access to medicine index

Methodology & Stakeholder Review

March 2010

access to medicine index

Methodology & Stakeholder Review

March 2010

ACKNOWLEDGEMENTS

The Access to Medicine Foundation together with RiskMetrics Group would like to thank all stakeholders for their time and input into this Methodology Review Process. Without their insights, commitment and valuable discussions this project would not have proceeded in the manner it has.

ACCESS TO MEDICINE FOUNDATION

The Access to Medicine Foundation is an international not for profit organization 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.

On behalf of:

Access to Medicine Foundation

Contact

Wim Leereveld

Chairman Access to Medicine Foundation

wleereveld@atmindex.org

+31 23 5339187

This report is prepared by:

RiskMetrics Group - ESG Analytics

RiskMetrics Group (NYSE:RISK) is a leading global provider of risk management and corporate governance products and services. Building on the 2009 acquisitions of Innovest Strategic Value Advisors and KLD Research & Analytics, RiskMetrics Group's ESG Analytics business has established itself as the world's leading provider of Environmental, Social and Governance data and analytics.

RiskMetrics Goup

Contacts

Perrine Dutronc

perrine.dutronc@riskmetrics.com

+33 1 42 68 51 44

Afshin Mehrpouya

afshin.mehrpouya@riskmetrics.com

+33 1 42 68 51 38

From the Founder

In 2008 we published the first Access to Medicine Index. It was an honor and a surprise to witness the worldwide attention it received and how quickly it was embraced by governments, global health organizations, investors and individuals around the world. It let us know early on that there was great support for our efforts and that we had the possibility of creating a tool that could have real impact towards helping the most at risk citizens of the world; those that lack access to medicines.

At the Access to Medicine Foundation we have always known that we could not take on this daunting task alone. Just as we rely on our core principles to guide our decisions and actions, we also rely on experts from the private, public and governmental sector to help deliver an innovative and creative solution to one of the world's most pressing global health challenges.

Now, as we approach the publication of the Access to Medicine Index 2010, I want to take this opportunity to express my gratitude towards the many organizations and individuals that have shown an unwavering commitment towards our initiative either through their service on the Expert Review Committee, the Board, Advisory Committee or through our Ambassador program. The support and patience shown to the Foundation, as well as the quality and quantity of feedback shared during the many meetings, surveys and roundtables have allowed us to create a methodology report that we hope will inspire and support pharmaceutical companies to fully embrace their role in helping to reduce this global health burden.

We learned quickly that the only way to create criteria that could be used for company analysis was through a constant process of collaboration and consensus building. This constant dialogue and debate led us to produce the Access to Medicine Methodology 2010, a framework for capturing pharmaceutical companies' efforts.

At the Access to Medicine Foundation, we continue to live up to the high standards we have set, but most importantly to continue to advance global awareness of the men, women and children around the world that lack access to this essential and basic human right. Together we have the opportunity to have an even greater impact on the world around us.

Thank you for your interest in the Access to Medicine Index and for your contining support. I invite you to read our 2010 Methodology report and to visit our website www.atmindex.org to learn more about the Foundation and the Access to Medicine Index.

Sincerely,

Wim Leereveld

Founder and Chairman of the Board

Table of Contents

List of Tables

Definitions

Active Licensee

A licensee of the intellectual capital of a final product for the purpose of manufacturing, which either currently manufactures the product or, in the case of recent licenses, is in the process of building capacity for starting manufacturing in the near future.

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 (pediatric formulations) characteristics.

Company Size

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

Non-Communicable Index Diseases

This term is used to refer to all the Non-Communicable diseases covered by the Index.

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.

Communicable Index Diseases

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

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

This refers to all the countries covered by the Index including Low and Medium Human Development Countries of the UN Human Development Index with adjustments based on country income levels. Please refer to the 'Geographic Scope' section for more details.

Innovative Research

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

Low Human Development Countries

This term is used to refer to the Low Human Development countries based on the UN Human Development Index.

Medium Human Development Countries

This term is used to refer to 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

Non-Exclusive Licensing

Licensing of the intellectual capital 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

Period of Analysis

The period of analysis of Index 2010 includes the full 2009 and 2010 fiscal years.

Products

Throughout this document, this term refers to drugs, vaccines, vector control products, microbicides, and diagnostic products.

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.

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 programs based on country needs

Strategic Pillar

The indicators under each Technical Area are broken down into four Strategic Pillars - Commitments, Transparency, Performance and Innovation.

Technical Area

The seven major technical areas under which the companies are analyzed in Index 2010 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

EXECUTIVE SUMMARY

This report sets out the methodology that underpins the Access to Medicine Index 2010. The Index will be the result of the evaluation and ranking of world's largest pharmaceutical companies and will be published in June 2010.

To formulate the 2010 Index methodology, we used a multi-stakeholder approach, calling on experts from academia, governments, intergovernmental organizations, institutional investors, non-governmental organizations and the pharmaceutical industry. These consultations were then formalized in an extensive Methodology Review Process consisting of three phases. In the first phase, we gathered stakeholder views on the Index methodology via an online questionnaire. The second phase comprised two stakeholder roundtables in Washington D.C. and London. Additionally, we organized several other stakeholder meetings, including a workshop in Nairobi, Kenya with non-governmental organizations from a number of the Index Countries. The third phase involved a rigorous methodology update guided by stakeholder feedback, in consultation with the Expert Review Committee.[a]

The 2010 methodology aims to increase the objectivity, robustness and usefulness of the Index and to bring it in line with changes in global access to medicine priorities. Guided by stakeholder feedback, the main enhancements of the Index 2010 methodology have been made in the following key areas:

- More focus on measuring the performance of the companies' access to medicine related initiatives by introducing several new performance indicators and separation of performance indicators under a separate Strategic Pillar
- Separation of originator and generics companies under two separate lists given the difference of the access to medicine drivers and business models in these two company sets
- Expansion of the disease coverage to 33 communicable and non-communicable diseases based on their social burden in the Index Countries (compared to mortality-based disease priorities used in Index 2008)

[a] The mandate of the ERC is purely advisory in nature, with the objective of providing guidance, recommendations and advice to the Access to Medicine Index team on the scope, structure, content and methodology of the second Access to Medicine Index assessment. The Access to Medicine Index team remains ultimately responsible for decisions on the final methodology associated reporting material, and the findings of the Access to Medicine Index.

The report is structured in two sections. The section “What We Measure” focuses on the scope of Index 2010 and the section “How We Measure” provides an overview of the structure and approach taken to company evaluation. A description of the Methodology Review Process as well as feedback provided by all the key stakeholder constituent groups can be found in the appendix.

Highlights of what we measure:

- Company Scope: Index 2010 aims to cover 27 companies, comprising 20 originators, of which 19 are publicly listed and one is a privately held, and seven generics manufacturers, of which six are publicly listed and one is privately held.
- Geographical Scope: Index 2010 focuses on the Low and Medium Human Development Countries based on the UN Human Development Index (UN HDI) 2008. Countries classified as ‘medium-high’ and ‘high’ according to the World Bank Country Classifications, are excluded.
- Disease Scope: Index 2010 covers a total of 33 diseases, consisting of a combination of the WHO Neglected Tropical Diseases, the top-10 non-communicable diseases and the top-10 communicable diseases based on Disability Adjusted Life Years (DALY).

Highlights of how we measure:

- Separating the indicators for company analysis under the four Strategic Pillars of Commitments, Transparency, Performance and Innovation
- Providing a comprehensive analysis of the companies’ product portfolio and research pipeline aimed at moving towards a more systemic understanding of the companies’ efforts related to access to medicine for the Index Diseases in the Index Countries
- More thorough analysis of companies’ activities in the following areas:
    - Registration (marketing approval) of products for Index Diseases in the Low Human Development Countries
    - Voluntary licensing activities of companies and the effectiveness of their technology transfer approaches

WHAT WE MEASURE

COMPANY SCOPE

Index 2010 covers 27 companies, comprising 20 originators of which 19 are publicly listed and one is a private company, and seven generics manufacturers, of which six are publicly listed and one is private. Selection of the companies is based on market capital (including only pharmaceutical operations) and relevance of products portfolio to the Index Diseases.

Other highlights of the company scope of Index 2010 are listed below:

- We will publish two comparative lists, one for originators and one for generics manufacturers, since the market failures and priorities with regard to access to medicines in the two types of operations are widely different.
- In Index 2010, for the first time, two companies which are not publicly listed but have products portfolio and initiatives relevant to access to medicine in the Index Countries are covered: Apotex and Boehringer-Ingelheim.
- Biotech companies are not covered by Index 2010. Their inclusion might be considered in future indices. It should be noted that Gilead, which has both biotechnology and pharmaceutical revenue streams, continues to be included in the Index given its highly relevant pharmaceutical product portfolio and operations.

To ensure methodology consistency for Index 2010, all companies are asked to provide data for the full 2008/2009 fiscal years. For more details about the rationale of company selection for Index 2010 please refer to Appendix 2 of this report.

Table 1. Company List for Index 2010 - Two Lists: One for Originators Companies and One Generics Manufacturers

	Ticker	Company	Country
1	JNJ-N	Johnson & Johnson	USA
2	ROG-VX	Roche Holdings Limited	CHE
3	PFE-N	Pfizer Inc	USA
4	NOVN-VX	Novartis AG	CHE
5	GSK-LN	GlaxoSmithKline PLC	GBR
6	SAN-FR	Sanofi-Aventis AS	FRA
7	ABT-N	Abbott Laboratories	USA
8	MRK-N	Merck & Company Inc	USA
9	AZN-LN	AstraZeneca PLC	GBR
10	BMY-N	Bristol-Myers Squibb Company	USA
11	LLY-N	ELI Lilly & Company	USA
12	BAY-FF	Bayer AG	DEU
13	NOVO'B-KO	Novo Nordisk A/S	DNK
14	MRK-FF	Merck Kgaa	DEU
15	GILD-O	Gilead Sciences	USA
16	4502-TO	Takeda Pharmaceutical Company	JPN
17	4568-TO	Daiichi Sankyo Company Limited	JPN
18	4503-TO	Astellas Pharma Inc	JPN
19	4523-TO	Eisai Company Limited	JPN
20	Not Publicly Listed	Boehringer-Ingelheim	DEU

Table 1. (Continued). Generics List for Index 2010

	Ticker	Company	Country
1	BOM:500124	Dr. Reddy's	IND
2	BOM:500359	Ranbaxy Laboratories Limited	IND
3	BSE: 524715	SunPharma	IND
4	TEVA-TV	Teva Pharmaceutical	ISR
5	BOM:500087	Cipla Limited	IND
6	MYL-O	Mylan Inc	USA
7	Not Publicly Listed	APOTEX	CAN

GEOGRAPHICAL SCOPE

Index 2010 focuses on the Low and Medium Human Development Countries based on the UN Human Development Index (UN HDI) 2008[b]. Also, countries classified as 'medium-high' and 'high' income brackets based on the World Bank Country Classifications[c] are excluded. UN HDI is used because its underlying criteria such as life expectancy at birth, adult literacy level, etc. are more aligned with healthcare needs compared to purely economic Indices such as the World Bank country classifications. (For more information on the underlying rationale and stakeholder feedback in this area please refer to Appendix 2.)

