Methodology Report 2012

Stakeholder Review - May 2012

access to medicine index

Acknowledgements

The Access to Medicine Foundation together with MSCI ESG Research would like to thank all stakeholders for their time and input to this Methodology Review Process. Both the Expert Review Committee and the Technical Subcommittees played crucial roles in the Index 2012 methodology development (p.63 - 64). Special thanks to Rachelle Harris, the technical expert and key contributor to methodology refinement, for her critical authorship in this report and keen strategic insight for Index 2012 and to Dr. Afshin Mehrpouya, Steering Committee Member, for his careful review and feedback.

Access to Medicine Foundation

The Access to Medicine Foundation is an international not-for-profit organisation dedicated to improving access to medicines to societies in need. Based in Haarlem, The Netherlands, the foundation publishes the Access to Medicine Index, the first index of its kind to rank pharmaceutical companies with respect to their efforts to enhance global access to medicines.

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Word from the Founder

The autumn of 2012 will again see the publication of the Access to Medicine Index. This will show to what degree the pharmaceutical industry is contributing to a fairer, healthier world. The Methodology Report 2012 defines exactly how the Index will do this – what we measure, how we measure it, and why.

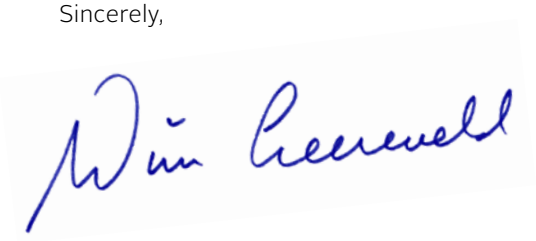
In effect, this report defines in detail what the world could expect of large pharmaceutical companies when it comes to their policies and progress in making medicines available to those who need them. It is the result of extensive consultation with all our stakeholders – governments, NGOs, the WHO, investors, academia, and, of course, the pharmaceutical companies themselves. I would like to express my thanks to everyone involved for their hard work, time and energy. In particular, I would like to thank the Expert Review Committee for their strategic guidance.

The consensus reached in this way by such a broad and large group of stakeholders has again led to a powerful measuring tool, which enables the world at large to ask the global pharmaceutical industry to do its part. It creates transparency, which will subsequently lead to progress.

As you will see, the changes compared to the 2010 methodology are evolutionary rather than revolutionary. To enable comparability, the same analytical framework is used. The changes and additions that have been made reflect changes in the global health environment, improved understanding of which interventions work best, and the evolving expectations of stakeholders.

I am proud that the Access to Medicine Index can play its part in creating stronger partnerships between the pharmaceutical industry and everyone else involved in global public health. We at the Foundation are driven by our ambition to achieve the highest possible impact on access to medicines for everyone – an impact that we know is going to change many lives for the better.

Sincerely,



Wim Leereveld
CEO & Founder

Table of Contents

Clickable Sections

List of Figures

Clickable Sections

List of Tables

Executive Summary

Access to medicines remains a very serious concern for billions of people suffering from disease and is still a primary challenge for the global health system. Reflecting the key role of the pharmaceutical industry in addressing the challenges of access, it is essential that the Access to Medicine Index's approach to monitoring and evaluating the performance of the industry in this work is robust, balanced and comprehensive.

Optimized Methodology

As such, the Index team, based on consultations with the industry and various civil society organizations, and in conjunction with the Expert Review Committee and Technical Subcommittees, has undertaken a review of the methodology for Index 2012. This multi-stakeholder consultative approach took place during 2011. It has enabled the Index team to make refinements that strive to capture the changing realities of the global health community, including the pharmaceutical industry and, most importantly, those in less affluent nations who suffer from diseases for which access to medicines is often problematic.

Maintaining Comparability

The shift in approach from Index 2008 to Index 2010 was a step-change for the Index, marking significant changes to the breadth, scope, and means of capturing and appraising information about the companies' approaches to access to medicines, based on a comprehensive analytical framework. The approach to the methodology review for Index 2012 has been more evolutionary than revolutionary, to enable comparability with the data captured by Index 2010. As a result, the same analytical framework will be used for Index 2012, with some adjustments that better reflect changes in the global health environment and the evolving expectations of industry by policy makers, deliverers and users. The approach will enable a solid analysis of industry trends and provide insight into the progress of initiatives.

This report provides a description of these methodological changes, which have been ratified by an independent Expert Review Committee (ERC) consisting of leaders from the public health policy community, industry, academia and civil society.

Summary of Key Changes

How we measure

- To underscore the relative importance of measuring companies' outputs and outcomes of access-to-medicine initiatives, rather than inputs, the overall weight of the Performance strategic pillar has been increased from 30% to 40%.
- The weighting of the Pricing, Manufacturing & Distribution Technical Area has been increased from 20% to 25% to emphasize its breadth and relative importance.

What we measure

- In addition to the 33 priority diseases that have been included in the Index 2012, consistent with Index 2010, the Disease Scope has been expanded to include maternal health and neonatal infections.
- This is in line with major global health policy objectives, including Millennium Development Goals (MDG) 5.A, to reduce by three quarters the maternal mortality ratio and 5.B, to achieve universal access to reproductive health. Addressing neonatal infections is in line with MDG 4, to reduce child mortality.

- The geographical scope is now based on the World Bank classification, which is updated yearly. This ensures that the list of countries covered is sufficiently dynamic to reflect the realities of global economic change and is consistent with the norms of global health organizations and reporting of several companies. The list also includes the countries of the UN Human Development Index to capture social inequalities that make improved access to medicines imperative.
- Companies engaged exclusively in the production of generic medicines have not been included in the Index 2012, although relevant 'originator' or 'research-based' companies with generic production operations will continue to be reviewed.

Figure 1 How we measure

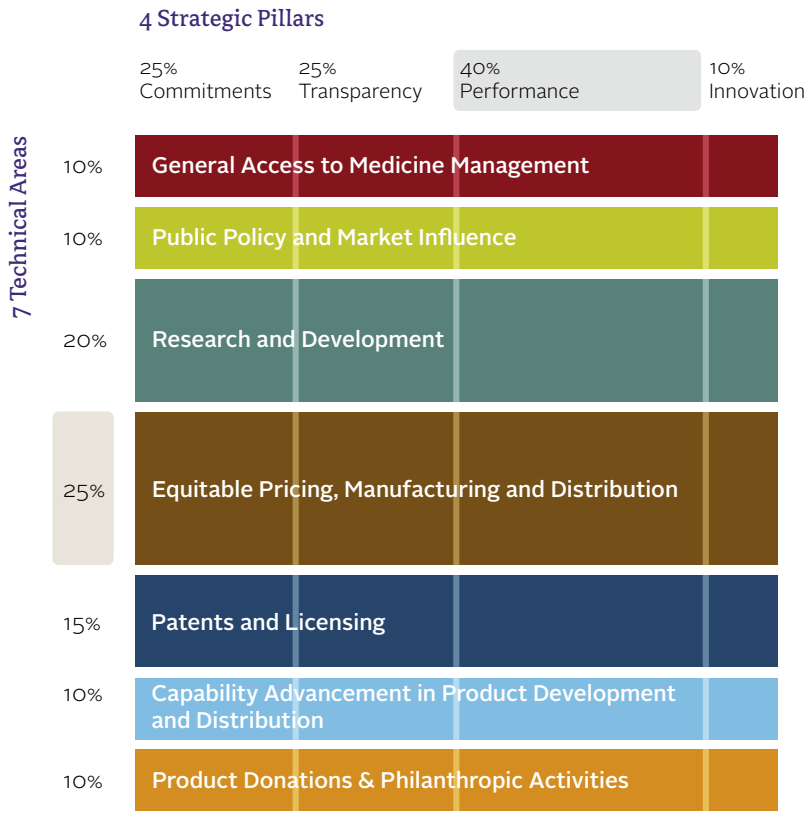


Figure 2 What we measure

Company Scope	20 originator pharmaceutical companies	
Geographical Scope	103 countries	91 World Bank-based 12 UN HDI-based
Disease Scope	Priority Diseases	top-10 communicable diseases top-10 non-communicable diseases 14 neglected tropical diseases maternal health neonatal infections
	Secondary Diseases	Ad hoc or regional health challenges
Product Type Scope	A broad scope to support prevention, diagnoses and treatments	

Indicators

- Based on inputs from Technical Subcommittees for each Technical Area, the indicators have been closely reviewed and refined. As a result, the indicators have been rationalized and updated. Index 2012 indicators have been reduced by 10% compared to the previous Index.
- Certain indicators - both new and existing - have been earmarked as relevant for longitudinal or trend analysis. This will enable us to present new, relevant insights in the longer term.

Process

A range of process enhancements have taken place, including an online data platform, to ensure that data collection will be more streamlined in Index 2012. While participation in the Index represents a commitment to access in itself, the continual goal to reduce the data collection burden for companies remains a priority.

What we measure

1 Company Scope

Index 2012 covers the same 20 originator companies included in Index 2010. Selection of the companies is based on market capitalisation, including only pharmaceutical operations, and the relevance of product portfolios to the Index Diseases (as defined by 'Disease Scope'). One unlisted company, Boehringer Ingelheim, is still included since it meets the size and 'portfolio' relevance criteria used by the Index team in company selection. Maintaining the 2010 list of originator companies covered by the Index will enable comparability and trend analyses over time.

Table 1 Index 2012 Company Scope

	Ticker	Company	Country	Market Cap[1]
1	JNJ-N	Johnson & Johnson	USA	179.09
2	PFE-N	Pfizer Inc.	USA	166.35
3	NOVN-VX	Novartis AG	CHE	137.73
4	ROG-VX	Roche Holdings Ltd.	USA	117.13
5	MRK-N	Merck & Co. Inc.	USA	114.91
6	GSK-LN	GlaxoSmithKline PLC	GBR	113.53
7	SAN-FR	Sanofi-Aventis AS	FRA	98.99
8	ABT-N	Abbott Laboratories Inc.	USA	87.53
9	NOVO'B-KO	Novo Nordisk A/S	DNK	64.29
10	AZN-LN	AstraZeneca PLC	GBR	61.44
11	BMY-N	Bristol-Myers Squibb Company	USA	59.72
12	BAY-FF	Bayer AG	DEU	52.98
13	LLY-N	Eli Lilly & Company	USA	48.11
14	4502-TO	Takeda Pharmaceutical Company	JPN	34.55
15	GILD-O	Gilead Sciences	USA	30.74
16	MRK-FF	Merck KGaA	DEU	21.72
17	4503-TO	Astellas Pharma Inc.	JPN	18.72
18	4568-TO	Daiichi Sankyo Company Limited	JPN	13.91
19	4523-TO	Eisai Company Limited	JPN	11.75
20	Not Publicly Listed	Boehringer-Ingelheim		Not Publicly Listed

1 Market Cap as of December 31st, 2011 (billion USD)

Exclusion of generics companies from the Index 2012

The performance of generics companies will not be captured in Index 2012. During the evolution of the Access to Medicine Index, a number of approaches have been debated, tried and tested in relation to whether the generics-only business model should be included or ranked by the Index. In Index 2010, as recommended through the stakeholder consultations, both generic and originator company activities were appraised, but in two separate lists and applying weight adjustments for all the companies based on the portion of their revenues sourced from generic operations.

Based on the feedback from the 2011 stakeholder consultations, the companies that exclusively have generic manufacturing operations will not be ranked in Index 2012. The Access to Medicine Foundation is conducting additional research and consultation to assess if and how generics companies will be profiled or evaluated by the Foundation in the future.

Analysis of originator companies' varied business models

The research-based pharmaceutical industry has undergone major shifts in its structure and organisation over the course of the last decade. With that has come some change to individual companies' business models. Some have remained purely research-based, whilst others have broadened to include generic manufacturing and supply functions. Some have adopted a model of product diversification while others remain focused on a core business area, which may be specific to one or a few areas of health. Others focus on supply of pharmaceutical therapies, preventative or therapeutic vaccines, or both, or varying combinations of these.

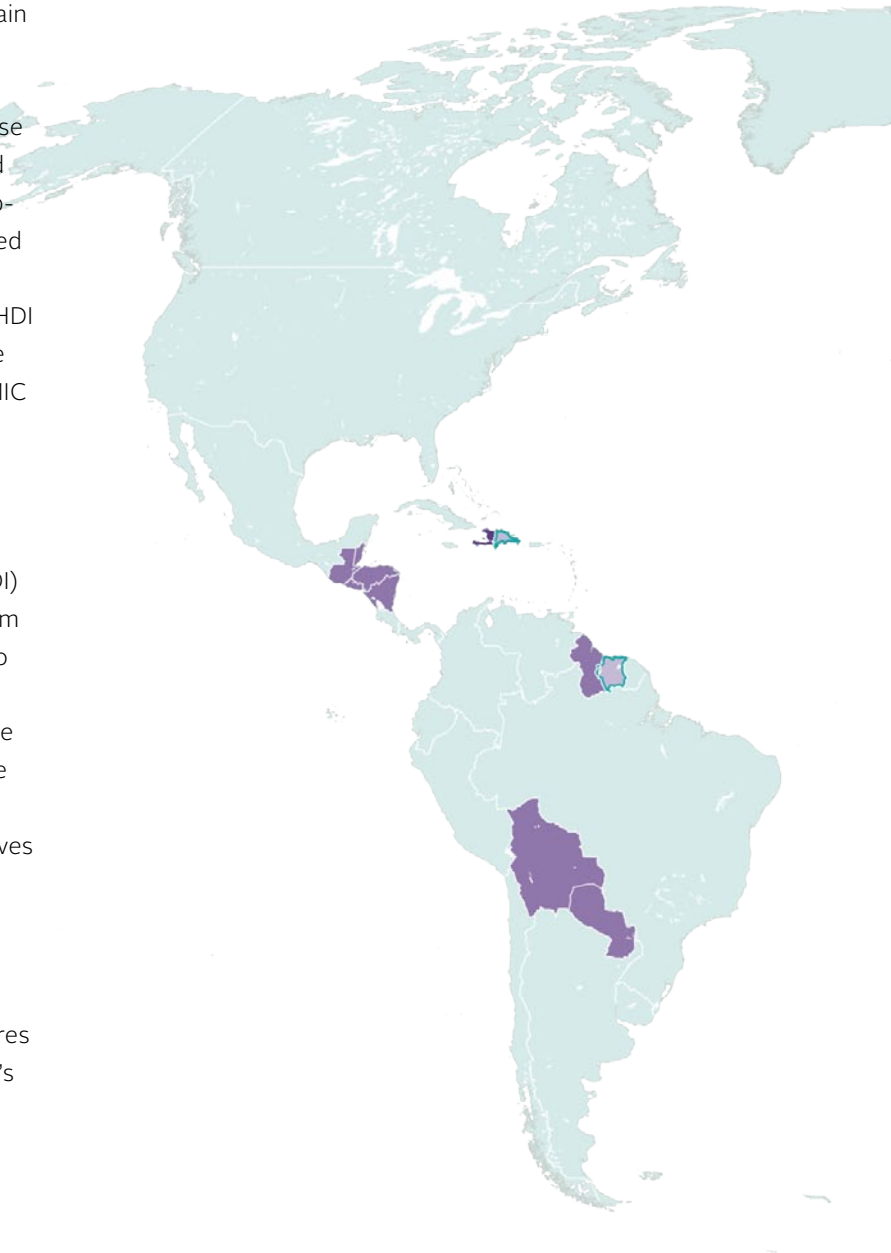
The Index 2012 will continue to measure originator company performance in relation to improving access to medicines regardless of these different business models and will actively encourage disclosure of all access to medicine related activities across the companies' different business units. Adjustments for such business model differences have been applied at the indicator level and reflected in the scoring guidelines. Such adjustments have been considered only when the dominant stakeholder viewpoint is that the Foundations' expectations from the company should be adjusted for specific business model attributes. Consequently, as in Index 2010, no weight adjustments have been undertaken at the Technical Area and Strategic Pillar levels.

