access to medicine index

Access to Medicine Index 2010

June 2010

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@accesstomedicineindex.org
+31 23 5339187

This report is prepared by:

RiskMetrics Group - ESG Analytics

On June 1st 2010, RiskMetrics was acquired by MSCI Inc. (NYSE:MXB)

RiskMetrics Group 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.

Editorial Team:

Lead Author
Afshin Mehrpouya

Senior Analyst
April Cody

Analysts
Suzanne Edwards
Julia Giguere
Samantha Sue Ping
Ioana Ursu

Technical Coordinator
Nathalie Gilet

RiskMetrics (MSCI) Contacts:

Perrine Dutronc
perrine.dutronc@riskmetrics.com
T. + 33 (0)1 73 03 43 59

Afshin Mehrpouya
afshin.mehrpouya@riskmetrics.com
T. +33 (0)1 73 03 43 47

Table of Contents

List of Tables

List of Figures

ACRONYMS

ABPI	Association of the British Pharmaceutical Industry
AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti-Retroviral
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
EMA	European Medicines Agency
ERC	Expert Review Committee
FDA	Food and Drug Administration
FDC	Fixed-Dose Combinations
GBD	Global Burden of Disease
HDI	Human Development Index
HIC	High-Income Country
HIV	Human Immunodeficiency Virus
IC	Index Country
ICB	Industry Classification Benchmark
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

FROM THE FOUNDER

Evidence of greater transparency and increased effort

Two years ago, the Access to Medicine Foundation published the first Access to Medicine Index report. With the help of many, we created a tool designed ultimately to give two billion people better access to much-needed medicine. Today, with the release of this second Index report, I am happy to say that progress has been made, even though many goals remain to be met.

Insufficient access to medicine is the result of many problems, such as poverty and weak national health systems. Governments in both developing and developed countries have a pivotal role to play in addressing these problems and the avoidable suffering and death they cause. But so do many others, including healthcare professionals, NGOs and the pharmaceutical industry. The Access to Medicine Index specifically addresses the last category.

I believe the Index can encourage both originator and generics companies to increase their contributions. In fact, we now have good evidence that the Index is working: several companies clearly made significant efforts to improve their performance and ranking in the Index 2010.

We need treatments for neglected diseases and we need ways to get existing treatments to people who cannot afford them. We need productive cooperation among academia, governments, NGOs and private companies. I am convinced that pharmaceutical companies are ready to do more, but that they do need broad consensus about what it is they should do. They would also welcome recognition for large private investments.

The Access to Medicine Index has brought together expertise and passion from all sectors to measure and rank the access to medicine efforts of the world's largest pharmaceutical companies. It has helped define and measure what are regarded as best practices in the field. By publishing the results, we reward companies that value social responsibility as a

means of increasing overall sustainability. Thus, the Index helps spark competition in this important field.

The Index 2010 reveals important progress since the Index 2008, in large part because pharmaceutical companies have shown far greater willingness to open up. What's more, this newfound transparency has brought to light increased implementation efforts, which have partly resulted from companies working together more often.

Performance as measured by the Index has been shown to help turn companies' good intentions into effective actions. Sound management, firm policy commitments, good monitoring and a focus on implementation and impact translate into reduced child mortality, and better treatments for neglected diseases for millions of people.

The Index has been recognized as a tool for increasing cooperation among the various stakeholders. Many are using it to help influence political agendas. By aligning the efforts of all, the Index has the potential to greatly improve global health. And make no mistake: we still have a long way to go.

I would like to thank the Foundation's Board, Executive Review Committee, Advisory Board and our Funders for their substantial contributions over the years. I also thank the growing number of collaborators and friends who believe in our mission and who have tirelessly supported our work. And to the pharmaceutical companies we have rated: thank you for doing so much in working with us.

With an eye already on the Index 2012,

Sincerely,

Wim Leereveld

Chairman and Founder, Access to Medicine Foundation

Executive summary

EXECUTIVE SUMMARY

The Access to Medicine Foundation aims to help poor people in developing countries gain access to medicine by encouraging the pharmaceutical industry to improve its commitments and practices related to this issue. The Foundation's major initiative is the Access to Medicine Index, which analyzes and ranks the access to medicine efforts of the world's largest pharmaceutical companies.

Over the last few years, much progress has been made in improving access to drugs, vaccines and diagnostic tests in developing countries. Several new organizations and funding mechanisms have been established and the pharmaceutical industry has shown increasing attention to both the need and the business opportunities.

However, neglected tropical diseases continue to cause significant health burden while research to develop treatments for them remains limited. Meanwhile, diarrhea and pneumonia continue to be leading child killers in low-income countries. HIV/AIDS, tuberculosis, malaria remain endemic in a large part of the world and developing countries are experiencing an increasing burden of non-communicable diseases. For millions of people worldwide, medications are expensive, non-existent, inaccessible or of low quality.

Addressing the global access to medicine problem demands the collaboration of multiple international and national stakeholders. However, there has been no consensus on the role of the pharmaceutical industry in this effort. Several organizations have attempted to define what should be expected from the industry, but because many stakeholders, including the pharmaceutical industry itself, were not consulted, such initiatives did not have a significant impact on industry practices.

The Access to Medicine Index

The Access to Medicine Index was established to address this gap by consulting multiple stakeholders, including the pharmaceutical industry, on the role that the industry can play in improving access to medicine in societies in need.

By ranking companies on how well they are contributing to access to medicine, this Index seeks to motivate positive change in the industry.

The first Access to Medicine Index was published in June 2008. It provided the first benchmark report on the access to medicine policies and practices of the 20 largest global pharmaceutical companies.

The Access to Medicine Index 2010

The Index 2010 is the second Index report. It ranks 27 pharmaceutical companies on their efforts to provide access to medicines, vaccines and diagnostic tests to people living in 88 countries.

The countries included in the Index were chosen from among those classified by United Nations Development Program's Human Development Index as having low or medium levels of human development.

The Index covers 33 priority diseases, including neglected tropical diseases, as well as the 10 most important communicable diseases and the 10 most important non-communicable diseases in terms of their health burden in the countries covered by the Index.

The companies include 20 originator companies – those who primarily market patented drugs they have developed - and seven companies whose primary business is the production and sale of generic medicines.

Data is collected across 111 indicators. The rankings are based on 106 indicators that measure activities across four strategic and seven technical areas. Five indicators were tagged as experimental and have not been used for ranking purposes because of insufficient and unreliable data.

The report provides an overall ranking of companies, as well as ranking according to the seven technical areas covered by the indicators. It also analyzes industry trends in commitments, transparency, performance and innovation and provides report cards for each company. The report cards identify each company's leading practices, the changes it has made since the last Index report and suggest areas for improvement.

Table 1. Structure and Key Indicators of the Access to Medicine Index 2010

		Strategic Pillars			
		Commitments 30%	Transparency 30%	Performance 30%	Innovation 10%
Technical Areas	A. General Access to Medicine Management	ATM Governance			
		ATM Management System			
		Stakeholder Engagement			
	B. Public Policy and Market Influence	Advocacy and Lobbying			
		Competition Behavior			
		Marketing Behavior			
	C. Research and Development	Innovative R&D			
		Adaptive R&D			
		Intellectual Property Sharing			
	D. Equitable Pricing, Manufacturing and Distribution	Marketing Approval (Registration)			
		Equitable Pricing			
		Manufacturing & Distribution			
	E. Patents & Licensing	Patents			
		Non-Exclusive Voluntary Licensing			
	F. Capability Advancement in Product Development and Distribution	Capacity Building in Research and Development			
		Capacity Building in Quality Management and Distribution			
	G. Product Donations and Philanthropic Activities	Donations			
		Philanthropy			

Enhancements since the Index 2008

Building on the lessons of Index 2008 and the extensive stakeholder feedback, while maintaining continuity with Index 2008 in most aspects, Index 2010 features important methodological refinements. In the Access to Medicine Index 2010, extensive efforts have been made to better measure the output and performance of the initiatives of the pharmaceutical companies under consideration.

Highlight of Enhancements in Access to Medicine Index 2010 Methodology

Separate measurement of performance from commitments and transparency

More focus on non-communicable diseases

Specific coverage of innovations in the sector

More diversified sources of information

Balanced attention to the scale and scope of the company activities and their size

In addition, in the Index 2010, originator and generics companies are compared in two separate lists. In Index 2008, the same list was used for all the companies. Another enhancement in Index 2010 is an increased focus on the emerging challenge of non-communicable diseases in the Low and Medium Human Development countries.

The following changes have been made to the scope of the Index:

- Index 2010 covers 33 diseases, up from 24 in Index 2008 including the Neglected Tropical Diseases and the top communicable and non-communicable diseases based on their health burden in the countries covered by the Index.
- There are 27 companies on Index 2010, comprising 20 drug originators (compared to 17 in Index 2008) and seven generics companies (compared to three in Index 2008).

Analysis

The analysis phase of the project started immediately following the finalization of the methodology in consultation with the Expert Review Committee[1] in November 2009. In this phase, the companies were analyzed across 106 indicators (compared to 28 in the Index 2008). 19 out of the 20 originator companies and three out of the seven generics companies responded to our data requests. The candid participation of the companies signifies the attention they are paying to the access to medicine issues and also the increasing importance of the Access to Medicine Index as an industry benchmark.

Access to Medicine 2010 covers company policy and practices for the 2008 and 2009 fiscal years.

Index 2010	Index 2008
33 diseases	24 diseases
20 originator drug companies	17 originator drug companies
7 generics companies	3 generics companies
19 out of 20 originator companies provided data requested	9 out of 17 originator companies provided data requested
3 out of 7 generics companies responded to requests for data	0 out of 3 generics companies responded to requests for data
106 indicators	28 indicators

[1] ERC is a committee of experts representing different stakeholders convened by the Access to Medicine Foundation 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 Access to Medicine Index 2010 assessment. The Access to Medicine Index Foundation remains ultimately responsible for decisions on the final methodology associated reporting material and the findings of the Access to Medicine Index.