Table 2. List of the UN HDI Low Human Development Countries

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
154	Nigeria	Sub-Saharan Africa	0.499	39	1852	Lower middle income
155	Lesotho	Sub-Saharan Africa	0.496	47.8	1440	Lower middle income
156	Uganda	Sub-Saharan Africa	0.493	38.5	888	Low income
157	Angola	Sub-Saharan Africa	0.484	46.7	4434	Lower middle income
158	Timor-Leste	East Asia & Pacific	0.483	21.2	668	Lower middle income
159	Togo	Sub-Saharan Africa	0.479	24.1	792	Low income
160	Gambia	Sub-Saharan Africa	0.471	20.9	1152	Low income
161	Benin	Sub-Saharan Africa	0.459	27.9	1259	Low income

[b] Human Development Report 2008 - HDI rankings - http://hdr.undp.org/en/statistics/
[c] World Bank - Country Classification; http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20420458~menuPK:64133156~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
162	Malawi	Sub-Saharan Africa	0.457	44.4	703	Low income
163	Zambia	Sub-Saharan Africa	0.453	53.9	1273	Low income
164	Eritrea	Sub-Saharan Africa	0.442	24.1	519	Low income
165	Rwanda	Sub-Saharan Africa	0.435	44.6	819	Low income
166	Côte d'Ivoire	Sub-Saharan Africa	0.431	38.6	1632	Lower middle income
167	Guinea	Sub-Saharan Africa	0.423	28.6	1118	Low income
168	Mali	Sub-Saharan Africa	0.391	30.4	1058	Low income
169	Ethiopia	Sub-Saharan Africa	0.389	33.3	700	Low income
170	Chad	Sub-Saharan Africa	0.389	32.9	1470	Low income
171	Guinea-Bissau	Sub-Saharan Africa	0.383	40.5	467	Low income
172	Burundi	Sub-Saharan Africa	0.382	38.2	333	Low income
173	Burkina Faso	Sub-Saharan Africa	0.372	29	1084	Low income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
174	Niger	Sub-Saharan Africa	0.37	28.7	612	Low income
175	Mozambique	Sub-Saharan Africa	0.366	45	739	Low income
176	Liberia	Sub-Saharan Africa	0.364	41.9	335	Low income
177	Congo	Sub-Saharan Africa	0.361	41.1	281	Lower middle income
178	Central African Republic	Sub-Saharan Africa	0.352	46.2	679	Low income
179	Sierra Leone	Sub-Saharan Africa	0.329	45.6	630	Low income

Table 3. List of the UN HDI Medium Human Development Countries (The countries marked grey are the ones excluded because of being classified as upper middle income or high income by the World Bank 2008 listing)

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
76	Turkey	Europe & Central Asia	0.798	6.5	11535	Upper middle income
77	Dominica	Latin America & Caribbean	0.797	..	7715	Upper middle income
78	Lebanon	Middle East & North Africa	0.796	6.3	9757	Upper middle income
79	Peru	Latin America & Caribbean	0.788	9.7	7088	Upper middle income
80	Colombia	Latin America & Caribbean	0.787	9.2	6381	Upper middle income
81	Thailand	East Asia & Pacific	0.786	12.1	7613	Lower middle income
82	Ukraine	Europe & Central Asia	0.786	8.1	6224	Lower middle income
83	Armenia	Europe & Central Asia	0.777	6.3	4879	Lower middle income
84	Iran	Middle East & North Africa	0.777	7.8	10031	Lower middle income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
85	Tonga	East Asia & Pacific	0.774	5	3677	Lower middle income
86	Grenada	Latin America & Caribbean	0.774	9.7	7217	Upper middle income
87	Jamaica	Latin America & Caribbean	0.771	8.3	6409	Upper middle income
88	Belize	Latin America & Caribbean	0.771	5.4	6679	Lower middle income
89	Suriname	Latin America & Caribbean	0.77	9.8	7268	Upper middle income
90	Jordan	Middle East & North Africa	0.769	6.4	4654	Lower middle income
91	Dominican Republic	Latin America & Caribbean	0.768	10.5	6093	Upper middle income
92	St. Vincent and the Grenadines	Latin America & Caribbean	0.766	6.7	7057	Upper middle income
93	Georgia	Europe & Central Asia	0.763	7.9	4009	Lower middle income
94	China	East Asia & Pacific	0.762	6.8	4682	Lower middle income
95	Tunisia	Middle East & North Africa	0.762	4.6	6958	Lower middle income
96	Samoa	East Asia & Pacific	0.76	6.6	3828	Lower middle income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
97	Azerbaijan	Europe & Central Asia	0.758	12.4	6172	Lower middle income
98	Paraguay	Latin America & Caribbean	0.752	9.7	4034	Lower middle income
99	Maldives	South Asia	0.749	12.1	5008	Lower middle income
100	Algeria	Middle East & North Africa	0.748	7.7	7426	Upper middle income
101	El Salvador	Latin America & Caribbean	0.747	9.6	5477	Lower middle income
102	Philippines	East Asia & Pacific	0.745	7	3153	Lower middle income
103	Fiji	East Asia & Pacific	0.743	6.9	4548	Upper middle income
104	Sri Lanka	South Asia	0.742	7.2	3896	Lower middle income
105	Syrian Arab Republic	Middle East & North Africa	0.736	4.6	4225	Lower middle income
106	Occupied Palestinian Territories	N/A	0.731	5.2	N/A	N/A
107	Gabon	Sub-Saharan Africa	0.729	27.1	14208	Upper middle income
108	Turkmenistan	Europe & Central Asia	0.728	16.2	4826	Lower middle income
109	Indonesia	East Asia & Pacific	0.726	8.7	3455	Lower middle income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
110	Guyana	Latin America & Caribbean	0.725	16.6	2782	Lower middle income
111	Bolivia	Latin America & Caribbean	0.723	15.5	3989	Lower middle income
112	Mongolia	East Asia & Pacific	0.72	11.6	2887	Lower middle income
113	Moldova	Europe & Central Asia	0.719	6.5	2396	Lower middle income
114	Vietnam	East Asia & Pacific	0.718	6.7	2363	Low income
115	Equatorial Guinea	Sub-Saharan Africa	0.717	35.6	27161	High income: non-OECD
116	Egypt	Middle East & North Africa	0.716	7.5	4953	Lower middle income
117	Honduras	Latin America & Caribbean	0.714	12.9	3553	Lower middle income
118	Cape Verde	Sub-Saharan Africa	0.705	7.5	2833	Lower middle income
119	Uzbekistan	Europe & Central Asia	0.701	11.9	2189	Low income
120	Nicaragua	Latin America & Caribbean	0.699	9.5	2441	Lower middle income
121	Guatemala	Latin America & Caribbean	0.696	12.5	4311	Lower middle income
122	Kyrgyzstan	Europe & Central Asia	0.694	11.7	1813	Low income
123	Vanuatu	East Asia & Pacific	0.686	8.8	3481	Lower middle income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
124	Tajikistan	Europe & Central Asia	0.684	13.1	1609	Low income
125	South Africa	Sub-Saharan Africa	0.67	31.7	9087	Upper middle income
126	Botswana	Sub-Saharan Africa	0.664	44	12744	Upper middle income
127	Morocco	Middle East & North Africa	0.646	8.2	3915	Lower middle income
128	Sao Tome and Principe	Sub-Saharan Africa	0.643	15.1	1534	Lower middle income
129	Namibia	Sub-Saharan Africa	0.634	35.9	4819	Upper middle income
130	Congo	Sub-Saharan Africa	0.619	30.1	3550	Lower middle income
131	Bhutan	South Asia	0.613	16.8	4010	Lower middle income
132	India	South Asia	0.609	16.8	2489	Lower middle income
133	Lao People's Democratic Republic	East Asia & Pacific	0.608	16.6	1980	Low income
134	Solomon Islands Diseases	East Asia & Pacific	0.591	16.1	1586	Lower middle income
135	Myanmar	East Asia & Pacific	0.585	21	881	Low income
136	Cambodia	East Asia & Pacific	0.575	24.1	1619	Low income
137	Comoros	Sub-Saharan Africa	0.572	15.3	1152	Low income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
138	Yemen	Middle East & North Africa	0.567	18.6	2262	Low income
139	Pakistan	South Asia	0.562	15.4	2361	Lower middle income
140	Mauritania	Sub-Saharan Africa	0.557	14.6	1890	Low income
141	Swaziland	Sub-Saharan Africa	0.542	48	4705	Lower middle income
142	Ghana	Sub-Saharan Africa	0.533	23.8	1247	Low income
143	Madagascar	Sub-Saharan Africa	0.533	24.4	878	Low income
144	Kenya	Sub-Saharan Africa	0.532	35.1	1436	Low income
145	Nepal	South Asia	0.53	17.4	999	Low income
146	Sudan	Sub-Saharan Africa	0.526	26.1	1887	Lower middle income
147	Bangladesh	South Asia	0.524	16.4	1155	Low income
148	Haiti	Latin America & Caribbean	0.521	21.4	1109	Low income
149	Papua New Guinea	East Asia & Pacific	0.516	20.7	1950	Lower middle income
150	Cameroon	Sub-Saharan Africa	0.514	35.7	2043	Lower middle income
151	Djibouti	Middle East & North Africa	0.513	28.6	1965	Lower middle income

HDI Rank	Country	Region	Human Development Index (2008)	Probability of not surviving to age 40 (% of cohort) 2000-2005	GDP Per Capita - USD	World Bank Classification (2008)
152	Tanzania (United Republic of)	Sub-Saharan Africa	0.503	36.2	1126	Low income
153	Senegal	Sub-Saharan Africa	0.502	17.1	1592	Low income

DISEASE SCOPE

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

- 14 of the WHO Neglected Tropical Diseases[d] (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)
- The top 10 communicable diseases based on Disability Adjusted Life Years (DALY) from the WHO Global Burden of Diseases[e]
- The top 10 non-communicable diseases based on DALYs from the WHO Global Burden of Diseases

Diseases are selected based on the following criteria:

- The disease incurs significant social costs in the Index Countries - For this criterion the DALY information from the WHO Global Burden of Disease project was used
- Pharmaceutical unfulfilled needs are a major contributor to the overall social burden of the disease

To ensure the best possible comparability between the pharmaceutical companies, discounted, non age-weighted WHO DALY data is 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[f]).

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 (for details about the rationale please refer to Appendix II):

- 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 lack of new products but failures in other parts of the product delivery value chain such as pricing, distribution, health infrastructure etc.

[d] World Health Organization Trropical Neglected Diseases; http://www.who.int/neglected_diseases/en/
[e] *2004 update*", Disease Control Priorities Project, WHO, 2008.
[f] The Disease Control Priorities Project ; http://www.dcp2.org/

The G-Finder report of the George Institute was an important reference in the process of finalizing research exclusions of Index 2010 for communicable diseases.[g] For details please refer to the "Disease Scope" section of Appendix 2.

For detailed International Classification of Disease listing for Index 2010, please refer to Appendix 3.

Table 4. Communicable Diseases on the WHO Neglected Tropical Diseases List to be covered in Index 2010

	Disease	Reference List		Disease	Reference List
1	Lymphatic Filariasis	GBD, NTD	8	Onchocerciasis	NTD
2	Schistosomiasis	NTD	9	Chagas disease	NTD
3	Human African Trypanosomiasis	NTD	10	Leprosy	NTD
4	Soil-transmitted Helminthiasis	NTD	11	Buruli ulcer	NTD
5	Trachoma	NTD	12	Dracunculiasis (guinea-worm disease)	NTD
6	Leishmaniasis	NTD	13	Fascioliasis	NTD
7	Dengue	NTD	14	Yaws	NTD

NTD: Neglected Tropical diseases covered by the WHO NTD department

GBD: Global Burden of Diseases ranked by standard DALYs (discounted, unweighted) low- and mid-income countries - updated 2004, published in 2008

Soil-transmitted Helminthiasis includes ascariasis, trichuriasis and hookworm disease

[g] G-FINDER: Global Funding of Innovation for Neglected Diseases – http://www.thegeorgeinstitute.org/research/health-policy/current-projects/g-find-global-funding-of-innovation-for-neglected-diseases.cfm

Table 5. Communicable Diseases on the GBD List to be covered in Index 2010

	Disease	Reference List	DALYs in LMIC – 2004	Annual Mortality in LMIC – 2004
1	Lower Respiratory Infections	GBD	93233137	3866897
2	Diarrheal diseases	GBD	72306348	2148340
3	HIV/AIDS	GBD	57843070	2017193
4	Tuberculosis	GBD	34014278	1447854
5	Malaria	GBD	33941524	888158
6	Measles	GBD	14839141	423333
7	Meningitis	GBD	11312859	336298
8	Pertussis	GBD	9832373	254323
9	Lymphatic filariasis	GBD, NTD	5940056	289
10	Tetanus	GBD	5277017	162606

Table 6. Non-Communicable Diseases on the GBD List to be covered in Index 2010

	Disease	Reference List	DALYs in LMIC – 2004	Annual Mortality in LMIC - 2004
1	Unipolar depressive disorders	GBD	55423705	11868
2	Ischemic heart disease	GBD	54800761	5861587
3	Cerebrovascular disease	GBD	31595000	41793423
4	Non-Communicable obstructive pulmonary disease	GBD	26522091	2737049
5	Diabetes Mellitus	GBD	16062898	914998
6	Asthma	GBD	14383499	265893
7	Osteoarthritis	GBD	12797915	3744
8	Cirrhosis of the liver	GBD	11977815	655083
9	Nephritis / nephrosis	GBD	8421239	611418
10	Epilepsy	GBD	7308772	131050

HOW WE MEASURE

PILLARS OF ANALYSIS FOR INDEX 2010

To accommodate the stakeholder demand for separation of ratings for inputs and outputs, a new Index structure is used in-which under the seven technical areas (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), the indicators are divided into the four categories of Commitments, Transparency, Performance and Innovation. Commitments and Transparency focus primarily on inputs and disclosure, while Performance indicators focus on outputs. Innovation indicators focus on introduction of innovative and unique initiatives by the companies across the seven technical areas. Product Donations & Philanthropic Activities have been merged.

