; for the 2014 Index, the number of conditions covered has been significantly increased.

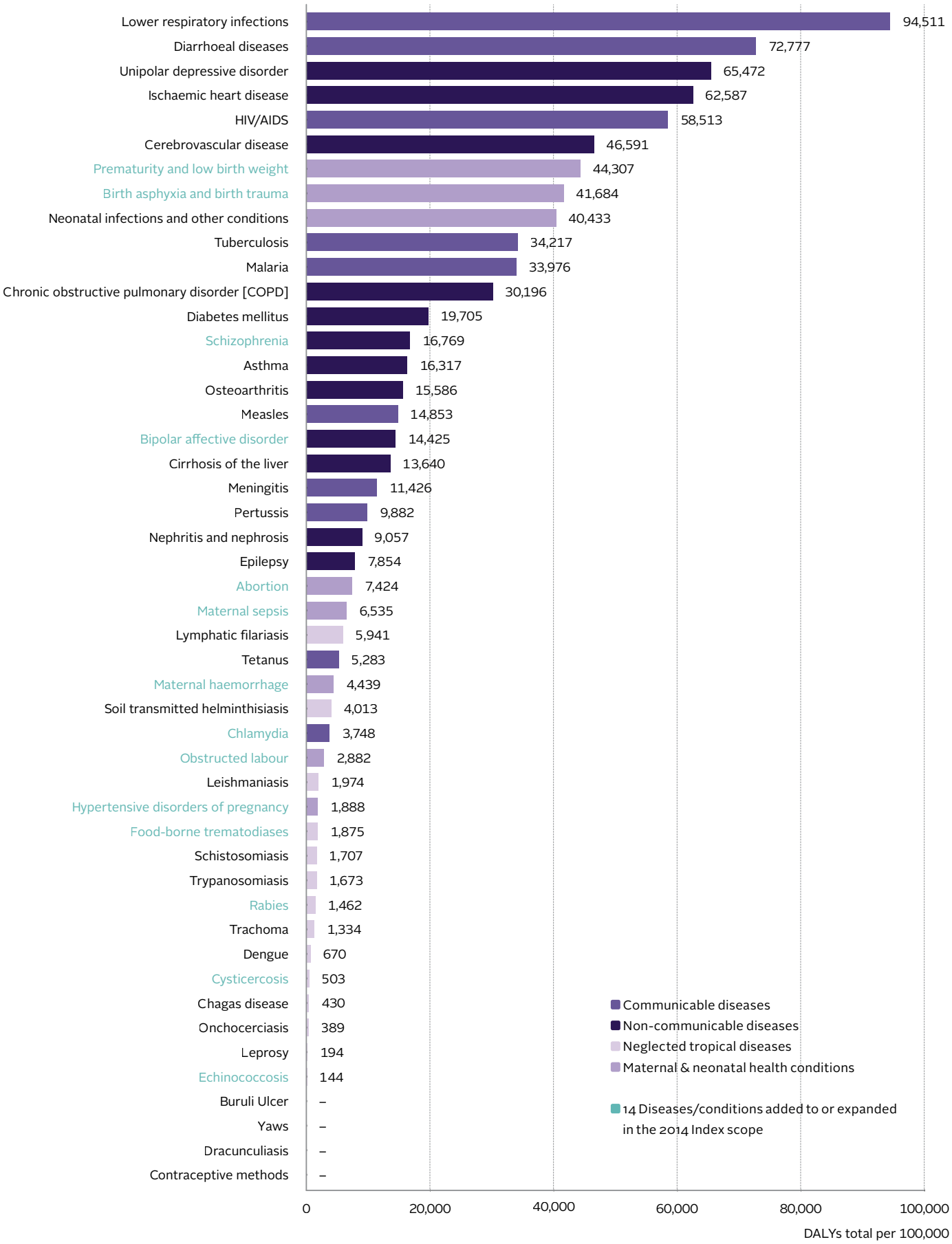
Table 4 **List of diseases included in the 2014 Access to Medicine Index - 47 diseases**

Disease	Global DALYs[7]
Communicable diseases (10)	
Lower respiratory infections	94,511
Diarrhoeal diseases	72,777
HIV/AIDS	58,513
Tuberculosis	34,217
Malaria	33,976
Measles	14,853
Meningitis	11,426
Pertussis	9,882
Tetanus	5,283
Chlamydia	3,748
Non-communicable diseases (12)	
Unipolar depressive disorder	65,472
Ischaemic heart disease	62,587
Cerebrovascular disease	46,591
Chronic obstructive pulmonary disorder [COPD]	30,196
Diabetes mellitus	19,705
Schizophrenia	16,769
Asthma	16,317
Osteoarthritis	15,586
Bipolar affective disorder	14,425
Cirrhosis of the liver	13,640
Nephritis and nephrosis	9,057
Epilepsy	7,854
Neglected tropical diseases (17)	
Lymphatic filariasis	5,941
Soil transmitted helminthisiasis	4,013
Leishmaniasis	1,974
Food-borne trematodiases	1,875
Schistosomiasis	1,707
Trypanosomiasis	1,673
Rabies	1,462
Trachoma	1,334
Dengue	670
Cysticercosis	503
Chagas disease	430
Onchocerciasis	389
Leprosy	194
Echinococcosis	144
Buruli Ulcer	N/A
Yaws	N/A
Dracunculiasis	N/A

Disease	Global DALYs[7]
Maternal and neonatal health conditions (8)	
Abortion	7,424
Maternal sepsis	6,535
Maternal haemorrhage	4,439
Obstructed labour	2,882
Hypertensive disorders of pregnancy	1,888
Prematurity and low birth weight	44,307
Birth Asphyxia and birth trauma	41,684
Neonatal infections and other conditions	40,433
Contraceptive methods	NA

14 Diseases/conditions added to or expanded in the 2014 Index scope

Figure 4 **DALYs of diseases in the 2014 Access to Medicine Index[7]**



Product Type Scope

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

It draws heavily on the definitions provided by the G-Finder 2012 Neglected Disease Research and Development: A Five Year Review[10] and remains unchanged from the 2012 Index. Contraceptive methods are included under maternal health conditions.

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 intended to prevent HIV.
Therapeutic vaccines	This covers vaccines intended to treat infection.
Preventive vaccines	This covers vaccines intended to prevent infection.
Diagnostics	Diagnostic tests designed for use in resource-limited settings (cheaper, faster, more reliable, greater ease of use in the field) are included.
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 that transmit Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.
Platform technologies	Only those products directed specifically at meeting the needs of countries covered by the Index are included. These comprise general diagnostic platforms, adjuvants and immunomodulators, and delivery technologies and devices.

How we measure

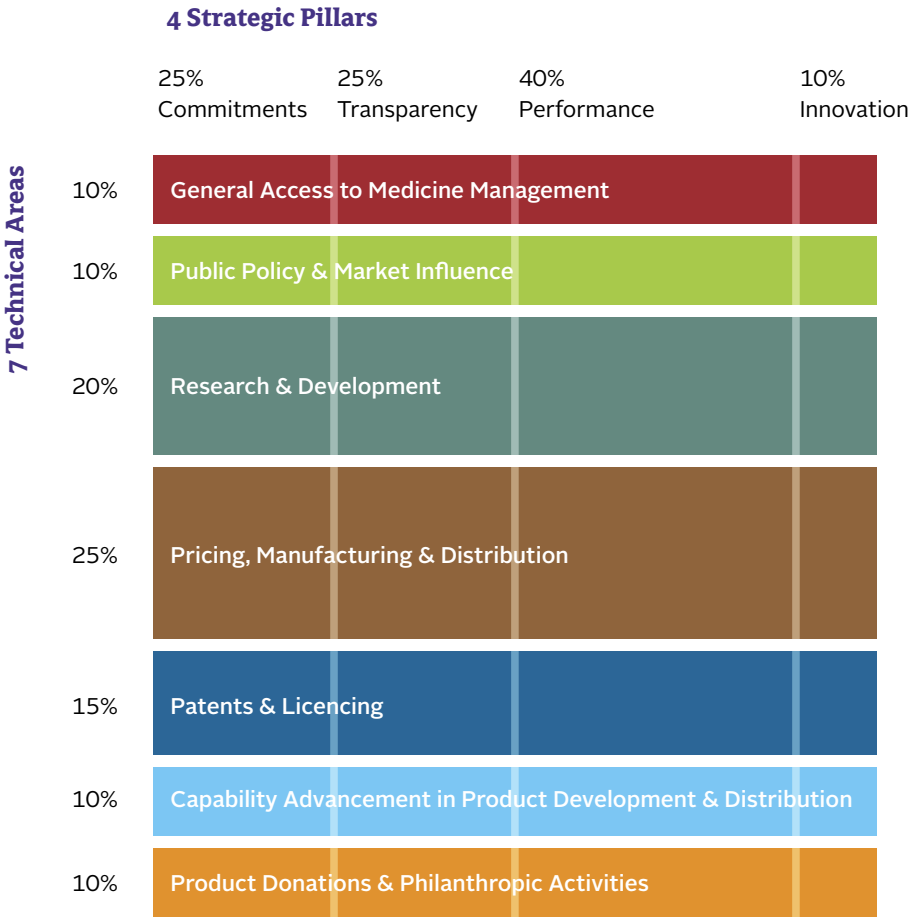
Approach to weights and analysis

The 2014 Index uses the same framework for analysis as the 2012 Index, which enables comparison and trend analysis. The framework is constructed along seven Technical Areas, with indicators measured across four Strategic Pillars. Stakeholders have identified the Technical Areas as areas where companies have the ability to influence access to medicine.

The Index is a relative ranking, where companies are compared with each other rather than against an absolute, ideal state. The highest attainable scores for each indicator do not reflect an ideal characteristic of industry behaviour, but a culmination of stakeholder views of what can be reasonably expected of companies. Additionally, companies do not receive negative scores in indicators, meaning they can never score below zero.

The Index measures company activity in seven Technical Areas that are considered to be the most important areas to focus on for improving access to medicine in countries included in the Index. For the 2014 Index, the Technical Areas and their respective weights remain as follows:

Figure 5 **How we measure**



An in-depth overview of the Technical Areas, including a description of and rationale for the key themes is available on the following pages.

Each Technical Area is assessed along four strategic pillars: Commitments, Transparency, Performance, and Innovation. The strategic pillars are organised to capture different 'stages' of company performance in improving access to medicine. Commitments are the first step to actualising practice as they define what the company values and aims to achieve, for example through a code of conduct, policy, or as a signatory to international agreements. Transparency regarding policies and practices shows the company's intent and allows it to be held accountable for its actions and values. Performance measures what companies actually do, which has the greatest impact on access to medicine, and as such, receives more weight. The final pillar, Innovation, captures how companies create or employ new and unique means to advance and lead industry practice to promote access to medicine.

25% I Commitments

In this pillar, the Index measures companies' values, strategies, policies, and codes of conduct for improving performance related to access to medicine. Companies receive more credit for commitments when they are publicly available in reports, statements, or other verifiable sources. The Index uses information collected in this pillar to track to what extent companies follow through on their commitments.

25% II Transparency

In this pillar, all the indicators focus on whether the companies disclose information regarding their access to medicine initiatives. They receive credit for disclosing information, either publicly or to the Index through one-on-one engagement, regardless of whether the content has a positive impact on access to medicine. This is to encourage companies to be transparent and accountable regarding their policies and activities. Public transparency is given more weight because it promotes accountability to a wider audience.

40% III Performance

This pillar focuses on what companies are actually doing to promote access to medicine through the implementation of initiatives within the seven Technical Areas. It shows where companies put policies and priorities into action to achieve what they committed to do. Because these actions can have the most meaningful impact on access to medicine, this pillar receives the most weight.

10% IV Innovation

As the pharmaceutical industry as a whole looks for ways to enter new markets and address current industry challenges, companies can develop innovative strategies and models that make access to medicine more sustainable. In this pillar, the Index measures what companies do to shape their core competencies to improve access to medicine. It identifies the industry as an important driver of change, recognising that it acts within an environment where multiple actors may influence the access to medicine landscape.

A General Access to Medicine Management

This Technical Area focuses on the integration of access to medicine issues into a company's core strategies, governance structures and management systems. The Index seeks to understand the strategic reasoning behind companies' access to medicine initiatives, as they tend to be most effective and sustainable when developed as part of a clear corporate strategy and supported by a strong rationale. This Technical Area also analyses the company's stakeholder engagement in relation to access to medicine issues, to assess to what extent companies consider stakeholder needs, conditions and perspectives.

2014

The analysis of company access to medicine strategies will be broadened in the 2014 Index to include an assessment of the extent to which companies tailor them to local needs, conditions and expectations. Measurements of innovation in this area will focus on business models that are both economically viable for the company and beneficial for access to medicine.

Managing for access to medicine outcomes

Assigning responsibility and accountability for access to medicine to the board ensures it is integrated into a company's corporate strategy. Clearly formulated quantitative and qualitative time-bound targets that are supported by performance management systems, and incentives to reward activities that promote access to medicine, can improve implementation and assessment.

Stakeholder engagement

Pro-active stakeholder engagement allows for constructive dialogue and knowledge sharing around access to medicine initiatives. Engaging with local stakeholders is particularly useful when tailoring access to medicine strategies to local conditions and needs. Paying attention to stakeholder views can enable companies to address relevant issues and incorporate perspectives.