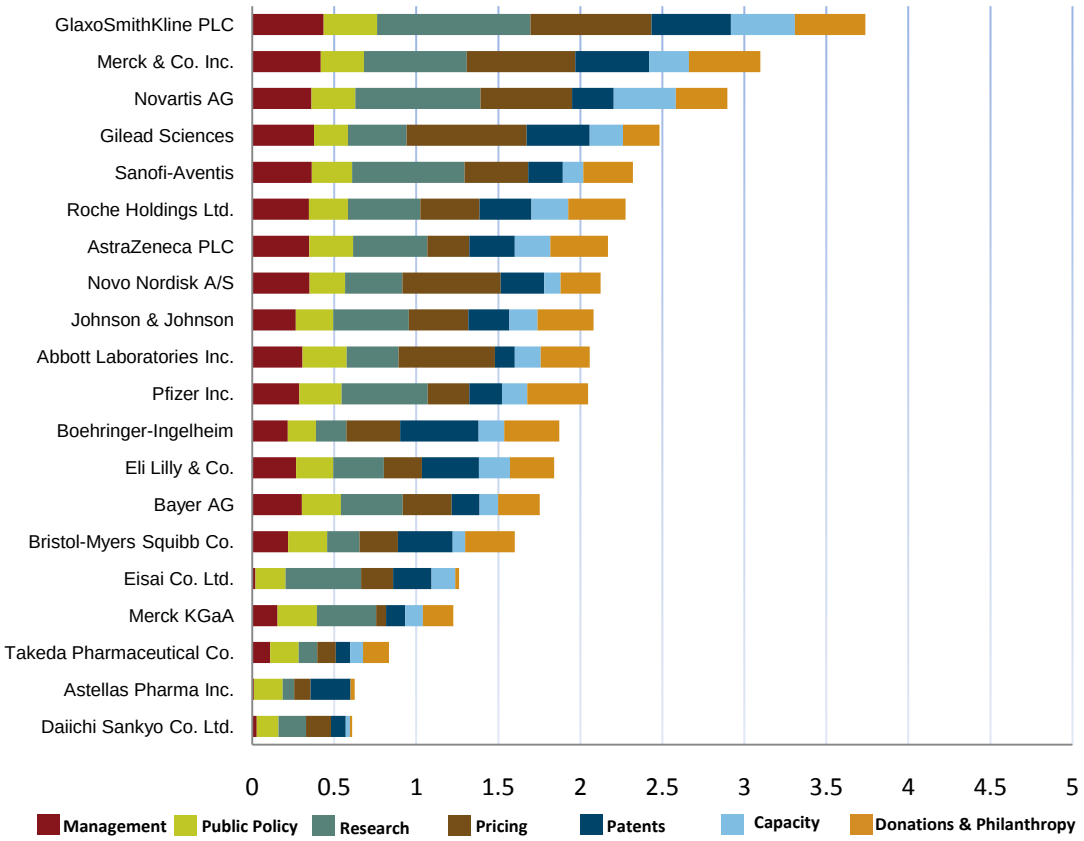
The Findings of Access to Medicine Index 2010

Originator Industry Trends

Since the launch of the Index 2008, we have seen a number of trends in the sector, including:

- Increased sharing of intellectual property, such as “compound libraries,” for research purposes
- An increase in the number of research collaborations targeting areas of need
- The development of several promising innovative approaches to access
- For the high-ranking originator companies, increased collaboration with generics companies, especially through non-exclusive voluntary licensing arrangements

Figure 1. Access to Medicine Index 2010 - Overall Ranking of Originator Companies*



* For more information about how to interpret this graph please refer to Appendix C, Ranking and Scoring Process.

Originator Company Ranking

The Index is a relative ranking. It does not evaluate companies against aspirational best practices but provides a comparison between companies.

Overall ranking

Top 3 originator companies

GlaxoSmithKline

Merck & Co.

Novartis

Most improved since the Index 2008

Gilead – rising from 15th to 4th

Pfizer – rising from 17th to 11th

GlaxoSmithKline, Merck &Co. and ***Novartis*** emerged as the top-, second- and third- ranking companies respectively. All have improved in their transparency, performance and commitments to access to medicine. While they still have a long way to go to realize their full potential both for improving access and for exploiting the growth opportunities in the Index Countries, they have proved to be some of the most innovative in the sector. They have also been unique in taking risks and experimenting with new business models. None of these companies is the leading company in all the technical areas. However, they have performed above average in most of them.

Two companies - ***Pfizer*** and ***Gilead*** have significantly improved their ranking since the Index 2008. Both have shown increased focus on access to medicine issues and have launched several new initiatives. The most significant decreases in rank were seen for ***Bayer*** (from 9th to 14th), ***Bristol-Myers Squibb*** (from 11th to 15th), ***Merck KGaA*** (from 13th to 17th) and ***Novo Nordisk*** (from second to 8th).

Changes in the company rankings since the Index 2008 are primarily explained by changes in company commitments, transparency, performance and innovation. However, refinements in the scoring process, more thorough analysis resulting from a higher level of disclosure by companies and the inclusion of more indicators to measure performance also partly account for ranking changes.

Generics Industry Trends

The major trends among the generics companies relevant to access to medicine are:

- More research activities for adapting existing products to the needs of developing countries.
- Emerging examples of capacity advancement in the poor countries
- For the high-ranking generics companies, increased collaboration with originator companies through non-exclusive voluntary licensing arrangements
- Low level of disclosure on the progress and outcome of access to medicine related initiatives

Table 2. Access to Medicine Index 2010 - Overall Ranking of Generics Companies

	Access to Medicine Management	Public Policy and Market Influence	R&D for Index Diseases	Equitable Pricing, Manufacturing & Distribution	Patents and Licensing	Capability Advancement in Product Development & Distribution	Product Donations & Philanthropy	Overall Ranking
Ranbaxy Laboratories Limited	High	Medium	High	High	High	No evidence found	Medium	1
Cipla Limited	Medium	Medium	Medium	Medium	High	High	High	2
Dr. Reddy's	High	High	Medium	Low	Low	Medium	Medium	3
Mylan Inc.	Low	Low	High	High	Low	No evidence found	Low	4
Sun Pharmaceuticals	Low	Low	No evidence found	Low	Low	High	No evidence found	5
Teva Pharmaceuticals Ltd	Low	High	No evidence found	No evidence found	Low	No evidence found	Low	6

Generics Companies Ranking

A total of seven generics companies are analyzed in the report. They are ***Apotex, Cipla, Dr. Reddy's, Mylan Inc., Ranbaxy Laboratories, Sun Pharmaceuticals*** and ***Teva Pharmaceuticals***. However, due to lack of sufficient information, ***Apotex,*** which is not a publicly listed company, has not been included in the rankings.

Ranbaxy, ***Cipla and Dr Reddy's*** emerged as the top-ranking companies, in order. All have significant market presence in the Index Countries and carry out adaptive research for Index Diseases.

The general low level of disclosure and responsiveness to data requests hampered our analysis of the generics companies. This, together with the small sample size made it difficult to illustrate the rankings in the same way as the originators.

Originator and Generics Ranking by Technical Area

Companies were also ranked according to their performance in seven technical areas as follows:

General Access to Medicine Management	
Originator:	Among originator companies, ***GlaxoSmithKline*** is ranked top, followed by ***Merck & Co***, then ***Gilead***. All three companies have clear access to medicine strategies that are grounded in a sustainable business rationale, demonstrate strong commitments in stakeholder engagement and have comprehensive management systems dedicated to managing their access to medicine activities. Rankings for ***Gilead, Merck & Co.*** and ***Pfizer*** showed the most improvement since the Index 2008.
Generics:	For the generics companies, activity in this area is weak across the sector. ***Ranbaxy*** is the only company which discloses initiatives and future objectives and ***Dr. Reddy's*** is the only company with annual reporting on sustainability which includes access to medicine initiatives.

Public Policy and Market Influence	
Originator:	Among originator companies, the leader in this area is ***GlaxoSmithKline***, with clear public policy disclosure, as well as no apparent litigations or controversies in Index Countries during the past five years in the area of lobbying and advocacy, anti-competitive behavior and ethical marketing. Yet the ranking is very close among the remaining companies within the top five, which includes ***Abbott, Novartis, AstraZeneca***, and ***Merck & Co***. Since the Index 2008, ***Abbott***, ***Sanofi-Aventis, Pfizer*** and ***Merck KGaA*** have improved their ranking most significantly.
Generics:	Disclosure on lobbying and advocacy positions and activities and marketing activities, remains weak across the generic sector. ***Dr. Reddy's*** is ranked top in this technical area.

Research and Development for Index Diseases	
Originator:	The top four originator companies in this technical area - ***GlaxoSmithKline***, ***Novartis***, ***Sanofi-Aventis*** and ***Merck & Co*** - all have strong detailed commitments to research for the Index Diseases, are involved in several research collaborations and have in their research pipelines several molecules for the Index Diseases, with specific Index Country purpose. Rankings were most significantly improved for ***Pfizer, Merck & Co***. and ***Gilead***.
Generics:	Generics Companies are rapidly expanding their adaptive research pipelines for Index Diseases, focusing on several key need areas. ***Ranbaxy*** is the highest performer in this area, with a mix of innovative and adaptive research for the Index Diseases and three research collaborations.