2 Geographical Scope

Index 2012 will focus on the Low-income and Lower-middle-income Countries (LIC and LMICs) based on World Bank classifications, updated in July 2011. This is a widely used, predominantly economic ranking. To capture certain exceptional countries that are considered by the World Bank to be more economically advanced overall (for example, Upper-middle-income Countries, or UMICs, whose Gross National Income per capita is between $3,976 and $12,275), but still have wide disparities in human development and well-being (according to the inequality-adjusted UN Human Development Index (HDI) 2011), Index 2012 applies an exception. This exception includes those UN HDI Medium-High Development Countries (MHDCs) that are not automatically captured by the World Bank LIC or LMIC rankings. An additional 10 (MHDC) countries are consequently included to supplement the World Bank LIC and LMIC categories.

Index 2010 used the UN Human Development Index (HDI) Low Human Development Countries (LHDC) and Medium Human Development Countries (MHDC) classification to define the geographical scope of the Index and filtered out the World Bank (WB) classified Upper Middle Income (UMIC) and High Income Countries (HICs). The challenge with this approach was that it was inconsistent with the approach taken by many prominent global health initiatives and it is not updated on a regular basis.

Note: the UN HDI has had a significant methodological review to its inequality adjustment function and differs from previous years. The UN HDI MHDC category captures countries whose GDP is too high for inclusion in the WB's LMIC category and is inequality-adjusted, factoring in inequalities in human development and well-being.



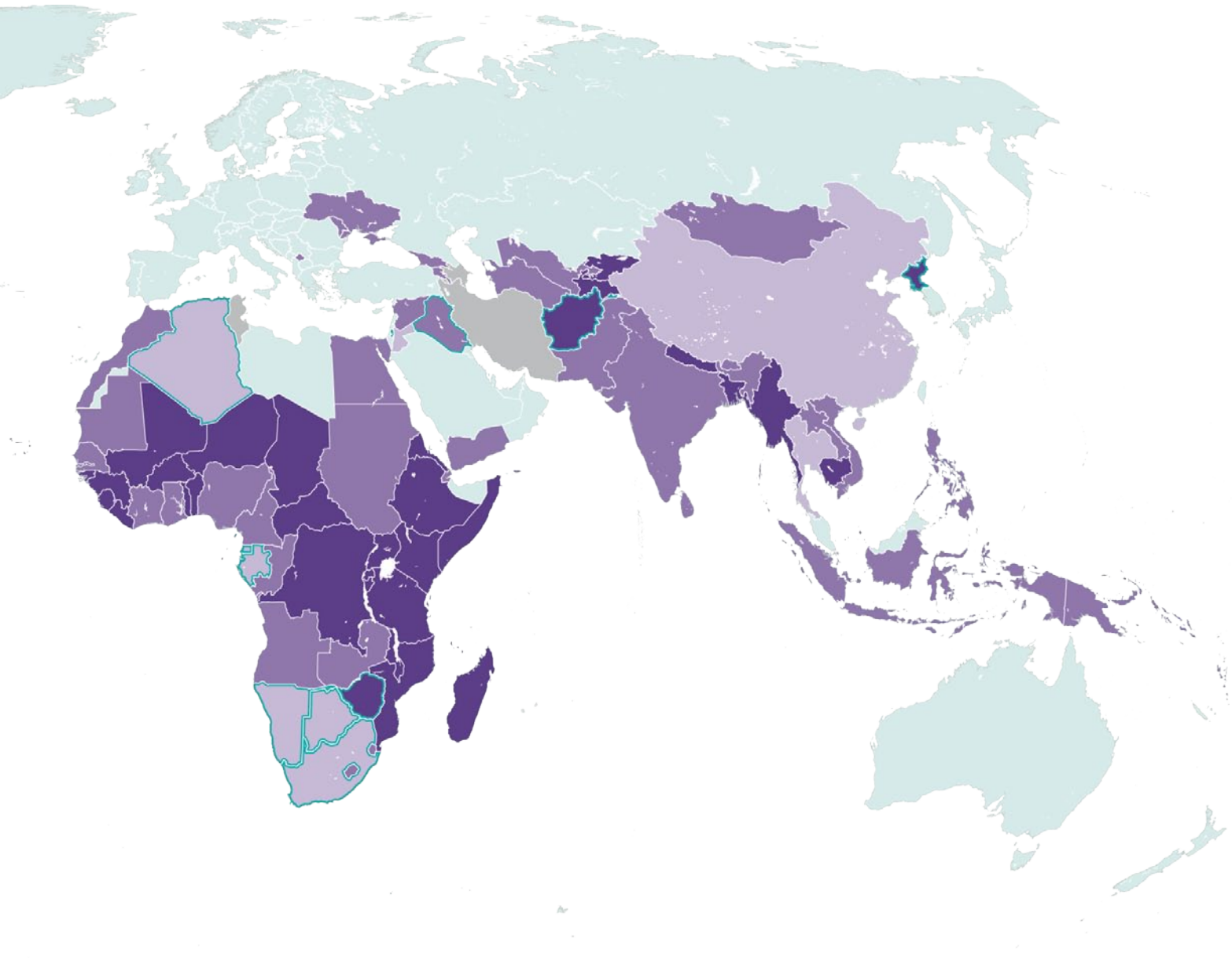


Figure 3 Geographical Scope

- Low-income Country (LIC) - World Bank income classification
- Lower-middle-income Country (LMIC) - World Bank income classification
- Medium Human Development Country (MHDC) - UN Human Development Index

- 18 New countries
- 3 Countries out of the scope

Table 2 List of the Index 2012 Countries - 103 Countries

Country	Classification
East Asia & Pacific	
Cambodia	LIC
China	MHDC
Fiji *	LMIC
Indonesia	LMIC
Kiribati *	LMIC
Korea, Dem. Rep.	LIC
Lao PDR	LMIC
Marshall Islands *	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 *	LMIC
Tuvalu *	LMIC
Vanuatu *	LMIC
Vietnam	LMIC
Europe & Central Asia	
Armenia	LMIC
Georgia	LMIC
Kosovo	LMIC
Kyrgyz Rep.	LIC
Moldova	LMIC
Tajikistan	LIC
Turkmenistan	LMIC
Ukraine	LMIC
Uzbekistan	LMIC
Latin America & Caribbean	
Belize	LMIC
Bolivia	LMIC
Dominican Rep.	MHDC
El Salvador	LMIC
Guatemala	LMIC
Guyana	LMIC
Haiti	LIC
Honduras	LMIC
Nicaragua	LMIC
Paraguay	LMIC
Suriname	MHDC

Country	Classification
Middle East & North Africa	
Algeria	MHDC
Djibouti	LMIC
Egypt, Arab Rep.	LMIC
Iraq	LMIC
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	LMIC
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	High Income
Eritrea	LIC
Ethiopia	LIC
Gabon	MHDC
Gambia, The	LIC
Ghana	LMIC
Guinea	LIC
Guinea-Bissau	LIC
Kenya	LIC
Lesotho	LMIC
Liberia	LIC

Country	Classification
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
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
Sudan	LMIC
Swaziland	LMIC
Tanzania	LIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LIC

Countries included in Index 2010 excluded in Index 2012

Tunesia
Azerbijan
Iran

LIC: Low-income Country
World Bank income classification

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

MHDC: Medium Human Development Country
UN Human Development Index

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

18 New countries
3 Countries out of the scope

3 Disease Scope

The Priority Diseases covered by Index 2012 remain largely consistent with Index 2010, although two additional areas have been added. A second tier has also been added to the Index 2012 Disease Scope to encompass additional public health priorities. These enhancements are discussed below.

Scope of Priority Diseases: Tier One

The Index 2010 disease scope covered a total of 33 diseases, consisting of a combination of the following disease lists with adjustments detailed in the section below:

- The top 10 communicable diseases based on Disability Adjusted Life Years (DALY) from the WHO Global Burden of Disease
- The top 10 non-communicable diseases based on DALYs from the WHO Global Burden of Disease
- 14 of the WHO Neglected Tropical Diseases (Lymphatic Filariasis was included in the Index 2010 both based on being on the WHO NTD list and being one of the top 10 communicable diseases based on WHO Global Burden of Diseases - DALY)

Diseases were selected based primarily on disease burden (aggregate global DALYs) and those diseases for which pharmaceutical interventions were irrelevant (such as violent death and trauma and snakebites) were excluded.

For Index 2012 two additional areas have been added as follows:

- Maternal conditions: This category has been included as it contributes to a high global disease burden and is a significant concern for global health policy, reflected in the Millennium Development Goals[2]. For Index 2012, this category addresses the following postnatal and antenatal conditions: Prevention of postpartum haemorrhage; Prevention of unsafe abortion; and Prevention of unwanted pregnancy. The rationale for focusing on these areas is as follows:
  - Among the top causes of diseases for females are maternal conditions, with, for example, pregnancy and childbirth being the fifth highest burden of disease (4.7%) in 2001[3].
  - Unintended pregnancies are known to be associated with adverse maternal outcomes, including unsafe abortion, and, although difficult to measure, related morbidity is considered high[4].
  - A significant unmet need for contraception persists in many Index countries, with high levels of unsafe abortion as a proxy indicator of that need. As such, prevention of unwanted pregnancy is considered a public health priority[5].
  - WHO estimates that post partum haemorrhage accounts for 25% of maternal deaths globally[6].
- Neonatal infections: This category includes only neonatal sepsis. Any other infections that occur during the neonatal period (0 day to 4 weeks of age), such as diarrhoea or pneumonia, are captured in the original Priority Disease list.

For the full scope of diseases and conditions covered by Index 2012, including the WHO ICD-10 codes, please see Appendix 2.

2 Millennium Development Goals (http://www.un.org/millenniumgoals/maternal.shtml, last accessed 12th April 2012)

3 WHO Global Burden of Disease (2002)

4 Dean T. Jamison, World Bank, Disease Control Priorities Project - 2006 and The World health report: 2005: make every mother and child count.

5 The World Health Report: 2005: make every mother and child count (WHO, 2005)

6 Ibid

Scope of Secondary Diseases: Tier Two

A second tier has been added to the disease scope, to capture significant access initiatives that fall outside the priority disease scope but still explicitly address public health concerns, as defined by DALYs.

- Other ad hoc or regional health challenges

  This includes any initiatives clearly based on healthcare needs in an Index Country with potential or realized positive impact on reducing health burden. This is to ensure that the Index captures those diseases that cause a significant burden in particular regions (e.g. the Human Papilloma Virus in Brazil or the outbreak of a cholera epidemic). Such initiatives are covered qualitatively as a second tier health condition.

Consistent with Index 2010, any innovative or leading initiatives that do not fall within the scope of the Tier One Index Disease categories listed above will be captured qualitatively in Index 2012.

Criteria and Exclusions for Disease Scope Selection

As with Index 2010, to ensure the best possible comparability between the pharmaceutical companies, discounted, non age-weighted WHO DALY data are used. Weighting can add subjectivity as it distorts access to medicine priorities depending on age groups. Present value discounting, however, affects all patient groups in the same way and is judged as a suitable adjustment for this analysis (despite the subjectivity of the choice of discount rate which is based on World Bank Disease Control Priorities).

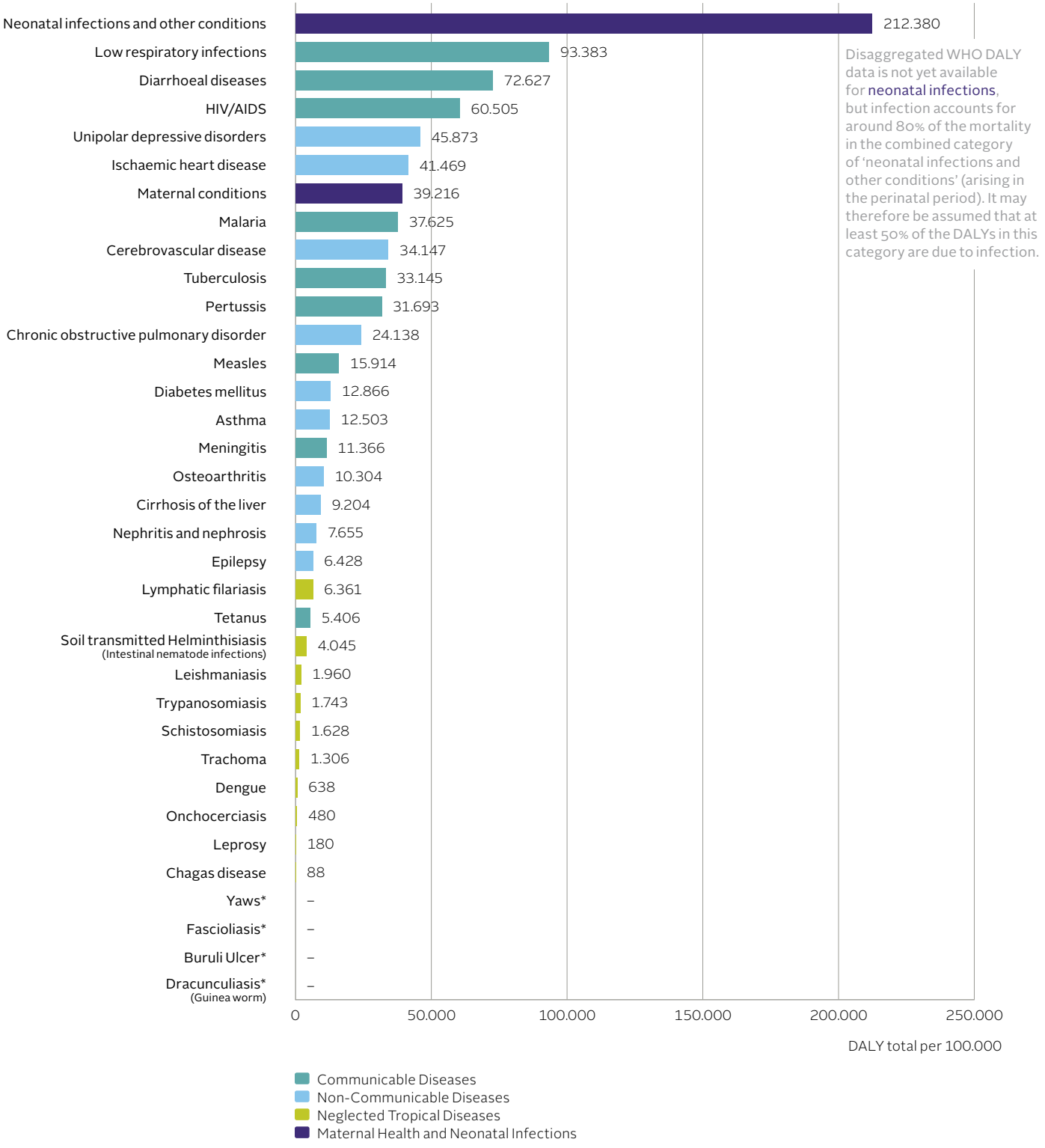
In addition, for Research and Development analysis, certain product categories for some diseases were excluded. The exclusions were established based on one of the below conditions:

- Where there is no market failure for research for a disease, such as the case of most of Innovative Research for non-communicable Index Diseases for which there is a viable market in the developing countries

- Where the bottleneck for access is not a lack of new products but failures in other parts of the product delivery value chain, such as pricing, distribution, health infrastructure etc.