Access to medicine strategy

Short-, medium- and long-term goals and targets are an important part of company strategies as they drive actions that improve access to medicine. A clear access to medicine strategy that is supported by a strong rationale can contribute to systematic, long-term access to medicine. Public visibility and transparency of companies' access to medicine policies, practices and outcomes enable stakeholders to hold companies accountable.

Innovation in business models

Innovative business models that address the needs of the poor can benefit patients as well as provide economic value for both society and the company.

B Public Policy & Market Influence

This Technical Area seeks to capture how companies deal with matters of business ethics that can influence access to medicine. The measures companies take to gain access to and penetrate markets and/or improve access to medicine can affect competition, prices and supply of medicine. These measures include engagement with policymakers and other stakeholders to influence policies and markets in ways that can affect patients' access to medicine, as well as the many political, regulatory and marketing processes companies employ to represent their interests.

2014

The 2014 Index will include company breaches of codes of conduct or laws surrounding ethical marketing, lobbying, corruption, bribery or anti-competitive behaviour that occur not only in countries covered by the Index, but now anywhere in the world. This is because breaches occurring outside the Index geographic scope can affect access to medicine in countries covered by the Index, but may not be reported or settled through formal public channels within these countries.

Lobbying

Disclosure of policies and activities regarding political and/or financial contributions and lobbying for company interests helps to determine potential conflicts of interest that can inhibit access to medicine. It also allows companies to be held publicly accountable for their actions in this area. Lobbying for additional measures to protect intellectual property in trade agreements is also included in this Technical Area, as this type of lobbying can have a market-wide influence.

Competitive behaviour

Competition between pharmaceutical companies can lead to improvements in affordability and access to medicine. Activities that can limit competition include entering into arrangements with generics manufacturers to delay their market entry, price collusion, or the use of data exclusivity laws. Waiving data exclusivity when there is a need for medicine can accelerate the market entry of products from competitor manufacturers.

Ethical marketing

Enforcing strong ethical marketing policies and practices can promote access to medicine by encouraging safe and rational use of medicine. Effective management of such codes, including monitoring and auditing of marketing and promotional programmes, improves adherence. Disclosure of marketing activities such as payments to healthcare professionals and key opinion leaders related to marketing practices increases the ability of the public – and especially patients – to determine where potential conflicts of interest or unwanted influence on the market may exist.

Anti-corruption and anti-bribery

Corrupt practices can affect patient safety and health, divert valuable resources from public health needs and erode confidence in companies. Strong anti-corruption and anti-bribery codes of conduct and enforcement of such codes internally and with external parties enhances public accountability.

Innovation in public policy and market influence

Innovative means of establishing and promoting ethical business practices in areas such as lobbying, pro-competitive practices, marketing, and anti-corruption and anti-bribery can support access to medicine. Innovative ways of advocating for improved access to medicine in developing countries without a conflict of interest and without losing profitability can foster sustainable solutions in this area.

C Research & Development

This Technical Area analyses in-house and collaborative research aimed at developing new or adapted products for high-burden diseases. The development of these products represents an important step in making them available for people in countries included in the Index and is therefore a crucial factor in improving access to medicine. This Technical Area also seeks to capture company policies and behaviour that influence access to medicine within the R&D processes. This covers clinical trial conduct, the provision of post-trial access to medicine, compliance with globally accepted standards and data transparency.

2014

The 2014 Index will place greater emphasis on how companies assess and target local public health needs as part of their R&D strategy. Additionally, measures of clinical trial conduct and trial-related disclosure have been expanded to include in-house trials as well as outsourced ones.

Product development

Product development refers to the creation of new drugs, vaccines and diagnostics that were previously unavailable or ineffective, as well as to the adaptation of existing products to suit conditions in the countries covered by the Index. Aligning the development of new and adapted products with international priorities and local needs can lead to the creation of novel and improved products. Additionally, new and adapted platform technologies can greatly improve the quality, delivery and efficacy of such medicine, and sharing such technologies with research partners can enable more and faster product development.

Collaborations and knowledge sharing

Engaging in collaborative R&D partnerships in any phase of product development enables resource sharing and mitigates risk, which can bring products to the market and patients more quickly. Sharing of intellectual property, knowhow, expertise, compounds, resources, processes and technologies can facilitate more efficient product discovery and development. The terms and conditions of partnerships can greatly affect the rate at which and terms under which products can be developed, and the disclosure of these terms allows parties involved to be held more accountable.

Clinical trial conduct, data transparency and post-trial access to medicine

Conducting ethical clinical trials, whether in-house or outsourced to third parties, facilitates appropriate treatment of patients and increased confidence in products. Compliance with internationally accepted standards such as Good Clinical Practice[11] and the Declaration of Helsinki[12] for both in-house and outsourced clinical trials can ensure ethical conduct towards trial participants, enhances the quality of data and improves patient safety. Effective management of clinical trial procedures through regular monitoring and auditing encourages compliance with codes of conduct, reducing the risk of breaches and harmful consequences. Sharing all data from trials conducted in countries included in the Index, regardless of outcome and whether run in-house or through a third-party, enhances research potential while limiting the need for additional investments. Publication of these data also increases the accountability of those who conduct clinical trials and allows healthcare providers, academics and patients to engage with them for further research and discussion. When products are developed in countries included in the Index geographic scope, providing patients with post-trial access to these products improves medicine availability.

Innovative R&D models

Innovative R&D models that target current gaps and issues in product and technology development can lead to improvements in the rate, quality and quantity of medicine that emerges from R&D pipelines.

D Pricing, Manufacturing & Distribution

This Technical area centres on how companies attempt to make products affordable and on the efficiency with which products are produced and distributed. Access to medicine is restricted if products are priced above what patients are able to pay. In addition to multiple factors that influence a product's price, both the prices set by pharmaceutical companies and the mark-ups added along the supply chain can significantly influence product affordability.
Along with effective price-setting strategies, brochure and packaging adaptation, product registration and timely filing for market approval can limit problems throughout the supply chain and improve access to medicine.

2014

The 2014 Index will measure all equitable pricing strategies, instead of only tiered pricing programmes, as was measured in the 2012 Index. In addition, it will assess how companies design, implement and monitor pricing schemes designed to maximise affordability by examining disclosure of volume of sales and price points intended for poor population segments.

Equitable pricing strategies

Pricing medicine in a way that addresses local needs can improve access to medicine for poorer population segments within the Index's geographic scope. Such pricing strategies can include tiered pricing schemes that differentiate product prices both between and within countries, and other equitable pricing schemes, typically based on socio-economic factors.

Accountability for sales agents' pricing practices

Mark-ups can significantly increase the price patients pay for medicine. Monitoring and auditing pricing practices of sales agents wherever possible can improve access to affordable medicine.

Brochure & packaging adaptation

Tailoring product and packaging attributes enhances the ability of patients to gain access to products and use them in the most effective way, and thereby facilitates rational use. This includes adapting brochures and packaging to local circumstances such as literacy levels, languages, cultural considerations and environmental conditions. Distinct packaging, branding and other types of adaptation also help limit diversion of differentially priced products between population segments.

Product registration and filing for marketing approval

For eligible, relevant and necessary products, applying for WHO Prequalification; seeking tentative approval from the US Food and Drug Administration, European Medicines Agency or other stringent regulatory authorities; and wide and rapid registration and filing for marketing approval are important steps that can facilitate timely access to products.

Drug recall policies & practices

When carried out effectively according to the global standards prescribed by WHO, product recalls can ensure that unsafe products are removed from the market as efficiently as possible. Public disclosure of recalls can enable patients who have obtained such medicine prior to the recall to gain access to the necessary care to limit the negative impact of recalled drugs.

Innovation in equitable pricing, manufacturing and distribution

Innovative equitable pricing and affordability models, including financing mechanisms, can promote sustained delivery of affordable products. In addition, innovation that addresses manufacturing and distribution issues can minimise costs, maximise efficiency and facilitate adequate supply of quality medicine.

E Patents & Licencing

This Technical Area focuses on companies' intellectual property protection strategies and practices, including those pertaining to the rights of countries to utilise Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities outlined in The Doha Declaration[13], and the possible impact of these practices on access to medicine. Engaging in pro-active intellectual property strategies for diseases included in the Index can make medicine more affordable and accessible.

2014

In 2014, the number of countries in which the Index assesses whether companies refrain from filing or enforcing patents has increased to incorporate low-income countries (LICs) and lower-middle-income countries (LMICs), in addition to Least Developed Countries (LDCs) covered by the Index. In addition, the Index will assess terms and conditions in non-exclusive voluntary licences and non-assert declarations and implications on access to medicine.

Intellectual property strategy

Allowing or enabling competition from generics manufacturers can improve affordability of quality medicine in countries covered by the Index. Research-based companies can facilitate such competition by refraining from patenting or enforcing patents in a manner that negatively affects access to medicine in countries with the greatest need. They can also do so by issuing access-oriented non-exclusive voluntary licences or non-assert declarations, engaging in innovative patent pooling ventures, and engaging in public health-oriented technology transfer and licencing agreements. Disclosure of patent filings and the terms and conditions of licences enables manufacturing parties to, for example, better navigate licencing negotiations.

Intellectual property aspects of trade

Transparency surrounding a company's position regarding the TRIPS agreement and the use of TRIPS flexibilities demonstrates its consideration of intellectual property challenges that affect access to medicine and allows a company to be held publicly accountable for its stance. By refraining from practices that challenge the TRIPS agreement or that challenge a country's use of TRIPS flexibilities, or by implementing licencing terms that support countries' rights in this area, companies can show their support of the TRIPS agreement and the rights to use TRIPS flexibilities.

Innovation in intellectual property strategies

Development and implementation of innovative models of intellectual property management can increase competition and the supply of medicine.

F Capability Advancement

This Technical Area focuses on the long-term, systemic engagement of companies with local stakeholders to strengthen local capacity to improve quality and accessibility of medicine. This includes activities related to research, development, production and distribution of medicine, as well as the local monitoring of product safety once it is on the market. Such activities can be implemented through partnerships and collaborations with local actors, and by contributing and/or transferring skills and expertise in areas where a need exists.

2014

The 2014 Index will place more emphasis on capability advancement initiatives that are aligned with local needs, including collaborations to strengthen the capacity and expertise of staff involved in supply chains and R&D.

Capacity building in Quality Management Systems and manufacturing standards

Access to medicine in countries covered by the Index can be improved through sustainable local production of quality medicine. Local capacity in manufacturing can be improved by training local in-house and third-party manufacturers to comply with globally accepted standards such as the WHO Good Manufacturing Practices (GMP)[14] or equivalent international/internal quality standards. It can also be improved by adequate technology transfer, and by implementing efficient Quality Management Systems (QMS). Including stringent international quality standards in contracts with local manufacturers can help to ensure that locally manufactured products are of sufficient quality, promoting increased access to safe and effective medicine.

Capacity building in R&D

Partnerships and collaborations with public sector research organisations and/or academic institutions in countries that the Index covers can contribute to the growth of local clinical trial and product development capacity. Such initiatives can also include training the necessary clinical, scientific or technical researchers and managers to administer these processes locally.

Capacity building in supply chain management

Efficient supply chains are needed to ensure quality products reach the people who need them. Strengthening locally appropriate supply chain capabilities can reduce product diversion, deterioration, stock-outs and counterfeiting. Additionally, a strong local supply chain can prevent information gaps, which improves overall forecasting and procurement management.

Capacity building in pharmacovigilance

Pharmacovigilance systems are an important driver of product quality and safety once medicine is on the market. Companies can contribute to strengthening national and regional pharmacovigilance systems by collaborating with local institutions to build pharmacovigilance capacity. This includes providing post-marketing surveillance data to governments to help them build strong central information repositories in line with national or regional plans.

Initiatives to build other capacities

Additional on-the-ground initiatives outside of the pharmaceutical value chain can help make products more accessible to patients, provided conflict of interest is fully absent. This may include collaborating with or contributing to initiatives run by reputable international organisations that are working with local stakeholders.

Innovation in local capability advancement

Innovative approaches to improving local capabilities in quality and supply chain management are important for improving product affordability, quality and overall access to medicine. Innovative ideas can focus on securing the pharmaceutical supply chain, demand forecasting, pharmacovigilance, and local quality management, as well as R&D and product development capacities.

G Product Donations & Philanthropic Activities

This Technical Area assesses how companies implement the donation of products aimed at controlling, eliminating and eradicating diseases affecting those most in need. It also focuses on philanthropic activities that bring financial assistance to people and organisations in the countries within the Index geographic scope. Successfully implemented product donations and philanthropic activities that are based on a clear underlying strategy can significantly contribute to improved health outcomes for those most in need.

2014

In the 2014 Index, this Technical Area will place more emphasis on strategic and integrated approaches towards product donations and philanthropic activities, including needs-based initiatives and impact assessments that determine effectiveness.

Product donations

Single- or multi-drug donations carried out in emergency situations or as part of a control, elimination or eradication programme can greatly decrease the burden and spread of disease among those who would not otherwise have any access to the necessary products. Product donations tend to be most effective when they are carried out in accordance with a sustainable strategy, supported by adequate supply and commitment, and aligned with local needs and priorities. Guidelines such as the WHO Guidelines for Medicine Donations[15] and the Partnership for Quality Medical Donations (PQMD) Principles and Standards[16] outline good manufacturing practices, criteria for suitable products and monitoring and evaluation standards for effective product donations. Following these globally accepted guidelines promotes access to safe, suitable products and improves the efficiency of product delivery to the intended recipients. Additionally, coordination and collaboration with national governments, NGOs, WHO and/or local organisations can ensure appropriate donations strategies and lead to successful delivery outcomes. Continual outcome reporting and health impact assessments can also assist in determining whether donations are implemented appropriately to address health needs.