Equitable Pricing, Manufacturing and Distribution	
Originator:	The top originator companies in this technical area are ***GlaxoSmithKline***, followed by ***Gilead***, then ***Merck & Co***. All have established inter-country tiered pricing policies based on affordability for Index Disease products in Index Countries; have strong commitments to high quality manufacturing for products destined for Index Countries and have implemented special packaging to both address the local needs of target communities and to prevent drug diversion from Index Countries to more affluent markets. Rankings were significantly improved for ***Abbott***, ***Novartis***, ***Bayer, Gilead and Pfizer.***
Generics:	Among generics companies, ***Ranbaxy*** is ranked top, followed by ***Mylan and Cipla.*** All of them have collaborated with international organizations which deliver medicines to the Index Countries at affordable prices. ***Ranbaxy*** and ***Mylan*** have committed to needs based registration of their HIV/AIDS products

Patents and Licensing	
Originator:	The leading originator companies in this technical area are ***GlaxoSmithKline***, followed by ***Boehringer-Ingelheim***, ***Merck & Co.*** and then ***Gilead***. All have above average disclosure to patent related policies. All these companies are also involved in non-exclusive voluntary licensing or similar activities with generics companies for at least one Index Disease related product. Three companies that have significantly improved in ranking compared to the Index 2008 are ***Roche, Novartis and AstraZeneca.***
Generics:	***Ranbaxy***, ranked top among the generics companies, is the only generics company with specific policy statements about trade aspects of patents. ***Ranbaxy*** and ***Cipla*** are the only generics companies covered by Index 2010 found to have current non-exclusive voluntary licensing activities for Index Diseases.

Capability Advancement in Product Development and Distribution	
Originator:	Leading originator companies in this technical area, in order, are ***GlaxoSmithKline***, ***Novartis***, ***Merck & Co.*** and ***Roche***. All display strong commitments to improving the capacity of Index Countries, are actively engaged in research collaborations with local institutions and have detailed initiatives related to improving the local supply chain or quality management systems. ***AstraZeneca***, ***Gilead*** and ***Roche*** have improved most significantly in ranking in this area.
Generics:	***Cipla*** is ranked as the leading generics company in this area, with success stories of collaborative manufacturing with Index Country organizations and governments. Initiatives in this area among the generics companies are scarce.

Product Donations and Philanthropic Activities	
Originator:	***Merck & Co.*** ranks top among the originator companies, followed by ***GlaxoSmithKline***, ***Pfizer,*** ***AstraZeneca*** and ***Roche***. All operate at least one long-term targeted drug donation program and have several ongoing philanthropic activities to build health infrastructure. ***Pfizer*** and ***Johnson & Johnson*** showed the most improvement in ranking since the Index 2008.
Generics:	All the generics companies covered in the Index 2010 have carried out multi-drug donations in some instances, but none commits to WHO guidelines for drug donations and none has been involved in a strategic, need-based single-drug donation program. **Cipla** is ranked top in this area.

Conclusion

All of the challenges that inspired the creation of the Access to Medicine Index still remain. Nonetheless, we are happy to observe the pharmaceutical companies' increased attention to the economic and social opportunities in the countries the Index covers. As the companies mature in their approach to these markets and work closely with other stakeholders, we are hopeful that they can have an increasingly positive impact on access to medicines.

Considering the pace of growth in the emerging markets and the challenges related to the upcoming expiration of patents for many blockbuster drugs, it is also in the companies' interest to better align their business models with the needs of these societies.

The Index 2010 was funded with the support of the following organizations:

- Bill & Melinda Gates Foundation
- Dutch Ministry of Foreign Affairs
- UK Department for International Development
- Oxfam Novib
- Humanist Institute for Cooperation with Developing Countries (HIVOS)
- Interchurch Organization for Development Co-operation (ICCO)
- Cordaid
- European Agency for the Development and Health (AEDES)
- Rabobank
- SNS Reaal

Introduction

Background

The Access to Medicine Foundation aims to help improve access to medicine in societies in need by encouraging pharmaceutical companies to improve their commitments, transparency and practices related to access to medicine (ATM). The Foundation's major initiative is the Access to Medicine Index, which ranks the world's largest pharmaceutical companies according to their ATM efforts. Specifically, the Access to Medicine Index aims to:

- Define the role of the pharmaceutical industry in addressing ATM-related issues in societies in need through discussion with major stakeholder groups, including the industry itself
- Define indicators through which companies' ATM efforts can be measured
- Analyze pharmaceutical companies' policies and practices and their effect on improving or hindering access to medicine, based on key performance criteria
- Provide companies and other stakeholders with a consistent benchmark report every two years
- Identify best practices, promote dialogue and act as a learning tool for the pharmaceutical industry

The Access to Medicine Index was first conceived in 2005, when the pharmaceutical sector was beginning to recognize needs and opportunities in the Index Countries. While some companies had already begun to develop ATM strategies and programs, the primary focus of stakeholders was on a range of topics regarded by some as controversial, such as patenting issues, anti-competitive schemes, unethical marketing practices and clinical trials. This was due to the vastly different viewpoints of civil society stakeholders and the industry about how to address ATM issues and what the role of the industry should be.

A variety of reports and studies had described the potential negative aspects and impacts of pharmaceutical companies' ATM-related practices. However, few initiatives engaged with pharmaceutical companies and other public and private stakeholders to collectively define the companies' role in the issue. As a result, stakeholders in both the developed and developing world made inconsistent demands on pharmaceutical companies.

The Access to Medicine Index project was launched to address this problem. Since

its inception, it has progressed to be one of the most frequently cited ATM benchmarks for pharmaceutical companies.

This is reflected in the deeper level of pharmaceutical company engagement with the project since the publication of the first Index in 2008. For instance, 19 out of the 20 originator companies and three out of seven generics companies responded to the information requests from the Access to Medicine Index 2010 team. This represents real progress since 2008, when only 9 out of 17 originator firms and none of the three generic firms included in the Index responded to our information requests. This signifies both increased general attention to ATM issues and higher awareness of the Access to Medicine Index. We hope the evolution of the Index as a key industry benchmark will allow it to help drive global efforts to build a healthier world.

Structure of the Report

This report is presented in four sections:

- Introduction: This outlines the Index context, objectives and methodology and discusses recent trends in ATM and in the industry.
- Originator Pharmaceutical Companies: This chapter describes originator company rankings and provides detailed analysis of company policies and performance.
- Generic Pharmaceutical Companies: This chapter provides generics company rankings and detailed analysis of company policies and performance.
- Achievements outside the Scope of the Access to Medicine Index 2010: This is a new section in the Access to Medicine Index that covers major ATM-related achievements of the pharmaceutical industry that are outside the scope of the Index.

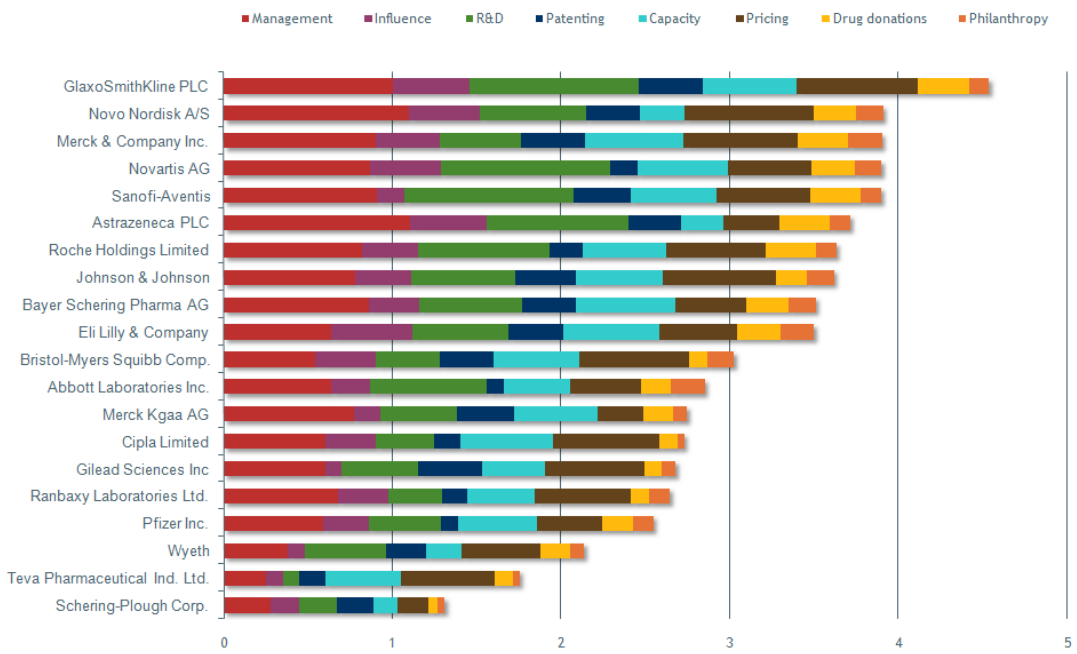
ACCESS TO MEDICINE INDEX 2008

The 2008 Access to Medicine Index provided the first benchmark evaluation of the ATM policies and practices of the 20 largest global pharmaceutical companies, including 17 originator and three generics companies. Its publication received wide national and international media and stakeholder attention.

It demonstrated that a ranking mechanism was an effective tool to bring stakeholder attention and industry focus to ATM. Since the Index was launched, most of the 20 companies analyzed in the report have responded to its findings, with several of them referring to the Index on their websites. Some lower-ranked companies have highlighted how they plan to improve their rankings in subsequent iterations of the Index, while some companies have adopted the Index indicators for their disclosure of ATM-related policies and practices.

The Access to Medicine Index 2008 report is available at www.accesstomedicineindex.org.