- The G-Finder report of Policy Cures was an important reference in the process of finalizing research exclusions of Index 2010 for communicable diseases and remains important for Index 2012.

Figure 4 Index 2012 Disease Scope by DALYs



Disaggregated WHO DALY data is not yet available for neonatal infections, but infection accounts for around 80% of the mortality in the combined category of 'neonatal infections and other conditions' (arising in the perinatal period). It may therefore be assumed that at least 50% of the DALYs in this category are due to infection.

* Neglected Tropical Diseases as classified by WHO, but for which have not been captured in the GDB Report 2008.

Source: Global Burden of Diseases ranked by standard DALYs, WHO, updated 2004, published 2008.

Table 3 Index 2012 Disease Scope - Priority Diseases

Disease	DALY total per 100.000
Communicable Diseases	
Low respiratory infections	93.383
Diarrhoeal diseases	72.627
HIV/AIDS	60.505
Malaria	37.625
Tuberculosis	33.145
Pertussis	31.693
Measles	15.914
Meningitis	11.366
Lymphatic filariasis	6.361
Tetanus	5.406
Non-Communicable Diseases	
Unipolar depressive disorders	45.873
Ischaemic heart disease	41.469
Cerebrovascular disease	34.147
Chronic obstructive pulmonary disorder	24.138
Diabetes mellitus	12.866
Asthma	12.503
Osteoarthritis	10.304
Cirrhosis of the liver	9.204
Nephritis and nephrosis	7.655
Epilepsy	6.428
Neglected Tropical Diseases	
Lymphatic filariasis	6.361
Soil transmitted Helminthisiasis (Intestinal nematode infections)	4.045
Leishmaniasis	1.960
Trypanosomiasis	1.743
Schistosomiasis	1.628
Trachoma	1.306
Dengue	638
Onchocerciasis	480
Leprosy	180
Chagas disease	88
Yaws*	–
Fascioliasis*	–
Buruli Ulcer*	–
Dracunculiasis* (Guinea worm)	–
Maternal Health and Neonatal Infections	
Neonatal infections and other conditions	212.380
Maternal conditions	39.216

* Neglected Tropical Diseases as classified by WHO, but for which have not been captured in the GDB Report 2008.

4 Product Type Scope

The product type scope for Index 2012 is necessarily broad to capture the wide-ranging product types available to support prevention, diagnosis and treatment of Index Diseases in the Index Countries. Drawing closely from the definitions provided by the G-Finder 2011 Summary of R&D (Annex 1), the scope is as follows, as in 2010:

Medicines

All medicines used to treat directly the target pathogen or diseases process regardless of formulation. Those medicines used only for symptomatic relief are not included.

Therapeutic vaccines

Investigational vaccines specifically intended to treat infection.

Preventive vaccines

Investigational vaccines specifically intended to prevent infection; including vaccine design, preclinical and clinical development and other activities essential for successful vaccine development and uptake.

Diagnostics

Diagnostic tests for use in resource-limited settings (cheaper, faster, more reliable, ease of use in the field).

Microbicides

Topical microbicides specifically intended to prevent HIV.

Vector control products

- Pesticides
  Only includes chemical pesticides intended for global public health use and which specifically aim to inhibit and kill vectors associated with transmitting relevant Index Diseases.
- Biological control products
  Only includes research and development of innovative biological control interventions that specifically aim to kill or control vectors associated with transmitting relevant Index Diseases.
- Vaccines targeting animal reservoirs
  Only includes research and development of veterinary vaccines specifically designed to prevent animal to human transmission of neglected diseases.

Platform technologies

- Adjuvants and immunomodulators
- Delivery technologies and devices
- General diagnostic platforms

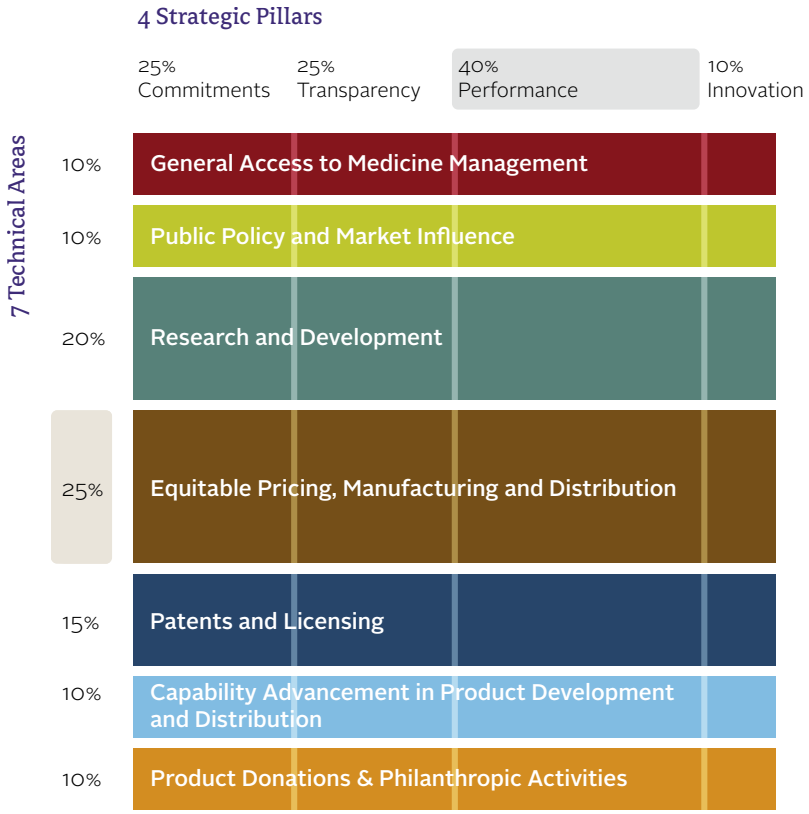
Note: This category has strict limitations which aim to identify only those R&D activities directed specifically at ID's or to meet IC-needs. Further details of how this is determined can be found in the G-Finder Report 2011.

How we measure

5 Approach to Weights and Analysis

Index 2012 includes the same levels of weights as Index 2010, maintaining consistency and allowing comparability of the data and analysis. This will permit trend analysis in key areas. The framework is constructed along 7 Technical Areas and 4 Strategic Pillars. The weights for Index 2012 for these two weighting levels are graphically demonstrated in the following section.

Figure 5 Framework of Analysis Index 2012



Technical Areas - weight adjustments

The seven Technical Areas remain as follows:
A General Access to Medicine Management, B Public Policy and Market Influence, C Research and Development, D Equitable Pricing, Manufacturing and Distribution, E Patents and Licensing, F Capability Advancement in Product Development & Distribution, G Product Donations and Philanthropy.

The weight adjustments of these Technical Areas were guided by the inputs from the different stakeholder groups. Equitable Pricing, Manufacturing & Distribution has gained 5%, bringing it to 25%, and Research & Development has decreased by 5%, bringing it to 20%.

Rationale:

- pricing, manufacturing and distribution have very direct relevance to access and
- many more activities are covered in this TA relative to the others, and this needs to be reflected in the scoring.

This TA has now 39 indicators, which cover six thematic areas. These include the following:

Pricing	Sales agents' pricing practices
	Pricing mechanisms based on affordability
Manufacturing	Quality Management for Index Disease products for Index Countries
	Product recalls - policies & practices
Distribution	Registration for use of products in Index Countries
	Brochure & packaging adaptation for Index Countries

The current approach acknowledges the implicit relationships between pricing, manufacturing and distribution and brings them together under one umbrella. Given the breadth of scope in relation to the other TAs, it has been agreed that its weight, relative to the other TAs, should be higher.

While some stakeholders have recommended a separation of matters related to pricing from those related to manufacturing and distribution (or supply chains), the Index team has decided to pursue the approach taken in Index 2010 and avoid adding complexity to the framework of the Index, the latter of which was also a strong request from many stakeholders.

Strategic Pillars - weight adjustments

Each Technical Area is assessed along four strategic pillars, as were used in Index 2010 as follows: Commitments, Transparency, Performance, and Business Model Innovation.[7] For these four strategic pillars, a weight distribution of 25%, 25%, 40%, and 10% respectively, is attributed.

7 In Index 2012, the Innovation Pillar has been renamed 'Business Model Innovation' to clarify that the Index is evaluating whether companies have been innovative in relation to how they tackle access to medicines

In Index 2012, the Performance pillar has increased to become the largest strategic pillar, at 40%, reflecting the widely held view that monitoring and evaluating performance drives results. Given the extreme urgency of achieving positive outcomes for those most in need of improved access to medicines, Index 2012 will focus on outcomes and impacts of company initiatives more than on inputs. As such, companies will receive higher scores for demonstrating positive actions and - where feasible - outcomes from these actions than for demonstrating only commitment to or transparency in particular areas of work.

Where outcomes or impacts of some company initiatives cannot yet be detected (due perhaps to the nascence of an initiative), the inputs and outputs - captured under the Commitment and Transparency pillars - are important proxies for outcomes. The Commitment and Transparency pillars give a sense of the direction of companies' access strategies and are a signal to stakeholders of whether things are progressing as desired by the global public health community. The Performance pillar is a reflection of the past and is a lagging indicator of performance while commitments are promises for the future and are leading indicators of companies' access to medicine performance.

Index 2012 will continue to use a combination of an absolute and a relative rating system. It will also strive to include as many quantitative indicators as deemed possible at this stage of maturity. Currently, lack of sufficient empirical research on best practices limits the use of absolute ratings for the quantitative indicators. Index 2012 will therefore use absolute rating for the qualitative indicators and relative rating for the quantitative indicators while maintaining the long-term goal for the Index to move towards an overall absolute rating system.

Moving forward, the Index will continue to work with relevant experts to establish a set of best practices for all indicators. By moving toward an absolute rating system, the Index will continue to motivate low performers to improve their access to medicine strategies while also inspiring high performers to do more.

Weights

Technical Areas

10% A

General Access to Medicine Management

This Technical Area strives to capture the companies' overall commitment to and management of access programmes. Under this Technical Area, the companies' general level of commitment and transparency in regard to access to medicine in the Index Countries are analyzed. Beyond strategic commitment and policy statements in this area, representation of access to medicine issues at the senior governance levels of the company, internal incentives structures to encourage good performance in work relating to improving access to medicines and also the companies' approach to monitoring and evaluating the inputs and outputs of its access to medicine initiatives are analyzed. Finally, this Technical Area also attempts to capture the companies' level of engagement with different stakeholders with the aim of supporting and maintaining a positive and constructive policy environment to improve access to medicine in the Index Countries.

10% B

Public Policy & Market Influence

This Technical Area strives to capture the companies' overall management of external relationships - with policy makers, competitors, and users or customers - that impact access. It includes three sub-areas of lobbying and advocacy practices (including anti-bribery and anti-corruption), competition policies and practices, and marketing policies and practices. It captures the influence of the companies on the marketplace and how the companies' influence impacts access to medicine in the Index Countries.

20% C

Research & Development

This Technical Area concentrates on the company efforts in research aimed at developing new or adapted remedies for high priority diseases in the Index Countries, where there is an unfulfilled research need and a market failure. It covers both in-house and collaborative research initiatives. Innovative and Adaptive R&D are separately analyzed under this Technical Area. It also captures any controversies related to clinical trials and companies' approach to monitoring ethical standards. Intellectual capital sharing and licensing details pertaining to collaborative research and impacts on access to medicine in the Index countries is highlighted as well.

25% D

Equitable Pricing, Manufacturing & Distribution

This Technical Area attempts to capture how the companies' pricing policies, and its supply chain for Index Disease products in the Index Countries. The main topics under this area are the companies' approaches to equitable (affordable) pricing across their product portfolios (including tiered pricing schemes), their criteria for deciding market entry and applying for market approval in the Index Countries, their methods of quality assurance for product delivery, and their approaches to packaging and distribution to and within Index countries.

15% E

Patents & Licensing

This Technical Area analyzes the companies' intellectual property protection strategies and practices in the Index Countries with regards to their impact on access to medicine. Major topics covered under this area are the companies' approach to TRIPs, TRIPs flexibilities and TRIPs Plus measures, including patent filing, in Index Countries. It also covers the companies' socially responsible and humanitarian use licensing practices, the use of non-exclusive voluntary licenses or non-assert declarations for Index Disease products in Index countries, and their stance towards patent pools and IP-sharing.

10% F

Capability Advancement in Product Development & Distribution

This Technical Area focuses on the company initiatives that are conducive to capacity advancement in product development and distribution in the Index Countries as well as activities related to national pharmacovigilance programmes in the Index Countries. It strives to capture efforts to increase absorptive capacity in Index Countries as an enabler for knowledge transfer, exchange, translation and adoption. Initiatives in this area can include research collaborations with Index Country organizations, development of quality management capacities, technology transfer (including know-how) to the local manufacturers or local in-house facilities, and contribution to the establishment of pharmacovigilance systems in the Index Countries. Initiatives to build other capacities outside the pharmaceutical value chain may be captured as long as no conflict of interest is detected.