Sustainable philanthropy

Financial support of local people and organisations can significantly enhance countries' local capacities. Investment in activities that align with global health priorities, with a clearly defined strategy, can improve local healthcare infrastructure and have a long-term positive impact on access to medicine. Monitoring and impact assessment are important for determining the effectiveness of activities in a company's philanthropic portfolio.

Innovation in donations and philanthropy

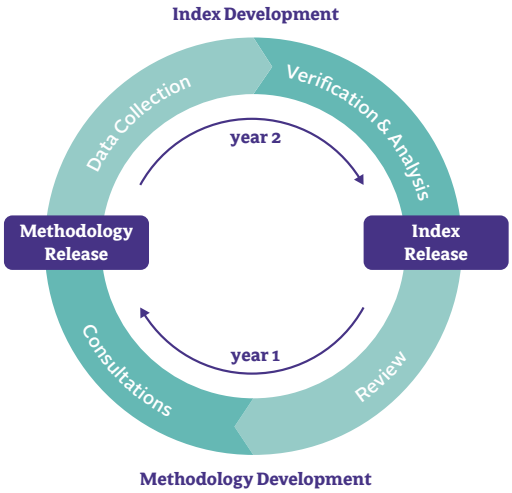
Innovative approaches to product donations and philanthropic activities can improve efficiency and increase the impact of programmes, enabling them to better address local challenges. Using innovative approaches to scale up product donations can allow such programmes to reach even more people in need. Methods to improve local healthcare infrastructure and facilitate better patient outcomes can help to reduce the need for long-term donations and philanthropic activities.

Refining the methodology

Developing the methodology

The Access to Medicine Index is a product of a two-year process known as the 'Index cycle'. During year one of the cycle, the Foundation focuses on reviewing and revising the Index methodology based on expert stakeholder feedback. Year two is spent collecting and analysing pharmaceutical company data according to the latest Index methodology, with the help of an independent research partner. The results are then published in a new Access to Medicine Index, and the cycle begins again.

Figure 6 **The Index cycle**



In 2013, the Foundation conducted a thorough review and extensive consultations to ensure that the 2014 Index reflects evolving access to medicine priorities while maintaining consistency with previous Index iterations for the purposes of comparison and trend analysis.

Internal and external review

The Index team began by conducting an extensive quantitative and qualitative analysis of the methodology and data from past indices, including:

- **Statistical analysis** to determine quality and robustness of indicators and related questions used to gather data. The analysis, the rigour of which was stepped up for the 2014 Index, used correlation matrices, response rate analysis and examination of the distribution of company performance per indicator and clusters of indicators. Moreover, the Index team analysed the most predictive and discriminatory indicators, highlighting those to be retained for longitudinal trend analysis and key areas for methodological improvement.

- **Qualitative analysis** of the indicators, analysing all data received and company response level to specific indicator questions. The relevance of these indicators to the access to medicine landscape was assessed through a literature review as well as through stakeholder consultations (see Appendix 1 for an overview of stakeholder engagement). The companies, countries, diseases and product types included in the Index were (re)evaluated using the latest relevant data (see What we measure).

In addition to the internal analysis, external feedback was collected from experts, stakeholders and the public through various channels, including a public online survey, calls with companies ranked in the 2012 Index and various stakeholder meetings (See Appendix 1 for more detail). This external feedback was incorporated into both the qualitative and quantitative aspects of the review process as well as subsequent consultations with the Technical Subcommittees (TSCs) and the Expert Review Committee (ERC).

Expert committee consultations

The Foundation follows a formal process of consultation with committees that provide strategic guidance, technical expertise and insight on stakeholder perspectives to contribute to the Index methodology. Technical experts were convened as Technical Subcommittees (TSCs) to give input per Technical Area. The Expert Review Committee (ERC), comprising experts from various stakeholder groups, provided strategic guidance for the overall methodology and approved the finalised methodology for the 2014 Index in September 2013.

The Foundation shared its proposals regarding the 2014 Index methodology with the members of each committee during a series of separate meetings. Each committee responded to these proposals with recommendations, many of which were subsequently incorporated into the 2014 Index methodology. For more detail on these committees' roles in the methodology development process, refer to Appendix 1 (p. 55).

Considerations and outcomes

Using the results of the internal indicator analysis, external feedback and committee consultations, the Index team refined the indicators in the 2012 Index to arrive at a new set of 95 indicators for the 2014 Index. These indicators are listed starting on p. 37. Throughout the methodology review and development process, several key themes for discussion emerged. The considerations and outcomes of some of these noteworthy discussion topics are highlighted below.

More meaningful measures of affordability

The 2012 Index indicated that more companies are using tiered pricing schemes and applying them to a broader range of products and in more countries. However, the size of the price differential between markets and the proportion of products covered in different countries were not ideal indicators, as the price offered to the lowest population segments could still be unaffordable. The internal review suggested that the focus of analysis should be shifted towards affordability rather than comparison of pricing programmes.

However, evaluating the affordability of pharmaceutical products presents a formidable challenge, as there is no consensus on standards, definitions or reference prices. This issue was discussed both in the Technical Subcommittee and Expert Review Committee, and feedback was also collected from many other experts. This topic was also debated at the Strategic Access to Medicine Workshop and the Foundation's stakeholder dialogue in Ghana in an attempt to identify more meaningful key performance indicators of affordability.

All stakeholders consulted agreed that affordability can be defined as the end user's ability to pay for products, and that a true measure of medicine affordability is only possible with a universally accepted reference price for each product. Participants at the Ghana meeting recognised that ensuring affordability is difficult for multiple reasons, with solutions requiring the involvement of multiple stakeholders. It was agreed that companies continue to play an important role, as they can set prices and develop equitable pricing initiatives based on strategies that – ideally – meet the needs of local communities and reflect the local context. Participants recognised these strategies are not easy to implement, as one size does not fit all products, diseases, geographic areas or healthcare systems.

As a result of the internal review and external consultations, it was agreed that volume of product sales to segments of populations can be useful as a measure of affordability, as it can help to capture the degree of price reduction and the extent to which a treatment is available in the poorest markets. However, factors such as therapeutic area and market size should be taken into account when doing so, as there are also cases for which sales volume is not meaningful (e.g. for treatment of secondary diseases).

With the diversity of diseases covered in the portfolio of marketed products and the variations within countries where companies are active, using a measure of price point of all prod-

ucts as a way to compare affordability of products is considered impossible at this point. The proposed direction for the 2014 Index methodology was to assess the strategy behind price decisions made by companies, including any internal measures of affordability such as uptake of products within different population segments. It was also concluded that volume of sales in countries covered by the Index should be tested as a potential measure of affordability.

The Index team piloted proposed measurements of pricing strategies with companies included in the Index to assess their feasibility. Of the 21 companies invited, eleven provided feedback about the level and type of data they could provide. Their input led to adjustments of the final indicators and corresponding data collection points.

As a result of this in-depth review, the 2014 Index methodology measures the rationale behind companies' equitable pricing strategies that aim to make products affordable for the poorest population segments. Analysis of equitable pricing schemes now includes disclosure of volume of sales to the poorest segments. This shift in focus eliminated the assessment of tiered pricing differentials. The Index will now capture all forms of equitable pricing strategies where companies include socio-economic needs and affordability in determining commercial pricing for diseases in the Index geographic scope.

R&D based on a public health need

The 2012 Index found that many companies have increased investment in relevant R&D in diseases covered by the Index, often through increased collaboration and knowledge sharing. R&D pipelines are thus addressing the need for more and better products in countries in the Index geographic scope. However, R&D continues to be important to monitor as there is still room for improvement in the availability of effective medicine for treating, preventing or diagnosing many diseases in countries covered by the Index.

The Index team's internal analysis and discussions regarding R&D yielded two main topics for further examination: the extent to which companies are addressing unmet needs in countries covered by the Index in their R&D portfolios, and clinical trial conduct in countries covered by the Index. The needs met by R&D pipelines could ideally be measured against an internationally agreed upon priority R&D agenda such as the WHO Priority Medicines Report[17], but such a standard is not currently available for all diseases and geographic regions. Moreover there is a lack of consensus regarding priorities in many areas of R&D. The 2014 Index will assess how companies' R&D pipeline (potentially) addresses public health needs. Best practices for collaboration were also discussed to differentiate between efforts that are truly collaborative and those that are not.

The second issue identified as a result of the Index team's internal analysis underwent a separate round of discussions with various experts and stakeholder group representatives, including the TSC and the ERC. The 2012 Index noted that while many companies have followed the internationally accepted guidelines for clinical trials[11,12], there was still a need for more stringent auditing and enforcement of clinical trial codes of conduct in the countries included in the Index. The importance of clinical trial data availability and ethical considerations for clinical trials conducted in countries covered by the Index were emphasised during these discussions and consequently given more attention in the 2014 Index methodology. The issue of post-trial access to medicine also continues to be important in the 2014 Index methodology, as sharing best practices in this area can increase access to people living in countries where clinical trials have been conducted.

Capturing (un)ethical company behaviour, wherever it occurs

The 2012 Index found that companies show more commitment to public accountability, stakeholder engagement and high standards of business ethics. However, recent allegations of bribery and corruption in China have highlighted the need for better management and enforcement of ethical business practices and public accountability. Companies can support policies and markets in a manner that promotes access to medicine, particularly by sharing

best ethical business practices in anti-corruption, anti-bribery and ethical marketing in countries where the regulations and enforcement may be weak or lacking. The 2014 Index methodology therefore places greater emphasis on companies' monitoring and auditing of ethical business practices.

The underlying issue in this area is the lack of public information available to assess company behaviour, as market influence often occurs through informal channels and can take place everywhere in the world. Many experts and stakeholders offered their input on how to capture lobbying and/or breaches, regardless of where they occur. As a result, the scope of relevant breaches has been expanded to include settlements, court cases, and fines that occur anywhere in the world, rather than solely in countries included in the Index.

The discussion with the TSC focused on differentiating between company behaviour that complies with the law and behaviour that is either favourable or unfavourable toward access to medicine in the Index geographic scope. Given the importance of capturing the effect of companies' practices on access to medicine, indicators in this Technical Area now include both legal and referenced definitions of terms related to Public Policy and Market Influence.

Reflecting a changing industry in the IP landscape

Since the publication of the 2012 Index, there have been important developments in the intellectual property landscape, such as the extension of the TRIPS implementation period for Least Developed Countries (LDCs). Additionally, one of the biggest drivers of change in the pharmaceutical industry is the development of patent systems in emerging markets—Brazil and South Africa most notably—which, like India previously, are reshaping to be more enabling of generic competition.

In the past years, research-based companies have made more acquisitions, joint-ventures and licencing deals with local generic manufacturers, giving companies an opportunity to tap into emerging markets while recouping R&D costs and thus improving access to medicine for people living in developing countries. Since these alliances can facilitate more efficiency in production and distribution, the stakeholders and TSCs involved in discussions on this topic felt that the 2014 Index should emphasise the importance of technology transfer and socially responsible licencing (SRL). The 2014 Index methodology now includes an indicator that investigates how the terms and conditions of licences support access to medicine in countries covered by the Index.

TSCs also felt that enabling the manufacture and distribution of affordable drugs in the countries covered by the Index could be facilitated by refraining from filing or enforcing patents not only in LDCs represented in the WTO but also in all Low-Income Countries (LICs) and Lower-Middle Income Countries (LMICs). The scope of countries examined in indicators relevant to patent filing and enforcement has thus been updated accordingly in the 2014 Index methodology.

Expanding the scope of the Index

When considering any change in scope, the Index team takes a methodological approach. It received considerable feedback from its online survey on the need to increase the scope of the Index to include more companies - including generics manufacturers – and more diseases, including mental health conditions, cancers and hepatitis. Both the Index team and external stakeholders also recognised the need to address disparity within countries and include higher-income countries that have a large number of people living in poverty.

The company scope for the 2014 Index was only changed to reflect splits, mergers or a change in the relevance of companies' products to the disease scope. It was proposed that the Index could encourage companies that have no operations in countries in the Index geographic scope to start doing so if they have relevant products in their portfolio. Such companies may be considered for assessment in future iterations of the Index.

Countries in the Index geographic scope were assessed using three selection criteria: World Bank classification[3], the UN Human Development Index[4] and the UN Inequality-Adjusted Human Development Index (IHDI)[5]. Discussions regarding the addition of IHDI criteria led to a unanimous ERC recommendation to include four new countries with a wide disparity of human development: Brazil, Columbia, Ecuador and Venezuela. Future iterations of the Index could see more countries included based on this set of criteria.

Since the majority of medicines in countries covered by the Index, including the majority of those in the most recent WHO essential medicines list[18], are generics, the Index methodology continues to capture products sold by generics subsidiaries of research-based companies, and may embark on an Index solely for generics companies in the future.