Figure 2. Access to Medicine 2008 Final Ranking



ACCESS TO MEDICINE INDEX 2010

Preparation for the second Index started immediately after publication of the first. As with the Index 2008, the Index 2010 was developed in three stages: stakeholder engagement, methodology update and company analysis.

Stakeholder Engagement

In the first phase, the Access to Medicine Index team reached out to experts from a variety of stakeholder groups including academics, governments, independent experts, the pharmaceutical industry, international organizations, investors and non-governmental organizations. This phase started in November 2008 and ended in July 2009. It included the following major milestones (for more information, please refer to Appendix B: Stakeholder Engagement Process):

- An online stakeholder survey
- A stakeholder workshop in Nairobi in February 2009, with participation of 19 Index Country NGOs
- Two multi-stakeholder roundtables in London and Washington in June 2009

Following completion of the stakeholder engagement process, the results were collated to provide the basis for the methodology update process.

Methodology Update

To ensure continued guidance during the methodology update process, the Access to Medicine Foundation established in 2009 an Expert Review Committee (ERC) comprised of stakeholder experts. The ERC is purely advisory in nature. It provides 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 team presented the updated methodology for the Index 2010 to the ERC in September 2009 and, after several rounds of review, the methodology was finalized in November 2009. A list of ERC members can be found in Appendix B: Stakeholder Engagement Process.

ACCESS TO MEDICINE INDEX 2010 METHODOLOGY

Throughout the methodology review process, the Access to Medicine Index team put special emphasis on maintaining continuity with the Index 2008. While maintaining this in most aspects, in response to stakeholder feedback, the following methodological enhancements were made in the Index 2010:

- Under each technical area (such as R&D, Patents & Licensing, etc.) indicators are divided into four strategic pillars: commitments, transparency, performance and innovation
- A new set of indicators have been introduced to capture innovation across the seven technical areas
- Several new indicators have been added to better evaluate the output and performance of ATM initiatives. Examples include:
    - Analysis of the companies' R&D pipeline and what proportion of molecules are devoted to the Index Diseases where there is a market failure
    - Analysis of the companies' product portfolio, evaluating for what proportion of products relevant to the Index Diseases the company has undertaken ATM programs
- Originator companies and generics companies are this time ranked separately
- The Product Donations and Philanthropic Activities technical areas have been merged. While acknowledging the important role that they, the merging was designed to shift the focus of the Index further towards other more sustainable ATM approaches

Table 3 illustrates the structure of the technical areas in the Index 2010 and the key topics covered by each of them. More information is provided in the 2010 Methodology & Stakeholder Review, available at www.accesstomedicineindex.org.

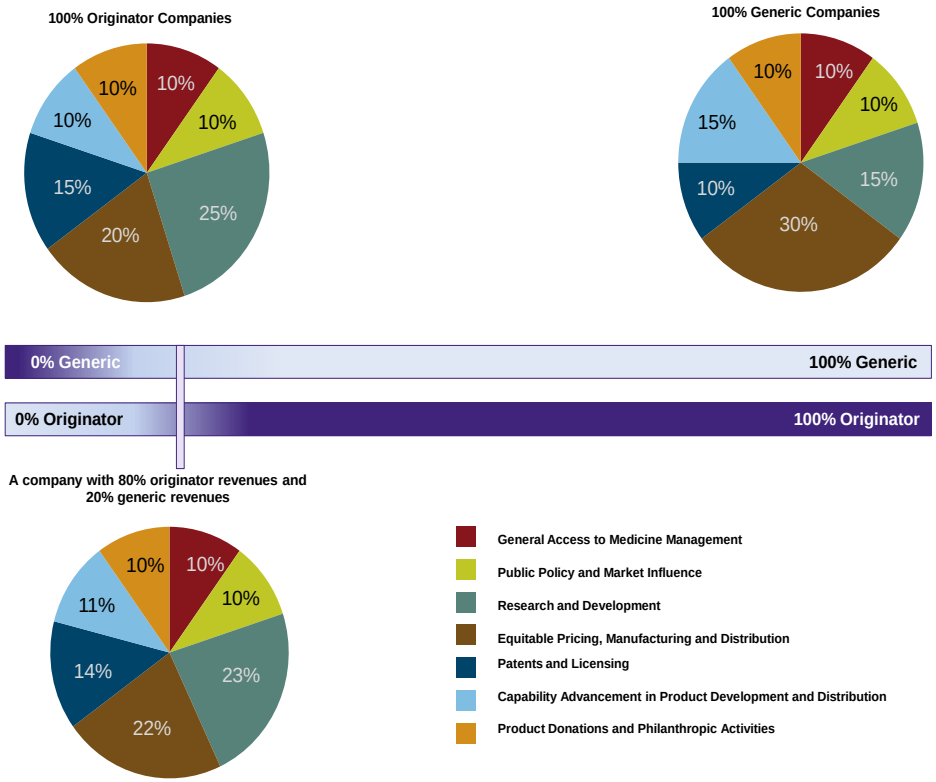
Table 3. Structure and Key Indicators of the Access to Medicine Index 2010

		Strategic Pillars			
		Commitments 30%	Transparency 30%	Performance 30%	Innovation 10%
Technical Areas	A. General Access to Medicine Management	ATM Governance			
		ATM Management System			
		Stakeholder Engagement			
	B. Public Policy and Market Influence	Advocacy and Lobbying			
		Competition Behavior			
		Marketing Behavior			
	C. Research and Development	Innovative R&D			
		Adaptive R&D			
		Intellectual Property Sharing			
	D. Equitable Pricing, Manufacturing and Distribution	Marketing Approval (Registration)			
		Equitable Pricing			
		Manufacturing & Distribution			
	E. Patents & Licensing	Patents			
		Non-Exclusive Voluntary Licensing			
	F. Capability Advancement in Product Development and Distribution	Capacity Building in Research and Development			
		Capacity Building in Quality Management and Distribution			
	G. Product Donations and Philanthropic Activities	Donations			
		Philanthropy			

Index 2010 Indicator Weights

In addition to separating originator and generics companies to reflect the difference between the two types of companies in the drivers for ATM, weight adjustments have been applied to the indicators. For generics manufacturing, the weights of Patent & Licensing and R&D are lower. This is because these indicators are more relevant to R&D based revenues. The weights of Equitable Pricing, Manufacturing and Distribution and Capacity Advancement in Manufacturing and Distribution are higher for generics manufacturing. In addition, inside technical areas some weight adjustments are applied too. For example under R&D, more weight is attributed to adaptive R&D indicators for generics manufacturing compared to innovative R&D indicators. To ensure that the weight adjustment is applicable to all companies with different mixes of generic and originator operations, dynamic weight adjustments are used. In this approach, the weights for each company's indicators are based on the percentage of its revenues from originator and generic sales. Regardless of company type, the weight of each technical area is split between commitment (30%), transparency (30%), performance (30%) and innovation (10%) indicators. The weights used for the different technical areas are shown in the graph below. This graph also provides an example of technical area weights for a company with 80% of its revenues from originator sales and 20% of revenues from generics manufacturing. The revenue split between originator and generics activity is based on the companies' disclosure on the revenues of subsidiaries dedicated to each of the mentioned revenue streams. For more information about indicator weights please refer to Appendix D, Indicators and Scoring Guidelines.

Figure 3. Weight Adjustments Based on Originator/Generics Revenue Split



ACCESS TO MEDICINE INDEX 2010 SCOPE

Adjustments have been made to the disease, company and geographical scope in the Index 2010. These adjustments attempt to better align the coverage of the Index with the healthcare priorities of the Index Countries. The scope of Access to Medicine Index 2010 is summarized in the tables below and more details are provided in Appendix A: Index 2010 Scope.

Table 4. Access to Medicine Index 2010 Scope

Disease Scope	Company Scope
Access to Medicine Index 2010 addresses the following diseases. For details about the approach to deciding the disease scope, please refer to the Access to Medicine Index 2010 Methodology and Stakeholder Review report. • The top 14 WHO Neglected Tropical Diseases (one disease appears in another category) • The top 10 Communicable Diseases based on Disability Adjusted Life Years lost to a disease (DALYs) from the WHO Global Burden of Diseases for Low and Medium Income Countries • The top 10 Non-Communicable diseases based on DALYs from the WHO Global Burden of Diseases for Low and Medium Income Countries	The number of companies evaluated has increased from 20 in the Index 2008 to 27, comprising 20 originators (compared to 17 in the Index 2008) and seven generics companies (compared to three in the Index 2008). The selection was based on market capitalization and relevance of the product portfolio to the Index Diseases. As with the Index 2008, biotech companies were not included in the Index 2010.
Geographic Scope	**Period of Analysis**
The Index 2010 focuses on 88 countries classified under the Low and Medium Human Development Countries in the UN Human Development Index 2008. Companies classified as high or upper middle income under world bank classification have been excluded	The Access to Medicine Index 2010 is based on data for the 2008 and 2009 fiscal years. The companies covered by the Index had different fiscal years; some December to December and others March to March.