Table 7. The Structure of Index 2010

Strategic Pillars	Commitments	Transparency	Performance	Innovation
Technical Areas	A. General Access to Medicine Management			
	B. Public Policy and Market Influence			
	C. Research & Development			
	D. Equitable Pricing, Manufacturing & Distribution			
	E. Patents & Licensing			
	F. Capability Advancement in Product Development and Distribution			
	G. Product Donations & Philanthropic Activities			

The Technical Areas of Access to Medicine Index 2010

A. General Access to Medicine Management
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 and also the company's approach to managing and measuring the inputs and outputs of its access to medicine initiatives are analyzed. Finally this technical area also attempts to capture the company's approach to engaging with different stakeholders with the aim of maintaining a positive and constructive stakeholder environment conducive to improved access to medicine in the Index Countries.

B. Public Policy & Market Influence
This technical area includes three sub-areas of lobbying and advocacy practices, competition policies and practices, and marketing policies and practices. All these three areas capture the influence of the companies on the marketplace and how the companies' influence impacts access to medicine in the Index Countries.

C. Research & Development
This technical area concentrates on the company efforts in research aimed at developing remedies for high priority diseases in the Index Countries, where there is an unfulfilled research need and a market failure. This technical area covers the companies' policies, disclosure and also output. This area covers both in-house and collaborative company initiatives. In addition, Innovative and Adaptive R&D are separately analyzed under this technical area.

D. Equitable Pricing, Manufacturing & Distribution
This technical area attempts to capture how the company produces, sets price and distributes its Index Disease products in the Index Countries. The main topics under this technical area are the equitable pricing approach of the companies across their products portfolio, the criteria for their market entry and obtaining marketing approval in the Index Countries and how they maintain high standards of quality in their product delivery to Index Countries.

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 technical area are patent enforcement in Index Countries, the companies' non-exclusive voluntary licensing practices and their stance towards patent pools.

F. Capability Advancement in Product Development & Distribution
This technical area focuses on the company initiatives that are conducive to increased capacity in product development and distribution in the Index Countries. Initiatives in this area can include research collaborations with Index Country organizations, quality management, technology transfer to the local manufacturers, and contribution to the establishment of pharmacovigilance systems in the Index Countries.

G. Product Donations & Philantropic Activities
This technical area concentrates on the companies' product donations and philanthropic activities. The indicators in this area aim to evaluate the effectiveness of the companies' donation programs and whether the companies' strategies in this area are aligned with the needs of the target communities. With regards to other philanthropic activities, the Index 2010 attempts to analyze the sustainability of such initiatives and also the companies' attempts in measuring and reporting their output.

The Four Strategic Pillars

The addition of these four strategic pillars is based on the mission of the Index: to improve transparency and motivate innovation among the pharmaceutical companies with the ultimate goal of improving global access to medicines for the societies in need. The new strategic pillars have the following positive impacts on the Index:

Under this strategic pillar, the inputs including policy statements or commitments are measured This strategic pillar is of critical importance because it is the area which 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.

In this strategic 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 the areas of 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. It should be noted that for each indicator, the analysts 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.

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 medicine 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 medicines, the performance indicators capture variables that are least affected by factors which the companies cannot control. For further details about the approach to performance used in Index 2010, please refer to the section 'Approach to Performance' in Appendix 2.

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 Innovations 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 and not under the 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 that 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 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.

INDICATORS FOR INDEX 2010

In the following section the detailed indicators used in Access to Medicine Index 2010 are listed. It should be pointed out that indicators which are marked as 'Experimental' will not have an effect on the companies' rating in Index 2010. Based on the data collected for Index 2010, such indicators may be refined and reintroduced in the following iterations of the Access to Medicine Index.

A. General Access to Medicine Management

commitments

A.I.1. The company has a governance system that includes direct board-level responsibility and accountability for its access to medicine initiatives for the Index Countries.

A.I.2. 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.3. 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.

transparency

A.II.1. The company publishes a publicly available annual report on its access to medicine policies and practices

A.II.2. The company publicly discloses information on a regular basis, regarding the overall resources dedicated to improving access to products for Index Diseases in the Index Countries.

A.II.3. The company publicly discloses quantitative and qualitative performance measures and targets for its access to medicine practices related to the Index Countries.

performance

A.III.1. Total full-time employees dedicated to access to medicine initiatives related to the Index Diseases and Index Countries across the company. (Experimental indicator)

A.III.2. The company has a management system including quantitative targets to implement and monitor its Access to Medicine strategy in the Index Countries.

A.III.3. The company 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.).

A.III.4. Percentage change in the company's revenue from sales in Low Human Development Countries compared to revenues from sales in the rest of the world during the past five years.

Innovation

A.IV.1. The company has adopted innovative (unique in the sector) approaches to implementing and measuring the output of its access to medicine initiatives across the company.

A.IV.2. The company has developed innovative (unique in the sector) initiatives for engaging with the stakeholders with the aim of improved access to the products for the Index Diseases in the Index Countries.

B. Public Policy & Market Influence

commitments

B.I.1. 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.

B.I.2. The company commits to endorse and support competition and to refrain from anti-competitive practices in the pharmaceutical markets in the Index Countries for products related to the Index Diseases.

B.I.3. The company refrains from pursuing data exclusivity for products related to the Index Diseases in the Index Countries.

B.I.4. The company commits to internal or external ethical codes for marketing of pharmaceutical products (WHO Ethical Criteria for Medicinal Drug Promotion or the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Marketing Practices).

B.I.5. The company commits to demand ethical marketing practices from its local sales agents and subsidiaries consistent with its own internal standards.

transparency

B.II.1.The company publicly discloses the positions it seeks through its advocacy activities related to access to medicines in the Index Countries (both direct advocacy and through industry associations).

B.II.2.The company annually and publicly discloses which individuals, patient associations, political parties, trade associations, and academic departments 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.

B.II.3. The company publicly discloses its board seats at industry associations and advisory bodies related to health access issues for the Index Diseases and the Index Countries.

B.II.4. The company publicly discloses its policies related to competition in areas such as data exclusivity, patent extensions etc. in the Index Countries.

B.II.5. The company publicly discloses detailed information regarding its marketing and promotional programs in the Index Countries, such as payments to physicians or other key opinion leaders and also its promotional activities for other healthcare providers, distributors etc.
B.II.6. 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.

performance

B.III.1. Has the company been involved in any controversial cases of lobbying activities in the Index Countries? Such cases include illegal payments to local governments or other forms of illegal influence which have resulted in fines or legal proceedings during the past five years.

B.III.2. Is there proof of the company's anti-competitive behavior in the Index Countries based on fines or litigation records during the past five years?

B.III.3. Have there been breaches of The International Federation of Pharmaceutical Manufacturers & Associations (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.4. 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 sales agents?

B.III.5. 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?

innovation

B.IV.1. The company has adopted an innovative (unique in the sector), sustainable approach to collaborating with its peers, which has resulted in improved access to essential medicines in the Index Countries.

B.IV.2. The company has adopted an innovative (unique in the sector) approach to improving the level of its own and its sales agents' compliance with the international marketing codes in this area, such as the IFPMA Code for Ethical Marketing and/or the WHO Code of Ethical Marketing.

C. Research & Development

commitments

C.I.1. 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.2. 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.3. The company commits to make available for free the products in the countries where the clinical trials for those products were carried out, consistent with codes such as the Helsinki Code for Clinical Trials.

transparency

C.II.1. The company discloses the resources dedicated to its research and development activities related to the Index Diseases for the Index Countries.

C.II.2. The company discloses the terms and conditions for its research collaborations related to the Index Diseases (with regard to Intellectual Property rights, duration etc.).

C.II.3. The company discloses the resources dedicated to its research collaborations related to the Index Diseases (both human resources and financial).

C.II.4. The company discloses its research pipeline related to both in-house research and collaborations targeting Index Diseases (where disclosure is not legally required).

C.II.5. 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.

performance

C.III.1. Portion of R&D investments dedicated to Index Diseases (exclusions apply - for details please refer to ”Approach to Performance” under Appendix II) out of the company's total R&D expenditures.

C.III.2. Share of research pipeline reflecting 'new molecules’ for Index Diseases including in-house and collaborative research (exclusions apply - for details please refer to ”Approach to Performance” under Appendix II).

C.III.3. Share of research pipeline 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 (e.g. pediatric formulations, Fixed Dose Combinations, delivery technologies suitable to Index Diseases, heat resistant preparations etc.).

C.III.4. Research collaborations 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).

C.III.5.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.

C.III.6. The company provides proof that the terms and conditions of its research collaborations are conducive to improving access to Index Disease products in the Index Countries for individuals with significant financial barriers to access.

C.III.7. Has the company been the subject of any breach of international codes or lawsuits related to its clinical trial practices in the Index Countries during the last five years?

C.III.8. The company provided proof of sharing its intellectual capital (includes molecules library, patented compounds, processes or technologies) on terms most conducive to access, with research institutions which develop products for Index Diseases targeted at the Index Countries.

innovation

C.IV.1. The company has adopted innovative (unique in the sector), sustainable business models for research into Index Diseases (exclusions apply - for details please refer to ”Approach to Performance” under Appendix II)

C.IV.2. 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.

D. Equitable Pricing, Manufacturing & Distribution

commitments

D.I.1.The company commits to implement inter-country tiered pricing models for the products related to the Index Diseases in the Index Countries targeting countries which experience the highest financial barriers to access.

D.I.2. The company commits to implement intra-country tiered pricing models for the products related to the Index Diseases in the Index Countries targeting individuals who experience the highest financial barriers to access.

D.I.3. The company commits to make its best efforts to control the pricing practices of its local sales agents with the aim of improving affordability and accessibility of the products.

D.I.4. The company commits to maintain its drug quality standards in the Index Countries at least equal to FDA, EMEA or WHO standards.

D.I.5. The company commits to create the processes and dedicate the resources needed to carry out effective drug recalls in the Index Countries where it operates.

D.I.6. The company commits to adapt the brochure and packaging of its products to the local language of the target communities in the Index Countries.

D.I.7. The company commits to register (obtain marketing approval for) its products for the Index Diseases in the Index Countries in need.

D.I.8. The company commits to make best efforts in the production and distribution of its products to prevent drug diversion in the Index Countries for the Index Diseases.

transparency

D.II.1. The company publicly discloses details of its equitable pricing approach for the Index Countries for products related to the Index Diseases.

D.II.2. The company publicly discloses the outcome of its equitable pricing programs (based on indicators such as number of patients having received the product, number of doses delivered based on the equitable price etc.)

D.II.3. The company publicly 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.

D.II.4. The company discloses information about its quality management systems for products destined for the Index Countries (standards, processes, resources, etc.).

D.II.5. The company publicly discloses information about the drug recalls and breaches it has been involved in related to drug quality issues in the Index Countries.

D.II.6. The company discloses the breakdown of its sales revenues for each product relevant to Index Diseases at the country level for the Index Countries.

D.II.7. The company publicly discloses information about its activities aimed at preventing drug diversion both in production and in distribution.

performance

D.III.1. The company has inter-country tiered pricing schemes for the Index Countries for the products for Index Diseases (to be analyzed across products portfolio including drugs, vaccines, diagnostic kits, vector controls, microbicides etc.), which aim at achieving affordable access to such products for the Index Countries.

D.III.2. The company has intra-country tiered pricing schemes in the Index Countries for Index Disease products (to be analyzed across products portfolio including drugs, vaccines, diagnostic kits, vector controls, microbicides,etc.) which aim at achieving affordable access to such products for those with the highest financial barriers to access.

D.III.3. What percentage of the total supply units made available by the company to the Index Countries was delivered at cost during the period of analysis (excluding donations)? (Experimental indicator– the method of calculation of cost to be clarified by the companies)

D.III.4. 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.5. Has the company attempted to register (obtain marketing approval for) its products for Index Diseases in the Index Countries in need?

D.III.6. Have drug recalls occurred due to quality issues in the Index Countries for products produced by the company or its voluntary licensees during the past five years?

ID.III.7. The company files for WHO Prequalification list or tentative approval of US Food and Drug Administration for its eligible products for the Index Diseases.

D.III.8. Do all company products, destined for Index Countries, for which tiered pricing is used, have special packaging or other distinct markers to prevent product diversion?

Innovation

D.IV.1. The company has introduced innovative approaches (unique in the sector) to equitable pricing which help with sustainable delivery of the products for Index Diseases to individuals in the Index Countries who face the highest financial barriers to access.

D.IV2. The company has introduced innovative approaches (unique in the sector) to manufacturing which help with sustainable delivery of products for Index Diseases in the Index Countries.

D.IV.3. The company has introduced innovative approaches (unique in the sector) to distribution of products for the Index Diseases which may help with sustainable delivery of such products for the Index Diseases in the Index Countries.

E. Patents & Licensing

commitments

E.I.1. The company commits to refrain from attempting to enforce its patents related to its products for the Index Diseases in the Least Developed Countries. (In this exceptional case instead of the UN HDI Low Human Development Countries (LHDCs), we refer to UN Least Developed Countries (LDCs) to maintain consistency with the demands of the Doha Declaration on TRIPS Agreement and Public Health.)

E.I.2. 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.