The past years have seen roadmaps and calls to action to control, eradicate and eliminate priority diseases. Notable are the London Declaration[19] in 2012, which has led to many global stakeholders stepping up efforts to address neglected tropical diseases; the WHO NCD Action Plan 2013-2020[20] and Sixty-Sixth World Health Assembly's Comprehensive Mental Health Action Plan for 2013-2020[21] which aims for better policies and practices in these areas in the coming years; and the Millennium Development Goals[22] and post-2015 priority setting discussions for the next round of MDGs, which include collaboration, data availability and improvements in maternal and child health. The 2012 Index found that companies are moving towards more targeted needs-based programmes to align with such calls in areas such as drug donations. To continue to encourage companies to address priority diseases in alignment with such multi-lateral movements, the 2014 Index methodology includes diseases based on their global burden, according to the latest WHO data[7]. As a result, two mental health conditions (schizophrenia and bipolar affective disorder) and hepatitis (as part of liver cirrhosis) were added to the scope. Although the aggregate global burden of cancer is high, it is not included in this year's methodology because individual forms of cancer – often requiring specialised diagnostics and treatments – do not have a high enough disease burden to be included in the 2014 Index methodology.

Changes in depth and breadth to better measure progress

The role of pharmaceutical companies in addressing the issue of access to medicine is complex and multifaceted. By measuring interlinked aspects of company behaviour in seven Technical Areas, the Index seeks to capture changes in areas where companies can meaningfully contribute to the advance of access to medicine. The 2014 Index methodology as a whole has been adjusted to address a complex, evolving landscape and several strategic changes have been made.

The 2012 Index showed that companies' approach to access to medicine is more organised and that products and pipelines are meeting more needs and that the pharmaceutical industry as a whole is gradually progressing in all areas. What remains to be seen is how the increasing number and scope of company initiatives will affect access to medicine in the countries included in the Index, but this impact measurement falls outside the Index's current framework of analysis. The 2014 Index can, however, place greater emphasis on how companies create and manage their access to medicine strategies in alignment with local needs and priorities, as well as how companies measure the outcomes of their programmes and, in turn, use these measurements to update their access strategies.

The 2014 Index methodology thus focuses on how local stakeholders and priorities inform and shape company strategies and the alignment of these strategies to global, regional, national and local priorities. The 2012 Index findings suggest that strategies that include this continuous feedback loop are already being developed and implemented within several companies, as reflected in the growth of stakeholder engagement, leadership and innovation of policies and processes in certain key areas.

To effectively measure company progress, the changing pharmaceutical industry landscape and blurring lines between generics and research-based companies must be reflected in the Index methodology. The 2014 Index methodology places more emphasis on the need for access to medicine in countries covered by the Index to become an integral part of 'business-as-usual' within companies. As a result, the revised methodology seeks to capture how well companies maintain profitability while fostering adequate access to medicine in the countries covered by the Index, thus facilitating sustainability in terms of health and economic benefits for local health systems as well as economic benefits for pharmaceutical companies and associated shareholders. This is evident in the ways in which indicators have been adjusted throughout most of the Technical Areas, including the decision to shift the focus of the Innovation pillar within General Access to Medicine Management Technical Area to business model innovation.

A lack of consensus on definitions and standards in many areas can make it difficult to find a clear, reasonable definition of a pharmaceutical company's role. In order to accommodate this in the Index framework, the 2014 Index methodology includes updated definitions, using both universally accepted definitions and working definitions to cover terms used when measuring and analysing access to medicine. Definitions used in the 2014 Index are listed in Appendix 3: References, Definitions & Acronyms (p. 65).

Indicators

Indicator-level changes

A list of all 95 indicators that will be used to assess companies in the 2014 Access to Medicine Index is available in the following pages. Indicators were retained, changed or deleted based on the following guidelines:

Indicators were retained when:

- The specific data available was of sufficient quality;
- They remained relevant to access to medicine; and
- In some cases, when they were usable for longitudinal analysis.

Indicators were considered for change when:

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

A General Access to Medicine Management

	2014 Indicator	Change/ rationale
A.I	**Commitments - 25%**	
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 for Index Countries.	
A.I.2	**Stakeholder engagement** The company commits to work with relevant stakeholders, including universities, patient groups, local governments, employees, local and international NGOs and peers with the aim of improving access to medicine.	
A.II	**Transparency - 25%**	
A.II.1	**Strategy: policies & practices** The company reports on its access to medicine strategy and discloses its overall rationale for its access to medicine activities.	Minor Change More focus on access to medicine strategy.
A.II.2	**Strategy: policies & practices** The company discloses goals and targets (both qualitative and quantitative) and performance measures for its access to medicine practices related to the Index Countries.	Minor Change Clarification of wording.
A.III	**Performance - 40%**	
A.III.1	**Governance: management structures, performance management & incentives** The company has a performance management system including quantitative targets to implement and monitor its access to medicine strategy in the Index Countries.	Minor Change Clarification of wording.
A.III.2	**Stakeholder engagement** Senior management participates in public debate and engages with different stakeholder groups with the goal of dialogue and knowledge sharing aimed at improved access to products for the Index Diseases in the Index Countries (the company organises/ facilitates/ hosts relevant conferences, symposia, workshops etc. attended by senior management).	Minor Change Clarification of wording.
A.III.3	**Governance: performance management & incentives** The company has internal incentive structures to reward effective delivery of initiatives that improve access to medicine in the Index Countries for the Index Diseases.	

	2014 Indicator	Change/ rationale
A.III.4	**Strategies, stakeholder engagement** The company has a system in place to incorporate external and local (market) perspectives on access to medicine needs in the development and implementation of access strategies.	New 2014 To capture needs-based access to medicine strategy based on local perspectives (Piloted).
A.IV	**Innovation - 10%**	
A.IV.1	**Innovation in general access to medicine management** The company has contributed to the development of innovative business models that meet the needs of patients in Index Countries.	Major Change To capture business model innovation that is economically viable and beneficial for access to medicine.

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

B Public Policy & Market Influence

	2014 Indicator	Change/ rationale
B.I	**Commitments - 25%**	
B.I.1	**Endorsement of competition** The company commits to endorse and support competition and to refrain from anti-competitive practices or pursue arrangements with generics that might delay their market entry in the pharmaceutical markets in the Index Countries for products related to the Index Diseases.	
B.I.2	**Non-pursuit of data exclusivity** The company's policies and practices surrounding data exclusivity do not impede access for products related to the Index Diseases in the Index Countries.	Minor Change To emphasise the utilisation or waiver of data exclusivity laws, which can impede or promote access.
B.I.3	**Ethical marketing** The company commits to enforce a code of conduct regarding ethical marketing practices for all sales agents and local third party distributors and contractors consistent with its own internal standards and any existing industry standards.	Minor Change Clarification of wording to highlight the importance of maintaining ethical marketing standards that are at minimum cohesive internally with industry standards.
B.I.4	**Anti-bribery/anti-corruption** The company commits to proactively engage in fighting corruption through its internal anti-bribery and anti-corruption codes of conduct, external commitments and memberships.	
B.II	**Transparency - 25%**	
B.II.1	**Lobbying** The company is transparent about its lobbying positions, political contributions and positions it seeks to promote where it has an impact on access to medicine in Index Countries, either directly or indirectly.	Minor Change Clarification of wording to increase standards and emphasise transparency beyond company policy.
B.II.2	**Influence** The company discloses membership and financial support of trade associations, think tanks, interest groups, or other organisations, including any potential governance conflict of interests, through which it might advocate its public policy positions at regional, national or international levels where relevant to access to medicine in the Index Countries.	Minor Change Clarification of wording to specify the groups or institutions of interest.
B.II.3	**Influence** The company discloses its board seats at industry associations and advisory bodies related to health access issues for the Index Diseases and the Index Countries.	

	2014 Indicator	Change/ rationale
B.II.4	**Endorsement of competition** The company discloses policies related to competition in areas such as data exclusivity, patent extensions or other arrangements with generic companies that might delay their market entry for Index products in the Index Countries.	
B.II.5	**Ethical marketing** The company publicly discloses detailed information regarding its marketing and promotional programmes in the Index Countries, such as payments to or promotional activities directed at physicians or other key healthcare professionals or opinion leaders.	Minor Change Clarification of wording to emphasise the importance of public disclosure.
B.II.6	**Ethical marketing, anti-bribery/ anti-corruption** The company voluntarily discloses all information regarding its breaches of internal and internationally recognised codes of conduct for ethical marketing, lobbying, bribery and/or corruption in any country in the last two years, including litigations related to marketing practices in the Index Countries.	Minor Change From five years to two years to avoid overlap of data collection and analysis between Indexes. Scope of countries expanded.
B.III	**Performance - 40%**	
B.III.1	**Lobbying, ethical marketing, anti-bribery/ anti-corruption** The company has been in breach of any national or international codes of conduct in any country in relation to lobbying, ethical marketing and/or bribery and corruption.	Minor Change Scope of countries expanded.
B.III.2	**Endorsement of competition** There is evidence* of the company's anti-competitive behaviour** that impacts access to medicine based on fines or litigation records during the past two years. *evidence to refer to fines or reports/controversies **excluding all IP anti-competitive practices	Minor Change From five years to two years to avoid overlap of data collection and analysis between Indexes. .
B.III.3	**Lobbying, ethical marketing, anti-bribery/ anti- corruption** Part a - The company has taken disciplinary action against third parties or employees who violate its code of conduct for ethical marketing or lobbying and anti-corruption. Part b (qualitative-no scoring) - The company has established stringent enforcement mechanisms for disciplinary action against third parties or employees that violate its codes of conduct for ethical marketing or lobbying and anti-corruption.	

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

	2014 Indicator	Change/ rationale
B.III.4	**Lobbying** Is there evidence that the company lobbies national or regional governments, or other companies and their trade associations, either directly or through third parties, to adopt additional measures to protect intellectual property and/or patent systems beyond the minimum standard outlined in the TRIPS agreement (e.g. data exclusivity, etc.)?	New 2014 Moved from Patents & Licencing section as indicator focuses on lobbying. Wording changed to be more specific of expectations of company performance surrounding trade negotiations.
B.IV	**Innovation - 10%**	
B.IV.1	**Innovation in public policy & market influence** The company has adopted an innovative (unique in the sector), sustainable approach to improving ethical business performance and interactions in Index Countries in areas relevant to increasing access to medicine such as marketing, advocacy, lobbying, anti-corruption, and pro-competition.	Minor Change Removed efficient to focus on ethical behaviour and include innovative direct advocacy activities.

C Research & Development

	2014 Indicator	Change/ rationale
C.I	**Commitments - 25%**	
C.I.1	**Innovative and adaptive R&D for Index Diseases** The company commits to carry out research focusing on the development of both innovative and new remedies for the Index Diseases and adaptive new formulations of its existing products for the Index Diseases with the goal of improving access to medicine in the Index Countries.	
C.I.2	**Collaborative R&D** The company commits to ensuring equitable access to products successfully developed through R&D partnerships.	
C.I.3	**Clinical trial conduct** The company commits to compliance with quality assurance and control, plus ethical standards when conducting clinical trials in Index Countries, consistent with codes such as Good Clinical Practice and the Declaration of Helsinki (regardless of whether the trials are conducted in-house or through a third-party, e.g. CRO).	Minor Change Expand to include quality, ethical commitment and post-trial access in both in-house and CRO conducted clinical trials.
C.II	**Transparency - 25%**	
C.II.1	**Resources towards R&D** The company discloses the resources dedicated to its research and development activities conducted in-house and/or in collaboration for Index Diseases suitable for Index Countries.	Minor Change Clarification of wording.
C.II.2	**Collaborative R&D** The company discloses the licencing details pertaining to its research collaborations related to the Index Diseases (with regard to Intellectual Property rights, access provisions etc.).	
C.II.3	**R&D for Index Diseases suitable to Index Countries' needs** The company discloses its research pipeline related to both in-house research and collaborations targeting Index Diseases (where disclosure is not legally required).	
C.II.4	**Clinical trial data** The company discloses information and results of all of its clinical trials conducted in Index Countries, regardless of the outcome and whether the trial was conducted in-house or through a third-party (e.g. CRO).	Minor Change Expand to availability of clinical trial information in registries of all clinical trials performed in Index Countries, plus publicly available clinical trial data.

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

	2014 Indicator	Change/ rationale
C.III	**Performance - 40%**	
C.III.1	**Resources towards R&D** Portion of financial R&D investments dedicated to Index Diseases out of the company's total R&D expenditures.	
C.III.2	**R&D for Index Diseases suitable to Index Countries' needs** Share of research pipeline reflecting 'new molecules' for Index Diseases including in-house and collaborative research.	
C.III.3	**R&D for Index Diseases suitable to Index Countries' needs** Share of research pipeline and products registered reflecting 'adapted products or new technologies' specific to an Index Disease and an unmet need in an Index Country, including in-house and collaborative research.	Minor Change Clarification of wording.
C.III.4	**Collaborative R&D** R&D partnerships in which the company has been involved, with the aim of developing products or formulations for Index Diseases specifically targeting access issues in Index Countries (adjusted for the number of molecules in the company's research pipeline).	Minor Change Clarification of wording.
C.III.5	**R&D for Index Diseases suitable to Index Countries' needs** Number of candidates relating to Index Diseases moving through research and development life cycle from early research phases to more advanced phases.	
C.III.6	**Collaborative R&D** The company provides evidence that the terms and conditions of its research collaborations are conducive to improving access to Index Disease products in the Index Countries for the individuals with significant financial barriers to access.	
C.III.7	**Clinical trial conduct** Has the company been the subject of any breach of international codes or lawsuits related to its clinical trial practices in the Index Countries during the last five years?	
C.III.8	**IP sharing** The company provides evidence of sharing its intellectual capital (e.g. molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g. WIPO Re: Search, CDD, OSDD) that develop products for Index Diseases on terms most conducive to access to medicine for the Index Countries.	Minor Change Clarification of wording.