Table 5. Index 2010 Disease Scope

Neglected Tropical Diseases	High Priority Communicable Diseases	High Priority Non-Communicable Diseases
Lymphatic filariasis (elephantitis)	Lower respiratory infections	Unipolar depressive disorders
Shistosomiasis (bilharzia)	Diarrheal diseases	Ischemic heart disease
Human African trypanosomiasis (sleeping sickness)	HIV/AIDS	Cerebrovascular disease
Soil-transmitted helminthiasis (hookworms or roundworms)	Tuberculosis	Non-communicable obstructive pulmonary disease
Trachoma	Malaria	Diabetes mellitus
Leishmaniasis (kala-azar [visceral])	Measles	Asthma
Dengue	Meningitis	Osteoarthritis
Onchoceriasis (river blindness)	Pertussis (whooping cough)	Cirrhosis of the liver
Chagas disease	Lymphatic filariasis	Nephritis / Nephrosis
Leprosy	Tetanus (lock-jaw)	Epilepsy
Buruli ulcer		
Dracunculiasis (guinea-worm disease)		
Fascioliasis		
Yaws		

Table 6. Index 2010 Company Scope

	Originator Companies			
	Ticker	Company	Country	Market Cap as of June 1st, 2010 (billion)
1	JNJ-N	Johnson & Johnson	USA	USD 160.80
2	PFE-N	Pfizer Inc	USA	USD 122.85
3	ROG-VX	Roche Holdings Limited	CHE	USD 119.07
4	MRK-N	Merck & Company Inc	USA	USD 105.05
5	NOVN-VX	Novartis AG	CHE	USD 104.28
6	GSK-LN	GlaxoSmithKline PLC	GBR	USD 87.49
7	SAN-FR	Sanofi-Aventis AS	FRA	USD 79.89
8	ABT-N	Abbott Laboratories	USA	USD 73.41
9	AZN-LN	AstraZeneca PLC	GBR	USD 60.55
10	NOVO'B-KO	Novo Nordisk A/S	DNK	USD 45.68
11	BMY-N	Bristol-Myers Squibb Company	USA	USD 39.91
12	BAY-FF	Bayer AG	DEU	USD 37.89
13	LLY-N	ELI Lilly & Company	USA	USD 37.81
14	4502-TO	Takeda Pharmaceutical Company	JPN	USD 32.48
15	GILD-O	Gilead Sciences	USA	USD 31.97
16	MRK-FF	Merck KGaA	DEU	USD 15.91
17	4503-TO	Astellas Pharma Inc	JPN	USD 15.06
18	4568-TO	Daiichi Sankyo Company Limited	JPN	USD 12.32
19	4523-TO	Eisai Company Limited	JPN	USD 9.69
20	Not Publicly Listed	Boehringer-Ingelheim	DEU	Not Publicly Listed

	Generics companies			
	Ticker	Company	Country	Market cap as of June 1st, 2010 (billion)
1	TEVA-TV	Teva Pharmaceutical	ISR	USD 50.62
2	BSE: 524715	SunPharma	IND	USD 7.44
3	MYL-O	Mylan Inc	USA	USD 5.94
4	BOM: 500087	Cipla Limited	IND	USD 5.53
5	BOM: 500124	Dr. Reddy's	IND	USD 5.02
6	BOM: 500359	Ranbaxy Laboratories Limited	IND	USD 3.82
7	Not Publicly Listed	Apotex	CAN	Not Publicly Listed

COMPANY ANALYSIS PHASE OF ACCESS TO MEDICINE INDEX 2010

Following the completion of the Access to Medicine Index 2010 methodology, company analysis started in November 2009. This process included:

- Analysis of the companies' publicly available information
- Submission of a tailored questionnaire to each company, to fill both quantitative and qualitative information gaps
- Analysis of company inputs including product portfolio and R&D pipeline
- Rankings were based on 106 indicators. This compares with evaluation based on 28 indicators in the Index 2008 (for details on the scoring process, please refer to Appendix C: Ranking and Scoring Process).

Some areas of improvement since the Index 2008 include:

- A marked increase in the number of responses; 19 out of the 20 originator companies covered by the Index 2010 responded to our data requests. The 20th originator company, ***Bristol-Myers Squibb,*** did not respond to our questionnaire but did provide feedback on its Access to Medicine Index 2010 profile. Out of the seven generics companies covered, three responded to our data requests, compared to zero response from the three generics companies covered by the Index 2008.
- A more thorough analysis of the companies' research pipelines and product portfolios
- Research of other data sources such as WHO pre-qualification and patent databases
- Interviews with several organizations working with the industry on different ATM related initiatives

Data Verification

Besides input from the companies, many independent sources of information were used, such as:

- Patent and registration databases
- Pricing surveys
- Litigation databases

In addition, interviews were conducted with organizations working closely with the companies on ATM related issues. Such organizations included product

development partnerships, international procurement agencies, donations management organizations and regulators. Such interviews provided our analysts with multiple viewpoints on the key issues related to individual companies and the industry. More information on this is available in the Sources section of each technical area chapter and the “Acknowledgement” section.

At the end of the analysis phase, the company profiles were reviewed by the companies themselves, to ensure there were no data discrepancies or errors in our data collection.

Despite these efforts, given the scale and scope of the data collected and analyzed, some data or analysis errors might have remained undiscovered and unresolved.

THE GLOBAL ACCESS TO MEDICINE LANDSCAPE

In the last few years significant progress has been made in improving access to treatments, vaccines and diagnostic tests. Increased availability of HIV drugs has led to a 10-fold rise in the number of people receiving treatment in low- and middle-income countries over the last five years[2]. In addition, there has been a significant expansion in the scale and scope of research activities for the neglected diseases. Moreover, the international institutional frameworks aimed at addressing ATM-related issues have achieved great progress. However, more must be done if the target of universal access to medicine is to be achieved.

Diarrhea and pneumonia continue to cause the highest mortality among the children in the Index Countries[3]. Epidemics of other diseases such as dengue, natural disasters such as earthquakes and human-made disasters such as wars and violence expose fragile health infrastructures and poor access to medicine. In addition, HIV/AIDS, tuberculosis, malaria and various tropical diseases remain endemic in a large part of the world. Medications remain expensive, inaccessible or have limited availability for a large proportion of the world population.

While the global economic crisis has raised fears of a worsening ATM situation, it has had little impact on the poorest nations, with the exception of some countries in Eastern Europe[4]. Nonetheless, stakeholders remain vigilant about the potential impact of a weak economy on access to medicine in the poor countries.

The following section provides an overview of the greatest ATM needs.

NEED FOR NEW PHARMACEUTICAL PRODUCTS

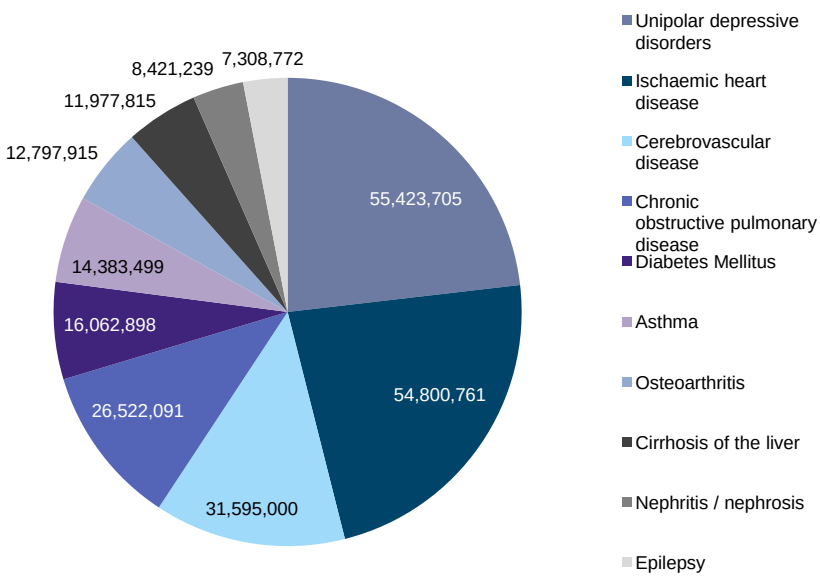
When there is no developed market for Index Country needs, economic incentives can be insufficient for pharmaceutical companies to develop new vaccines and therapeutic and diagnostic products.

A major area of unmet need for research & development (R&D) and market failure is neglected tropical diseases (NTD). Such diseases cause significant health burden in poor countries but are mostly absent in the developed world. They continue to receive an insufficient share of global pharmaceutical research.

[2] WHO (2009) Towards universal access: scaling up priority HIV/AIDS interventions in the health sector. Progress report. Geneva: the World Health Organization
[3] WHO (2010). Sources and prices of selected medicines for children: http://www.who.int/medicines/publications/essentialmedicines/Sources_Prices2010.pdf

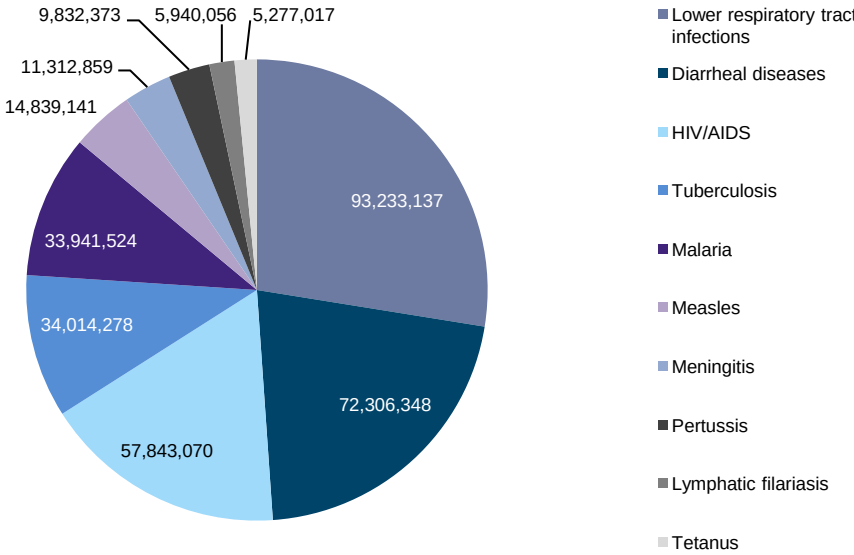
[4] IMS Health (2010). "Tracking the Effect of the Economic Crisis on Pharmaceutical Consumption", report prepared for the World Health Organization, 14 January 2010. Available at: http://www.who.int/medicines/areas/policy/imsreport/en/index.html

Figure 4. Health Burden of the Top Ten Non-Communicable Diseases in the Low and Medium Income Countries Covered by Index 2010 (DALYs)



Source: Based on data from WHO. 2008. Global Burden of Disease 2004 Update

Figure 5. Health Burden of the Top Ten Communicable Diseases in the Low and Medium Income Countries Covered by Index 2010 (DALYs)



Source: Based on data from WHO. 2008. Global Burden of Disease 2004 Update

During the past few years, the emergence of several research collaborations, new international funding mechanisms and more industry engagement have resulted in important steps towards addressing this need. However, there is still a long way to go. Consider the human toll caused by the dengue outbreaks currently afflicting several countries in the Americas, where a total of 344,346 cases – 7,838 of them severe – were reported between the end of January and the end of April 2010[5].