E.3. The company commits to provide non-exclusive voluntary licenses for the Index Disease products to generics manufacturers with the aim of increased accessibility and affordability.

E.I.4. The company commits to charge license fees from its voluntary licensees which are conducive to manufacturing of affordable Index Disease products for sale in Index Countries.

E.I.5. The company commits to share its intellectual property (patents, molecules library) with the institutions carrying out research and development for the Index Diseases aimed at improved access to medicine in the Index Countries.

E.I.6. The company commits to waive its rights in the Index Countries to the intellectual capital generated in public private partnerships for the Index Diseases.

transparency

E.II.1. The company publicly discloses its stance with regard to patent related issues in the Index Countries such as TRIPS+, usage of TRIPS flexibilities based on the Doha Declaration on TRIPS by the Index Countries, and patent extensions for products related to the Index Diseases in the Index Countries.

E.II.2. The company publicly discloses the patent status of its products for the Index Diseases in the Index Countries.

E.II.3. The company discloses detailed information about the voluntary licenses issued for its products related to the Index Diseases for the Index Countries. (Such as license duration, license territory, technology transfer etc.)

performance

E.III.1. 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 Low Human Development Countries, and acting against usage of TRIPS flexibilities by the Index Countries based on the Doha Declaration on TRIPS.

E.III.2. Does the company actively engage in issuing non-exclusive voluntary licenses for the Index Countries for its products related to the Index Diseases?

E.III.3. Does the company have effective technology transfer regimes in place to improve the quality and production capacity of its voluntary licensees?

E.III.4. The company supports patent pools such as UNITAID both for centralized procurement and for development of new remedies for the Index Diseases in the Index Countries.

innovation

E.IV.1. The company has adopted innovative (unique in the sector) initiatives aiming at increased effectiveness of its voluntary licensing programs.

E.IV.2. The company has engaged in innovative (unique in the sector), sustainable programs with the aim of decreasing the impact of patent enforcement on the affordability and accessibility of medicine to the individuals with financial barriers to access.

F. Capability Advancement in Product Development & Distribution

commitments

F.I.1. The company commits to assist its Index Country voluntary licensees and contract manufacturers with their quality management systems aimed at achieving international standards such as the FDA, EMEA, WHO Good Manufacturing Practices, etc.

F.I.2. 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.3. The company commits to support the implementation of pharmacovigilance systems in the Index Countries.

transparency

F.II.1. The company provides information about the mechanisms it applies to ensure that Index Country licensees and contract manufacturers maintain high quality of production consistent with international standards such as the FDA, EMEA and/or WHO Good Manufacturing Practices etc.

F.II.2. The company provides information about its collaborations with Index Country organizations with the aim of creating local research capacity for the Index Diseases.

F.II.3. The company discloses details regarding its activities related to establishing pharmacovigilance systems in the Index Countries.

performance

F.III.1. Is there proof that the company assists local licensees or contract manufacturers to achieve international drug manufacturing standards (such as FDA, EMEA or the WHO Good Manufacturing Practices) in the Index Countries?

F.III.2. Is there proof that the company participates in public-private partnerships in the Index Countries with the aim of increasing local capacity for research? Does the company support the research carried out by Index Countries' academic institutions?

F.III.3. The company actively engages in establishing and supporting pharmacovigilance-related programs in the Index Countries during the analysis period.

Innovation

F.IV.1. The company has introduced innovative (unique in the sector) approaches to working with the Index Country organizations to improve the quality and accessibility of the products for Index Diseases, in areas such as countering drug diversion, counterfeiting, and local quality management.

F.IV.2. The company has introduced innovative (unique in the sector) approaches to working with the Index Country organizations which help improve the local research capacity for the Index Diseases.

G. Product Donation & Philanthropic Activities

commitments

G.I.1. 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.

G.I.2. The company commits to make its best efforts to assure the donated products are administered to patients in the target Index Country.

G.I.3. 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.

transparency

G.II.1. The company publicly discloses the process for deciding the drug types and destinations for its donations programs in the Index Countries.

G.II.2. The company publicly discloses detailed information about the type, volume and destination of the donated products in the Index Countries.

G.II.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.4. The company publicly discloses the output and the amount of resources dedicated to its philanthropic activities in the Index Countries.

performance

G.III.1. Has the company been fined or been proven to have breached the WHO Guidelines for Drug Donations during the last five years?

G.III.2. Has the company prematurely terminated any of its donations programs in the Index Countries during the last five years?

G.III.3. The value of donated products which were donated based on targeted, need based strategic donation programs to the Index Countries during the period of analysis (single drug donations) adjusted for the company size).

G.III.4. Value of the company's philanthropic activities (excluding drug donations) in the Index Countries during the period of analysis adjusted for company size?

Innovation

G.IV.1. The company has introduced innovative (unique in the sector), sustainable approaches to managing drug donations which may result in increased effectiveness and efficacy.

G.IV.2. The company has introduced innovative (unique in the sector) approaches to philanthropic programs in the Index Countries which may result in sustainable health improvements.

APPROACH TO WEIGHTS AND ANALYSIS

In Index 2010, there are three levels of weights:

- Strategic weights for the four strategic pillars of Commitments, Transparency, Performance and Innovation: For these four strategic pillars, a weight distribution of 30%, 30%, 30%, and 10% is attributed. Following further maturity of the performance indicators and availability of more data from the companies it is possible that in the following indices the weight of Performance be increased to better reflect the importance of this pillar.

- Weights for the technical areas of 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: the weight adjustments of these technical areas were guided by the inputs from the different stakeholder groups; given some technical areas have merged compared to the last Index, the weights of such areas have been combined.

- Weights for the subcategories under the above-mentioned seven technical areas (for example the subcategories of R&D, etc.): the weight adjustments in these areas were based on the inputs from the online survery and on the weights from Index 2008.

The weights for Index 2010 for the first two weighting levels are graphically demonstrated in the following section.

Table 8. Weights for Index 2010

Technical Area	100% Revenue from Patented Products	100% Revenue from Generics Products
	P	G
A. General Access to Medicine Management	10%	10%
B. Public Policy & Market Influence	10%	10%
C. Research & Development	25%	15%
D. Equitable Pricing, Manufacturing & Distribution	20%	30%
E. Patents & Licensing	15%	10%
F. Capability Advancement in Product Development & Distribution	10%	15%
G. Product Donations & Philanthropic Activities	10%	10%
SUM	100%	100%

Not all companies are either 100% generics- or 100% research-based; consequently, the weights for all the companies are adjusted based on their revenue streams from these two sources. Examples of such adjustments are provided in the following table according to companies' generics/originator sales breakdown:

Table 9. Sample Weight Calculations based on Generics/Originator Revenue Breakdown

Technical Area	% of Revenues from Generics Sales				
	0	6%	37%	83%	100%
A. General Access to Medicine Management	10%	10.0%	10.0%	10.0%	10%
B. Public Policy & Market Influence	10%	10.0%	10.0%	10.0%	10%
C. Research & Development	25%	24.4%	21.3%	16.7%	15%
D. Equitable Pricing, Manufacturing & Distribution	15%	14.7%	13.2%	10.9%	10%
E. Patents & Licensing	20%	20.6%	23.7%	28.3%	30%
F. Capability Advancement in Product Development & Distribution	10%	10.3%	11.9%	14.2%	15%
G. Product Donations & Philanthropic Activities	10%	10.0%	10.0%	10.0%	10%

Relative vs. Absolute Ratings

Index 2010 will continue to use a combination of an absolute and a relative rating system but will strive to include as many quantitative indicators as deemed possible at this stage of the Index's maturity. Currently, lack of sufficient empirical research on best practices limits the use of absolute ratings for the quantitative indicators. Index 2010 will therefore use absolute ratings 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 would like to work with academia, industry, NGOs and independent experts to establish a set of best practices for all indicators. By moving toward an absolute rating system, the Index will continue to push low performers to improve their access to medicine strategies while also inspiring high performers to do more.

SOURCES OF INFORMATION

For the benchmarking process, the RiskMetrics Group obtains data from the following sources:

- Corporate documents: annual reports, environmental and social reports, securities filings, 10k and other, websites, etc.
- Government, multilateral organization 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), FDA (drug quality and promotion), EMEA, WHO (Prequalification, registration, patents, pricing), WTO (Compliance with TRIPS), and DFID (Meta).
- On-line news databases: Factiva, LexisNexis etc.
- 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.
- NGOs and non-profit organizations: reports from and interviews with Non-Governmental Organizations familiar with the companies' operations
- Other third-party sources: reports and interviews with the stakeholders we consulted during the development of the Index framework including investors, consultants and academics.
- Company directors: 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. The companies are now in the process of responding to a detailed information collection package which covers primarily these areas and also other areas where our analysts need additional information from the companies.

OTHER ENHANCEMENTS

- During the analysis process, RiskMetrics conducts interviews with several non-profit and international procurement organizations engaged in different areas around access to medicine, to make sure the analysts have a better understanding of the business and social context before establishing the company rating. While such information might not yield comparable data across all the companies for scoring purposes, it can be very helpful in achieving a comprehensive qualitative understanding of the companies' business practices 'on the ground'.
- Index 2010 has a specific focus on how the pharmaceutical companies can influence the behavior of their local sales agents in the Low and Medium Human Development Countries with the aim of more affordability and accessibility of products for Index Diseases. The Index 2010 provides a comprehensive analysis of the companies' product portfolio and research pipeline aimed at moving towards a more systemic understanding of the companies' efforts related to access to medicine for the Index Diseases in the Index Countries
- Diversification of sources of information for analysis and interviews with Index Country actors to make sure the Index 2010 provides a richer understanding of the on-the-ground realities of access to medicine
- More thorough analysis of companies' activities in the following areas:
    - Registration (marketing approval) of products for Index Diseases in the Low Human Development Countries.
    - Competition behavior
    - Research and development pipeline of the companies
    - Market portfolio of the companies and their relevance to the Index Diseases
    - Voluntary licensing activities of companies and the effectiveness of their technology transfer approaches.

APPENDIX 1: MULTI-STAKEHOLDER PROCESS

For Index 2010, the update process was designed and launched in late 2008 and the stakeholder outreach started in January 2009. The update process started with the distribution of an online questionnaire among the stakeholder representatives. Following collection and analysis of the data from the survey, the first roundtable was held in February 2009 in Nairobi, Kenya with a strong presence of local NGOs from Africa as well as Latin America and India. In June of 2009, the Washington D.C. and London multi-stakeholder roundtables were held.

This document includes an overview of the roundtables in Washington D.C., London, and Nairobi, as well as the online survey.

THE 2009 ONLINE SURVEY

A detailed questionnaire was distributed among thought leaders in Access to Medicines from different stakeholder groups. The questionnaire included issues raised by different stakeholders following the publication of Index 2008. It included questions in key areas such as:

- Geographical coverage of the Index
- Disease coverage
- Company coverage
- Approach to the analysis and rating of generics drug manufacturers
- Approach to the analysis and rating of biotech companies
- The tone of the report
- The relative weight of policy vs. performance indicators
- The weight of the analysis criteria

The stakeholder groups included governments, NGOs, industry, investors, experts and academics. We received 65 comprehensive responses which included both quantitative and qualitative data (a response rate of around 20%). The responses to the online survey were one of the key inputs into the framework update process (the anonymous responses to the online survey can be provided upon request).

As demonstrated in the below tables, the governments were the only stakeholder that was comparatively highly underrepresented in the online survey. Despite the Index Team's continuous efforts to improve its engagement with Index Country governments in the following months, only limited success in this area was achieved.

Table 10. Responses by Stakeholder Group

	No. of responses	% of total respondents
Academics	11	13.4%
Consultants	12	14.6%
Government	5	6.1%
Industry	21	25.6%
Investors	15	18.3%
NGOs	18	22%

Table 11. Responses by Geographic Area

	No. of responses	% of total respondents
Africa	5	6.10%
Asia	2	2.40%
Europe	48	58.50%
Middle East	1	1.20%
North America	26	31.70%

THE 2009 ACCESS TO MEDICINE WORKSHOP IN NAIROBI

We plan to organize a local workshop on an annual basis to ensure engagement and involvement of local players in the development of the Index. This process not only focuses on feedbacks for improvements in the framework but also aims at exploring ways to make the Index more useful to the players on the ground. In 2009, the workshop was held in Nairobi, Kenya. Eighteen local NGOs were represented in the two-day workshop. The feedbacks from the roundtable were diverse and rich.

Along with the online survey, multi-stakeholder roundtables and other input sources, comments from the Nairobi workshop were one of the sources of stakeholder feedback used in the methdology update process.

THE 2009 UNITED STATES AND EUROPE ROUNDTABLES

The roundtables are one of the key processes through which we involve multi-stakeholder representatives to discuss the required changes in the Access to Medicine Index framework. Well-known international representatives of access to medicine stakeholders were invited to the roundtables for Index 2010. The stakeholder groups included: academics, NGOs, investors, the pharmaceutical industry associations, transnational organizations, governments, and independent experts.