10% G

Product Donations & Philanthropic Activities

This Technical Area concentrates on the companies' product donation initiatives and philanthropic activities. It strives to capture the effectiveness of the companies' single and multi-drug donation programmes and whether their strategies are aligned with the needs of the target communities. With regards to other philanthropic activities, the Index 2012 attempts to analyze the sustainability of such initiatives, including their relevance to national health priorities or development plans, and also the companies' attempts in measuring and reporting the output of these initiatives.

Weights

Strategic Pillars

25% I

Commitments

In this pillar, the inputs - including policy statements or commitments in more concrete forms - are measured. It covers companies' strategies related to access to medicines and their policy stance in areas with potential impact on access. It is of critical importance because it is the area that includes leading variables. While the Performance pillar captures current performance based on past initiatives, the Commitments pillar is a key factor affecting the future performance of the companies under coverage. Along with commitment indicators in each area such as R&D, Patents & Licensing, etc., this section also includes a set of general indicators, which capture the company's overall commitments to access to medicine in the Index Countries.

25%

II Transparency

In this pillar, all the indicators are focused on whether the companies disclose the needed information for external assessment of their access to medicine initiatives without adopting a normative position on the content of the disclosure. Transparency-related analysis is carried out across all of the Technical Areas. It should be noted that for each indicator, the Index will capture whether the data was publicly available or whether it was made available through one-on-one engagement with the companies. As a result, it will be possible to compare both public and engagement-based disclosures of the companies.

40%

III Performance

This is one of the most controversial and highly demanded aspects of the Index. The Performance pillar focuses on the performance and implementation of the companies' access to medicines initiatives across different dimensions. The ideal performance variable is the company's impact or the social burden of the Index Diseases in the Index Countries, but this variable is affected by many external factors, which are beyond the companies' control. For different aspects of access to medicine, the performance indicators capture variables that are least affected by factors that the companies cannot control.

10%

IV Business Model Innovation

The sustainability of access to medicine initiatives is dependent on developing innovative business models. Such business models can result in financial sustainability of the access to medicine projects and resilience towards issues such as lack of infrastructure, political instability etc. in the Index Countries. It should be pointed out that, under the strategic pillar of Business Model Innovation (previously referred to only as 'Innovation'), only innovations along the drug development and supply chain are captured. In other words, projects launched by the companies in areas such as building health infrastructure, healthcare education and patient awareness are covered under the Philanthropy area (or other Technical Areas if conflicts of interest are adequately managed), not under the Business Model Innovation pillar. This is based on the frequently iterated stakeholder viewpoint that the pharmaceutical companies should be primarily rated based on activities consistent with their core competencies, and while other innovative activities should be taken into consideration, they should not have significant weight and visibility in the Index.

Having a separate strategic pillar for Business Model Innovation is compatible with the strategic goal of the Index to be a driver for innovation in provision of access to medicine in the Index Countries. This pillar has maintained a relatively lower weight in Index 2012 than the other pillars. This is because there is a relatively greater degree of subjectivity concerning the appraisal and measurement of the innovativeness of initiatives. Comparability across the companies is also limited in this area. Finally, this pillar primarily captures inputs whereas Index 2012 places a greater emphasis on outcomes and impacts than inputs. Not withstanding this, innovative initiatives can of course achieve desired outcomes, and can therefore concurrently be scored under the performance pillar.

6 Sources of Information

For the benchmarking process, the MSCI team obtains data from a wide range of sources, including corporate reports, conference reports, peer reviewed journals and the grey literature.[8]

8 Please note this list of sources is not exhaustive at the current stage of data collection, and will be updated in the final Index 2012 report once the research collection phase is finalized.

Journals/ Articles

The Lancet, E-drug, ICIUM-3 conference abstracts, PLoS, British Medical Journal.

Corporate documents

Annual reports, environmental and CSR reports, securities filings, 10k and other, websites.

Government and multilateral organisation data

Publications, databases and interviews with governmental officials, e.g. the Center for Responsive Politics (Public Policy Influence & Advocacy), the US National Institutes of Health (R&D and Clinical Trials), PubMed (drug indications), FDA (drug quality and promotion), EMEA, WHO (Prequalification, registration, patents, pricing).

Website content and reports

clinicaltrials.gov, WTO(Compliance with TRIPS), ICH-GCP (Research Ethics), ANDI Network, WIPO Re:Search, UN (UNHR - clinical trial conduct, UNDP - IP Rights, UNITAID, UNCTAD, UNGRI, UNICEF), OECD (anti-corruption), WBI, CHAI, and World Economic Forum (PACI).

Online news databases & MSCI Search Engines

LexisNexis, Impact Monitor.

Other online databases

Policy Cures ('G-Finder'), globalhealthprogress.org (Capacity building, philanthropy & R&D), mims.com, REPRISK.

Industry sources

Pharmaceutical industry publications and reports, e.g. IFPMA, ABPI, PhRMA, EFPIA, NEFARMA, LEEM, Industry journals, e.g. BioExecutive, PharmaFocus, Pharmaceutical Executive, and Pharmatimes.

Not for Profit and Civil Society

Either reports from and/or interviews with Non-Governmental Organizations familiar with the companies' operations have taken place with the following entities:
African Medicines Regulatory Harmonisation Initiative (AMRHI, NEPAD), Campaign for Global Development (CG Dev), CARE, Center for Political Accountability, Centre for Research on Multinational Corporations (SOMO), Competition Authorities reports, Concept Foundation, Elizabeth Glazer Pediatric AIDS Foundation, European-Developing Country Clinical Trials Program (EDCTP), Global Fund for AIDS, TB and Malaria Price Reporting Mechanism, Health Action International (HAI), Institute for One World Health (iOWH), Médecins Sans Frontières (MSF), Nuffield Council on Bioethics, South Centre, United Nations Industrial Development Organization [(UNIDO) /GTZ partnership project for local production in Africa], Wellcome Trust.

Multilateral agencies
European Commission, European Parliament Directorate General for External Policies Policy Department, United Nations (UN), World Health Organization (WHO), World Intellectual Property Organization (WIPO), World Trade Organization (WTO).

Government agencies
DFID

Other third-party sources
International agreements and codes of conduct were consulted, including the Partnering Against Corruption Initiative (PACI) of the World Economic Forum and Declaration of Helsinki. Reports and interviews with the stakeholders we consulted during the development of the Index framework including investors, consultants and academics.
Only specific information is sought from company representatives where there are gaps in data or inconsistencies among the above-mentioned sources. The companies are the primary source of information in areas such as research pipeline details and products portfolio details. They respond to a detailed information collection package, including an online questionnaire and email and phone communications, which covers primarily these areas and also other areas where our analysts need additional information from the companies.

7 Other Enhancements

Data Collection and Handling

The Index 2012 has modified Index 2010's online platform for data collection. Following a staggered rollout, each company is sent their online questionnaire that has been pre-populated using publicly available information, wherever possible. The online platform for Index 2012 is designed to provide a safe and secure portal to streamline data collection for analysis, while easing the data collection burden on the companies. The platform supports the Index 2012's effort to engage in longitudinal analysis, by creating a database to track companies' progress over time. Further, the Index team will use third-party interviews to verify some of the analysis. The Index team hopes that these efforts will address stakeholder feedback regarding increasing transparency around how the indicators change, the validity process, and data integrity for ranking when missing values occur.

Ranking and Scoring Process

The Index 2012 has undergone a thorough review of the indicators and scoring guidelines that will be used to appraise and rank the companies. Index 2010 ranked overall company performance in terms of policies and practices relating to access to medicines as well as in terms of performance under each Technical Area. The Index 2012 will provide additional sub-rankings, providing a more nuanced and dynamic analysis of company performance over time and in different areas of activity.

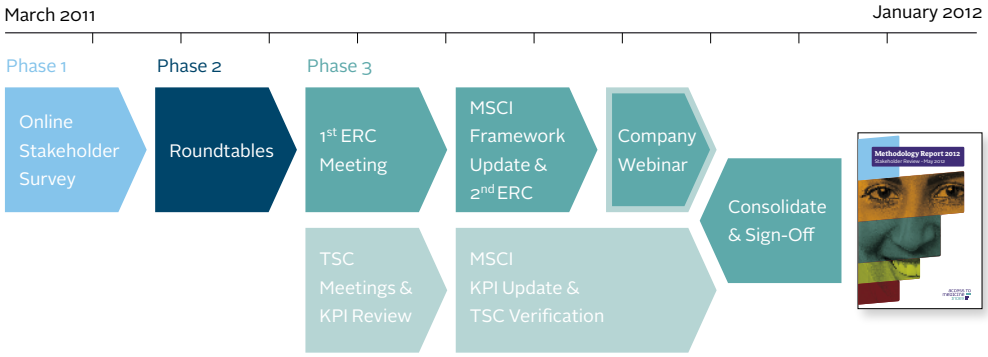
Indicator Review

8 Refining the Indicators

As in 2010, a set of indicators has been developed to reflect the full set of industry activities that can affect access to medicines, insofar as it is feasible and practicable to capture this data. The indicators are arranged in relation to the various themes within each of the seven Technical Areas and, where appropriate, across the four Strategic Pillars.

In an effort towards continuous improvement of the Index, an evaluation of the Index 2010 indicators was conducted to inform the review and refinement process. This process included an internal review by the Index Team's analysts, external consultation through a stakeholder survey (involving a diverse set of stakeholders) as well as in-depth follow up discussion with the Index's Technical Subcommittees (TSCs). The TSC experts complement the work of the Expert Review Committee (ERC), the Index's multi-stakeholder advisory committee that continues to provide guidance at a strategic level for the Access to Medicine Index.

Figure 6 Review Process



Many stakeholder recommendations to amend the indicators have been integrated into the scoring guidelines rather than into the indicator text directly. In some cases this is to enable longitudinal analysis, in others to ensure accuracy with changes in the global health landscape. In the majority of such cases, the scoring guidelines have been amended to be much more specific and ensure that there is both stringency and consistency in the way in which the scoring is carried out.

Summary of Stakeholder Feedback

The Index's stakeholder consultations provided helpful feedback on a range of areas concerning the Index's scope and approach as follows:

- **Enhancing measurement of Performance in relation to access to medicines**
  Many stakeholders gave feedback about the relative weight of the three most dominant Pillars (Commitment, Transparency and Performance) and it was generally agreed that Performance should be weighted most heavily, with Commitment carrying the smallest relative weight, and Transparency falling in the middle. This has been reflected in the Pillar

weights for 2012 (now revised) and discussed in the section 'Approach to Weights and Measures'. The stakeholder survey also revealed a desire to go beyond the global level and appraise company policies and activities that address challenges at the local level. The Index 2012 indicators have been refined to achieve this, for example looking for policies and codes of practice relating to the behaviours of third party distributors in-country.

- **Enhancing measurement of business model innovation in relation to access to medicines**
  Strong feedback from the stakeholder surveys, round table meetings and TSC meetings also highlighted a degree of confusion and misunderstanding around the purpose of the 'Innovation' Pillar. In Index 2010, this Pillar was intended to capture innovations in policies and initiatives related to access to medicines. As such, and to avoid causing any further confusion, for 2012 it has been renamed to 'Business Model Innovation'. This reflects that the Index wishes to appraise and rank companies for any novel and leading initiatives that will make an impact on access to medicines but may not have been captured by the indicators in the other pillars. Regarding this pillar, there were also requests from stakeholders to improve the way in which innovations in addressing access to medicines are defined, captured and scored. This has prompted a thorough review of the indicators in this pillar (as with all others) to improve relevance, consistency and accuracy in reporting.

- **Enhancing measurement of Commitment to improving access to medicines**
  Reflecting stakeholder and TSC feedback that the Commitment indicators should be even more meaningful and dealt with in a consistent manner, the scoring guidelines that underpin the indicators have been enhanced. They now explicitly specify more demanding modes of commitment by companies and require greater stringency in the evidencing of these.

- **Improvements to measurement of company behavior in-country**
  The review process enabled requests by stakeholders to cease using controversies or litigations in developed country markets as a proxy for behaviours in Index Countries. Instead, the Index relies on evidence of litigation and controversial behavior in Index countries.

- **Reflecting changes in the global health and R&D environment**
  Also based on stakeholder feedback and consultations with experts, the indicators have been updated to reflect changes in the environment and global health landscape since the Index 2010. For example, as the Medicines Patent Pool has had a change of name (from UNITAID), this has been reflected in the indicators. Additionally, any new initiatives, such as WIPO Re:Search or the United Nations Guiding Principles on Business and Human Rights, have also been captured in the scoring guidelines for relevant indicators.

- **Measuring activities outside the R&D value chain**
  Ratified by the ERC, the Index team has responded to multiple stakeholder feedback to improve the way in which the Index gives credit for access-related activities or initiatives that fall outside the standard pharmaceutical R&D value chain. In the scoring process, these activities will now be assigned to higher value Technical Areas if conflicts of interest are adequately managed (based on whether or not the multilateral agencies have signed up to partnerships relating to these activities), giving greater weight than if captured in the Product Donation and Philanthropy Technical Area (which is where they will be captured if conflicts of interest have not been contained).

- **Measuring the companies' approach to Manufacturing**
  Quality assurance is an essential aspect of building capability to ensure safe manufacture and supply of medicine. Index 2012 will focus on the transfer of quality assurance (QA) skills and practices under the Capability Advancement in Product Development and Distribution Technical Area. This will measure the extent to which a company's QA capacity is transferred. Unlike in 2010, the analysis will include in-house activities as a means of technology and knowledge transfer. Furthermore, in Index 2010 credit was not given to companies for transferring manufacturing capabilities to LICs (or the LHDCs, using the Index 2010 UN HDI country ranking). In Index 2012, this will be judged on a case-by-case basis and credit will be given to companies if manufacturing adds value to QA practices in local pharmaceutical industries, particularly in the LICs.

- **Capturing the companies' approach to Corruption and Controversies**
  Based on consistent stakeholder feedback relating to the importance of stemming bribery and corruption for achieving all development goals, and Access to Medicine Foundation's commitment to raise the visibility of anti-corruption, which can be an inhibitor to access, Index 2012 will specifically cover corruption/anti-corruption practices at the indicator level by including key performance indicators to capture anti-corruption measures taken by companies based on evidence of anti-bribery codes of conduct and whether these are disclosed and enforced, whether companies are members of PACI or if they are a signatory of the UN Global Compact.

Summary of Technical Subcommittee Feedback

As part of the indicator review, many additional issues were also discussed explicitly by the Technical Subcommittees (TSC), as discussed below. Each TSC included two to four international experts from varied backgrounds, including global health professionals, academics, and consultants. For an overview of the contributors, see Appendix 1. The TSCs met in September 2011, to provide valuable technical input on the majority of the Index's indicators and carefully reviewed specific Technical Areas and provided recommendations for refining some indicators and adding or removing others. This feedback was very detailed, a summary of which has been provided in the following section.