Along with the need for more innovative research on tropical neglected diseases, emergence of drug-resistant strains of HIV/AIDS and tuberculosis also demand attention from developers of new medicines.

Besides research into new drugs, adaptive research for existing medications is another high-priority area of need. Such adaptations include formulations for specific age groups, combined doses for increased patient compliance or formulations adapted to Index Country environmental conditions. For example, while HIV/AIDS is also a disease of the developed world, pediatric forms of HIV rarely occur outside poor countries.

Lack of viable markets for HIV/AIDS pediatric formulations and the difficulty of carrying out pediatric clinical trials result in insufficient R&D investments.

Similar needs exist for a range of different adapted formulations of existing treatments[6].

Several new initiatives have created a more favorable environment for research in these areas. Product development partnerships[7] such as Drugs for Neglected Diseases Initiative (DNDi), PATH and the Medicines for Malaria Venture (MMV) have played a crucial role in bringing together the industry and the other stakeholders to overcome the market failures in research for Index Diseases. Other initiatives, such as the G-Finder project of the George Institute[8], have also played an important role in exposing gaps in R&D investments for the high-priority disease areas.

More information on this topic can be found in the Research and Development sections in both the Originator and Generic Pharmaceutical Company chapters.

[5] Pan American Health Organization (2010). Epidemiological Alert: Update on Dengue Outbreaks in the Americas (22 April 2010) Available at: http://new.paho.org/hq/index.php?option=com_content&task=view&id=2788&Itemid=2206. Accessed June 5, 2010.

[6] WHO (2010) Sources and prices of selected medicines for children: http://www.who.int/medicines/publications/essentialmedicines/Sources_Prices2010.pdf

[7] International public private partnerships aimed at developing new pharmaceutical remedies for areas of unfulfilled need.

[8] www.georgeinstitute.org

NEED FOR MORE AFFORDABILITY OF EXISTING MEDICINES

While the need for new products is significant and urgent, making existing treatments available to patients in need is vital because they can have an immediate impact. Cost is a major obstacle to this effort.

For example, treatment for multi-drug resistant tuberculosis (MDR-TB) can cost up to 100 times more than standard treatment[9]. Medicines for diabetes mellitus continue to be unaffordable in the majority of least developed and developing countries and on average cost the equivalent of two days' wages. This can reach up to the equivalent of eight days' wages in Ghana[10]. Such unaffordable prices, combined with lack of sufficient healthcare financing in such countries and the resulting high out-of-pocket payments by patients, are major barriers to access.

For medicines with expired patents, generics companies can play an important role in decreasing prices through increased supply and competition.

This is demonstrated by significant reductions in the cost of key anti-retrovirals (ARV). For example, in May 2000, the brand-name version of a common HIV combination therapy (3TC/d4T/NVP) was offered for approximately USD 10,400 per patient per year[11]. In October of the same year, an Indian generic drug firm offered the combination for USD 800 and by October 2001--after several subsequent price reductions by generic firms and originator pharmaceutical companies--the price of the triple-combination therapy offered by generic drug firms and pharmaceutical companies dropped to USD 295 and USD 712, respectively (see Generic section)[12].

For specific therapeutic areas such as second-line HIV/AIDS medicines, new formulations and antibiotics for resistant strains of bacteria, patented products play an important role. The 500,000 to 800,000 patients who currently need second-line ARVs are potent indicators of the scale of need for patented products. [13]

For such patented products, pharmaceutical companies can play an important role through their patent and equitable pricing practices. There are a number of global initiatives working in partnership with the industry to make medicines more affordable. These include the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), Global Alliance for Vaccines and Immunization (GAVI), Affordable

[9] UNAID)2008) MDR-TB more common in people living with HIV
[10] Health Access International(2007) Access to affordable essential medicines

[11] Médecins Sans Frontières (2010). "A Matter of Life and Death: The Role of Patents in Access to Medicines." Available at: http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf Accessed May 3, 2010.
[12] Ibid
[13] WHO (2007) Prioritizing second-line antiretroviral drugs for adults and adolescents: a public health approach. Report of a WHO working group meeting. Geneva: the World Health Organization

Medicines Facility - malaria (AMFm), the Global Health Initiative (GHI) and UNITAID.

More information on how companies are adjusting their patent, voluntary licensing and pricing mechanisms to adapt to Index Country needs is available in the Patents & Licensing and Equitable Pricing, Manufacturing and Distribution sections in both the Originator and Generic Pharmaceutical Company chapters.

NEED FOR MORE ACCESSIBILITY OF EXISTING TREATMENTS

For new pharmaceutical products to become accessible to patients, they must be registered (obtain marketing approval) in the countries in need. Registration continues to be an important bottleneck in countries with insufficient regulatory teams and resources. Also, pharmaceutical companies may not register their products in some nations if those nations' markets are not deemed economically viable.

In such cases of market failure or lack of national regulatory capacity for registration, recently introduced international mechanisms are playing an important role.

The European Medicines Agency's (EMA) "Article 58" process continues to provide a valuable mechanism by which the EMA is able to provide regulatory opinions and evaluations for medicinal products sold outside the European market. The feedback obtained via Article 58 can then be used to support and facilitate registration in the Index Countries[14].

The prequalification program of WHO has also become a powerful tool for establishing a global defined set of quality standards for medicines. This mechanism is an important facilitator for companies' registration efforts in the Index Countries and also for organizations and agencies seeking to procure medicines in bulk.

Following registration, high-quality and sufficient production capacity and an effective supply chain are essential for making a product accessible to patients.

Both counterfeit or fake products and genuine but substandard products remain big challenges in the Index Countries.

Several reports show that in many Index Countries, over 40% of pharmaceutical products available to patients face significant quality issues such as contamination or low levels of active ingredients[15]. International processes such as the WHO prequalification process are helping both suppliers and purchasers better evaluate product quality. Nonetheless, major steps still need to be taken in this area to ensure that products

[14] The European Medicines Agency (2005). Evaluation of Medicines for Human Use. 23 May 2005. Available at: http://www.who.int/immunization_standards/vaccine_regulation/article_58_guidelines_0505.pdf

[15] MSF (2008)Substandard medicines in resource-poor settings: a problem that can no longer be ignored

destined for the Index Countries have high quality standards. The difficulty of conducting effective and timely product recalls in many Index Countries further increases the risk posed by such products.

An essential part of increased accessibility is the expansion of drug production. To make this viable, international organizations such as the Clinton Foundation and UNITAID have worked to aggregate demand and create market incentives for increasing the supply of essential drugs. In addition, several companies have engaged in non-exclusive voluntary licensing and technology transfer to international and local generics companies.

In local supply chains, stock-outs resulting from slow purchasing processes and weak forecasting capabilities have been major barriers to the efficacious delivery of pharmaceutical products. Hospitals, local health dispensaries and medical centers throughout the Index Countries struggle to maintain stable inventories of much-needed drugs. In Kenya, it is estimated that only 50% of health dispensaries and 65% of hospitals carry the amount of essential medicines needed[16].

A discussion of what role the pharmaceutical industry is playing in addressing these deficiencies can be found in the section on Capacity Advancement in Product Development & Distribution in both the Originator and Generic Pharmaceutical Company chapters.

[16] MOH / WHO / HAI Africa (2008). Monitoring of Medicine Prices and Availability. Nairobi

THE RISING CHALLENGE OF NON-COMMUNICABLE DISEASES

A major emerging issue is the increasing health burden of non-communicable diseases including cardiovascular ailments, cancer and diabetes. Non-communicable diseases account for approximately 60% of all deaths worldwide and 80% of these deaths occur in low- and middle-income countries[17]. The health burden from chronic conditions is growing due to the ageing of populations, changing lifestyles and past successes in combating infectious diseases[18].

Non-communicable diseases now constitute the highest burden of disease in many Index Countries, resulting in these countries facing a so-called "double burden of disease".

The disability-adjusted-life year (DALY) is a measure of health burden developed by WHO that considers years of healthy life lost due to illness or disability. The Index defines the high-priority diseases using DALY measures for different diseases and Index Countries. Use of DALYs enables a balanced analysis of diseases

[17] Daar, Abdallah S., Singer, Peter A., Persad, Deepa L. et al. (2007). "Grand Challenges in Chronic non-communicable diseases." Nature. Vol. 450.
[18] Ibid.

characterized by a high level of mortality yet little disability (e.g. measles) and diseases with a low level of mortality yet higher level of disability (e.g. depression).

According to the WHO Global Burden of Disease project, the top three communicable diseases based on DALYS in the low and medium income countries include lower respiratory infections (81,648,000), diarrheal diseases (64,490,000) and HIV/AIDS (41,319,000).

Non-communicable diseases with the highest DALYs in the Index Countries include unipolar depressive disorders (55, 423,705 DALYs), ischemic heart disease (54,800,761 DALYs) and cerebrovascular diseases (31,595,000 DALYs).