	2014 Indicator	Change/ rationale
C.III.9	**Clinical trial conduct** The company provides evidence of ensuring compliance with Good Clinical Practice and the Declaration of Helsinki when conducting trials in Index Countries, regardless of whether the trial was conducted in-house or through a third-party (e.g. CRO).	Minor Change Expand to quality and ethical compliance of both in-house and CRO conducted clinical trials.

C.IV Innovation - 10%

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 Index Diseases.	

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

D Pricing, Manufacturing & Distribution

	2014 Indicator	Change/ rationale
D.I	**Commitments - 25%**	
D.I.1	**Equitable pricing strategies** The company commits to implement equitable inter-country pricing models for the products related to the Index Diseases in the Index Countries to ensure affordability.	Major Change Expanded to include all equitable pricing models.
D.I.2	**Equitable pricing strategies** The company commits to implement equitable intra-country pricing models for the products related to the Index Diseases in the Index Countries to ensure affordability.	Major Change Expanded to include all equitable pricing models.
D.I.3	**Accountability for sales agents' pricing practices** The company adopts clear policies to control the pricing practices of its local sales agents with the aim of improving affordability and accessibility of the products.	
D.I.4	**Drug recalls** The company has in place the policies, procedures and resources needed to carry out effective drug recalls (product and packaging) in the Index Countries where it operates.	
D.I.5	**Brochure & packaging adaptation** The company commits to needs-based (facilitation of rational use) brochure and packaging adaptation for its products destined for Index Countries (at least equal to local regulatory requirements).	
D.I.6	**Filing for marketing approval/registration** The company commits to file for marketing approval or product registration of its products for the Index Diseases in the Index Countries in need.	
D.II	**Transparency - 25%**	
D.II.1	**Equitable pricing schemes** The company discloses the volume of its sales to the lower tiers covered under equitable pricing programs to ensure affordability.	Major Change To include disclosure of volume of sales as a measure of affordable pricing strategies (Piloted).
D.II.2	**Equitable pricing schemes** For equitably priced products relating to the Index Diseases in the Index Countries, the company discloses target prices for the lower tiers and how it determines these prices.	Major Change To measure disclosure of price points offered to poorest tiers & the companies' rationale behind setting these prices (Piloted).

	2014 Indicator	Change/ rationale
D.II.3	**Filing for marketing approval/registration** The company discloses its decision-making process regarding registration (marketing approval) and also the status of marketing approvals for each product related to Index Diseases in the Index Countries.	Minor Change Clarification of wording.
D.II.4	**Drug recalls** The company publicly discloses information about the drug recalls and breaches it has been involved in related to drug quality issues in the Index Countries.	
D.III	**Performance - 40%**	
D.III.1	**Equitable pricing strategies** Do the company's equitable pricing programmes for products relating to Index Diseases cover all or a significant percentage of Index Countries?	Minor Change Clarification of wording.
D.III.2	**Equitable pricing strategies** Does the company take into consideration needs-based affordability when making pricing decisions for relevant products targeted at the poorest population segments in relevant countries?	Major Change To meaningfully compare pricing strategies across a diverse range of products, countries and companies (Piloted).
D.III.3	**Filing for marketing approval/registration** Has the company attempted to register (obtain marketing approval for) its products for Index Diseases in the Index Countries in need?	
D.III.4	**Drug recalls** Have drug recalls occurred due to product or packaging quality issues in the Index Countries for products produced by the company, its licencees or other manufacturing partners during the past two years? If so, how has the company dealt with them?	Minor Change Include company response to drug recalls and change from five years to two years to avoid overlap of data collection and analysis between Indices.
D.III.5	**Filing for marketing approval/registration** The company files for WHO Prequalification list, tentative approval of US Food and Drug Administration, European Medicines Agency or other stringent regulatory authority approval for its eligible products for the Index Diseases.	
D.III.6	**Equitable pricing schemes** Do products for Index Diseases destined for Index Countries for which tiered pricing is used have special packaging or other distinct markers to prevent product diversion?	

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

	2014 Indicator	Change/ rationale
D.IV	**Innovation - 10%**	
D.IV.1	**Innovation in equitable pricing** The company has introduced innovative approaches (unique in the sector) to equitable pricing which help with sustainable delivery of the products for Index Diseases to individuals in the Index Countries who face the highest financial barriers to access.	
D.IV.2	**Innovation in manufacturing & distribution** The company has introduced innovative approaches (unique in the sector) to manufacturing and distribution of products for the Index Diseases which may help with sustainable delivery of such products for the Index Diseases in the Index Countries.	

E Patents & Licencing

	2014 Indicator	Change/ rationale
E.I	**Commitments - 25%**	
E.I.1	**Patent filings** The company commits to not file for or enforce patents related to its products for the Index Diseases in LDCs, LICs and LMICs.	Major Change To expand the scope to LICs and LMICs in addition to LDCs.
E.I.2	**IP strategies** The company commits as part of a wider access-oriented strategy to issue non-exclusive voluntary licencing (NEVL) or binding non-assert declarations (NAD) for manufacturing and supply of the patented product.	Minor Change To refine the expectation of relevant licences utilised for promoting competition and increased access.
E.II	**Transparency - 25%**	
E.II.1	**TRIPS flexibilities** The company discloses its explicit support of usage of TRIPS flexibilities based on the Doha Declaration on TRIPS and public health.	
E.II.2	**Patent filings** The company discloses the patent status of its products for the Index Diseases in the Index Countries.	
E.II.3	**IP strategies** The company discloses detailed information about the voluntary licencing activities it is engaged in and its binding non-assert clauses for products related to the Index Diseases for the Index Countries (such as licence duration, licence territory, technology transfer, etc.).	
E.III	**Performance - 40%**	
E.III.1	**IP strategies** Does the company actively engage in issuing multiple non-exclusive voluntary licences and/or use legally binding non-assert declarations/clauses for the Index Countries for its products related to the Index Diseases?	Minor Change Clarification of wording.
E.III.2	**Technology transfer** Does the company have technology transfer agreements that accelerate and facilitate generic product development?	Minor Change Emphasis on access to medicine and public health-oriented components of agreements versus milestones.

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

	2014 Indicator	Change/ rationale
E.III.3	**IP strategies** The company supports patent pools such as The Medicines Patent Pool for development of new/adaptive remedies for the Index Diseases in the Index Countries.	
E.III.4	**IP strategies** Are the contents of the non-exclusive voluntary licencing and/or legally binding non-assert declarations/clauses access-oriented for its products related to the Index Diseases in Index Countries?	New 2014 To capture the quality of licences and key access provisions.
E.III.5	**IP strategies** Is there evidence that the company employs an IP strategy that is conducive to access to affordable products for Index Diseases in the Index Countries (e.g. actively engage in pro-competitive approaches by avoiding anti-competitive practices such as evergreening, thicketing, protection of research tools etc.)?	Minor Change Clarification of wording.
E.IV	**Innovation - 10%**	
E.IV.1	**Innovation in patents and licencing** The company has engaged in innovative (unique in the sector), sustainable programmes aimed at decreasing the impact of the exclusivity conferred by patent protection that could result in increased affordability and accessibility of medicine to individuals with financial barriers to access (e.g. adopted innovative socially responsible licencing practices aiming at increased effectiveness of its licencing programmes).	

F Capability Advancement in Product Development & Distribution

	2014 Indicator	Change/ rationale
F.I	**Commitments - 25%**	
F.I.1	**Capacity building in QMS and manufacturing standards** The company commits to assist Index Country manufacturers in building quality management systems aimed at achieving international quality standards (e.g. FDA, EMA, WHO Good Manufacturing Practices or recognised national certifications) and ensure that local staff employed at in-house facilities operating in Index Countries follow the same standards.	Minor Change Clarification of wording.
F.I.2	**Capacity building in pharmacovigilance** The company commits to support the development and/or implementation of national pharmacovigilance programmes in the Index Countries.	
F.II	**Transparency - 25%**	
F.II.1	**Capacity building in pharmacovigilance** The company discloses details of its capability advancement activities related to the development and/or implementation of national pharmacovigilance programmes and the company discloses post-marketing surveillance data to Index Country governments.	Major Change Extend pharmacovigilance disclosure to include measure of what companies disclose to governments.
F.II.2	**Capacity building in QMS and manufacturing standards** The company discloses details of its local in-house facilities' quality standards and details of contracts with local manufacturers (including licencees and contract manufacturers) that evidence obligations to maintain good quality standards similar to those it applies internally in developed countries or at least consistent with international standards such as the FDA, EMA and/or WHO Good Manufacturing Practices.	New 2014 To capture transparency in companies' local manufacturing quality standards to ensure they meet required standards.
F.II.3	**Capacity building in R&D** The company discloses details of its partnerships/collaborations with Index Country public sector research institutes or universities evidencing how they aim to create local research capacity and product development for Index Diseases.	New 2014 To capture transparency in companies' local research partnerships to measure how they advance local capacity.
F.II.4	**Capacity building in supply chain management** The company discloses details of how it is transparent with other stakeholders across the supply chain to enhance local capabilities by preventing product diversion, stock-outs, counterfeiting, information gaps and improving demand forecasting and drug regulation.	New 2014 To capture transparency in companies' collaborations across the local supply chain and how they improve local supply chain management.

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

	2014 Indicator	Change/ rationale
F.III	**Performance - 40%**	
F.III.1	**Capacity building in QMS and manufacturing standards** Is there evidence that the company assists local Index Country manufacturers or in-house manufacturing facilities to achieve international good manufacturing standards* in the Index Countries through training or technology transfer? * Such as FDA, EMA or the WHO Good Manufacturing Practices or equally recognised national certifications.	Minor Change Clarification of wording to specify technology transfer.
F.III.2	**Capacity building in R&D** Is there evidence that the company participates in local partnerships with public sector research institutes or universities in the Index Countries with the aim of increasing local capacity for health research (including clinical trials capacity) and product development?	
F.III.3	**Capacity building in supply chain management** The company is engaged in programmes/partnerships with Index Country governments (e.g. MoH/procurement, logistics and distribution agencies) and other distributors to develop locally appropriate supply chain capabilities with the aim of improving affordability, accessibility and quality of the delivered Index Disease products.	
F.III.4	**Capacity building in pharmacovigilance** The company is actively engaged in developing and implementing national pharmacovigilance-related programmes in the Index Countries.	
F.III.5	**Initiatives to build other capacities** The company carries out other initiatives (where there is no conflict of interest) with potential for improving capacity of Index Country organisations to address access to medicine in those countries.	
F.IV	**Innovation - 10%**	
F.IV.1	**Innovation in capability advancement** The company has introduced innovative (unique in the sector) approaches to local capacity advancement, working with Index Country organisations to improve the quality and accessibility of products for Index Diseases.	Major Change Expand to include all four areas of Capability Advancement in this indicator.

G Product Donations and Philanthropic Activities

	2014 Indicator	Change/ rationale
G.I	**Commitments - 25%**	
G.I.1	**Drug donations** The company commits to comply with the WHO Guidelines for Medicine Donations – Revised 2010 in the Index Countries for all its drug donation activities.	Minor Change Updated to Revised WHO Guidelines.
G.I.2	**Drug donations** The company commits to ensuring that donated products are administered to patients in the Index Countries.	
G.I.3	**Sustainable philanthropy** The company commits to and explains its rationale for investing in health infrastructure-related philanthropic projects (outside of the standard value chain) in the Index Countries and their relevance to long-term sustainable access to medicine in Index Countries.	
G.I.4	**Single-drug donations** The company commits to delivering single-drug donation programmes, in line with the WHO Guidelines for Medicine Donations – Revised 2010.	Minor Change Updated to Revised WHO Guidelines.
G.II	**Transparency - 25%**	
G.II.1	**Drug donations** The company discloses the process and criteria for deciding the drug types and destinations for its single-drug donation programmes in the Index Countries.	
G.II.2	**Drug donations** The company discloses detailed information about the type, volume and destination of products that are part of its multi-drug donation programmes donated in the Index Countries.	
G.II.3	**Sustainable philanthropy** The company discloses the amount of resources dedicated to and achievements resulting from its philanthropic activities in the Index Countries.	