- **Equitable pricing, manufacturing and distribution**
  This TSC provided technical input on indicators related to company initiatives regarding pharmaceutical product pricing, manufacturing and distribution, and capacity advancement in these areas.

  As mentioned earlier, the need to give outcomes and impacts (via the Performance pillar) more weight is felt most strongly in relation to the Equitable Pricing, Manufacturing and Distribution Technical Area, and most keenly in relation to equitable pricing. The TSC discussed ways in which the impacts of such programs might be measured, acknowledging the current challenges associated with obtaining reliable data relating to patient access to equitably priced products. Given the barriers currently faced by the Index due to an absence of reliable patient access data and a dearth of comparable end-point pricing data, reliable proxy measures have been developed. Accordingly, the Index 2012 will measure companies' tiered pricing programs according to the difference between

the average price of products in the lowest tier (Tier 0) and those in the highest Tier. Companies consistently demonstrating the highest differentials in price for the Index Diseases (i.e. providing significantly lower prices for Index Countries) will be scored most favorably.

In relation to company initiatives trying to ensure equitable pricing, several industry respondents have reiterated that controlling pricing practices of distributors is often impossible, beyond the control of the company, or is illegal, as pricing is subject to market forces. However, the Index team still urges companies to take steps to ensure that their access-related values and priorities are integrated throughout the value chain and, as with all policy issues across all Technical Areas, will reward companies for developing and trying out new initiatives to effect positive change and for high levels of transparency regarding pricing data.

- **Intellectual property and competition**
  This TSC provided technical input on indicators related to intellectual property protection, corporate research-sharing policies and practices, competition practices of the pharmaceutical companies vis-à-vis peers and generics manufacturers and behaviours relating to the international regulatory environment.

  Reflecting wide feedback, the Patents and Licensing indicators have been enhanced to reflect a greater range of IP practices than just non-exclusive voluntary licensing or waiving of all rights in Index Countries, which were the main strategies promoted by the Index in 2010. Instead, the Index 2012 will measure companies on their use of socially responsible licensing practices and humanitarian use exemption clauses, as well as legally-binding non-assert declarations (NADs) (non-legally binding NADs are not treated equally by Index 2012). This will ensure that IP practices are looked at more holistically in terms of access to medicine. Indicators such as E.I3 and E.II.3, which had previously presented difficulties for Index 2010 have now been refined to include these practices in order to make the indicators more meaningful.

  Company practices related to the transfer of confidential technical know-how will also be measured and the use of milestones in licensing agreements to support such technical transfer will be measured.

  Company activities in relation to TRIPs and TRIPs Plus will continue to be monitored and appraised, particularly as regards various strategies that may delay generic entry or promote enforcement of patents in the Index Countries.

- **Research and development**
  This TSC provided technical input on indicators covering in-house and collaborative research and technology transfer related to R&D for Index diseases.

  For a specific set of indicators, they recommended that there be a greater focus on output rather than input measures. For example, there has been a shift away from measuring the numbers of peer-reviewed journals produced in collaborative R&D partnerships, to trying to capture the progress of projects along the R&D value chain.

Furthermore, the way in which the Index measures company behavior in relation to clinical trials was reviewed by the TSC, and in Index 2012 a greater focus will be given to the degree to which trial participants are given post-trial access to the medicines being tested.

The way in which the Index captures company approaches to the intellectual property (IP) generated in R&D collaborations, including public private partnerships, was also reviewed. Index 2012 will take a broad approach to IP management strategies, not requiring companies to waive all rights to such IP, but instead will measure company use of socially responsible licensing and humanitarian use exemption approaches that place an explicit emphasis on access.

In line with a widely held view to simplify the list of indicators, the TSC also reviewed indicators around commitment of resources to R&D for Index Diseases, which had been captured in two separate indicators in 2010, depending on whether the activities were in-house or done in collaboration. The outcome is that the two areas have been merged into one indicator that emphasises the importance of investment in R&D collaborations as much as in-house R&D, but will be scored separately.

- **Promotions, marketing and anti-corruption**

  This TSC provided technical input on indicators related to promotional and marketing activities involving access to medicine in the Index Countries as well as indicators covering anti-corruption policies and practices of pharmaceutical companies.

  The TSC recommended that the Index 2012 capture initiatives related to fighting corruption within a single broad indicator on lobbying and ethical marketing and this approach has been implemented. These activities will be scored separately, but measured within a single indicator.

  To ensure a greater focus on performance than in 2010, certain commitment-based indicators will be dropped and performance indicators added. For example, commitments to international codes on ethical marketing (captured in indicator B.I.4) will be replaced with indicators measuring any breaches of those codes. Additionally, the TSC recommended taking a more stringent approach to measuring companies For example, where the focus had previously been on measuring commitments to ensure ethical marketing practices from third parties, the emphasis for 2012 will be appraising the steps the companies take to monitor and enforce such practices.

  Furthermore, based on TSC feedback, indicator B.III.4 has been significantly amended to reflect a more rigorous approach to evaluating company performance in relation to their agreements with third party distributors. For 2012, this indicator focuses on the measures the companies have in place for monitoring, enforcing and taking disciplinary action against those third parties that breach international codes and standards related to ethical marketing. A similar approach has been adopted in relation to measuring company efforts to prevent negative employee behaviors and encourage compliance with relevant codes of conduct.

  The consultation processes have revealed that Index 2010's indicator B.IV.1 was not considered to be a particularly meaningful indicator. As such, it has been replaced with

an indicator seeking to measure initiatives that promote ethical and efficient business performance and interactions in Index countries in areas such as marketing, lobbying, anti-corruption, pro-competition, particularly in the use of employee incentive schemes.

As noted earlier, the TSC also wanted the Index to clarify the requirements around certain commitment indicators to ensure consistency in the scoring. For example B.I.1, which is around commitment to transparency in lobbying activities, has had adjustments to the relevant scoring guidelines to ensure that the target (that is, who is being lobbied) is specified.

- **Capability advancement in manufacturing**
  Responding to stakeholder feedback, the TSC and ERC agreed that in-house manufacturing should be included under capacity advancement as it supports technology transfer, builds local knowledge and stimulates local economies.

Approach to Indicator Review

As a result of the combined ERC and TSC process, new indicators have been added, existing indicators rationalised and the scoring guidelines enhanced to:

- remove redundant or repetitive indicators and obtain an overall lower number of indicators to 101
- attempt to capture company performance and outcomes as far as possible, using proxy measures where necessary
- capture company commitment to and transparency around policies where performance data is unavailable or unreliable
- give higher rewards to companies making more specific, concrete or onerous commitments
- ensure alignment with national health and development plans to improve sustainability of access to medicines initiatives
- reward companies for monitoring and enforcement of compliance with codes of conduct by employees and third party contractors where outcome measures are not available
- capture realisation of commitments, including analysis of the life cycle of philanthropic initiatives.

Table 4 Indicator Changes from 2010 to 2012

Summary	Indicators
Total Index 2010 Indicators	111
Total Added	12
Total Removed	22
Total Index 2012 Indicators	101[9]

9 Includes 2 Experimental Indicators which are not scored

Index 2012 Indicators

The complete set of Index 2012 indicators are listed in the following section. The table includes the following information: the left column 'Index 2012 indicator' lists all of the renumbered indicators for 2012, per Technical Area. The right column 'Change' explains the type of change per indicator; as well as the rationale for any 2012 KPI revisions and a reference to the 2010 indicators.

A General Access to Medicine Management

	Index 2012 Indicator	Change/Rationale
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 the Index Countries.	Unchanged
A.I.2	Stakeholder engagement The company commits to work with the stakeholders including universities, patient groups, local governments, employees, local and international NGOs and peers with the aim of improving access to medicines in the Index Countries for the Index Diseases.	Unchanged
A.I.3	Governance: performance management & incentives The company commits to the development of internal incentive structures to reward effective delivery of initiatives that improves access to medicines in the Index Countries for the Index Diseases.	New To measure commitments to incentivising employees to perform well in relation to improving access to medicines for the Index Diseases in the Index Countries.
II	**Transparency - 25%**	
A.II.1	Strategy: policies & practice The company reports on its access to medicine policies and practices and discloses its overall rationale for its Access to Medicine activities.	Major revision Merged with Index 2010 Commitment Indicator [A.I.2] "The company publishes a publicly available annual report on its access to medicine policies and practices." [A.II.1] & "The company has a public policy in place in-which it explains the rationale for its access to medicine activities in the Index Countries and the overall firm objectives in this area." [A.I.2]
A.II.2	Strategy: policies & practice The company discloses quantitative and qualitative performance measures and targets for its access to medicine practices related to the Index Countries.	Unchanged

	Index 2012 Indicator	Change/Rationale
III	**Performance - 40%**	
A.III.1	Governance: management structures, performance management & incentives The company has a management system including quantitative targets to implement and monitor its Access to Medicine strategy in the Index Countries.	Unchanged
A.III.2	Stakeholder engagement Senior management participates in public debate and engages with the 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 (measured through sponsoring and participating in relevant conferences, workshops, etc.).	Minor revision (wording)
A.III.3	Strategy: policies & practice Trends in the company's sales in the LIC and LMIC markets compared to sales in the rest of the world during the past five years.	Major revision To capture trends in companies' footprints in emerging markets as a signal of increased activity or agility. Changed to focus on sales rather than revenues and disaggregated LMICs from LICs as these represent different objectives.
A.III.4	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.	New To measure performance correlated to the Commitment Indicator regarding incentive structures.
IV	**Innovation - 10%**	
A.IV.1	Innovation in general access to medicine management The company has adopted innovative (unique in the sector) approaches to General Access to Medicine Management including ATM governance, ATM Management System and stakeholder engagement.	Unchanged

B Public Policy and Market Influence

	Index 2012 Indicator	Change/Rationale
I	**Commitments - 25%**	
B.I.1	Lobbying The company commits to transparency in its lobbying activities and the positions it seeks to promote where it has an impact on access to medicine in the Index Countries.	Unchanged
B.I.2	Endorses 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.	Minor revision (wording)
B.I.3	Non-pursuit of data exclusivity The company refrains from pursuing data exclusivity for Index Diseases, for products related to the Index Diseases in the Index Countries.	Minor revision (wording)
B.I.4	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.	Major revision Revised to be more action- (i.e. performance) oriented through focus on enforcement of codes of conduct. Codes of conduct may also be universal/global, rather than expecting different codes for ICs than for other countries.
B.I.5	Anti-bribery/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	New To explicitly capture commitment to fighting Corruption & Bribery - recommended by the ATM Foundation's Technical Subcommittee.

	Index 2012 Indicator	Change/Rationale
II	**Transparency - 25%**	
B.II.1	Lobbying The company discloses the positions it seeks through its advocacy activities related to access to medicines in, or with potential impact on, the Index Countries (direct advocacy).	Minor revision (wording)
B.II.2	Lobbying The company discloses any potential governance conflict of interests and/or interest groups or institutions it financially supports, 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 revision (wording)
B.II.3	Lobbying 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.	Minor revision (wording)
B.II.4	Endorses competition & non-pursuit of data exclusivity 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.	Minor revision (wording)
B.II.5	Ethical marketing The company 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 revision (wording)
B.II.6	Ethical marketing, anti-bribery/corruption The company voluntarily discloses all information regarding its breaches of internal and internationally recognized codes of conduct for ethical marketing, bribery and/or corruption in Index Countries in the last five years and also litigations related to marketing practices in the Index Countries.	Minor revision (wording) Merged KPIs [B.II.6] and [B.III.3] from Index 2010. For more reliable data the KPI now includes global codes addressing bribery and/or corruption. "The company publicly discloses information regarding its breaches of codes (such as the IFPMA Ethical Marketing Guidelines) and also litigations related to marketing practices in the Index Countries." [B.II.6] "Have there been breaches of the IFPMA Code of Pharmaceutical Marketing Practices or litigations or fines levied against the company related to marketing behavior in the Index Countries during the past five years?" [B.III.3]

	Index 2012 Indicator	Change/Rationale
III	**Performance - 40%**	
B.III.1	Lobbying, ethical marketing, anti-bribery/ corruption The company has been in breach of any national or international codes of conduct in relation to lobbying, ethical marketing and/or bribery and corruption.	Minor revision (wording) Revision to focus more squarely on lobbying and bribery and corruption.
B.III.2	Endorses competition Is there evidence* of the company's anti-competitive behaviour** in the Index Countries based on fines or litigation records during the past five years?	Minor revision (wording) * Evidence refers to fines or reports/controversies **Excluding all IP anti-competitive practices
B.III.3	Lobbying, ethical marketing, anti-bribery/ corruption The company has taken disciplinary action against third parties or employees who violate its codes 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 which violate its codes of conduct for ethical marketing or lobbying and anti-corruption.	Major revision Focus on disciplinary action and enforcement processes or procedures for combined lobbying/corruption and marketing violations. More action and outcome-oriented and economical. Previously difficult to obtain data. Recommended by the ATM Foundation's Technical Subcommittee. Merged KPIs [B.III.5] and [B.III.4] from Index 2010. Does the company have an employee code of conduct in place for the Index Countries, which emphasizes ethical marketing principles equivalent to the company's codes in this area for the Western markets?" [B.III.5] "Does the company include ethical marketing requirements consistent with international codes and standards (such as the IFPMA Code of Pharmaceutical Marketing Practices) in its agreements with its Index Country distributors?" [B.III.4]
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 and efficient business performance and interactions in Index countries in areas such as marketing, lobbying, anti-corruption, pro-competition.	Major revision Addressing companies' innovative employee incentive measures that reward employees for development of sustainable access to medicines initiatives, including ethical marketing, anti-corruption or pro-competition. Looking for public disclosure that internally these measures are taken seriously.