The two roundtable events for 2009 were:

- US Roundtable: Washington D.C. on 24 June, chaired by Femke Markus
- Europe Roundtable: London on 30 June, chaired by Sophia Tickell

The participants of each Roundtable meeting were made up from a variety of stakeholder groups, all active in some capacity on the access to medicines agenda. The participants' involvement is intended to ensure different viewpoints and perspectives are taken into consideration in establishing the latest Access to Medicine Index methodology. The Access to Medicine Index team remains ultimately responsible for decisions on the final methodology, associated reporting material, and the findings of the Access to Medicine Index.

The participants in the roundtables are listed in the following table.

Table 12. 2009 Roundtable Participants by Stakeholder Group

	Washington DC, 24 June 2009	London, 30June 2009
Academics	*Joseph Fortunak*, Howard University	*Alan Whiteside*, University of KwaZulu-Natal *Elias Mossialos*, London School of Economics (LSE)
Government	*Sally Schlippert*, World Bank *Tatiana Popa*, International Finance Corporation (IFC)	*Charles Clift*, Department For International Development (DFID)
Independent Experts	*Jeff Sturchio*, Global Health Council *Jeanne Shen*, Global Alliance for Vaccines and Immunisation (GAVI Alliance) *Jonathan Mwiindi*, Individual Expert, previously with Ecumenical Pharmaceutical Network (EPN)	*Wilbert Bannenberg*, Medicines Transparency Alliance (META) *Javier Guzman*, George Institute for International Health / G-Finder *Maggie Brenneke*, SustainAbility *Jan Bultman*, Independent Consultant
Industry	*Dilip Shah*, Indian Pharmaceutical Association (IPA & IGPA)/ Vision Consulting *Corry Jacobs*, The Pharmaceutical Research and Manufacturers of America (PhRMA)	*Brendan Barnes*, European Federation of Pharmaceutical Industries and Associations (EFPIA) *Guy Willis*, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
Investors	*Lauren Compere*, Boston Common Asset Management / Interfaith Center on Corporate Responsibility (ICCR) *Nadira Narine*, Interfaith Center on Corporate Responsibility (ICCR)	*My-Linh Ngo*, Henderson Global Investors
NGOs	*David Ripin Brown*, Clinton Foundation	*Robyn Scott*, Founder of Mothers for All, Independent Consultant & Writer
Chair	*Femke Markus*, Access to Medicine Index	*Sophia Tickell*, SustainAbility Co-chair: *Femke Markus*, Access to Medicine Index
Observer	*Regine Webster*, Consultant at the Gates Foundation	*Helen Vieth*, London School of Economics (LSE)

OTHER FEEDBACK SOURCES

In addition to the above primary routes for obtaining stakeholder feedbacks, the Access to Medicine Index 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, roundtables and other feedback processes were studied by the Expert Review Committee which is a committee in charge of providing guidance and advice to the Index team on the annual update of the Index methodology (please see the following section). We maximized our efforts to ensure that all the stakeholders receive equal representation in the stakeholder engagement process.

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. Convened in 2009, the mandate of the ERC is purely advisory in nature, with the objective of providing guidance, recommendations and advice to the Access to Medicine Index team on the scope, structure, content and methodology of the second Access to Medicine Index assessment. The ERC members' involvement is intended to ensure different viewpoints and perspectives 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. 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.

For a list of Expert Review Committee members please refer to the table below. Following collection of the stakeholder feedback through the aforementioned process, the methodology was updated by the Access to Medicine Foundation team. In the process of compiling the new methodology, the work in progress was presented to all the stakeholder review committee members over several webinars. Finally, a draft of the new methodology, along with the consolidated stakeholder feedback, was presented to the ERC in person on 14 September 2009 in London. Based on the ERC feedback, multiple updates and reviews, the methodology was finalized by mid November 2009. It should be pointed out that additional adjustments were made to the indicators after the start of the company analysis phase based on our sensitivity analysis in order to ensure the highest possible levels of feasibility, variability and comparability of the indicators.

Table 13. The Access to Medicine Index 2010 Expert Review Committee

Index 2010 Expert Review Committee	
Academics	Elias Mossialos, London School of Economics
Government	Charles Clift, Department For International Development
Independent Experts	Sophia Tickell, SustainAbility (Chair)
Industry	Guy Willis, International Federation of Pharmaceutical Manufacturers & Associations
Investors	My-Linh Ngo, Henderson Global Investors
NGOs	Eva Ombaka, NGO Consultant
Multi-Lateral Organizations	Richard Laing, World Health Organization

APPENDIX 2: METHODOLOGY UPDATE RATIONALE

WHAT WE MEASURE

In the table below the overall changes of scope of Index 2010 are outlined.

Table 14. Scope changes for Index 2010

	Index 2008	Index 2010
Company Coverage	20 - Including 17 originators and three generics manufacturers.	27 - Including 20 originators and seven generics manufacturers
Geographical Scope	Low and Medium Human Development Countries from the UN Human Development Index.	Low and Medium Human Development Countries from the UN Human Development Index – with the exception of countries classified as medium-high or high income by the World Bank.
Disease Scope	24 - Combination of WHO Tropical Index Diseases and the top Communicable and Non-Communicable diseases from the Global Burden of Disease list based on mortality.	33 - Combination of WHO Tropical Index Diseases and the top Communicable and Non-Communicable diseases from the Global Burden of Disease list for the Low and Medium Human Development Countries based on DALY.

COMPANY SCOPE

Index 2008 Company Scope

The Index I company list was developed in December 2007 using data from Thomson Financial. All companies including generic, research-based, and mixed companies were included in the same Index. Weight adjustments were used to make the data comparable between these three company categories. Selection was based on market capital. Genentech, Amgen and Takeda were removed from the list due to their portfolios targeting people in the developed world, and two major Indian generic manufacturers, Cipla and Ranbaxy, were added (Teva was already selected based on market capital).

Table 15. Companies covered in Index 2008

Rating	Ticker	Company	Country
1	GSK-LN	GlaxoSmithKline PLC	GBR
2	NOVO'B-KO	Novo Nordisk	DNK
3	MRK-N	Merck & Company	USA
4	NOVN-VX	Novartis AG	CHE
5	SAN-FR	Sanofi-Aventis SA	FRA
6	AZN-LN	AstraZeneca PLC	GBR
7	ROG-VX	Roche Holdings Ltd.	CHE
8	JNJ-N	Johnson & Johnson	USA
9	BAY-FF	Bayer AG	DEU
10	LLY-N	Eli Lily & Company	USA
11	BMY-N	Bristol Myers Squibb Co	USA
12	ABT-N	Abbott Laboratories	USA
13	MRK-FF	Merck Kgaa AG	DEU
14	CIPLA-BY	Cipla Limited	IND
15	GILD	Gilead Sciences Inc.	USA
16	PFE-N	Pfizer	USA
17	WYE	Wyeth	USA
18	TEVA-TV	Teva Pharmaceutical Industries Limited	ISR
19	SGP	Schering-Plough	DEU
20	BOM:500359	Ranbaxy Laboratories Limited	IND

2009 Stakeholder Feedback

The 2009 stakeholder review raised important questions in regard to the Index company list:

1) Should generic manufacturers be covered by the Index?

2) Should insulin manufacturers be covered by the Index?

3) Should biotechnology companies be covered by the Index?

Generic Manufacturers

With regard to coverage of generic companies, the dominant viewpoints from the online survey, the stakeholder roundtables and the Nairobi workshop all were that generic companies are important players in the access to medicine area and that the Index needs to provide a better coverage of these companies. Several of the generic companies were listed in the section for new company suggestions in the online survey. For the debate regarding the need for separate lists or one list for generic and one for originator companies, please refer to the 'Approach to Generics Manufacturers' section.

Biotechnology Companies

With regard to biotechnology companies, the dominant viewpoint in the roundtables and the survey was that they need to be covered; however, there were divergent views about the method and timing. Two comments pointed out that they should be covered in the coming years but not immediately, and one respondent suggested covering the biotech companies in a separate Index. In the roundtables and the Nairobi workshop this issue was not thoroughly debated.

Insulin Manufacturers

Stakeholder comments about the insulin manufacturers have been scarce and very divergent. One example is that an industry commented from the online survey: "It does not seem obvious why they should not be treated like any other company; they should be judged against their area of special expertise in the proposed Index scope", while another industry comment stated the opposite view: "All companies' contributions to access to medicines should be evaluated on the same weighting of criteria".

Approach in Index 2010

Based on stakeholder feedback, the list has been expanded to include four more generic manufacturers. This is consistent with the dominant viewpoint among stakeholders, and also the goal of the Index to better cover generic companies, which are deemed as critical players in the countries under coverage. The selection of the generic companies is based on market capital and drug portfolio relevance to the Index Disease list.

Diabetes is one of the diseases with high DALY in the countries under coverage, and insulin manufacturers are covered by Index I. Recommendations are that insulin manufacturers be covered by Index II as well.

Finally, we suggest keeping biotech companies out of Index II. Their inclusion might be considered in future indexes. It should be noted that Gilead, which has both biotechnology and pharmaceutical revenue streams, continues to be included in the Index given its highly relevant drug portfolio and operations.

To ensure methodology consistency for Index II, all companies are asked to provide data for the full 2008-2009 fiscal years.

Details of the Enhancements to the Index 2010 Company List

- Exclusion of Chugai & Genentech: Roche owns more than 50% of Chugai and Genentech and the latter is a biotech company. We will continue to analyze Roche and its subsidiaries (as was done in Index 2008).
- Removal of Schering-Plough: In March 2009, Merck & Co. announced it is acquiring Schering-Plough Corp for USD 41.1 billion. We will include information on Schering-Plough in the analysis of Merck from the date of acquisition.
- Removal of Wyeth: In January 2009, Pfizer Inc. announced it is acquiring Wyeth for USD 68 billion. We will include information on Wyeth in the analysis of Pfizer from the date of acquisition.
- Exclusion of Allergan: Allergan's product portfolio consists mainly of medical aesthetic and dermatology products.
- Addition of four generics: Dr. Reddy's, Mylan Inc., Sun Pharmaceuticals and Apotex have been added to the list of generics manufacturers.
- Four Japanese (Eisai, Daiichi, Takeda, Astellas) companies and the unlisted firm, Boehringer-Ingelheim were added to the Index.
- Diabetes is one of the diseases with high DALY in the countries under coverage, and insulin manufacturers are covered by Index 2008. We will continue to cover Insulin manufacturers in Index 2010.

Approach to Generics Manufacturers

In the table below, the approach to generics manufacturers in Index 2008 and Index 2010 are outlined:

Table 16. Approach to Generics Manufacturers

	Index 2008 Approach to Generics Manufacturers	Index 2010 Approach to Generics Manufacturers
Number of Generics Manufacturers	3	7
Dedicated Indicators for Only Generics Manufacturers	Both generics and originator companies were scored on the same indicators.	Generics and originator companies are scored on comparable indicators.
Inclusion of Additional Indicators Relevant to Generics Manufacturers	In Index 2008, there were no dedicated indicators to capture generics-specific activities.	In Index 2010, there are dedicated indicators to capture specific activities for manufacturing of generics drugs.
Weight Adjustments	One set of weight adjustments was used for originators and an additional set of weight adjustments was used for generics manufacturers.	Weight adjustments are carried out for all 27 companies based on the portion of their revenues that are sourced from the sale of generics products.
Publication of Generics Index	Generics and originator companies were included in the same Index.	Two separate company comparisons will be published; one for generics and one for originators.

Index 2008 Approach to Generics Manufacturers

One of the challenges facing any comparative analysis is the normalizations needed to make the studied entities comparable. In the case of companies in the pharmaceutical sector, there is a wide variety of business models. Some of the business models existing in this sector are:

- Dominant patented drug production and sales such as Merck and GSK
- Dominant generics products sales such as Teva, Apotex and Mylan
- Mix of research-based and generics such as Novartis

In Index 2008, all the companies including generics, research-based, and mixed companies were included in the same Index. Weight adjustments were used to make the data comparable. For example, for the generic manufacturers, a lower R&D weight and higher pricing and capacity advancement weights were used. However, despite the weight adjustments, due to several reasons such as low level of reporting by generic

companies about their access to medicine initiatives, they rated lower than most of the research-based firms.

2009 Stakeholder Feedback

The 2009 feedback from stakeholders presented three alternative solutions for assessing research-based and generics companies.

- Separate indexes: One option suggested in the Nairobi Workshop, and echoed by some survey respondents and participants at the Washington D.C. and London roundtables, was to have a separate Index for each business model. To begin with, there would be one for originator companies and one for generics, with the possibility of additional indices for other business models in the future, such as biotech companies.