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

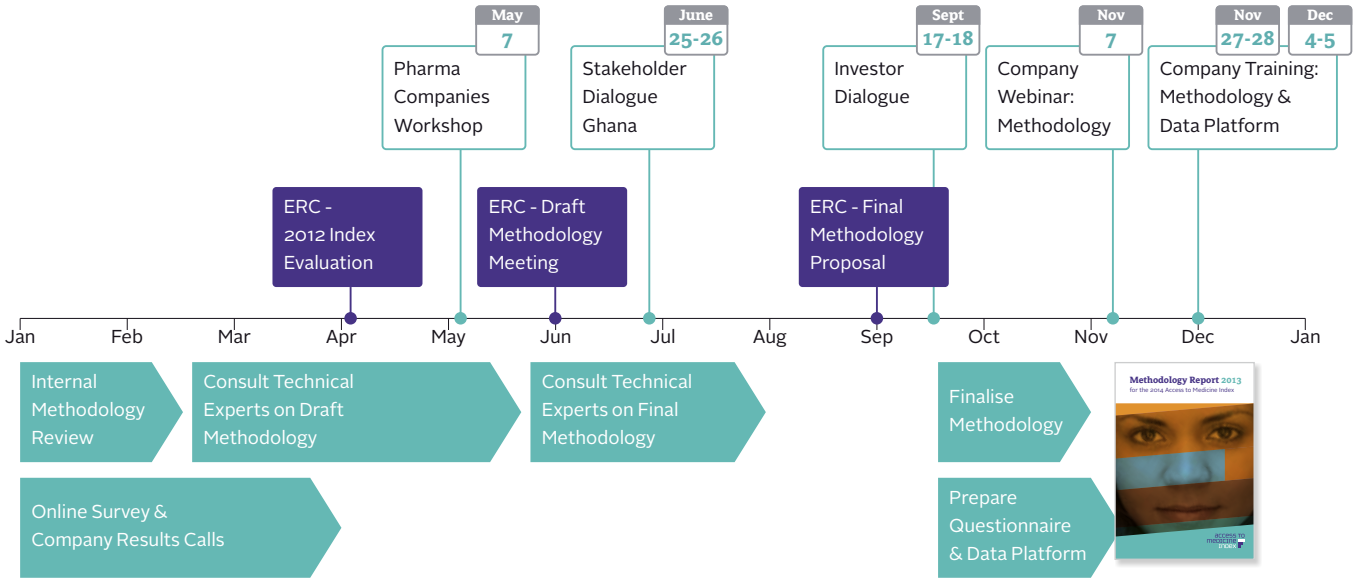
	2014 Indicator	Change/ rationale
G.III	**Performance - 40%**	
G.III.1	**Drug donations** The company monitors outcomes and impact of single-drug donation programmes during the reporting period.	Minor Change Clarification of wording.
G.III.2	**Drug donations** The value of donated products which were donated based on targeted, needs-based strategic donations programmes to the Index Countries during the period of analysis (single-drug donations adjusted for the company size).	
G.III.3	**Drug donations** The scale and scope of donated products to the Index Countries during the period of analysis.	
G.III.4	**Sustainable philanthropy** There is evidence that the company's philanthropic activities (excluding drug donation programmes) are aligned with and support implementation of national health system development plans and stated health priorities in the Index Countries.	
G.IV	**Innovation - 10%**	
G.IV.1	**Innovation in product donations** The company has introduced innovative (unique in the sector), sustainable and impactful approaches to managing drug donations, which may result in increased effectiveness and efficacy.	
G.IV.2	**Innovation in sustainable philanthropy** The company has introduced innovative (unique in the sector) approaches to philanthropic programmes to make it more sustainable and linked to better health outcomes in the Index Countries, which may result in sustainable health improvements.	

Note: unless otherwise specified, indicator has remained the same as in the 2012 Index

Appendix 1: Review & Consultations

Stakeholder dialogue

Figure 7 **Developing the Methodology**



Between January and October 2013, the Index team engaged with stakeholders in a variety of settings to understand multiple perspectives and stay up-to-date on developments in the dynamic access to medicine landscape. Information and insights gathered during these dialogues were incorporated into the Foundation's internal methodology review process and consultations with the Technical Subcomittees (TSCs) and Expert Review Committee (ERC).

Online survey & company results calls

From February 12th to March 4th, 2013, the Foundation invited Index readers, contributors and representatives from relevant stakeholder groups to share their feedback on various aspects of the development of the 2012 Index, from the methodology to the presentation of the 2012 Index results. A total of 134 people representing seven stakeholder groups throughout the world responded. Pharmaceutical industry representatives were most prevalent within the survey respondent group.

Between January and April 2013, the Foundation offered representatives of all 20 companies measured in the 2012 Index the opportunity to give their feedback on Index methodology, processes and results in individual conference calls with the 2012 Index team. Eleven of the 20 companies measured by the Index participated in these calls.

Feedback from both the survey and the company calls indicated that stakeholders' perceptions of the Index are evolving. Not only is the Index valued for its ability to compare companies' access to medicine initiatives, but increasingly stakeholders - including pharmaceutical companies - are looking to the Index for guidance on expectations and best practices. At the same time, some stakeholders remain watchful, and sometimes critical, of what and how the Index measures. This criticism is important in helping the Index team to understand stakeholders' expectations as it continually looks for ways to make the Index as relevant and informative as possible.

Strategic Access to Medicine Workshop

In May 2013, representatives of companies measured by the Index gathered near Amsterdam for a Strategic Access to Medicine Workshop to discuss how more inclusive business models can be developed to incorporate access strategies into core business, and how best practices can be shared. Participants concluded that creating internal support for access to medicine strategies, taking advantage of opportunities for industry-wide collaboration, and recognising external stakeholder expectations are important ways to move forward in this area.

Stakeholder Dialogue: Ensuring Quality Affordable Medicines in Developing Countries

In June 2013, members of the Index team travelled to Accra, Ghana to host a multi-stakeholder dialogue in Ghana of key experts from developing countries to discuss important issues identified in the 2012 Access to Medicine Index. Over the course of 1.5 days, participants debated how to define and measure affordability as well as the best ways to monitor safety and quality of medicines. It was concluded that strong definitions and standards for affordable

pricing as well as better comparability between tiered pricing programmes are needed, and that regional harmonisation of regulatory approaches is the way forward for pharmacoviligance. It was also clear that both research-based and generics companies have an important role to play in ensuring safe, affordable medicines in countries covered by the Index.

Investor dialogue
In addition to multiple investor consultations throughout the year, Foundation members attended a series of meetings in Paris with representatives of both mainstream and socially responsible investment (SRI) firms in September 2013. The discussions focused on how the Index can be used as a tool for investors to better understand potential risks, opportunities and best practices for access to medicine in low- and middle-income countries. Investors stated that many Index indicators are already relevant to their work. They suggested that including more emerging economies, measuring companies' long-term performance, and the risks associated with their access to medicine activities, could further increase the utility of the Index for them.

Committee consultation process

Technical Subcommittees
Between February and September 2013, the Foundation's research team convened groups of experts to serve as Technical Subcommittees (TSCs) for Technical Areas in the methodology framework. These TSCs gave specific input and advice in response to the team's proposals for the Technical Areas of Public Policy & Market Influence; Research & Development; Pricing, Manufacturing & Distribution and Patents & Licencing in the 2014 Index methodology. For the remaining Technical Areas of General Access to Medicine Management, Capability Advancement and Donations & Philanthropy, experts were consulted individually but did not convene as TSCs.

TSCs were convened for at least one meeting and, if necessary, reconvened for follow-up discussions. Suggestions from TSCs were integrated into proposals for the Expert Review Committee. Where necessary, the Expert Review Committee's feedback to the TSC's initial suggestions was subsequently discussed with TSCs to go over any additional considerations. The final TSC comments were incorporated into the final 2014 Index methodology proposal for approval by the ERC in September 2013.

Expert Review Committee
The Foundation's research team met with the Expert Review Committee (ERC) in April, June and September 2013. The role of the ERC is to provide the Foundation with strategic guidance with regard to the Index's scope and indicators in each of the seven Technical Areas.

In June 2013, the ERC was presented with the draft methodology framework proposal for the 2014 Access to Medicine Index. Based on the ERC's feedback, the research team conducted pilot tests with companies in order to determine the feasibility of potential new indicators within the General Access to Medicine Management and Pricing, Manufacturing & Distribution Technical Areas. Following the integration of initial comments, the reconvened TSCs where applicable, and the results of the pilots, the ERC gave its support to the final methodology proposal for the 2014 Index at a meeting in September 2013.

Contributors to this report

Expert Review Committee

- Hans Hogerzeil, *University of Groningen, Switzerland*
- Marja Esveld, *Ministry of Health, The Netherlands*
- Richard Laing, *World Health Organization (WHO), Switzerland*
- Dennis Ross-Degnan, *Harvard University, USA*
- Regina Kamoga, *Community Health and Information Network (CHAIN), Uganda*
- Natacha Dimitrijevic, *Hermes Equity Ownership Services, UK*
- Peter Shelby, *International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland*
- Dilip Shah, *Indian Pharmaceutical Alliance, India*

Technical Subcommittees

B Public Policy & Market Influence

- Michele Forzley, *Georgetown University Law Center, USA*
- Jillian Kohler, *University of Toronto, Canada*

C Research & Development

- Jennifer Dent, *Bio Ventures for Global Health, USA*
- Javier Guzman, *Policy Cures, UK*

D Pricing Manufacturing & Distribution

- Jaime Espin, *Andalusian School of Public Health, Spain*
- Niranjan Konduri, *Management Sciences for Health, USA*
- Prashant Yadav, *University of Michigan, USA*

E Patents & Licencing

- Peter Beyer, *World Health Organization (WHO), Switzerland*
- Esteban Burrone, *Medicines Patent Pool, Switzerland*
- Warren Kaplan, *Boston University, USA*

Additional contributors

- Afshin Mehrpouya, *Hautes études commerciales (HEC) Paris, France*
- Rachelle Harris, *Department for International Development (DFID), UK*
- 'Strategic Access to Medicine Workshop' participants, *May 2013, Amstelveen, The Netherlands*
- 'Stakeholder Dialogue: Ensuring quality affordable medicine in developing countries' participants, *June 2013, Accra, Ghana*
- 'Investor Dialogue' participants, *September 2013, Paris, France*

Appendix 2: ICD-10 Coverage

ICD-10 Coverage

Table 5 **ICD-10 Coverage**

	Global DALYs[7]	Index Disease	Name ICD-10 Classifications
Communicable Diseases			
1	94,511	**Lower respiratory infections**	J10 – Influenza due to other identified influenza virus J11 – Influenza, virus not identified J12 – Viral pneumonia, not elsewhere classified J13 – Pneumonia due to Streptococcus bruption J14 – Pneumonia due to Haemophilus bruption J15 – Bacterial pneumonia, not elsewhere classified J16 – Pneumonia due to other infectious organisms, not elsewhere classified J17 – Pneumonia in diseases classified elsewhere J18 – Pneumonia, organism unspecified J20 – Acute bronchitis J21 – Acute bronchiolitis J22 – Unspecified acute lower respiratory infection
2	72,777	**Diarrhoeal diseases**	A00 – Cholera A01 – Typhoid and paratyphoid fevers A03 – Shigellosis A04 – Other bacterial intestinal infections A06 – Amoebiasis A07 – Other protozoal intestinal diseases A08 – Viral and other specified intestinal infections A09 – Other gastroenteritis and colitis of infectious and unspecified origin
3	58,513	**HIV/AIDS**	B20 – Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases B21 – Human immunodeficiency virus [HIV] disease resulting in malignant neoplasms B22 – Human immunodeficiency virus [HIV] disease resulting in other specified diseases B23 – Human immunodeficiency virus [HIV] disease resulting in other conditions B24 – Unspecified human immunodeficiency virus [HIV] disease
4	34,217	**Tuberculosis**	A15 – Respiratory tuberculosis, bacteriologically and histologically confirmed A16 – Respiratory tuberculosis, not confirmed bacteriologically or histologically A17 – Tuberculosis of nervous system A18 – Tuberculosis of other organs A19 – Miliary tuberculosis
5	33,976	**Malaria**	B50 – Plasmodium falciparum malaria B51 – Plasmodium vivax malaria B52 – Plasmodium malariae malaria B53 – Other parasitologically confirmed malaria B54 – Unspecified malaria
6	14,853	**Measles**	B05 – Measles
7	11,426	**Meningitis**	A39 – Meningococcal infection G00 – Bacterial meningitis, not elsewhere classified G03 – Meningitis due to other and unspecified causes
8	9,882	**Pertussis**	A37 – Whooping cough
9	5,283	**Tetanus**	A33 – Tetanus neonatorum A35 – Other tetanus
10	3,748	**Chlamydia**	A55 – Chlamydial lymphogranuloma (venereum) A56 – Other sexually transmitted chlamydial diseases

	Global DALYs[7]	Index Disease	Name ICD-10 Classifications
Non- Communicable Diseases			
1	65,472	**Unipolar depressive disorders**	F32 – Depressive episode F33 – Recurrent depressive disorder
2	62,587	**Ischaemic heart disease**	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
3	46,591	**Cerebrovascular disease**	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
4	30,196	**Chronic obstructive pulmonary disorder [COPD]**	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
5	19,705	**Diabetes mellitus**	E10 – Insulin-dependent diabetes mellitus E11 – Non-insulin-dependent diabetes mellitus E12 – Malnutrition-related diabetes mellitus E13 – Other specified diabetes mellitus E14 – Unspecified diabetes mellitus
6	16,769	**Schizophrenia**	F20 – Schizophrenia F21 – Schizotypal disorder F22 – Persistent delusional disorders F23 – Acute and transient psychotic disorders F24 – Induced delusional disorder F25 – Schizoaffective disorders F28 – Other nonorganic psychotic disorders F29 – Unspecified nonorganic psychosis
7	16,317	**Asthma**	J45 – Asthma J46 – Status asthmaticus
8	15,586	**Osteoarthritis**	M15 – Polyarthrosis M16 – Coxarthrosis [arthrosis of hip] M17 – Gonarthrosis [arthrosis of knee] M18 – Arthrosis of first carpometacarpal joint M19 – Other arthrosis
9	14,425	**Bipolar affective disorder**	F30 – Manic episode F31 – Bipolar affective disorder
10	13,640	**Cirrhosis of the liver**	K70 – Alcoholic liver disease K74 – Fibrosis and cirrhosis of liver B18 – Chronic viral hepatitis