C Research and Development

	Index 2012 Indicator	Change/Rationale
1	**Commitments - 25%**	
C.I.1	Innovative and adaptive R&D for IDs 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.	Major revision Merged KPIs [C.I.1] and [C.I.2] from Index 2010. Will continue to make the distinction between adaptive (incremental) and innovative (breakthrough) research in the scoring guidelines. "The company commits to carry out research focusing on the development of new remedies for the Index Diseases with the goal of improving access to medicine in the Index Countries through in-house R&D and/or research collaborations. (Innovative Research)" [C.I.1] "The company commits to carry out research and development aimed at developing new formulations (such as fixed dose combinations, pediatric formulations, heat-resistant preparations etc.) of the existing products for the Index Diseases suitable to the Index Countries. (Adaptive Research)" [C.I.2]
C.I.2	Clinical trials conduct The company commits to provide products for free to the clinical trial participants in Index Countries (i.e., post-trial access), at minimum consistent with codes such as the Helsinki Code for Clinical Trials.	Minor revision (wording)
C.I.3	R&D partnerships conducive to access & IP sharing The company commits to ensuring equitable access to products successfully developed through R&D partnerships.	Major revision Revised KPI [C.I.5]. from Index 2010. To put emphasis on access to those in need rather than relinquishing of all rights in all cases. "The company commits to waive its rights in the Index Countries to the intellectual capital generated in public private partnerships for the Index." [C.I.5].
C.I.4	Accountability for conduct of CROs The company commits to ensuring that partner CROs uphold ethical standards when conducting clinical trials in Index Countries, at minimum consistent with codes such as the Helsinki Code for Clinical Trials.	New New Indicator to measure commitment to ensuring that third party CROs conducting clinical trials in Index Countries on companies' behalf uphold the highest ethical standards.

	Index 2012 Indicator	Change/Rationale
II	**Transparency - 25%**	Major revision Merged KPIs [C.II.1] and [C.II.3] from Index 2010.
C.II.1	R&D for IDs suitable to the ICs' needs The company discloses the resources dedicated to its research and development activities conducted in-house and/or in collaboration for Index Diseases suitable for the Index Countries.	"The company discloses the resources dedicated to its research and development activities related to the Index Diseases suitable the Index Countries (exclusions apply - for details please refer to the Access to Medicine Index 2010 Methodology Document)" [C.II.1] "The company discloses the resources dedicated to its research collaborations related to the Index Diseases (both human resources and financial)" [C.II.3].
C.II.2	R&D partnerships conducive to access & IP sharing The company discloses the licensing details pertaining to its research collaborations related to the Index Diseases (with regard to Intellectual Property rights, access provisions etc.).	Minor revision (wording)
C.II.3	Innovative and adaptive R&D for IDs The company discloses its research pipeline related to both in-house research and collaborations targeting Index Diseases (where disclosure is not legally required).	Minor revision (wording)
C.II.4	Clinical trials conduct & Accountability for conduct of CROs The company discloses information about the result 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 (i.e. CRO).	Major revision Focus on Clinical trials results alone rather than post trials access disclosure (which was also previously measured). Revised KPI [C.II.5] from Index 2010. "The company discloses information about the result of its clinical trials in the Index Countries and its approach to providing access to the products in the countries where the products are tested (when it is beyond legal requirements)." [C.II.5]
C.II.5	Accountability for conduct of CROs The company discloses information about contract partners for clinical trials (i.e. CROs) in Index Countries.	New Focus on transparency around which CROs are conducting business for companies (clinical trials) in Index Countries to enable better monitoring by stakeholders.
III	**Performance - 40%**	
C.III.1	R&D for IDs suitable to the ICs' needs Portion of financial R&D investments dedicated to Index Diseases (exclusions apply - for details please refer to the Access to Medicine Index 2012 Methodology Document) out of the company's total R&D expenditures.	Unchanged

	Index 2012 Indicator	Change/Rationale
C.III.2	Innovative R&D for IDs Share of research pipeline reflecting 'New molecules' for Index Diseases (exclusions apply - for details please refer to the Access to Medicine Index 2012 Methodology Document) including in-house and collaborative research.	Unchanged
C.III.3	Adaptive R&D for IDs Share of research pipeline and products registered reflecting 'adapted molecules or new technologies' specific to an Index Disease and an unmet need in an Index Country, including in-house and collaborative research.	Minor revision (wording)
C.III.4	R&D partnerships conducive to access & IP sharing Research and product development partnerships in which the company has been involved, with the aim of developing products or new formulations for Index Diseases specifically targeting Index Countries' needs (adjusted for the number of the molecules in the company's research pipeline).	Unchanged
C.III.5	Experimental Indicator R&D for IDs suitable to the ICs' needs Number of candidates relating to Index Diseases moving through research and development life cycle from early research phases to more advanced phases.	Major revision Projects relating to Index Diseases moving through research and development life cycle from early research phases to more advanced phases Focus on capturing progress of candidates progressing through the pipeline as more tangible measure of outcomes than quantities for peer-reviewed articles. Replacement of KPI [C.III.5] from Index 2010. "Peer-reviewed research papers published as a result of the research collaborations of the company with public-private partnerships or universities relevant to the Index Diseases (R&D exclusions apply - for details please refer to the Access to Medicine Index 2010 Methodology Document)." [C.III.5]
C.III.6	R&D partnerships conducive to access & IP sharing The company provides evidence that the terms and conditions of its research collaborations are conducive to improving access to Index Disease products access the Index Countries for the individuals with significant financial barriers to access.	Unchanged
C.III.7	Clinical trials 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?	Unchanged

	Index 2012 Indicator	Change/Rationale
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 Research, CDD, OSDD) that develop products for Index Diseases on terms most conducive to access for the Index Countries.	Minor revision (wording)
C.III.9	Accountability for conduct of CROs The company provides evidence about the steps it takes to ensure that partner CROs uphold ethical standards when conducting clinical trials in Index Countries, at minimum consistent with codes such as the Helsinki Code for Clinical Trials.	New Focus on monitoring by company management of CROs that are conducting business for companies (clinical trials) in Index Countries. Looking for number of audits and processes for enforcement and taking meaningful disciplinary action.

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.	Major revision Merged KPIs [C.IV.1] and [C.IV.2] from Index 2010. "The company has adopted innovative (unique in the sector), sustainable business models for research into Index Diseases (excluding New molecules for non-communicable Infectious Diseases)." [C.IV.1] "The company has engaged in innovative (unique in the sector) sustainable models for sharing intellectual property and patent rights with the other entities, which may result in improved access to suitable products for Index Diseases in the Index Countries." [C.IV.2]

D Equitable Pricing, Manufacturing and Distribution

	Index 2012 Indicator	Change/Rationale
1	**Commitments - 25%**	
D.I.1	Tiered or equitable pricing schemes The company commits to implement inter-country tiered pricing models for the products related to the Index Diseases in the Index Countries such that the average price in lowest tier is significantly lower than the average price in the highest tier.	Minor revision (wording)
D.I.2	Tiered or equitable pricing schemes The company commits to implement intra-country tiered pricing models for the products related to the Index Diseases in the Index Countries such that the average price in lowest tier is significantly lower than the average price in the highest tier.	Minor revision (wording)
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.	Minor revision (wording)
D.I.4	Drug recall policies & practices The company has in place the policies, procedures and resource needed to carry out effective drug recalls (product and packaging) in the Index Countries where it operates.	Minor revision (wording)
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).	Minor revision (wording)
D.I.6	Filing for marketing approval/registration for use of products in ICs The company commits to file for marketing approval or product registration of its products for the Index Diseases in the Index Countries in need.	Minor revision (wording)

	Index 2012 Indicator	Change/Rationale
II	**Transparency - 25%**	
D.II.1	Tiered or equitable pricing schemes The company discloses the percentage of its global revenues covered under equitable/tiered pricing programmes.	Major revision Focus on disclosure of proportion of global revenues covered by tiered pricing programmes, to focus on volume Revised from KPI [D.II.1] from Index 2010. "The company publicly discloses details of its equitable pricing approach for the Index Countries for products related to the Index Diseases." [D.II.1]
D.II.2	Tiered or equitable pricing schemes For products relating to the Index Diseases in the Index Countries, the company discloses its average prices in the lowest tiers and average prices in the highest tiers OR the percentage reduction from the average prices in the highest tier to the average prices in the lowest tier.	Major revision Focus on disclosure of average price reductions between highest and lowest tiers (and not actual price as this is potentially erroneous to commercial negotiations with suppliers). Revised from KPI [D.II.2] from Index 2010. "The company publicly discloses the outcome of its equitable pricing programmes (based on indicators such as number of patients having received the product, number of doses delivered based on the equitable price etc.)" [D.II.2]
D.II.3	Filing for marketing approval/registration for use of products in ICs The company discloses its decision process regarding registration (marketing approval) and also the status of marketing approvals for each product related to Index Diseases in the Index Countries.	Unchanged
D.II.4	Quality management systems for products for ICs The company discloses information about its quality management systems for products destined for the Index Countries (standards, processes, resources, etc.).	Unchanged
D.II.5	Drug recall policies & practices 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.	Unchanged
III	**Performance - 40%**	
D.III.1	Tiered or equitable pricing schemes Do the company's equitable/tiered pricing programmes for products relating to Index Diseases cover all or a significant percentage of the market in Index Countries?	Major revision Aiming to measure proportion of tiered pricing programmes within company's total revenues, as a proxy for the company's overall commitment to tiered pricing. Revised from KPI [D.III.3] from Index 2010. "What percentage of the total supply units made available by the company to the Index Countries was delivered for free or at cost during the period of analysis (excluding donations)? (Experimental indicator)" [D.III.3]

	Index 2012 Indicator	Change/Rationale
D.III.2	Tiered or equitable pricing schemes The difference in average price of products for Index Diseases in Index Countries in the lowest tier vs. the average price of products for Index Diseases in the highest tier (globally) is significantly lower than the average price in the highest tier (such that the differential is beneficial for access) OR the percentage reduction between the average prices in the highest tier to the average prices in the lowest tier is significant (such that the differential is beneficial for access).	Major revision Reflects average price differences between lowest and highest tiers. Revised from KPI [D.III.4] from Index 2010. "The company's average ex-manufacturing price for the Index Countries where equitable pricing has been used (the price for social segments with financial barriers to access) by the company divided by the average price for the product in developed markets over the last three years (2009, 2008, 2007) (Experimental indicator)" [D.III.4]
D.III.3	Filing for marketing approval/registration for use of products in ICs Has the company attempted to register (obtain marketing approval for) its products for Index Diseases in the Index Countries?	Unchanged
D.III.4	Drug recall policies & practices Have drug recalls occurred due to product or packaging quality issues in the Index Countries for products produced by the company, its licensees or other manufacturing partners during the past five years?	Minor revision (wording)
D.III.5	Filing for marketing approval/registration for use of products in ICs 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.	Minor revision (wording)
D.III.6	Brochure & packaging adaptation 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.	Minor revision (wording)

	Index 2012 Indicator	Change/Rationale
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.	Unchanged
D.IV.2	Innovation in manufacturing and 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.	Unchanged

E Patents & Licensing

	Index 2012 Indicator	Change/Rationale
I	**Commitments - 25%**	
E.I.1	Patents not filed in ICs (or binding NADs in place) The company commits to not filing for patents related to its products for the Index Diseases in LDCs.	Major revision Greater emphasis on the change that is needed, which is no filing of patents in the Index Countries, especially the LICs.
E.I.2	Fully respects TRIPS flexibilities The company commits to respect the right of the Index Countries to use the TRIPS flexibilities in-line with the Doha Declaration on the TRIPS Agreement and Public Health in the Index Countries.	Unchanged
E.I.3	Access-oriented IP/deal-making strategy for ICs The company commits to engage in non-exclusive voluntary licensing (NEVL) or use humanitarian use exemption (HUE) and binding non-assert clauses for exclusive voluntary licensing (EVL) where NEVL haven't been obtainable under principles of humanitarian/socially responsible licensing.	Major revision More explicit to ensure that several valid strategies are used, to reflect on the ground realities in deal-making. Revised from KPI [E.I.3] from Index 2010. "The company commits to engage in non-exclusive licensing for the Index Disease products to generics companies with the aim of increased accessibility and affordability. [Consider non-exclusive voluntary licenses equivalent to non-assert declarations]" [E.I.3]
E.I.4	Transfers technology and uses milestone-based agreements The company commits to engage in technology transfer related to the manufacturing, testing, storage and handling of products for Index Diseases (or APIs) through use of appropriate milestones.	New Focus on capturing the transfer of technical know-how and hardware in relation to furthering product development in relation to ID's - evidence of commitment.
II	**Transparency - 25%**	
E.II.1	Fully respects TRIPS flexibilities The company discloses its support of usage of TRIPS flexibilities based on the Doha Declaration on TRIPS and public health.	Minor revision (wording) Revised wording to ensure expectations are more specific regarding the Doha Declaration and TRIPS flexibilities.

	Index 2012 Indicator	Change/Rationale
E.II.2	Patents not filed in ICs (or binding NADs in place) The company discloses the patent status of its products for the Index Diseases in the Index Countries.	Unchanged
E.II.3	Access-orientated IP/deal-making strategy for ICs The company discloses detailed information about the voluntary licensing activities it is engaged in and its binding non-assert clauses for products related to the Index Diseases for the Index Countries. (Such as license duration, license territory, technology transfer etc.)	Minor revision (wording)

III Performance - 40%

E.III.1	Access-orientated IP/deal-making strategy for ICs Does the company actively engage in non-exclusive voluntary licensing and/or use legally binding non-assert declarations/clauses for the Index Countries for its products related to the Index Diseases?	Minor revision (wording)
E.III.2	Transfers technology and uses milestone-based agreements Does the company have technology transfer agreements in place as part of its license agreements and milestones/deliverables related to technology transfer and transfer of technical know-how in its licensing activities?	Major revision Focus on more concrete milestones in licensing agreements as a means to capture evidence of transferring technology to the Index Countries. Revised from KPI [E.III.3] from Index 2010. "Does the company have effective technology transfer regimes in place to improve the quality and production capacity of its voluntary licensees?" [E.III.3]
E.III.3	Support for IP sharing (MPP) 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.	Minor revision (wording)
E.III.4	Fully respects TRIPS flexibilities Is there evidence that the company actively lobbies national or regional government public health authorities or other companies and their trade associations, either directly or through third parties, for TRIPS+ measures (e.g. data exclusivity etc)?	New Indicator to monitor whether companies actively lobby, either directly or through third parties, for TRIPS+ measures.