- One Index, same weights: Some participants at the roundtables suggested that we continue to assess research-based companies and generics manufacturers alongside each other, but that we should use the same weights for all companies. Companies should be held to the same standards, especially given the growing trend whereby originator companies and generics manufacturers have increasingly overlapping business units. Research-based companies are moving into Generics Manufacturing, and generics companies are strengthening R&D branches to develop new formulations for developing markets. The increasing overlap in their business units requires the same standards of evaluation.

- One Index, different weights: The final option was to maintain the Index as in Index 2008, with research-based, generics and biotech companies evaluated in one Index, and weight adjustments based on the business model to make the data comparable. Several online survey respondents and some London Roundtable participants supported this option.

Approach in Index 2010

Although the three alternatives for evaluating pharmaceutical companies with different business models were discussed and supported by some stakeholders, it has been determined that the dominant viewpoint among the stakeholders is that generics manufacturers and research-based companies should be evaluated in two separate lists. Stakeholders also agreed that there should be more generics companies included in the Index given the significant role they play in providing access to medicines in Low and Medium Human Development Countries. Finally, given that increasingly research-based pharmaceutical companies are expanding their generics operations and vice versa, instead of applying two distinct sets of weights to the generics and originator companies for this Index, we apply weight adjustments for all the companies based on the portion of their revenues sourced from generics operations. (For more information please refer to the Approach to Weights and Analysts section of this appendix.)

Geographical Scope

Index 2008 Geographical Scope

In Index 2008, the geographical scope covered the Low and Medium Human Development Countries based on the UN Human Development Index. No adjustments were made based on country income levels.

2009 Stakeholder Feedback

In the online survey, 63% of the participants stated that the geographical scope of the Index should not be expanded to include issues pertaining to developed countries' access to medicines. This majority was consistent among all the stakeholder groups with the exception of independent experts, whose responses were equally divided. In the cases where expansion (to include developed countries) was recommended, the stakeholders' argument was that the scale and scope of health access issues in certain developed countries, especially uninsured or underinsured individuals, demanded urgent attention. The stakeholders who opposed expanding the geographical focus of the Index mostly emphasized the global priorities and the possibility of diluting the message of the Index by expanding it to developed world issues.

In the roundtables, the dominant viewpoint was not to cover developed world access issues at this point.

Approach in Index 2010

For Index 2010 we will concentrate on the global list of Low and Medium Human Development Countries of the UN Human Development Index. We recommend excluding the countries that are classified as having 'High Income' and 'Medium High Income levels' based on the World Bank 2008 country listings. Given the high number of Medium Human Development Countries, for some Performance indicators, the collected data will be verified in a subset of such countries, which is selected based on the following criteria:

- Availability of information with acceptable quality
- Countries that are representative of all the major geographical areas
- Countries where all the globally high DALY diseases are represented

The reason for choosing the Human Development Index above other listings such as the World Bank's data is that such listings are primarily based on economic indicators. In contrast, the Human Development Index includes more relevant social indicators such as life expectancy and infant mortality rates.

We exclude Middle-High and High Income countries in order to avoid focusing on countries whose governments have enough financial resources in place to address the countries' health access issues.

Disease Scope

Index 2008 Disease Scope

Index 2008 focused on reviewing companies' activities in relation to the Global Burden of Disease (GBD) as defined by the Disease Control Priorities Project and to the Neglected Tropical Diseases (NTD) covered by the WHO NTD department. Out of a total of 26, the Index included 10 Communicable Diseases from the WHO NTD list, as well as six Communicable and 10 Non-Communicable Diseases from the GBD list, based on data for 1990 to 2001[h]. The choice was made based on the diseases covered under the Global Disease Burden that contribute to 1% or more of total deaths in the world according to the Disease Control Priorities Project.

2009 Stakeholder Feedback

One of the key priorities for Index 2010 voiced by the engaged stakeholders was the need for a deeper analysis, including exhaustive performance measurements. Disease coverage is a major pillar for such an analysis and should therefore be revised with regard to current health priorities in the regions covered by the Index. For this reason, the question was raised at the Washington D.C. and London Roundtables, as well as in the 2009 Stakeholder Survey, whether disease coverage should be extended in general and should cover the Non-Communicable diseases in more detail. Roughly 77% of the survey respondents were opposed to raising the overall number of diseases covered, worrying that larger disease coverage would be established at the expense of a deeper analysis.

But considering the growing threat of Non-Communicable diseases in Low and Medium Human Development Countries, most of the roundtable participants agreed upon expanding the Index for deeper and more specific coverage of these diseases. One stakeholder from the industry argued that there were divergent opinions regarding communicable and non-communicable diseases and that these differences should be captured by the Index.

An NGO stakeholder pointed out that today, 80% of non-communicable disease deaths occurred in low- and middle-income countries, and suggested that the Index include these as "Non-Communicable diseases [which] now represent 50% of the global burden of disease."

Overall in the stakeholder surveys, there was a consensus that the disease coverage should continue to comprise both Communicable and Non-Communicable Diseases with high impact in the Index Countries.

[h] Published in 2004.

Approach in Index 2010

Following the stakeholders' suggestions for improvement, Index 2010 aims at adjusting its disease coverage based on the below criteria:

- Diseases having the most significant social impact in the Low and Medium Human Development Countries, as the priority is to have an Index disease list with the most significant social impact on the defined countries
- Diseases on which pharmaceutical sector initiatives can have a major impact in terms of social burden and/or mortality
- Diseases for which hardly any treatments are available, and market failure impedes the development/distribution of treatments.

The two sources used for Index 2008 have proven to meet these requirements. Yet for Index 2010, updated[i] Disability Adjusted Life Years (DALY) data for Low and Medium Human Development Countries are used instead of aggregated mortality rates for the entire developing world (as in Index 2008).

The move from mortality-based to DALY-based disease selection meets the goal of the Index of not only focusing on diseases with high mortality but also diseases which cause significant disability and have considerable social costs. For reference, mortality rates for the Index Diseases have been captured and presented in this report.

The WHO publishes three sets of DALY data for the Global Burden of Diseases:

- Standard DALYs (3% time discounting and non-uniform age weight).
- Discounted, non-age-weighted DALYs (3% time discount).
- Undiscounted and non-age-weighted DALYs.

To ensure the best possible comparability between the pharmaceutical companies, the second set, the discounted, non age-weighted data, is 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[j]).

It should be noted that, considering that the disease coverage is based on DALY, it has resulted in covering diseases such as unipolar depressive disorders, asthma, osteoarthritis and epilepsy, which were not covered in Index 2008.

[i] *"2004 update"*, Disease Control Priorities Project, WHO, 2008.
[j] The Disease Control Priorities Project ; http://www.dcp2.org/

As mentioned, Index 2010 aims to focus on areas where there is a market failure. There is significant overlap for Non-Communicable disease priorities between the developed and developing world. Consequently, to avoid assessing the companies in areas where there is no market failure, for Non-Communicable diseases only incremental efforts of the company for the Low and Medium Human Development Countries are taken into consideration. Such efforts include adaptive research tailored to Index Countries, specific pricing, licensing, and technology transfer regimes for the Index Countries. As for Communicable diseases, as a basis for defining areas where there is market failure for research, criteria from major global projects on R&D for neglected diseases such as the G-Finder report of the George Institute are applied.[k] A summary of communicable disease R&D restrictions consistent with the G-Finder Report is provided below:

Diarrhoeal disease research coverage includes Diarrhoea caused by cholera, shigella and cryptosporidium and ONLY includes pharmacological interventions that target the pathogen, not supportive therapies. Diarrhoea caused by rotavirus: ONLY includes developing country-specific R&D.

Meningitis R&D coverage includes the following restrictions

- Covers ONLY meningitis caused by N. meningitides: ONLY includes R&D on vaccines specifically for developing-country registration. Such a vaccine must, at a minimum: a) provide coverage against N. meningitidis serotype A; b) be a conjugate vaccine; c) be designed for use in infants less than two years of age
- For multi-valent vaccines covering Western and developing country strains, developing country-specific initiatives is covered only

It should be pointed out that outside the Research & Development technical area, all the products for Index Diseases are covered.

Details of the Changes Compared to Index 2008

- Removal of all types of cancers: Trachea, bronchus and lung cancers do qualify to be on the list; however, given the low efficacy of therapies in this area and high overlap of palliative therapies with other cancers, these were excluded.
- Removal of perinatal conditions: Though perinatal conditions are one of the major causes of death among children according to the WHO GBD list, they should not be included in the list, as they are not directly relevant to the pharmaceutical sector.
- Exclusion of snakebite: Snakebite has been excluded, as its most efficient treatment, antivenom, is not produced by the pharmaceutical companies under coverage and thus no comparative data can be deducted.

[k] NEGLECTED DISEASE RESEARCH & DEVELOPMENT: HOW MUCH ARE WE REALLY SPENDING?; The George Institute; 2009 http://www.thegeorgeinstitute.org/shadomx/apps/fms/fmsdownload.cfm?file_uuid=409D1EFD-BF15-8C94-E71C-288DE35DD0B2&siteName=iih

- Exclusion of violence, smoking and other types of health issues that cannot be directly addressed by pharmaceutical companies.
- Exclusion of nutritional and endocrine diseases, given this disease category is more in line with producers of neutriceuticals and fall under the endocrine category; diabetes mellitus is separately captured.
- Addition of four Non-Communicable diseases: unipolar depressive disorders, asthma, osteoarthritis and epilepsy. These diseases were all added based on DALY according to the WHO GBD list.
- Addition of three Communicable diseases: meningitis, pertussis and tetanus. These diseases were all added based on DALY according to the WHO GBD list.
- Addition of six neglected tropical diseases: buruli ulcer, dracunculiasis, fascioliasis, soil-transmitted helminthiasis; trachoma and yaws were added, since they are included in the WHO NTD list.

HOW WE MEASURE

In the table below the changes for the structure of Index 2010 are outlined:

Table 17. Structure Changes for Index 2010

	Index 2008	Index 2010
Pillar Structure	8 Technical Areas: 1. Access to Medicine Management 2. Public Policy & Influence 3. R&D into Neglected Tropical Diseases and GBD 4. Equitable Pricing 5. Patenting 6. Capability Advancement 7. Drug Donations 8. Philanthropic Activities	7 Technical Areas: A. General Access to Medicine Management B. Public Policy and Market Influence C. Research & Development D. Equitable Pricing and Distribution E. E. Patents & Licensing F. Capability Advancement in Product Development and Distribution G. Product Donations & Philanthropic Activities 4 Strategic Pillars: 1. Commitments 2. Transparency 3. Performance 4. Innovation
Indicator Structure	Indicators were scored on a 1 to 5 basis. All the indicators were based on a combination of binary conditions which defined the different score levels to be assigned to the company for each indicator.	Indicators will be scored 0 to 5 to ensure the maximum spread. Scores are based on a combination of binary conditions which defined the different score levels to be assigned to the company for each indicator. In addition to the qualitative indicators, additional quantitative indicators have been included under the Performance pillar.
Weightings	In Index 2008, the weights were divided between the eight Technical areas. Further weight adjustments were carried out for generics and for Novo Nordisk.	In Index 2010, the weights have been divided between the four Strategic Pillar areas: Commitments 30%, Transparency 30%, Performance 30%, and Innovation 10%. Companies are evaluated on all seven Technical Areas within each of the four Strategic Pillar areas. The weighting of the Technical areas are adjusted based on the percentage of companies' sales from patented or generics products (see Table 9 for detailed Index 2010 weight adjustments).
Relative Vs. Absolute Rating	In Index 2008 a combination of a relative and an absolute rating system was used. Companies were scored on a 1 to 5 scale using a "best in class" approach.	Index 2010 will continue to use a combination of a relative and an absolute rating system. A relative rating system will be used for the quantitative indicators and an absolute rating system will be used for the qualitative indicators. The lack of sufficient empirical research on best practices limits the use of an absolute rating system for quantitative indicators at this time. Companies are scored from 0 to 5 on all indicators.

Pillars of Analysis

Index 2008 Pillar Approach

Index 2008 was based on the eight technical areas of Access to Medicines: Management, Public Policy & Influence, R&D into Neglected Tropical Diseases & GBD, Equitable Pricing, Patenting, Capability Advancement, Drug Donations, and Philanthropic Activities. Companies were rated for their overall policies and performance across these areas and also for their relative policies and performance for each individual area. The scoring was from 1 to 5.

2009 Stakeholder Input

Respondents were also asked whether they would add additional areas to the analysis framework. A few comments appeared across various stakeholder groups, namely to merge Product Donations and Philanthropic Activities, and to better capture the performance of pharmaceutical companies' activities on the ground.

An academic respondent stated that "I would exclude Philanthropic Activities, and I would elaborate other indicators more."

An investor representative suggested the need for "Some kind of practice/on the ground score which can highlight examples of poor or excellent practice which doesn't quite fall in line with top-down management and governance."