	Global DALYs[7]	Index Disease	Name ICD-10 Classifications
11	9,057	**Nephritis and nephrosis**	N00 – Acute nephritic syndrome N01 – Rapidly progressive nephritic syndrome N02 – Recurrent and persistent haematuria N03 – Chronic nephritic syndrome N04 – Nephrotic syndrome N05 – Unspecified nephritic syndrome N06 – Isolated proteinuria with specified morphological lesion N07 – Hereditary nephropathy, not elsewhere classified N08 – Glomerular disorders in diseases classified elsewhere N10 – Acute brupt-interstitial nephritis N11 – Chronic brupt-interstitial nephritis N12 – Tubulo-interstitial nephritis, not specified as acute or chronic N13 – Obstructive and reflux uropathy N14 – Drug- and heavy-metal-induced brupt-interstitial and tubular conditions N15 – Other renal brupt-interstitial diseases N16 – Renal brupt-interstitial disorders in diseases classified elsewhere N17 – Acute renal failure N18 – Chronic kidney disease N19 – Unspecified kidney failure
12	7,854	**Epilepsy**	G40 – Epilepsy G41 – Status epilepticus

Neglected Tropical Diseases

1	5,941	**Lymphatic filariasis**	B74.0 – Filariasis due to Wuchereria bancrofti B74.1 – Filariasis due to Brugia malayi B74.2 – Filariasis due to Brugia timori
2	4,013	**Soil transmitted helminthisiasis**	B76 – Hookworm diseases B77 – Ascariasis B78 – Strongyloidiasis B79 – Trichuriasis B80 – Enterobiasis B81 – Other intestinal helminthiases, not elsewhere classified
3	1,974	**Leishmaniasis**	B55 – Leishmaniasis
4	1,875	**Food-borne trematodiases**	B66.0 – Opisthorchiasis B66.1 – Clonorchiasis B66.3 – Fascioliasis B66.4 – Paragonimiasis
5	1,707	**Schistosomiasis**	B65 – Schistosomiasis [bilharziasis]
6	1,673	**Trypanosomiasis**	B56 – African trypanosomiasis
7	1,462	**Rabies**	A82 – Rabies
8	1,334	**Trachoma**	A71 – Trachoma
9	670	**Dengue**	A90 – Dengue fever [classical dengue] A91 – Dengue haemorrhagic fever
10	503	**Cysticercosis**	B69 – Cysticercosis
11	430	**Chagas disease**	B57 – Chagas disease

	Global DALYs[7]	Index Disease	Name ICD-10 Classifications
12	389	**Onchocerciasis**	B73 – Onchocerciasis
13	194	**Leprosy**	A30 – Leprosy [Hansen disease]
14	144	**Echinococcosis**	B67 – Echinococcosis
15	NA	**Buruli Ulcer**	A31.1 – Cutaneous mycobacterial infection
16	NA	**Yaws**	A66 – Yaws
17	NA	**Dracunculiasis**	B72 – Dracunculiasis

Maternal Health Conditions

1	7,424	**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
2	6,535	**Maternal sepsis**	O85 – Puerperal sepsis O86 – Other puerperal infections
3	4,439	**Maternal haemorrhage**	O44 – Placenta praevia O45 – Premature separation of placenta [bruption placentae] O46 – Antepartum haemorrhage, not elsewhere classified O67 – Labour and delivery complicated by intrapartum haemorrhage, not elsewhere classified O72 – Postpartum haemorrhage
4	2,882	**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	1,888	**Hypertensive disorders of pregnancy**	O10 – Pre-existing hypertension complicating pregnancy, childbirth and the puerperium O11 – Pre-existing hypertensive disorder with superimposed proteinuria O12 – Gestational [pregnancy-induced] oedema and proteinuria without hypertension O13 – Gestational [pregnancy-induced] hypertension without significant proteinuria O14 – Gestational [pregnancy-induced] hypertension with significant proteinuria O15 – Eclampsia O16 – Unspecified maternal hypertension
6	N/A	**Contraceptive methods**	Combined hormonal contraceptives, progestogen-only contraceptives, emergency contraceptive pills, intrauterine devices (IUD), copper emergency IUD, barrier methods (condoms, spermicide, diaphragm with spermicide, cervical cap)

Neonatal Health Conditions

1	44,307	**Prematurity and low birth weight**	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

	Global DALYs[7]	Index Disease	Name ICD-10 Classifications
2	41,684	**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	40,433	**Neonatal infections and other 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 P23 – Congenital pneumonia P35 – Congenital viral diseases P36 – Bacterial sepsis of newborn P37 – Other congenital infectious and parasitic diseases P38 – Omphalitis of newborn with or without mild haemorrhage P39 – Other infections specific to the perinatal period P50 – Fetal blood loss 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

Appendix 3: References, Definitions & Acronyms

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Definitions

Access Initiative
[working definition, for purposes of measurement]
An act, strategy, activity or programme aimed at improving the affordability, availability, acceptability, accessibility, and/or quality of health products to the end user.

Adaptive Product
Research in the development of new version of existing products, aimed at modifying those products to specifics of a local environment (including geographic, social, demographic, or other characteristics) that form barriers to access of existing products. Development of heat-resistant formulations, fixed-dose combinations and paediatric formulations are examples of adaptive R&D activities. This excludes minor adjustments that do not meet medical or practical local needs.[77]

Advocacy
Efforts by an individual, company or organisation to promote positive action towards improving health by educating and/or creating awareness among the public (e.g., civil education, public campaigns) or legislators. Advocacy does not support or oppose a specific issue of legislation, but rather informs the community on the health issue at hand.[23-28]

Affordability
[working definition, for purposes of measurement]
The end user's ability-to-pay for products. This is taken into account in the Index when assessing pricing strategies for products.[29-31]

Anti-competitive Behaviour
Any practice by a company or group of companies that has, is intended to have, or is likely to have, the effect of restricting, distorting or preventing competition in order to maintain or increase their market position and/or profits. Anti-competitive behaviour leads to disadvantage or detriment of competitors, customers and suppliers such that higher prices, reduced output, less consumer choice, loss of economic efficiency and misallocation of resources (or combinations thereof) are likely to result.[32-35]

Audit
An internal or external examination of an organisation's accounts, processes, functions and performance to produce an independent and credible assessment of their compliance with applicable laws, regulations and audits.[36]

Bolar Provision
Flexibility of the TRIPS Agreement which allows for countries to permit manufacturers to use a patented invention to obtain marketing approval before expiry of the patent and without the permission of the patent owner. The generic producers can then market their versions as soon as the patent expires.[37,38]

Breaches
Acts that are in violation/disregard of or non-compliant with laws, rules, guidelines or codes.[36, 39-41]

Bribery
The offering, promising, giving, accepting or soliciting of an advantage as an inducement for an action which is illegal, unethical or a breach of trust. Inducements can take the form of gifts, loans, fees, rewards or other advantages (taxes, services, donations, etc.). Facilitation payment is a form of bribery and is defined as a payment (money, goods or services) to a government official to perform or speed up the performance of an existing duty.[36, 42]

Clinical Trial Phases
The phases of tests in medical research and drug development that generate safety and efficacy data for health interventions.
- Phase I: In these studies a study health intervention (e.g. medicine) is investigated in a small group of healthy volunteers. This phase is to determine the safety profile of the intervention (and how medicines can be metabolised and excreted).
- Phase II: In these initial studies a study medicine is investigated in a small group of patients to determine efficacy to treat a specific condition and determine safety profiles.
- Phase III: During this phase the efficacy and safety of a health intervention (e.g. medicine) is studied in different large patient populations. Different doses are tested and its efficacy and safety are compared to other therapeutic agents. When favourable results are demonstrated in this phase, regulatory approval for marketing can be obtained.
- Phase IV: These are studies that are conducted after market approval. Typically, they investigate risks, benefits and optimal use in a large population.[79]

Code of Conduct
Statement of principles, values and rules that establishes a set of expectations and standards on responsible practices by an organisation, government body, company, affiliated group or individual. This includes minimal levels of compliance and disciplinary actions for the organisation, its staff and volunteers.[36]

Collaborative Research
Research performed jointly by more than two parties where knowledge and/or expertise and resources are shared towards one or more common goals. This could involve academic institutions, government agencies and divisions, pharmaceutical companies, biotechnology companies and other public or private organisations.

Company Size
[working definition, for purposes of measurement]
Size of corporations based on revenues. This excludes all subsidiaries with non-pharmaceutical activities, unless otherwise stated.

Compound/Molecule Libraries
[working definition, for purposes of measurement]
Collections of molecules/compounds used to explore complex disease pathways and to assist in the characterisation of disease targets that may be candidates for further development into health interventions.

Compulsory Licence
A formal ruling set by law or arbitration by a government to allow a third party (e.g. pharmaceutical manufacturer) to produce a patented product or use a patented process without needing to obtain consent of the patent owner.[80]

Conflict of Interest
A situation where a professional or a company has a vested interest that creates a risk that professional judgement or actions will be unduly influenced. The interests at stake could be, for example, money, status, knowledge or reputation.[67,68]

Corruption
The abuse of entrusted power for private or corporate gain. Corruption can be classified as grand, petty and political, depending on the amounts of money lost and the sector where it occurs;
- Grand Corruption: Acts committed at a high level of government that distort policies or the central functioning of the state, enabling leaders to benefit at the expense of the public health good.
- Petty Corruption: Everyday abuse of entrusted power by low- and mid-level public officials in their interactions with ordinary citizens and healthcare professionals, who often are trying to receive or provide basic health services and products in places like hospitals, schools, and other community organisations.
- Political Corruption: Manipulation of policies, institutions and rules of procedure in the allocation of health resources and financing by political decision makers, who abuse their position to sustain their power, status and wealth.[36]

Country Classifications
[working definition, for the purposes of measurement]
Categorisations of countries based on the UN Human Development Index, UN Department of Economic and Social Affairs classification and on the income level categories according to the World Bank. The relevant categories used are (–with source):
- Least Developed Countries (LDC) – UN Department of Economic and Social Affairs
- Low-income countries (LIC) – World Bank
- Lower-middle-income country (LMIC) – World Bank
- Upper-middle-income countries (UMIC) – World Bank
- High income – (non) OECD countries – World Bank
- Low human development countries (LHDC) – UN Human Development Index
- Medium human development countries (MHDC) – UN Human Development Index
- High human development countries (HHDC) – UN Human Development Index

Data Exclusivity
Protection of originator pharmaceutical company's data preventing other parties from using these data for a commercial purpose. Concretely, this protection prevents other parties from using these data for a commercial purpose. Concretely, this protection prevents generics product manufacturers from proceeding to clinical trials and health authorities from evaluating generic product market authorisation applications during this period.[72]

Declaration of Helsinki
A set of principles regarding human experimentation developed for members of the medical community. This code of conduct is for ethical clinical trial conduct, and essential principles revolve around respect for the individual and the right to make informed decisions. It aims to protect the rights and wellbeing of the individual participating in human research. The Declaration of Helsinki was initially adopted in 1964 as a reaction to the lack of a general accepted code of conduct for human research and is frequently updated (last update: 2013[81]).

Disability Adjusted Life Year (DALY)
One DALY can be thought of as one lost year of 'healthy' life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability.[82]

Doha Declaration on the TRIPS Agreement and Public Health
An agreement between governments affirming that the TRIPS agreement should not prevent TRIPS member countries from protecting public health interests. The Doha Declaration (14 November 2001) clarified the flexibilities of TRIPS member states in navigating pharmaceutical patents. It granted member states the right to grant compulsory licenses; to determine what constitutes a national emergency or extreme urgency; and that each member is free to establish its own regime for the exhaustion of intellectual property rights.[83]

Drug Diversion
Channelling lower-priced medicines from developing countries into developed countries or from lower income segments to high-income segments, or from public to private sector, within a country.[84]

Drug Recall
Actions taken by a company or medicine regulatory authority to remove from the market products or batches of products that are found to be either defective or potentially harmful. Recalls include those due to both packaging and quality or safety issues. The Index captures those recalls of products that are subject to GMP standards, i.e. medicines, vaccines, microbicides and other medicinal products for human use.[85]

Equitable Pricing
[working definition, for purposes of measurement]
A targeted pricing strategy that ensures the poor gain access to medicine by affordable pricing that is locally appropriate, implemented on a case-by-case basis.[87]

Ethical Clinical Trial Conduct
Guidelines regarding ethical and scientific quality standards for designing, conducting, recording, and reporting findings from trials that involve participation of human subjects. Rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society. Principles from Good Clinical Practice and the Declaration of Helsinki, among others, are used as guidelines to guarantee ethical clinical trial conduct.[86]

Ethical Marketing
Promotional activities (both hidden and public) that are aimed at the general public, patients, healthcare professionals/students and opinion leaders in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.[45-48]

Evergreening of Patents and Patent Clusters
Patent clusters around an existing medicine is patenting of new forms or other minor variations of existing products that have no additional therapeutic value and display limited inventiveness. This can be used to prolong patent protection in an inappropriate manner, creating a negative effect on access to medicines, as well as on further innovation – a strategy referred to as 'evergreening'. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) defined evergreening as a term popularly used to describe patenting strategies "when, in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term".[74]

Generics
A pharmaceutical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. [73]

G-Finder References for Disease Scope
G-FINDER only includes infectious diseases that follow three criteria:
- Disproportionally affect the developing world
- There is a need for new products (i.e. there is no existing product OR improved or additional products are needed)
- There is market failure (i.e. there is insufficient commercial market to attract R&D by private industry).[90]

Good Clinical Practice (GCP)
An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. GCP is set up by the International Conference on Harmonisation (ICH) that aims to harmonise technical requirements for registration of medicines for human use globally.[49]

Good Manufacturing Practices (GMP)
Guidelines for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. WHO has established detailed guidelines for GMP. Many countries have formulated or harmonised their own requirements for national GMP, often based on WHO GMP.[50]

Healthcare Infrastructure
Basic physical and organisational structures needed to deliver health care. This extends from healthcare-related services provided to communities, hospitals and other healthcare-related facilities.[92, 93]

Index Country
Any country covered by the 2014 Index. Please refer to the 'Geographic Scope' section for more details.