Pharmaceutical firms need to adapt to this evolution in the disease profile of Index Countries.

Throughout the Access to Medicine Index 2010, special attention has been paid to how pharmaceutical companies are applying their ATM strategies and practices to their products for non-communicable diseases.

PHARMACEUTICAL INDUSTRY TRENDS AND THEIR IMPLICATIONS FOR ACCESS TO MEDICINE

Changes in the structure and scope of the pharmaceutical sector have been driven by several important developments.

PATENT EXPIRATIONS AND FEWER NEW "BLOCKBUSTER" DRUGS

One of the most significant challenges facing the industry is the unprecedented number of patent expirations scheduled in the coming years. Many of them are for "blockbuster" drugs. According to IMS Health Inc., the global pharmaceutical industry faces a cumulative loss of USD 137 billion in sales in the period 2009-2013 due to patent expirations and heightened generic competition[19]. Moreover, the flow of new products entering the market has slowed in recent years, as R&D efforts have not resulted in new blockbusters.

Due to the challenges posed by the expired patents, the companies are paying increasing attention to Index Country markets as a significant growth opportunity.

Also, developed-world drug companies are embarking on strategic alliances with or purchasing generics companies, particularly in India and promoting their own branded generic products. This dynamic will have major implications for ATM in the Index Countries. More information on this issue can be found in the Generic Pharmaceutical Companies chapter.

A RAPID CONSOLIDATION TREND

2008 and 2009 witnessed an unprecedented number of mergers and acquisitions.

Two of the most significant transactions were ***Pfizer's*** acquisition of ***Wyeth*** and the purchase of ***Schering-Plough*** by ***Merck & Co.***

For both ***Pfizer*** and ***Merck & Co.***, the integration of ATM programs and strategies are still in the initial stages. Both companies have acquired significant research pipelines, compound libraries and Index Country distribution networks through these purchases. It remains to be seen in the next iterations of the Index how they succeed in realizing the potential

[19] IMS Health. (2009). "IMS Forecasts Global Pharmaceutical Market Growth of 4-6% in 2010; Predicts 4-7% Expansion Through 2013." IMS Health Press Release. Available Online: http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=500e8fabedf24210VgnVCM100000ed152ca2RCRD. (Accessed March 4, 2010).

values of these acquisitions in the Index Countries.

The movement of originators into the generics space has been one of the most interesting and dominant trends in recent M&A and collaborative activities. Some of the major activities in this area have been:

- **Daiichi** purchased majority shares in ***Ranbaxy*** (India)
- ***Sanofi-Aventis*** acquired ***Zentiva (***Czech Republic), ***Medley (***Brazil) and ***Laboratories Kendrick*** (Mexico)
- ***Abbott*** purchased the Healthcare Solutions business of ***Piramal*** (India) in 2010
- ***GlaxoSmithKline*** entered into a strategic alliance with ***Dr. Reddy's*** (India) and acquired a 19% shareholding in **Aspen** (South Africa)
- ***Pfizer*** entered into an alliance with ***Aurobindo*** (India)

The increased number of acquisitions and collaborations with generics companies has the potential to drive the price of patented products down by providing originator companies with the low-cost production and distribution capacity of generic firms. However, they might also hamper generic competition following the expiry of product patents. It remains to be seen how such partnerships and acquisitions translate into changes in company practices on the ground.

THE GENERICS COMPANIES AND ACCESS TO MEDICINE

Emergence of large international generics companies, especially in India is one of the pharmaceutical sector's most important developments of the past decade. The large number of recent patent expiries of "blockbusters" creates significant growth opportunities for these companies in the future.

International generics companies have provided the world with additional low-cost and high-quality manufacturing capacity. Such companies have driven affordability and accessibility through price competition for off-patent drugs and have applied their manufacturing capacity to branded products of originator companies through voluntary licensing agreements.

While originator companies can improve future access through mechanisms such as innovative research on new products needed in developing countries, generics companies are key drivers of access to existing treatments. Some originator and generics companies perceive each other as a threat, while others engage in constructive collaboration models such as non-exclusive voluntary licensing agreements. Such arrangements can help originator companies recoup R&D costs

through license fees while the generics companies deliver supply capacity and a competitive cost base to feed new markets. Yet, such licensing activities are mostly in their infancy. The potential of non-exclusive licensing to transform access has yet to be realized by more collaboration between originators and generics companies.

By analyzing originator and generics companies in separate lists, the Index 2010 is able to highlight the different roles each group can play in improving or hindering ATM in Index Countries.

For generics companies, adaptive research, competition behavior and maintenance of focus on the Index country are key access drivers, but product registration and quality management are also significant factors.

Historically, the generics companies - especially those from India - have mostly targeted Index Countries. However, a more favorable regulatory environment and quality improvements in generic manufacturing are making Western markets more accessible and attractive to generics companies. How such a shift in focus in the generic market will affect ATM is yet to be determined. The Access to Medicine Index team will monitor these developments carefully.

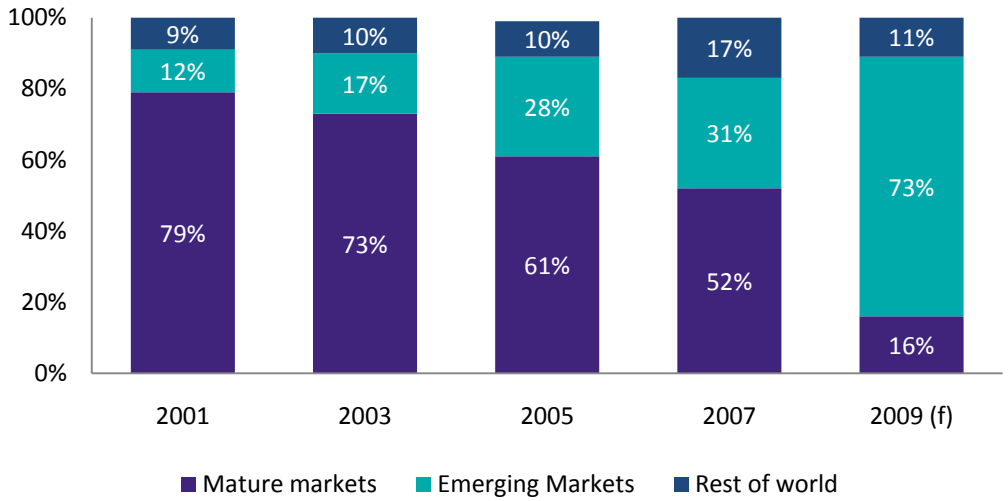
More information on the role played by the generics companies in ATM can be found in the Generic Pharmaceutical Companies chapter.

THE BUSINESS CASE

The pharmaceutical industry license to operate is based on development and delivery of affordable, accessible and high-quality pharmaceutical products. To ensure long-term sustainability, the pharmaceutical industry must balance economic objectives with fulfilling its role in society. In this context, it is important to note that an active and innovative approach to the Index Country markets is also backed by a more immediate economic rationale.

With so many significant drugs expected to lose patent protection soon and a shortage of promising replacements in the pipeline, the “blockbuster” model that enabled companies to build their businesses around a select number of products in the 1990s is no longer sustainable. In addition to diversifying product portfolios and building R&D pipelines through M&A activity, another strategy for pharmaceutical companies has been expansion into the Index Countries.

Figure 6. Contribution of Emerging and Mature Markets to the Global Growth of the Pharmaceutical Industry



Source: IMS Health, Market Prognosis, March 2009

In the past, investment in Index Countries was not the most attractive option due to risky operating environments. Today, however, rapid economic growth, improving healthcare systems, changing lifestyles, population growth, along with lower R&D and manufacturing costs, signal great potential for meaningful pharmaceutical industry growth opportunities in these regions. According to IMS Health Inc., emerging economies represented only 12% of growth in the pharmaceutical sector in 2001; in 2009, however, they are expected to represent 73% of global growth.

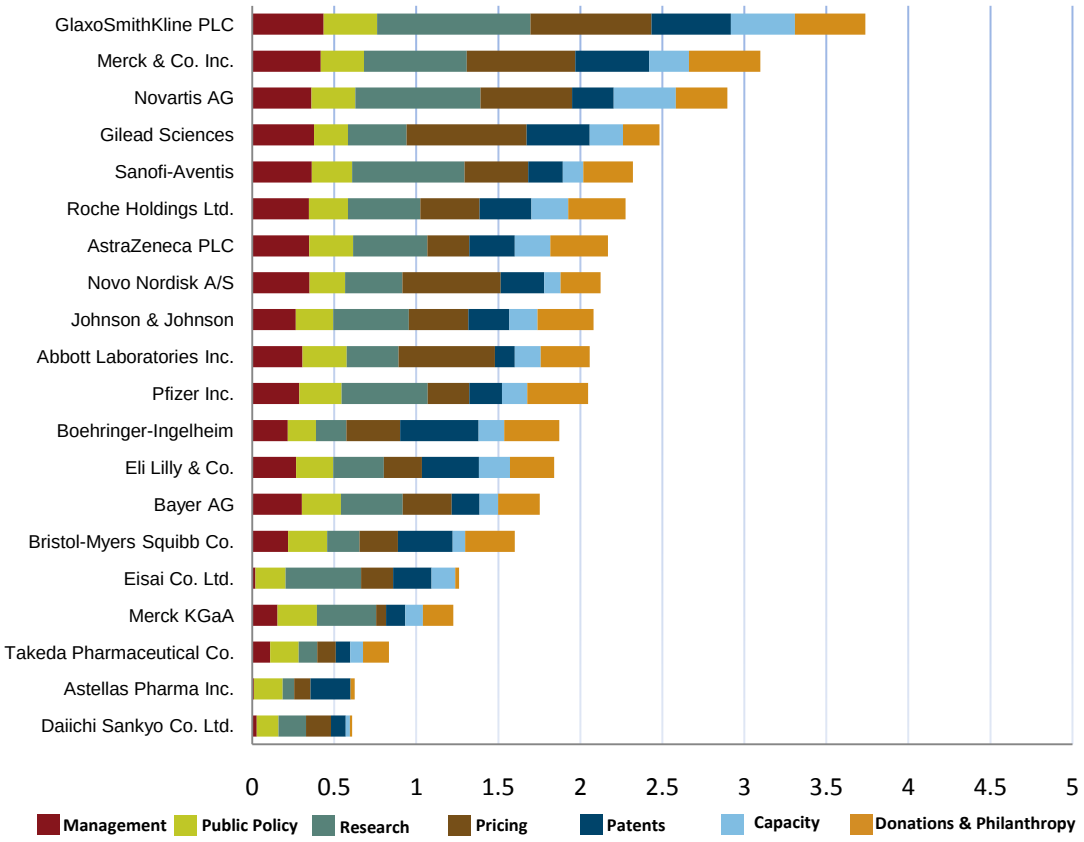
The movement of pharmaceutical companies into Index Country markets is an endeavor that demands a deep understanding of the needs and constraints in these markets, as well as innovation to develop new business models that are tailored to them.