Similarly, participants in the Nairobi workshop agreed that Philanthropic Activities should not be included in the technical areas because they are not based on a sustainable business model. They also argued that the operational performance of companies' access to medicine initiatives was not sufficiently captured.

In the Washington D.C. Roundtable, each attendee expressed his or her own view on the weightings of various pillars; however the following appeared to be the dominant viewpoints amongst attendees:

- Product Donations and Philanthropic Activities should be grouped together.
- Less weight should be given to the Access to Medicine Management area.
- Each technical area should include a measurement based on health outcomes.
- Companies should be rewarded for creative solutions throughout the value chain.
- R&D and Equitable Pricing should have the highest weightings.

In the London Roundtable participants suggested merging the pillars as following:

- Access to Medicine Management and Public Policy & Advocacy

- R&D for Index Diseases
- Technology Transfer and Capability Advancement
- Patenting and Equitable Pricing
- Product Donations & Philanthropic Activities

They also agreed that the R&D and Equitable pricing areas should be attributed more weight. Two participants suggested placing equal weights on all the technical areas.

With regard to the number of technical areas, there were several comments in the London and Washington Roundtables suggesting fewer technical areas so that the Index can emphasize the most critical areas. Both in Washington and in London, the dominant proposition was to combine the Product Donations and Philanthropic Activities areas. In the Washington Roundtable, two stakeholders suggested inclusion of a new pillar focusing on company innovations in access to medicines.

Approach in Index 2010

Based on this input, Index 2010 includes a separate Performance pillar that attempts to capture the performance and implementation of companies' policies and programs. In addition, as further delineated in the body of the document, the indicators for Commitments, Transparency, Performance and Innovation are separated under four separate Strategic Pillars. The pillar of Innovation includes a new set of indicators which aim to capture the company's unique and innovative initiatives under different technical areas.

APPROACH TO PERFORMANCE

Table 18. Changes in the Approach to Performance in Index 2010

	Index 2008	Approach to Performance in Index 2010
Approach to Performance	In Index 2008, there was no differentiation between scoring companies' Commitments, Transparency or Performance. As such, performance indicators were generally in the form of demanding 'proof' or 'evidence' of the principles the company committed to.	In Index 2010, there is a separate Performance pillar that measures companies' performance in the seven Technical areas. Size-based adjustments are used for all the quantitative indicators.

Index 2008 Approach to Performance

In Index 2008, the Performance indicators were mostly in the form of demanding 'evidence' and 'proof' of the companies' compliance' with the principles to which they have committed. In addition, in some areas the companies are analyzed using binary indicators which capture the existence of programs in different access to medicine-related areas. Examples of Index 2008 indicators for the Performance of R&D include:

- The company provides evidence of in-house investment in R&D into new treatments for Index Diseases.
- The company with in-house investment in R&D into new treatments for Index Diseases provides evidence of partnerships with groups with developing-country health expertise, such as product development public-private partnerships, academic institutions, and/or the World Health Organization.

In the Index 2008 scoring model there was no differentiation between indicators evaluating companies' commitments, transparency and performance.

2009 Stakeholder Feedback

One of the consistent feedbacks stakeholders have given about the structure of Index 2008 is that it did not place enough emphasis on measuring companies' performance on the ground. This issue was raised in Nairobi by the local NGOs and in the Washington D.C. Roundtable. In the London Roundtable, an independent expert and an investor representative both emphasized the importance of the separation of commitments from performance. Many international NGOs also independently raised the issue that the way the data was presented in Index 2008 focused excessively on the policies of the companies while failing to capture and accurately present the performance of the companies on the ground.

In the survey, most of the stakeholder groups indicated that more focus on performance was needed.

Approach in Index 2010

The overall approach to Performance for Index 2010 is listed below:

- Separating all the Performance indicators under the Performance strategic pillar
- Limiting the Performance indicators to extra-firm footprint of the firm's efforts. Such indicators will attempt to get as close as possible to the point of drug delivery to the patient, while avoiding indicators which are affected by too many external factors
- Normalizing the Performance indicators in terms of company size (excluding the revenues from subsidiaries with non-pharmaceutical activities) or other relevant scale variables

In Index 2010, we use size-adjusted quantitative Performance indicators for all the pillars of analysis related to the initiatives of the companies' efforts to improve access to essential medicines. The approach for analyzing Performance in different areas is explained below. Examples of Performance indicators are provided in the table below.

Table 19. Examples of Performance Indicators for Index 2010

Performance Indicators
A.III.3. The company 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.).
B.III.2. Is there proof of the company's anti-competitive behavior in the Index Countries based on fines or litigation records during the past five years?
C.III.1. Portion of R&D investments dedicated to Index Diseases (exclusions apply - for details please refer to the Approach to Performance under Appendix II) out of the company's total R&D expenditures.
D.III.2. The company has intra-country tiered pricing schemes in the Index Countries for Index Disease products (to be analyzed across products portfolio including drugs, vaccines, diagnostic kits, vector controls, microbicides,etc.) which aim at achieving affordable access to such products for those with the highest financial barriers to access.

Performance Indicators
E.III.2. Does the company actively engage in issuing non-exclusive voluntary licenses for the Index Countries for its products related to the Index Diseases?
F.III.1. Is there proof that the company assists local licensees or contract manufacturers to achieve international drug manufacturing standards (such as FDA, EMEA or the WHO Good Manufacturing Practices) in the Index Countries?
G.III.1. Has the company been fined or been proven to have breached the WHO Guidelines for Product Donations during the last five years?

Public Policy and Market Influence

In this technical area, the Performance measurements are or should be focused on companies' lobbying, competition behavior and ethical marketing conduct, including litigations and fines and breaches of international codes. It should be noted that measurement of litigations face several difficulties including:

- Most private-private (e.g. originator – generics) litigations end in settlements, i.e. there is no ruling, which makes it difficult to judge.
- The weak legal and regulatory infrastructure in Low and Medium Human Development Countries results in scarcity of relevant litigations in these areas.
- Many litigations take years to reach a ruling, which means at the time that the ruling is achieved the company practices might have already changed.
- The final performance of the company practices subject to litigations regarding access to medicines in the Low and Medium Human Development Countries is difficult to judge.

Research & Development Performance

To capture the Performance of the companies' R&D programs for Index Diseases, the primary basis of analysis is their research pipeline. In other words, we measure the number of Index Disease products in different stages of development. Similar to all the other quantitative indicators under Performance, these numbers are adjusted for company size or other relevant scale factors. Pipeline analysis separately captures the company's R&D activities in innovative research (research for new molecules/remedies) and adaptive research (research for new formulations of existing compounds) suitable for Low and Medium Human Development Countries. In addition, companies' research collaboration pipelines are analyzed separately from companies' in-house pipelines.

Equitable Pricing and Distribution Performance

With regard to pricing, the Index 2010 captures the companies' equitable pricing initiatives at product level. Another approach to capturing the final Performance of pricing in the target countries is to capture the trends in the total number of supply units of the Index Diseases' products sold in the countries under coverage. While this number is partially diluted by external factors such as the state of the countries' health infrastructure, it can be argued that given all the pharma companies are more or less affected by the same external factors in these countries, this measurement can be considered a valid comparison basis for overall company pricing and distribution performance.

In terms of registration, we measure the number of Low Human Development Countries where Index Disease products are registered by the company. Based on our discussions with a subset of the companies under coverage, such information can be provided by most of the companies and is also in many cases publicly available.

Patents & Licensing Performance

In the area of Patents, we measure Performance through capturing the litigations that the company has been involved in with regard to their patenting practices and the rulings on these cases. Also, there will be indicators capturing company attempts to enforce patents in the Low Human Development Countries, which is against the WTO Doha Declaration on Trade Related Aspects of Intellectual Property Rights. It should be pointed out that given the companies are banned from patenting their products in the Low Human Development Countries until 2016, most of the intellectual capital-related issues are not applicable to such countries and access is much more reliant on registration and pricing issues (although the patenting exceptions for Low Human Development Countries are not used by some of these countries).

With regard to voluntary licensing, we measure the number of non-exclusive voluntary licenses issued for each patented product. In addition, as an experimental indicator, the number of supply units of products made under each license for Index Disease products are measured. Such an indicator can capture the effectiveness of the licensing program including the technology transfer. It can also help avoid giving companies credit for voluntary licenses that are not operational. It should be pointed out that the effect of local production on access to medicines is still debated, and some stakeholders state that local production in countries without competitive advantage for production can result in inefficiencies and even higher prices and lower quality. Consequently specific indicators measuring local licensing efforts (against international licensing efforts to large generics manufacturers) of the companies are not included in Index 2010.

Capability Advancement in Product Development and Distribution Performance

In terms of Technology Transfer (Capability Advancement), the Index 2010 captures company practices at product level. Aggregates at the company level are used for scoring. The Index 2010 attempts to capture technical details about the type of technology transfer included in the companies' licensing practices for different products.

With regard to transfer of research capacity, the company's public-private partnerships in the Index Countries that may result in increased local research capacity are analyzed.

Product Donations & Philanthropic Activities Performance

In the area of Product Donations, we capture the number of breaches the company has been involved in and also the total value of the donated products.

With regard to philanthropic programs, we only rate the companies for their public disclosure of performance data, since each program has its own distinct performance indicators, and comparison of information regarding the companies' diverse projects therefore is virtually impossible.

Approach to Competition and Marketing Behaviour

Index 2008 Approach to Competition and Marketing Behavior

In the last Index there were few Commitment-related indicators linked to competition behavior and one indicator related to Ethical Marketing, which dealt with commitment to the WHO Ethical Criteria for Medicinal Drug Promotion for pharmaceutical companies.

2009 Stakeholder Input

The stakeholder viewpoints in this area were highly divergent. With regard to competition behavior, the generics manufacturers have been very vocal especially through their representation at the Washington D.C. Roundtable. In addition, the NGOs who have responded to our online survey have made statements such as "Malpractices should also be sought and penalized." Independent experts present in both the Washington D.C. and the London Roundtable have also pointed out the importance of competition behavior and the potential negative impact of anti-competition practices on access to medicines. In contrast, the industry and some independent experts have pointed out the difficulty of taking a stance in such areas given there is no empirical proof that such practices can have adverse effects on access to medicines, and also because capturing the true nature of such complex cases is difficult and very subjective.

Approach in Index 2010

Several recent reports have attempted to measure the impact of anti-competition behavior on access to medicines.[I] Ethical marketing-related issues are also frequently cited as key causes for limitation of customer choice, influencing the clinical decisions and delaying entry of affordable medications into the marketplace. Requirements in this area from the pharmaceutical companies have been compiled into several codes such as the WHO Ethical Criteria for Medicinal Drug Promotion and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Ethical Marketing Practices. Consequently, we believe, given their impact on access to essential medicines, that these areas need to be better covered by the Index.

The overall approach to competition and marketing behavior for Index 2010 is to include these topics under two subcategories of 'ethical marketing' and 'competition behavior'. These two subcategories are part of the 'Public Policy and Market Influence' area. The malpractice indicators are included in the Commitments, Transparency and Performance pillars. The Performance indicators are mostly based on litigations that resulted in rulings against the company in the relevant areas.

Examples of the indicators in this area are provided in the table below:

Table 20. Examples of Competition and Marketing Behavior Indicators for Index 2010

[I] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

	Commitments	Transparency	Performance
Ethical Marketing	B.I.4. The company commits to internal or external ethical codes for marketing of pharmaceutical products (WHO Ethical Criteria for Medicinal Drug Promotion or the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Marketing Practices).	B.II.5. The company publicly discloses detailed information regarding its marketing and promotional programs in the Index Countries, such as payments to physicians or other key opinion leaders and also its promotional activities for other healthcare providers, distributors etc.	B.III.3. Have there been breaches of The International Federation of Pharmaceutical Manufacturers & Associations (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?
Competition Behavior	B.I.2. The company commits to endorse and support competition and to refrain from anti-competitive practices in the pharmaceutical markets in the Index Countries for products related to the Index Diseases.	B.II.4. The company publicly discloses its policies related to competition in areas such as data exclusivity, patent extensions etc. in the Index Countries.	B.III.2. Is there proof of the company's anti-competitive behavior in the Index Countries based on fines or litigation records during the past five years?

Highlights of changes in this area are provided below:

- The companies' Commitments, Transparency, Performance and Innovation are measured both in Ethical Marketing and Competition Behavior areas.
- Performance measurement in this area is based on concluded relevant litigations against the company during the five years preceding the analysis; in other words, the normative basis for judgment will be the stance of the judiciary bodies of the countries.
- For Ethical Marketing we use the WHO Ethical Criteria for Medicinal Drug and the IFPMA Code of Pharmaceutical Marketing Practices as the basis for analysis, for Originator Companies, with focus on the latter code given that it is more specific and facilitates audits.

Approach to Weights and Analysis

Index 2008 Approach to Weights

As demonstrated in the image below, in Index 2008 the weights were divided between the eight technical areas of analysis.