Index Disease
Any disease covered by the 2014 Index. Please refer to the 'Disease Scope' section for more details.

(Inter)National Health Priority
Areas for action stated either by national governments or by multilateral organisations, such as the Millennium Development Goals.[91]

Impact Assessment
[working definition, for purposes of measurement]
Process of predicting and evaluating the effects that a policy, programme or activity has on the health of a population, and the distribution of those effects within the population. This includes the effect on patient outcomes, epidemiology, healthcare infrastructure and other effects that relate to public health and can include also wider socio-economic impacts.[69, 70]

In-house Research
Research into the development of innovative or adaptive compounds that is executed by the research-based pharmaceutical company without outsourcing to contract research organisations.

Innovation
[working definition, for purposes of measurement]
Leading and unique practices.

Innovative Product
Research aimed at developing new products for one or more unmet medical needs (in contrast to Adaptive Product).[77]

Intellectual Property (IP)
The rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time in exchange of publication of the innovation. Industrial IP is protected traditionally to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The protection is usually given for a finite term (typically 20 years in the case of patents).[41]

Inter-Country* Equitable Pricing
** All Index Countries where a product is used to treat Index Diseases will come into this category.*
A targeted pricing scheme at the country level which takes into account affordability for the poorest countries.[84, 87]

Intra-Country* Equitable Pricing
** All Index Countries where a product is used to treat Index Diseases will come into this category.*
A targeted pricing scheme where a company has different pricing tiers within an Index Country based on the socioeconomic profiles of different population segments, taking into account affordability for the poorest segments in the country.[84, 87]

Lobbying
Any activity carried out to influence a government or institution's policies and decisions in favour of a specific cause or outcome. Direct lobbying occurs via communication with a legislator, legislative staff, legislative body or government employee who may participate in the formulation of legislation. Grass-roots lobbying is an attempt to influence legislation by encouraging the public to contact legislators about a specific issue. Even when allowed by law, these acts can become distortive if disproportionate levels of influence exist.[23-26,28,36]

Long-term
[working definition, for purposes of measurement]
A project, commitment, engagement, initiative, or plan is considered long-term when its duration is 5 years or longer.

Molecules
[working definition, for purposes of measurement]
Any New Chemical Entities (NCEs), New Biological Entities (NBEs) or any new drug or vaccine candidates.

Multi-drug Donations
[working definition, for purposes of measurement]
A gift of products for which there is no clear, defined long-term strategy. This may include a company donating a range of medicines based on stock availability, which may or may not be based on the explicit needs of a country. Donations made during emergency situations, such as conflict and natural disasters, are included here.

National Pharmacovigilance Programmes
Nationwide systems or projects (in Index Countries) to establish and support a database of adverse drug reactions for informed regulatory decision making; and to improve the rational and safe use of medical drugs, the assessment and communication of the risks and benefits of drugs on the market, and the education of patients. A comprehensive national pharmacovigilance system should include efficient surveillance, effective communication methods, and collaboration with the relevant stakeholders to ensure pharmacovigilance activities are incorporated.[53]

New Drug Application (NDA)
A formal request to a regulatory authority for market authorisation of a medicine. An NDA contains all the pre-clinical and clinical information obtained during the testing phase.[95]

Non-Assert Declaration
A legally binding commitment that contains an explicit set of conditions, including permitted actions and designated territories, for which the patent owner commits not to enforce patent rights. This allows for a generic version of a patent protected product to be produced in a resource-limited setting.[77, 94]

Non-Exclusive Voluntary Licencing (NEVL)
A contract in which the patent holder allows the contracting party to use the patent, either against a payment of royalties or free of charge for a defined period of time.[77, 94]

Originator Company
A company that has at least one product authorised worldwide for marketing (normally as a patented product).[75]

Outside the Value Chain
[working definition, for purposes of measurement]
Activities beyond the scope of the company's normal operations and distribution channels.

Parallel Import
Import of a patented or trademarked product from a country where it is marketed, usually to obtain a lower price.[77]

Patent
An intellectual property right providing an inventor with a legal monopoly to prevent others from making, using, or selling the new invention for a defined period of time, subject to a number of exceptions. Also includes the obligation to publish the invention. A patent does not automatically mean the product is safe for consumers or that it can be supplied. Patented medicines still have to go through rigorous testing and approval before they can receive market authorisation.[37]

Patent Pool
Portfolio of patents and other relevant intellectual property rights held by various actors made available through a joint licencing scheme to third parties (e.g. generics manufacturers) against the payment of royalties.[96]

Patent Thicketing
A strategy used to block competition by filing a dense web of overlapping patents that extensively covers a single technological niche, where a competitor becomes entangled in a 'thicket' of patents. This obstructs entry to market, thereby impeding access.[97]

Pay-for-Delay
An agreement between an originator company and one or more generics companies to postpone the launch of a competing product for a certain period of time in order to delay generic competition and the consequential lowering of prices.[55-57]

Performance Management Systems
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
For the 2014 Index, the time period for which data will be analysed covers fiscal years 2012 and 2013, where company activities must be ongoing between June 2012 and the end of May 2014, as this is the cycle of the Index. Programmes that have ended before June 1st 2012 are not included. Additionally, any activities that were already assessed in the 2012 Index will not be scored as innovative or new in relevant indicators. The Index team assesses most recent policies, codes and stances, up to final submission.

Pharmacovigilance
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Medicines need to be monitored, and any adverse drug reactions need to be remedied in a timely manner through pharmacovigilance systems.[98]

(Corporate) Political Contributions
Any direct or indirect gift, either in cash or in kind, to support a political cause or an individual. Examples include gifts of property or services, advertising or promotional activities endorsing a political party, and the purchase of tickets to fundraising events.[36]

Pre-clinical Research
Research aimed at assessing potential efficacy and toxicity prior to testing a product. Typically, both *in vitro* and *in vivo* tests are performed. During *in vitro* tests data is collected to determine chemical and biological properties of products in an isolated laboratory setting. When results are positive, *in vivo* tests are used to determine toxicity and ability to treat or prevent a particular disease or symptom in living animals.[58, 59]

Prequalification of Medicines
A service provided by WHO to assess the quality, safety and efficacy of certain medicinal products (mainly for HIV/AIDS, TB, malaria and reproductive health) for procurement by UN agencies and/or from UN funds.[88]

Pro-access
[working definition, for purposes of measurement]
An adjective to ensure positive provisions that address public health needs. A pro-access licence will have explicit terms embedded within it that ensure timely medicine development and market registration, safe and acceptable products delivered to populations who need them. A pro-access price is one that is affordable to the lowest socio-economic quintiles and commercial imperatives will be balanced against patient needs.

Products
[working definition, for purposes of measurement]
Products, technologies or commodities, which are described in the product type scope: medicines, therapeutic vaccines, preventive vaccines, diagnostics, microbicides, vector control products, and platform technologies.

Rational Use
The scientifically sound use of medicines. Rational use requires that patients receive the appropriate medicine, in the proper dose, for an adequate period of time, and at a cost which is affordable to them and their community.[61]

Revenue
The 'top line' or 'gross income' figure from which costs are subtracted to determine net income. The Index 2014 looks at total sales revenues generated over the past three years (2011-2013).

Single-drug Donations
[working definition, for purposes of measurement]
A gift of products for which a defined strategy exists as to the type, volume, and destination of donated products. Single-drug donations are based on long-term, targeted donation programmes based on country needs, usually targeted at one disease.

Socially Responsible Licencing (SRL)
A licencing concept that involves various principles or provisions (such as territorial scope, pricing and milestones for delivery) in licencing agreements aiming to achieve certain social outcomes such as access to, and affordability of, crucial technologies for people in need.[77, 94]

Spurious/Falsely-labeled/Falsified/Counterfeit (SFFC) medicines
The term counterfeit medical product describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting. Medical products (whether generic or branded) that are not authorised for marketing in a given country but authorised elsewhere are not considered counterfeit.[76]

Strategic Pillar
As part of the Index's analytical framework, the indicators under each Technical Area are broken down into four Strategic Pillars – Commitments, Transparency, Performance and Innovation.

Subsidiary
[working definition, for purposes of measurement]
A company that is owned or controlled by another firm or company[99]; subsidiaries include firms in which a company owns more than 50% of the outstanding voting stock, as well as firms in which a company has the power to direct or cause the direction of the management and policies.

Sustainable
[working definition, for purposes of measurement]
Targeted activities aimed at enhancing access locally in the long run.

Technical Area
As part of the Index's analytical framework, the seven major Technical Areas under which the companies are analysed in Index 2014 are: General Access to Medicine Management; Public Policy & Market Influence; Research & Development; Pricing, Manufacturing & Distribution; Patents & Licencing; Capability Advancement in Product Development & Distribution; and Product Donations & Philanthropic Activities.

Technology
An application of organised knowledge and skills in the form of products, devices, procedures and systems developed to solve a health problem and improve quality of lives (see product scope for detailed overview of included technologies).[60,61]

Technology Transfer
The process by which any party gains access to another party's technical information or know-how and successfully learns and absorbs it into its research, development or manufacturing processes.[100]

Tiered Pricing
A pricing scheme where a company adapts product prices based on the purchasing power of consumers in different geographic or socioeconomic segments. Tiered pricing takes into account affordability of medicines and other products for low-income segments, and is therefore a form of equitable pricing.[87]

Trade-Related Aspects of Intellectual Property Rights (TRIPS)
A multilateral agreement that was issued to protect Intellectual Property rights around the world under international rules, where all countries must make patents eligible for pharmaceutical products and processes. The World Trade Organization's TRIPS Agreement covers five broad issues:
- How basic principles of the trading system and other international intellectual property agreements should be applied
- How to give adequate protection to intellectual property rights
- How countries should enforce those rights adequately in their own territories
- How to settle disputes on intellectual property between members of the WTO
- Special transitional arrangements during the period when the new system is being introduced.[89]

Transparency
Characteristic of a company of providing clear disclosure of information regarding corporate governance and accountability, conflicts of interest, medicines policies, licencing details, product-specific pricing schemes, clinical trial conduct and data and market authorisations in a comprehensible, accessible and timely manner towards the general public and healthcare professionals.[36,48,62]

Treatment
First-line treatment: Refers to standard medicines that are the first choice for health interventions. This choice is based on favourable clinical results in a large population.
Second-line treatment: When efficacy of first-line therapy is low or when it induces too many adverse effects, additional medicines may be added to or substitute previously initiated treatment.

TRIPS+ (or TRIPS Plus)
Measures contained in multilateral, regional, plurilateral or national intellectual rules and practices that protect intellectual property rights beyond the minimum standards set out in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and may hinder Index Country governments from acting in the public interest. This covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions under the TRIPS Agreement.[77]

Whistle-blower
An informant who exposes wrongdoing by a company that threatens public interest, such as neglect or abuse, within an organisation, either internally or publicly, in the hope of stopping it.[36,66]

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
CDD	Collaborative Drug Discovery
CRO	Contract Research Organisation
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
DALY	Disability Adjusted Life Year
DFID	UK Department for International Development
EMA	European Medicines Agency
ERC	Expert Review Committee
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices
HDI	Human Development Index [UN]
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonisation
IHDI	Inequality-Adjusted Human Development Index [UN]
IP	Intellectual Property
LDC	Least Developed Country [UN]
LHDC	Low Human Development Country [UN]
LIC	Low Income Country [WB]
LMIC	Lower Middle Income Country [WB]
MDG	Millennium Development Goal
MHDC	Medium Human Development Country [UN]
MIC	Middle-Income Country [WB]
MoH	Ministry of Health
NAD	Non-Assert Declaration
NBEs	New Biological Entities
NCEs	New Chemical Entities
NEVL	Non-Exclusive Voluntary Licencing
NEVLs	Non-Exclusive Voluntary Licences
NGO	Non-Governmental Organisation
NTD	Neglected Tropical Disease
OSDD	Open Source Drug Discovery
R&D	Research and Development
SRL	Socially Responsible Licencing
SFFC	Spurious/Falsely-labelled/Falsified/Counterfeit
TRIPS	Trade-related Aspects of Intellectual Property Rights
TSC	Technical Subcommittee
UN	United Nations
WB	World Bank
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Photography
Wim Leereveld, Jayasree Iyer
Yara InMedia, *The Netherlands*

Design
Explanation Design BV,
The Netherlands