	Index 2012 Indicator	Change/Rationale
E.III.5	Access-orientated IP/deal-making strategy for ICs 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 such as legally binding NADs and/or avoids anti-competitive practices such as evergreening, thicketing, protection of research tools etc)? products for Index Diseases in the Index Countries	Major revision Focus on both proactive and defensive actions with respect to ATM and patenting. Revised from KPI [E.III.1] from Index 2010. "Is there proof of the company's patenting practices which result in decreased affordability or accessibility of products for Index Diseases in the Index Countries? Such practices include patenting in Least Developed Countries and acting against usage of TRIPS flexibilities by the Index Countries based on the Doha Declaration on TRIPS." [E.III.1]

IV Innovation - 10%

E.IV.1	Innovation in patents & licensing 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 medicines to individuals with financial barriers to access (e.g., adopted innovative socially responsible licensing practices aiming at increased effectiveness of its licensing programmes).	Minor revision (wording)

F Capability Advancement in Product Development and Distribution

	Index 2012 Indicator	Change/Rationale
1	**Commitments - 25%**	
F.I.1	Capacity building in QMS and manufacturing standards The company commits to assist Index Country (IC) manufacturers and local staff employed at in-house facilities operating in ICs in building quality management systems aimed at achieving international quality standards (e.g. FDA, EMA, WHO GMP or recognised national certifications).	Major revision Inclusion of in-house facilities in Index Countries. Revised from KPI [F.I.1] from Index 2010. "The company commits to assist its Index Country licensees and contract manufacturers with their quality management systems aimed at achieving international standards such as the FDA, EMA, WHO Good Manufacturing Practices, etc." [F.I.1]
F.I.2	Capacity building in R&D The company commits to engage in local scientific research partnerships with public sector research institutes and/or universities with the aim of developing indigenous capacity in basic, applied or clinical research, including clinical trials, in Index Countries.	Major revision Captures a broader range of partnerships and commitment to development of indigenous research and product development capacity through these, including clinical trials capacity building through CROs or other contractors. Revised from KPI [F.I.2] from Index 2010. "The company commits to engage in research focused public-private partnerships with Index Country organizations and to support research at the Index Country academic institutions with the aim of increasing local capabilities in this area." [F.I.2]
F.I.3	Capacity building in supply chain management The company commits to assist 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.	Unchanged
F.I.4	Capacity building in pharmacovigilance The company commits to support the development and/or implementation of national pharmacovigilance programmes in the Index Countries N.B. emphasis here is on national pharmacovigilance programmes (vs. global programmes)	Minor revision (wording) Looking for involvement in development of national programmes/ capacity & acknowledged role in drug quality and safety.

	Index 2012 Indicator	Change/Rationale
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 in the Index Countries. (N.B. emphasis here is on national pharmacovigilance programmes [vs. global programmes].)	Minor revision (wording) Focus on development of sustainable indigenous capacity through development of a national programme rather than ad hoc activities.
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 (such as FDA, EMA or the WHO Good Manufacturing Practices or equally recognised national certifications) in the Index Countries.	Minor revision (wording) Includes in-house facilities and focus on LICs to be more impact-oriented
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?	Minor revision (wording)
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.	Minor revision (wording)

	Index 2012 Indicator	Change/Rationale
F.III.4	Capacity building in pharmacovigilance The company is actively engaged in developing and implementing national pharmacovigilance-related programmes in the Index Countries.	Minor revision (wording)
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 organizations to address access to medicine in those countries.	New Focus on capacity advancement initiatives where there is clearly no conflict of interest.

IV Innovation - 10%

F.IV.1	Innovation in capability advancement in quality control The company has introduced innovative (unique in the sector) approaches to working with the Index Country organizations to improve the quality of the products for Index Diseases.	Minor revision (wording)
F.IV.2	Innovation in capability advancement in research product development and other capacities The company has introduced innovative (unique in the sector) approaches to working with the Index Country organizations which help improve the local research and product development capacity and other capacities for the Index Diseases.	Minor revision (wording)

G Product Donations and Philanthropic Activities

	Index 2012 Indicator	Change/Rationale
I	**Commitments - 25%**	
G.I.1	Policies and practice in relation to drug donations The company commits to comply with the World Health Organization Inter-Agency Guidelines for Drug Donations in the Index Countries for all its drug donation activities.	Unchanged
G.I.2	Policies and practice in relation to drug donations The company commits to ensuring that donated products are administered to patients in the Index Countries	Minor revision (wording)
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 medicines in Index Countries.	Major revision Merged KPIs [G.I.3] and [G.II.3] from Index 2010. Focus on the company policy behind philanthropic activities and linkage to ATM/ sustainability. "The company commits to invest in health infrastructure-related philanthropic projects in the Index Countries with the aim of sustainable and efficacious pharmaceutical supply systems." [G.I.3] "The company publicly discloses the rationale behind its philanthropic activities and their relevance to long-term sustainable access to medicines in the Index Countries." [G.II.3]
G.I.4	Commitment to single-drug donation programmes The company commits to delivering single-drug donation programmes, in line with WHO Inter-Agency Guidelines for Drug Donations.	New Looking for a commitment to single drug donation programmes, as widely seen to have more positive effects than multi-drug donation programmes.
II	**Transparency - 25%**	
G.II.1	Policies and practice in relation to drug donations The company discloses the process and criteria for deciding the drug types and destinations for its drug donation programmes in the Index Countries.	Minor revision (wording)
G.II.2	Policies and practice in relation to 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.	Minor revision (wording)

	Index 2012 Indicator	Change/Rationale
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.	Minor revision (wording)

III Performance - 40%

G.III.1	Experimental Indicator Commitment to single-drug donation programmes For the companies' single-drug donation programmes, what were the outcomes or impacts of these programmes during the reporting period?	New Focus on outcomes/impacts of Single drug donation programmes.
G.III.2	Policies and practice in relation to 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)	Unchanged
G.III.3	Policies and practice in relation to drug donations The scale and scope of donated products to the Index Countries during the period of analysis.	Unchanged
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.	Major revision Focus on linking philanthropic activities to national health plans in order to ascertain whether they are both demand-led and sustainable rather than judging them by their monetary value. (The 'national' aspect should implicitly capture initiatives with international NGOs and multilaterals like GAVI as their projects should also be tied into plans that are owned, overall, by the national Ministries of Health). Revised KPI [G.III.4] from Index 2010. "Value of the company's philanthropic activities (excluding drug donations) in the Index Countries during the period of analysis adjusted for company size? (Experimental Indicator)" [G.III.4]

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.	Minor revision (wording)

	Index 2012 Indicator	Change/Rationale
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.	Minor revision (wording)

Appendix 1: Stakeholder Review Process

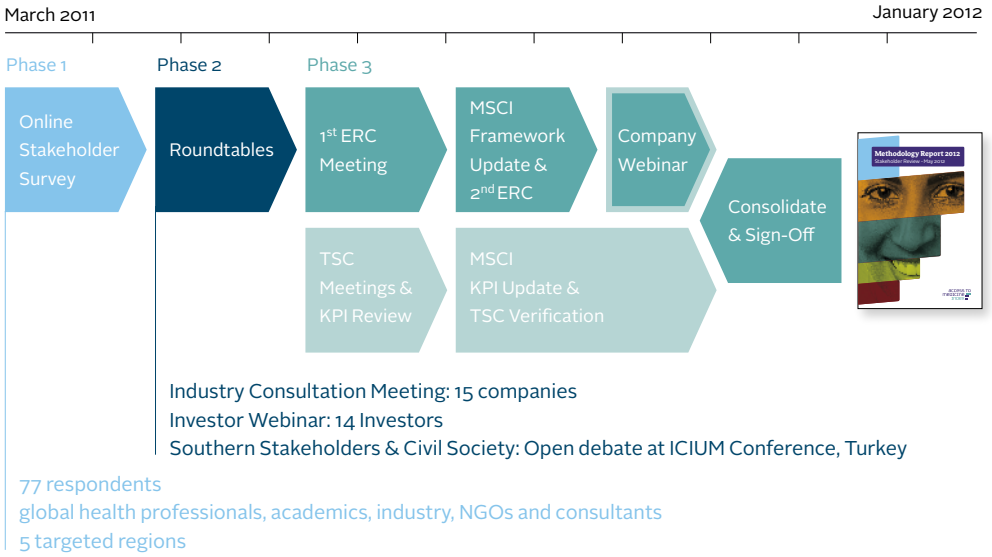
9 Stakeholder Engagement 2012

The 2012 methodology was developed vis-à-vis a multi-stakeholder approach, which guided refinements and enhancements to the 2010 Index methodology. The goals of the stakeholder engagement process were three-fold:

- to adjust the methodology to reflect changing global healthcare priorities,
- to refine and improve the methodology based on lessons learned from past Indices and
- to evaluate company policies and performance to better reflect the access to medicine realities on the ground.

This approach included three phases of consultations.

Figure 7 Process of Input



The **online stakeholder survey** represented the launch of external feedback. This detailed online questionnaire survey was publicly available and brought in the feedback from diverse **stakeholder groups**, including global health professionals, academics, industry, NGOs, and consultants. The second phase involved high level consultations with several stakeholder groups, including industry, investors, southern stakeholders and civil society. The third phase encompassed a **methodology review process** guided by political and technical representation that was separated into the Expert Review Committee (ERC) and the Technical Subcommittees (TSC).

Figure 8 Stakeholder Engagement

The Expert Review Committee

The Expert Review Committee (ERC) is made up of individuals from a variety of stakeholder groups, all active in some capacity on the access to medicines agenda. The committee has reviewed the methodology for Index 2012 on two separate occasions in July and October 2011, ensuring verification of the outputs from the Technical Subcommittee (TSC) process.

Convened in 2009, the mandate of the ERC is purely advisory in nature, with the objective of providing strategic guidance, recommendations and advice to the Access to Medicine Index team on the scope, structure, content and methodology of the third Access to Medicine Index assessment. The ERC members' involvement is intended to ensure different viewpoints are taken into consideration in establishing the latest Access to Medicine Index methodology, and is intended to further build on the preceding consultation exercises that have taken place.

Table 5 Expert Review Committee 2012

Chair	Sophia Tickell, Meteos
Government	Charles Clift, Centre on Global Health Security at Chatham House
Multi-lateral Organisations	Richard Laing, World Health Organization
Investors	My-Linh Ngo, Henderson Global Investors
Industry	Eduardo Pisani, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
NGOs	Tim Reed, Health Action International (HAI)
Academia	Dennis Ross-Degnan, Harvard Medical School
Government	Sakthivel Selvaraj, Public Health Foundation of India
Generics Industry	Dilip Shah, International Generic Pharmaceutical Alliance (IGPA)

Technical Subcommittees

The Technical Subcommittee process was a new addition in 2012, leveraging the expertise of global health professionals, academics and consultants representing Technical Area expertise. The TSC members were consulted individually and as a group addressing key indicators across the Technical Areas of the Access to Medicine Index. They provided detailed feedback on the Index 2012 indicator refinement process, taking the methodology to a new level of precision and refinement of our key performance indicators. An overview of the outcomes of the TSC process is provided in 'Summary of the Technical Subcommittee Feedback' on p. 32.

Note: Government representatives, academics and global health organizations have been indicated as the stakeholders groups that were comparatively underrepresented in the online survey. The Technical Subcommittee review is a key highlight of academic and civil society consultation that has greatly improved the Index 2012 methodology refinement process.

Table 6 Technical Subcommittee Contributors

Equitable pricing, manufacturing and distribution	Margaret Ewen, Health Action International, Netherlands Alan Staple, Clinton Health Action Initiative, USA Prashant Yadav, University of Michigan, USA
Intellectual property and competition	Kevin Outterson, University of Boston, USA Chan Park, Medicine Patent Pool, USA Warren Kaplan, University of Boston, USA Peter Beyer, World Health Organization, Switzerland
Research and development	Dr. Javier Guzman, Policy Cures, UK Dr. Paul Wilson, Columbia University, USA
Promotions, marketing and anti-corruption	Michelle Forzley, Global Public Health Attorney, USA John Chalker, Management Sciences for Health Center for Pharmaceutical Management, UK Jillian Kohler, University of Toronto, Canada

The Access to Medicine Index team remains ultimately responsible for decisions on the final methodology associated with reporting material, and the findings of the Access to Medicine Index. Following collection of the stakeholder feedback through the aforementioned process, the methodology was updated by the Access to Medicine Foundation.

Other Sources of Feedback

In addition to the above primary routes for obtaining stakeholder feedback, the Access to Medicine Foundation remains open to feedback from other entities willing to provide comments and suggestions. Maintaining openness through engaging and building partnerships with all the stakeholder groups is crucial to the long-term success, legitimacy and impact of the Index. It should be pointed out that no single feedback mechanism has disproportionately affected the Index methodology. Rather, the output of the survey, in depth consultations and other feedback processes were studied by the Expert Review Committee. We maximized our efforts to ensure that all the stakeholders receive equal representation in the stakeholder engagement process.

Appendix 2: ICD-10 Coverage

10 ICD-10 Coverage

Table 7 ICD-10 Coverage[10]

Communicable

	Reference List	Index Disease	Name ICD-10 Classifications
1	NTD	Buruli Ulcer	Buruli Ulcer (A31.1)
2	NTD	Chagas Disease	Chagas disease (B57)
3	NTD	Dengue	Dengue (A90-A91) • A90: Dengue fever (classical dengue) • A91: Dengue hemorrhagic fever
4	GBD_10Inf	Diarrhoeal diseases	Intestinal infectious diseases excluding A02 and A05 • 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: Diarrhoea and gastroenteritis of presumed infectious origin
5	NTD	Dracunculiasis (guinea-worm disease)	Dracunculiasis (B72)
6	NTD	Fascioliasis	Fascioliasis (B66.3)
7	GBD_10Inf	HIV/AIDS	Human immunodeficiency virus [HIV] disease (B20-B24) • 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
8	NTD	Human African Trypanosomiasis	African Trypanosomiasis (B56)
9	NTD	Leishmaniasis	Leishmaniasis (B55)
10	NTD	Leprosy	Leprosy (A30)
11	GBD_10Inf	Lower Respiratory Infections	Influenza and pneumonia (J10-J18) • J10: Influenza due to other identified influenza virus • J11: Influenza, virus not identified • J12: Viral pneumonia, not elsewhere classified • J13: Pneumonia due to Streptococci pneumonia • J14: Pneumonia due to Haemophilus influenza • J15: Bacterial pneumonia, not elsewhere classified

10 The Reference list in the ICD-10 table classifies diseases by their global reference point for inclusion in Index 2012 as follows: NTD [Neglected Tropical Disease], GBD_10Inf [Global Burden of Disease (i.e. DALYs) - top 10 Infectious], GBD_10NC [Global Burden of Disease - top 10 Non-Communicable], and MDG [Millennium Development Goals]