Weight adjustments were carried out for generics companies and other companies with different business models. The weight adjustments were based on stakeholder feedback about the relative importance of each technical area for the generics companies.

Table 21. Index 2008 Weight Adjustments for Originator and Generics Companies

	Technical Area	Originator	Generics Companies
A	Access to Medicine Management	20%	25%
B	Public Policy and Lobbying	10%	10%
C	R&D for Index Diseases and the Global Disease Burden	20%	10%
D	Patents and Licensing	10%	5%
E	Capability Advancement	15%	25%
F	Equitable Pricing	15%	15%
G	Product Donations	6%	6%
H	Philanthropic Activities	4%	4%

2009 Stakeholder Feedback

One of the questions posed to stakeholders via the survey, the Washington D.C. and London Roundtables, and the Nairobi Workshop, was how the areas of the analysis and their weights should be adjusted in the next iteration of the Index. Similar type of input about the weights was obtained during the stakeholder roundtables.

The survey asked stakeholders to rate the importance (1-5) of each criterion in demonstrating best practices in providing access to medicines. Overall, stakeholders agreed that R&D, Patents & Licensing and Equitable Pricing were the most important factors, while Product Donations and Philanthropic Activities were the least important.

Approach in Index 2010

Below are the explanations for the Index 2010 weighting scheme:

- The weights for the technical areas (R&D, Equitable Pricing & Registration etc.) for the companies whose revenue is 100% sourced from patented products is based on the stakeholder input averages with adjustments for the merged areas of Product Donations & Philanthropic Activities.

- The weights for the companies whose revenue is 100% sourced from generics products also rely on stakeholder inputs based on the general argument that given their business model the generics companies are more focused on price-based competition, manufacturing and distribution rather than on developing new molecules. A weight of 15% for the R&D technical area has been maintained because such companies still need to carry out research on new preparations and formulations for Index Disease products. In addition, such companies need to focus on quality aspects of the medications to ensure they maintain quality systems that would result in consistently high quality productions. The weight for Equitable Pricing and Distribution has been increased, because, given their business model, the generics manufacturers' key contribution to access to medicines and to Index Disease products can be registering products in the Low and Medium Human Development Countries and also providing competitive prices in those areas. Finally, the weight for Patents & Licensing has been decreased because most of the indicators in this area are not applicable to generics manufacturing operations.

- The 30%, 30%, 30%, 10% weights for the strategic pillars are based on the following arguments:

a. Transparency and Commitments are equally emphasized as strategies of the Index. While commitments and strong Access to Medicine governance results in sustainability and consistence of Access to Medicine initiatives, transparency is a must to assure accounability and healthy competition in the access to medicine initiatives.

b. Performance, which also includes the company's implementation efforts, is assigned a starting weight of 30%, because at the time of analysis, we are not confident that data collection for all the indicators will be possible and that the data will be comparable and noise free. In the upcoming revisions of the Index, we suggest increasing this weight to reflect the strategic importance of achieving actual results on the ground.

c. While the Index aims to be a driver for Innovations in drug development and delivery for Index Diseases, the challenges of measuring innovations include the subjectivity of such a measurement as well as the difficulty of comparing the performance of the companies' innovative initiatives. Consequently, for this revision of the Index, a weight of 10% is assigned to this pillar.

Index 2008 Approach to Relative vs. Absolute Ratings

In Index 2008, scoring was completed using a combination of a relative and an absolute rating approach. Companies' performances were rated on a 1 to 5 scale relative to each other using a so-called 'best-in-class' approach awarding five points to the best practices that were found and rating others accordingly.

2009 Stakeholder Input

One of the questions posed to stakeholders via the Washington D.C. and London Roundtables and the Nairobi Workshop was whether the Index should move from a relative to an absolute rating system. While most stakeholders agree that over the long term, the Index should move to an absolute rating approach, all stakeholders are in agreement that the current lack of empirical research on best practices deems it impossible to move to an absolute rating system at this time. For example, an NGO representative at the Washington D.C. Roundtable commented: "relative rankings are based on evidence of what actually is happening. How would you construct an absolute rating?" An industry representative stated that "if you have an absolute best practice, then you would have to overhaul the entire Index." Such comments illuminate the consensus amongst stakeholders that moving to an absolute rating system for the quantitative indicators is not possible given the current shortfall of empirical research on the topic.

Approach in Index 2010

Index 2010 will continue to use a combination of an absolute and a relative rating system but will strive to include as many quantitative indicators as deemed possible at this stage of the Index's maturity. Currently, lack of sufficient empirical research on best practices limits the use of absolute ratings for the quantitative indicators. Index 2010 will therefore use absolute ratings for the qualitative indicators and relative rating for the quantitative indicators while maintaining the long-term goal of the Index to move towards an overall absolute rating system in the future.

APPENDIX 3: ICD-10 COVERAGE

Table 22. List of ICD-10 Coverage

ID	Reference List	GBD Category	Index Disease Name	ICD-10 Classifications
1	NTD	Communicable	Buruli Ulcer	Buruli Ulcer (A31.1)
2	NTD	Communicable	Chagas Disease	Chagas' disease (B57)
3	NTD	Communicable	Dengue	Dengue (A90-A91) - A90: Dengue fever (classical dengue) - A91: Dengue hemorrhagic fever
4	GBD_10Inf	Communicable	Diarrheal 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: Diarrhea and gastroenteritis of presumed infectious origin
5	NTD	Communicable	Dracunculiasis (guinea-worm disease)	Dracunculiasis (B72)
6	NTD	Communicable	Fascioliasis	Fascioliasis (B66.3)
7	GBD_10Inf	Communicable	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	Communicable	Human African Trypanosomiasis	African Trypanosomiasis (B56)
9	NTD	Communicable	Leishmaniasis	Leishmaniasis (B55)
10	NTD	Communicable	Leprosy	Leprosy (A30)

ID	Reference List	GBD Category	Index Disease Name	ICD-10 Classifications
11	GBD_10Inf	Communicable	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 - 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	Communicable	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	Communicable	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	Communicable	Measles	Measles (B05)
15	GBD_10Inf	Communicable	Meningitis	Meningococcal infection (A39) Bacterial meningitis, not elsewhere classified (G00) Meningitis due to other and unspecified causes (G03)
16	NTD	Communicable	Onchocerciasis	Onchocerciasis (B73)
17	GBD_10Inf	Communicable	Pertussis	Pertussis/Whooping cough (A37)
18	NTD	Communicable	Schistosomiasis	Schistosomiasis (B65)

ID	Reference List	GBD Category	Index Disease Name	ICD-10 Classifications
19	NTD	Communicable	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	Communicable	Tetanus	Tetanus (A33-A35) - A33: Tetanus neonatorum - A34: Obstetrical tetanus - A35: Other tetanus
21	NTD	Communicable	Trachoma	Trachoma (A71)
22	GBD_10Inf	Communicable	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 Sequelae of tuberculosis (B90)
23	NTD	Communicable	Yaws	Yaws (A66)
24	GBD_10NC	Non-Communicable	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	Non-Communicable	Cerebrovascular disease	Cerebrovascular diseases (I60-I69) - I60: Subarachnoid hemorrhage - I61: Intracerebral hemorrhage - I62: Other nontraumatic intracranial hemorrhage - I63: Cerebral infarction - I64: Stroke, not specified as hemorrhage 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

ID	Reference List	GBD Category	Index Disease Name	ICD-10 Classifications
26	GBD_10NC	Non-Communicable	Asthma	Chronic lower respiratory diseases (J45-J46) - J45: Asthma - J46: Status asthmaticus
27	GBD_10NC	Non-Communicable	Cirrhosis of the liver	Alcoholic liver disease (K70) Fibrosis and cirrhosis of the liver (K74)
28	GBD_10NC	Non-Communicable	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
29	GBD_10NC	Non-Communicable	Epilepsy	Epilepsy (G40-G41) - G40: Epilepsy - G41: Status epilepticus
30	GBD_10NC	Non-Communicable	Ischaemic heart disease	Angina pectoris (I20)
31	GBD_10NC	Non-Communicable	Nephritis / nephrosis	Glomerular diseases (N00-N08) - N00: Acute nephritic syndrome - N01: Rapidly progressive nephritic syndrome - N02: Recurrent and persistent haematuria - N03: Chronic nephritic syndrome - N04: Nephrotic syndrome - N05: Unspecified nephritic syndrome - N06: Isolated proteinuria with specified morphological lesion - N07: Hereditary nephropathy, not elsewhere classified - N08: Glomerular disorders in diseases classified elsewhere 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 induced-tubule-interstitial and tubular conditions - N15: Other renal tubule-interstitial diseases - N16: Renal tubulo-interstitial disorders in diseases classified elsewhere Renal failure (N17-N19) - N17: Acute renal failure - N18: Chronic renal failure - N19: Unspecified renal failure

32	GBD_10NC	Non-Communicable	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
33	GBD_10NC	Non-Communicable	Unipolar depressive disorders	Unipolar depressive disorders (F32-F33) - F32: Depressive episode - F33: Recurrent depressive disorder

ACRONYMS

ABPI	Association of the British Pharmaceutical Industry
AIDS	Acquired Immune Deficiency Syndrome
ATM	Access to Medicine
CEO	Chief Executive Officer
DALY	Disability Adjusted Life Years
DC	Developing Country
DFID	Department for International Development (UK Government)
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMEA	European Agency for the Evaluation of Medicinal Products
ERC	Expert Review Committee
FDA	Food and Drug Administration
GBD	Global Burden of Disease
HDI	Human Development Index
HIC	High-Income Country
HIV	Human Immunodeficiency Virus
ICB	Industry Classification Benchmark
ICCR	Interfaith Center on Corporate Responsibility
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IP	Intellectual Property
LHDC	Low Human Development Country
LIC	Low-Income Country
MHDC	Medium Human Development Country
MIC	Middle-Income Country

NDRA	National Drug Regulatory Authority
NGO	Non-Governmental Organization
NTD	Neglected Tropical Diseases
PPP	Public-Private Partnership
PDP	Product Development Partnership
PhRMA	The Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization

GLOSSARY

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.”

Medium Human Development Countries

All Medium Human Development Countries in the Human Development Index (HDI):

Albania	Egypt	Malaysia	São Tomé and Principe
Algeria	El Salvador	Maldives	Saudi Arabia
Antigua and Barbuda	Equatorial Guinea	Mauritius	Solomon Islands
Armenia	Fiji	Mongolia	South Africa
Azerbaijan	FYR of Macedonia	Morocco	Sri Lanka
Bangladesh	Gabon	Myanmar	Sudan
Belarus	Georgia	Namibia	Suriname
Belize	Ghana	Nepal	Syrian Arab Republic
Bhutan	Grenada	Nicaragua	Tajikistan
Bolivia	Guatemala	Oman	Thailand
Bosnia and Herzegovina	Guyana	Pakistan	Timor-Leste
Botswana	Honduras	Palestinian territories	Togo
Brazil	India	Papua New Guinea	Tunisia
Cambodia	Indonesia	Paraguay	Turkey
Cape Verde	Islamic Republic of Iran	Peru	Turkmenistan
China	Jamaica	Philippines	Uganda
Colombia	Jordan	Republic of Moldova	Ukraine
Comoros	Kazakhstan	Romania	Uzbekistan
Congo	Kyrgyzstan	Russian Federation	Vanuatu
Dominica	Lao People's Democratic Republic	Saint Lucia	Venezuela

Dominican Republic	Lebanon	Saint Vincent and the Grenadines	Vietnam
Ecuador	Libyan Arab Jamahiriya	Samoa (Western)	Zimbabwe

Low Human Development Countries

All Low Income Countries (LICs) in the Human Development Index (HDI):

Angola	Djibouti	Lesotho	Rwanda
Benin	DR Congo	Madagascar	Senegal
Burkina Faso	Eritrea	Malawi	Sierra Leone
Burundi	Ethiopia	Mali	Swaziland
Cameroon	Guinea	Mauritania	The Gambia
Central African Republic	Guinea-Bissau	Mozambique	United Republic of Tanzania
Chad	Haiti	Niger	Yemen
Côte d'Ivoire	Kenya	Nigeria	Zambia

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.

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.

DISCLAIMER

As a multi-stakeholder and collaborative project, the findings, interpretations, and conclusions expressed herein may not necessarily reflect the views of all members of the stakeholder groups or the organizations they represent. The report is intended to be for information purposes only and is not intended as promotional material in any respect. The material is not intended as an offer or solicitation for the purchase or sale of any financial instrument. The report is not intended to provide accounting, legal or tax advice or investment recommendations. Whilst based on information believed to be reliable, no guarantee can be given that it is accurate or complete.

Access to Medicine Index
Spaarne 35
2011 CD Haarlem
The Netherlands
T +31 (0)23 533 91 87

info@atmindex.org
www.accesstomedicineindex.org