	Reference List	Index Disease	Name ICD-10 Classifications
			• J16: Pneumonia due to other infectious organisms, not elsewhere classified • J17: Pneumonia in diseases classified elsewhere • J18: Pneumonia, organism unspecified Other acute lower respiratory infections (J20-J22) • J20: Acute bronchitis • J21: Acute bronchiolitis • J22: Unspecified acute lower respiratory infection
12	GBD_10Inf	Lymphatic filariasis	Lymphatic filariasis (B74.0 - B74.2) • B74.0: Filariasis due to Wuchereria bancrofti • B74.1: Filariasis due to Brugia malayi • B74.2: Filariasis due to Brugia timori
13	GBD_10Inf	Malaria	Malaria (B50-B54) • B50: Plasmodium falciparum malaria • B51: Plasmodium vivax malaria • B52: Plasmodium malariae malaria • B53: Other parasitologically confirmed malaria • B54: Unspecified malaria
14	GBD_10Inf	Measles	Measles (B05)
15	GBD_10Inf	Meningitis	Meningococcal infection (A39) Bacterial meningitis, not elsewhere classified (G00) Meningitis due to other and unspecified causes (G03)
16	NTD	Onchocerciasis	Onchocerciasis (B73)
17	GBD_10Inf	Pertussis	Pertussis/Whooping cough (A37)
18	NTD	Schistosomiasis	Schistosomiasis (B65)
19	NTD	Soil-transmitted Helminthiasis	Soil-transmitted Helminthiases (B76-B81) • B76: Hookworm diseases • B77: Ascariasis • B78: Strongyloidiasis • B79: Trichuriasis • B80: Enterobiasis • B81: Other intestinal helminthiases, not elsewhere classified
20	NTD	Tetanus	Tetanus (A33-A35) • A33: Tetanus neonatorum • A34: Obstetrical tetanus • A35: Other tetanus
21	NTD	Trachoma	Trachoma (A71)
22	GBD_10Inf	Tuberculosis	Tuberculosis (A15-A19) • Respiratory tuberculosis, bacteriologically and histologically confirmed • A16: Respiratory tuberculosis, not confirmed bacteriologically and histologically • A17: Tuberculosis of nervous system • A18: Tuberculosis of other organs • A19: Miliary tuberculosis
23	NTD	Yaws	Yaws (A66)

Non-Communicable

	Reference List	Index Disease	Name ICD-10 Classifications
24	GBD_10NC	Chronic obstructive pulmonary disease & Asthma	Chronic lower respiratory diseases (J40-J46) • J40: Bronchitis, not specified as acute or chronic • J41: Simple and micropurulent chronic bronchitis • J42: Unspecified chronic bronchitis • J43: Emphysema • J44 : Other chronic obstructive pulmonary disease • J45: Asthma • J46: Status asthmaticus
25	GBD_10NC	Cerebrovascular disease	Cerebrovascular diseases (I60-I69) • 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
26	GBD_10NC	Cirrhosis of the liver	Alcoholic liver disease (K70) Fibrosis and cirrhosis of the liver (K74)
27	GBD_10NC	Diabetes Mellitus	Diabetes mellitus (E10-E14) • 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
28	GBD_10NC	Epilepsy	Epilepsy (G40-G41) • G40: Epilepsy • G41: Status epilepticus
29	GBD_10NC	Ischaemic heart disease	Ischaemic heart diseases (I20-I25) • 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
30	GBD_10NC	Nephritis /nephrosis	Glomerular diseases (N00-N08) • N00: Acute nephritic syndrome • N01: Rapidly progressive nephritic syndrome • N02: Recurrent and persistent haematuria

	Reference List	Index Disease	Name ICD-10 Classifications
			• 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 Renal tubule-interstitial diseases (N10-N16) • N10: Acute tubule-interstitial nephritis • N11: Chronic tubule-interstitial nephritis • N12: Tubulo-interstitial nephritis, not specified as acute or chronic • N13: obstructive and reflux uropathy • N14: Drug- and heavy-metal inducedtubule-interstitial and tubular conditions • N15: Other renal tubule-interstitial diseases • N16: Renal tubulo-interstitial disorders in diseases classified elsewhere Renal failure (N17-N18) • N17: Acute renal failure • N18: Chronic renal failure
31	GBD_10NC	Osteoarthritis	Arthorisis (M15-M19) • M15: Polyarthrosis • M16: Coxarthrosis [arthrosis of hip] • M17: Gonarthrosis [arthrosis of knee] • M18: Arthrosis of first carpometacarpal joint • M19: Other arthrosis
32	GBD_10NC	Unipolar depressive disorders	Unipolar depressive disorders (F32-F33) • F32: Depressive episode • F33: Recurrent depressive disorder

Maternal conditions and neonatal infections

	Reference List	Index Disease	Name ICD-10 Classifications
33	MDG	Maternal conditions and neonatal infections[11]	• O04: Medical abortion • O13: Gestational [pregnancy-induced] hypertension without significant proteinuria • O14: Gestational [pregnancy-induced] hypertension with significant proteinuria • O15: Eclampsia • O72: Postpartum haemorrhage • P36 : Bacterial sepsis of newborn • Contraceptives (topical, oral, patch-based & implants, intra-uterine devices)

11 The ATM Foundation's online platform collects data for products falling under the ICD-10 codes O00-O99 for exploratory purposes. Some of this data may be used for qualitative analysis. However, for scoring purposes, only products that fall under the ICD-10 codes noted in this table will be evaluated.

11 Definitions

Active Licensee
An 'active license' is defined as a license under which production is happening or the licensee is planning to start production in the near future, in contrast to a 'dormant license.' Active voluntary licensing includes only full licensing of the final product for manufacturing by the licensee. Multiple 'active' voluntary licenses should be in place for the drug to be counted without global or regional marketing exclusivity for the licensee. An active license is a license under which production is happening or the licensee is actively progressing towards production.

Adaptive Research
Research involving the development of new formulations of existing compounds aimed at adapting those compounds to possess specific environmental (heat-resistant formulations), social (fixed-dose combinations) or demographic (paediatric formulations) characteristics.

Candidates
The number of molecules or compounds in a company's R&D pipeline.

Collaborative Research
Research done jointly by a number of parties including academic researchers, governments and pharmaceutical companies and/or in public-private partnerships.

Communicable Index Diseases
This term is used to refer to all the communicable diseases covered by the Index.

Company Size
Where we refer to company size in this report, it is based on revenues excluding subsidiaries with non-pharmaceutical activities.

Compound/Molecule Libraries
These libraries are collections of molecules/compounds used to explore complex disease pathways and to assist in the characterization of disease targets.

Compulsory license
Government allows a third party to produce a patented product or use a patented process without the consent of the patent owner.

DALY (Disability Adjusted Life Years)
WHO definition: 'The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.'

Data exclusivity
Data exclusivity refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications.

Differential pricing
Also referred to as 'equity pricing' or 'preferential pricing' refers to the concept that essential drugs prices should in some way reflect countries' ability to pay as measured by their level of income.

Drug Diversion
Channeling lower-priced drugs from developing-countries into developed markets or from lower-income segments to high-income segments within a country.

Drug Recall
A drug is removed from the market because it is found to be either defective or potentially harmful. This is done either by the drug manufacturers or by the drug regulatory authority.

Evergreening of drugs
Extension of a patent(s) on a branded drug through obtaining IP protection on new applications or fields of use. Typically, it is a metabolite or other very close chemical relative or a reformulation of a highly profitable, branded drug.

Exhaustion of IPR
Limit of Intellectual Property Rights under which, a product protected by an IP rights once marketed by the company or by others with company consent, the IP rights of commercial exploitation over this given product can no longer be exercised by the company as they are 'exhausted'.

Generics Manufacturing
In this document, Generics Manufacturing refers to manufacturing of pharmaceutical products by a company, which does not hold the patent for the product (produced under voluntary license or based on TRIPS flexibilities etc.), or to a product whose patent has expired.

Generics
The term *Generics* is defined as; 1) products where the key patent has expired and/or; 2) the product is produced under license.

For example, the term 'generic' products refers to products for which a company is carrying out in-license manufacturing of an on-patent product. The Index does not aim to capture innovative

molecules licensed at the pre-clinical and clinical stages of development; therefore, this definition of 'generics' applies only to in-license manufacturing of final (post-phase III) products.

Generics Revenue Stream
The term 'generics' is used to describe products generated from two types of revenue streams. The 'generic manufacturing revenue' stream is therefore defined as any revenue stream for which the company has: 1) had minimal engagement in the research process for drug development; 2) been primarily engaged in manufacturing and distribution of the product and; 3) has minimal control over IP management or additional licensing of the product. This would include:

- Manufacturing/sales of a product whose patent has expired
- Revenues from contract manufacturing services
- Manufacturing/sales of an in-licensed on-patent product - this includes only in-licensing of the final product (post phase III) and not in-licensing along pre-clinical and clinical development stages because in the latter cases the company is still in charge of resource intensive clinical trial R&D activities and in most of such cases the company has full or partial control on sub-licensing and IP management of the product.

Humanitarian License Reservation/Humanitarian Use Exemption
A provision in a license agreement by a licensor to reserve in advance the possibility of granting rights to third parties to achieve social and access outcomes for people in need.

In-house Research
Research done by a company internally to discover new drugs.

Index Diseases
Throughout this report, this term is used to refer to all the diseases covered by the Index including the WHO Neglected Tropical Diseases and high-priority diseases based on the WHO Global Burden of Disease list. Please refer to the 'Disease Scope' section for more details.

Index Countries
All the countries covered by the Index. Please refer to the 'Geographical Scope' section for more details.

Innovative Research
Research aimed at developing new breakthrough compounds / remedies (in contrast to Adaptive Research)

Inter-country* tiered pricing
Inter-country preferential pricing is when the company has special pricing schemes at the country level which take into consideration affordability for the very poorest countries.

Intra-country* tiered pricing
In developing countries, incomes may be highly skewed. Intra-country preferential pricing is when a company has different pricing tiers inside the Index countries based on the socioeconomic profile of different social segments. Intra-country tiered pricing can be better suited to countries where an expanding middle class co-exists with poor communities. This method of pricing increases access to medicines for the poorest sections.

* The term 'country' in 'intra' and 'inter' is used as a general term to define any differential pricing policies that a company has implemented in the Index countries that varies between countries and within countries (taking into account access barriers). All Index countries where a product is used to treat Index-diseases will come into this category.

Low Human Development Countries
The Low Human Development countries based on the UN Human Development Index.

Medium Human Development Countries
The Medium Human Development Countries, as defined in the UN Human Development Index, excluding Medium High Income countries, based on the World Bank country income level categories.

Multi-drug Donations
Donations for which there is no clear, defined 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.

NDA (New Drug Application)
An NDA contains all the preclinical and clinical information obtained during the testing phase.

Non-Assert Declaration
A legally-binding commitment by a rights holder not to enforce certain patents in a defined group of countries. Allows a generic version of a patent-protected article to be produced in a resource-limited setting.

Non-Communicable Index Diseases
All the Non-Communicable diseases covered by the Index.

Non-Exclusive Licensing
Non-Exclusive Licensing of the intellectual property of a final product to another organization for manufacturing, distribution and sales of that product in the license territory, without provision of exclusivity to that organization.

Non-Exclusive Voluntary Licensing
Authorization given voluntarily by the patent holder to generic companies on a non-exclusive basis, allowing more than one company to produce the patented article as if it were a generic.

Originator Company
A company whose revenues are mostly from sales of patented products and focuses on research and development, aimed at developing new pharmaceutical products.

Outside the value chain
Activities beyond the scope of the company's normal operations and distribution channels.

Parallel import
Unauthorized imports of a patented or trademarked product from a country where it is already marketed.

Patent
An intellectual property right providing an inventor with a legal monopoly right to prevent others from making, using, or selling the new invention for a defined period of time, subject to a number of exceptions.

Patent Pool
Portfolio of patents and other relevant intellectual property rights held by various actors made available on a non-exclusive basis to third parties, (e.g. generic manufacturers) against the payment of royalties.

Period of Analysis
The period of analysis of Index 2012 includes the full 2010 and 2011 fiscal years.

Pharmacovigilance
Defined by the World Health Organization (WHO) as the 'science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.'

Prequalification of medicines by WHO
A service provided by WHO to assess the quality, safety and efficacy of medicinal products in order to accelerate introduction of successful candidates into use.

Products
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.

Reference to G-Finder 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)

Revenue
The total sales revenues generated over the past five years (2007-2011). It is the 'top line' or 'gross income' figure from which costs are subtracted to determine net income.

Single Drug Donations
Donations 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.

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

Spurious/falsely-labeled/falsified/counterfeit (SFFC) medicines
Drugs that are deliberately mislabeled which include the products with wrong ingredients, insufficient ingredient or fake packaging.

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
A company that is owned or controlled by another firm or company; 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.

Technical Area
As part of the Index's analytical framework, the seven major Technical Areas under which the companies are analysed in Index 2012 are: General Access to Medicine Management, Public Policy & Market Influence, Research & Development, Equitable Pricing, Manufacturing & Distribution, Patents & Licensing, Capability Advancement in Product Development & Distribution, and Product Donations & Philanthropic Activities.

Technology Transfer
Technology transfer refers to any process by which any party gains access to another's technical information and successfully learns and absorbs it into its research, development or manufacturing process.

Trade-Related Aspects of Intellectual Property Rights (TRIPS)
The WTO'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.

TRIPS + (or TRIPS Plus)
Measures contained in multilateral, regional, plurilateral or national intellectual rules and practices that protect IP 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.

Very Poorest
Inhabitants who have an income below the poverty line with no discretionary disposable income; the poverty threshold, or poverty line, is the level of income below which one cannot afford to purchase all the resources one requires to live. The poverty line is usually determined by finding the total cost of all the essential resources that an average human adult consumes in one year. This approach is needs based in that an assessment is made of the minimum expenditure needed to maintain a tolerable life.

12 Acronyms

ABPI	Association of the British Pharmaceutical Industry
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
	Access to Medicine
CDD	Collaborative Drug Discovery
CRO	Contract Research Organization
DALY	Disability Adjusted Life Years
DC	Developing Country
DFID	Department for International Development (UK Government)
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ERC	Expert Review Committee
EVL	Exclusive Voluntary Licensing
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
GBD	Global Burden of Disease
GMP	Good Manufacturing Practices (WHO)
GPP	Good Participatory Practice (Guidelines for Biomedical HIV Prevention Trials of UNAIDS)
HDI	Human Development Index
HIC	High-Income Country
HIV	Human Immunodeficiency Virus
HUE	Humanitarian Use Exemption
HUL	Humanitarian Use Licensing
ICB	Industry Classification Benchmark
ICCR	Interfaith Center on Corporate Responsibility
IC	Index Country
ID	Index Disease
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
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]
MHDC	Medium Human Development Country
MIC	Middle-Income Country
MPP	Medicines Patent Pool
NAD	Non-Assert Declaration
NCE	New Chemical Entities
NDRA	National Drug Regulatory Authority
NEVL	Non-Exclusive Voluntary Licensing
NGO	Non-Governmental Organization
NTD	Neglected Tropical Diseases
OSDD	Open Source Drug Discovery
PPP	Public-Private Partnership
PhRMA	The Pharmaceutical Research and Manufacturers of America
R&D	Research and Development

TA	Technical Area
TB	Tuberculosis
TRIPS	Trade-related Aspects of Intellectual Property Rights
TSC	Technical Subcommittee
UN	United Nations
UNWTO	United Nations World Trade Organizations
WB	World Bank
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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