The Access to Medicine Index aims to be an effective medium for motivating such innovation and learning in the industry.

Originator pharmaceutical companies

OVERALL RANKING

Figure 7. Overall Ranking of Originator Companies



Note that the Access to Medicine Index is a relative index. A score of five on a scale of zero to five for the majority of the indicators simply signifies the leading practice among the companies under coverage. The Index does not evaluate companies against aspirational best practices. Instead, it enables a comparison of current ATM practices of the researched pharmaceutical companies.

The period of analysis (fiscal years 2008 and 2009) has been ripe with changes in company practices which are reflected in the number of changes in the companies' rankings. This is because most companies in the sector are still in the early stages of developing their Index Country and ATM related strategies. The areas of R&D, equitable pricing and ATM management have seen especially significant improvements since the launch of Index

2008. For more information, please refer to the respective sections of this chapter.

The leading companies in Index 2010, ***GlaxoSmithKline***, ***Merck & Co.*** and ***Novartis,*** have made extra efforts to maintain their leading positions. All these companies have improved in their transparency, commitments to ATM and performance. While they still have a long way to realizing their full potentials both for improving access and exploiting the growth opportunities in the Index Countries, they have proved to be some of the most innovative in the sector. These companies have also been unique in taking risks and experimenting with new business models. None of these companies has been the leading company in all the technical areas. However, these companies have performed above average in most of the areas.

Two companies have seen major improvement in their Index 2010 rankings, ***Pfizer*** (from 17th in Index 2008 to 11th in Index 2010) and ***Gilead*** (from 15th in Index 2008 to 4th in Index 2010). Both have demonstrated increased focus on ATM issues compared to the last Index and have launched several ATM-related initiatives. Among new initiatives launched by ***Pfizer*** are three new research collaborations and ***Gilead*** has expanded its non-exclusive licensing practices. Both also have significantly improved their disclosure compared to Index 2008. For more information on company practices, you can refer to their respective Report Cards in the following section or the company profiles.

The ranking of four companies has decreased significantly compared to the Access to Medicine Index 2008: ***Bayer*** (from 9th in Index 2008 to 14th in Index 2010), ***Bristol-Myers Squibb*** (from 11th in Index 2008 to 15th in Index 2010), ***Merck KGaA*** (from 13th in Index 2008 to 17th in Index 2010) and ***Novo Nordisk*** (from 2nd in Index 2008 to 8th in Index 2010).

The decrease in the ranking of ***Novo Nordisk***, is partially because, in Access to Medicine Index 2010, insulin producers are analyzed based on the same weights and scoring guidelines as all the other originator companies. Consequently the company's ranking has been affected by its narrow scope of ATM related activities and also its empty research pipeline for the Index Diseases. As for ***Bayer***, in addition to some changes in performance, the company's ranking has been affected by the exclusion of the company's activities in maternal care and family planning from the scope of Access to Medicine Index 2010. The Index 2010 covers only initiatives that fall under its geographical and disease scope. This is to ensure comparability between the companies and focus on high priority areas. For more information please refer

to Access to Medicine Index 2010 scope under Appendix A.

Bristol-Myers Squibb and ***Merck KGaA*** have been overtaken by other companies which have launched several new ATM related initiatives during the period of analysis.

An important finding in Index 2010 has been a positive trend in the policies and practices of the Japanese companies. While these companies lag most of their peers on ATM issues, they have shown promising signs of improvement. All four Japanese companies engaged with the Index 2010 team openly and all are in the process of further developing their Access to Medicine strategies and targets. Among these companies, ***Eisai*** is actively engaging in neglected diseases research and making concrete and ambitious commitments for expanding its initiatives in the Index Countries.

Besides changes in company policies and practices, Index 2010 ranking changes compared to Index 2008 have also been influenced by methodology enhancements and more disclosure by the companies.

In some areas, such as pricing and assessment of R&D activities, the Index depends on information provided by the companies. Consequently, the significantly improved level of disclosure by most of the originator companies (from nine companies in Index 2008 to 19 companies in Index 2010) is a welcome trend.

Partly because of better reporting, Index 2010 has carried out a more thorough analysis of R&D pipelines and equitable pricing practices compared to Index 2008. More-granular performance measurement has also influenced the results of our rankings. The Access to Medicine Foundation envisages only incremental changes in the methodology of the upcoming iterations of the Index. Consequently, changes in future rankings would more exclusively demonstrative of changes in company policies and practices.

Commitments

While current performance signifies success of past strategies, commitments promise future performance of the companies.

The leading companies in Access to Medicine Index 2010 make detailed ATM related commitments and set future objectives for fulfilling their commitments.

In addition such companies have explicit policy statements and commitments about all the important issues with potential impact on ATM such as patents and competition related issues.

Several companies in the sector such as ***Eisai***, ***GlaxoSmithKline***, ***Novartis***, ***Pfizer*** and ***Sanofi-Aventis*** have improved their ATM strategies and commitments during the period of analysis. These companies have all moved towards better aligning their business strategies and access needs.

Most of the originator companies covered by the Index 2010 carry out annual reporting of their policies and have introduced board level representation of access to medicine related issues. This is a sign of increased integration of emerging markets opportunities and access to medicine in the companies' business strategy across the sector.

Transparency

The Index 2010 emphasizes public disclosure as a means for accountability and stakeholder engagement. Leading companies such as ***GlaxoSmithKline, Merck & Co and Novartis*** are open in their public policy stances, research pipelines and investments. In addition, for the first time in the sector***,*** ***GlaxoSmithKline, Roche*** and ***Merck & Co.*** have committed to disclosing details about their marketing practices in the Index Countries in the future.

Interestingly, some of the top companies in the Access to Medicine Index 2010 are not among the top companies in transparency. While ***Gilead*** has leading practices in several areas, its public disclosure on policy positions, lobbying and marketing practices in the Index Countries is inferior to that of other highly ranked companies.

All the companies remain weak in certain disclosure areas, such as public disclosure of marketing activities in the Index Countries, lobbying practices in the Index countries and public disclosure of the terms and conditions of research collaborations. And with some exceptions, most of the companies in the sector do not disclose the outcomes of their programs, e.g. the number of patients receiving a given medicine.

Disclosure and competition on performance or outputs, rather than number of programs or inputs would support clearer evaluation of ATM efforts.

Performance

Access to Medicine Index 2010 has introduced several new indicators aimed at better measuring the performance and output of the companies' ATM practices. This helps give a fuller picture of larger trends in the industry. During the period of analysis, the major positive performance trends included:

- More intellectual property sharing with other research organizations with the aim of development of new products for Index Diseases
- New research collaborations with product development partnerships
- For the high-ranking originator companies, increased collaboration with generics companies, especially through non-exclusive voluntary licensing arrangements

Both increased research collaborations and more intellectual property sharing across the sector are promising developments for addressing neglected diseases.

Tiered pricing practices across the sector have seen a mild increase compared to the last Index with a total of thirteen companies undertaking inter-country tiered pricing with special access provisions for a subset of Index Countries and Index Diseases. Intra-country tiered pricing remains to be a limited to only eight companies. Most tiered pricing initiatives are confined to HIV/AIDS, malaria and tuberculosis.

Still, patent and competition-related litigations and controversies remain pervasive in the sector. Only four companies under coverage (***Boehringer-Ingelheim***, ***Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Merck & Co.***) are engaging in non-exclusive voluntary licensing or similar activities for Index Diseases with the generics companies. This practice remains limited to HIV/AIDS. Such initiatives signify a more constructive approach to competition with the generics companies with great potentials for improving ATM (for more information, please refer to the Patents and Licensing chapter).

Innovation

The innovation indicators of Access to Medicine Index 2010 exposed several outstanding efforts across the sector. Only initiatives that are unique and are undertaken with explicit ATM-related objectives are covered by the Index. In addition, a higher score was accorded to the companies that disclosed the resources dedicated to such initiatives and/or their output. For the period of analysis, 28 innovative initiatives were found across the sector.

Novartis (in five technical areas), ***GlaxoSmithKline*** (In four technical areas), ***Pfizer*** (in four technical areas) ***Gilead*** (in three technical areas), ***Novo Nordisk*** (in three technical areas) and ***Boehringer-Ingelheim*** (in two technical areas) were the companies with the most innovative initiatives. Overall, eleven companies out of the 20 Originator companies covered by Index 2010 have undertaken at least one innovative initiative related to ATM. For more information about innovations please refer the "Recent Innovations" section at the end of each technical area chapter.

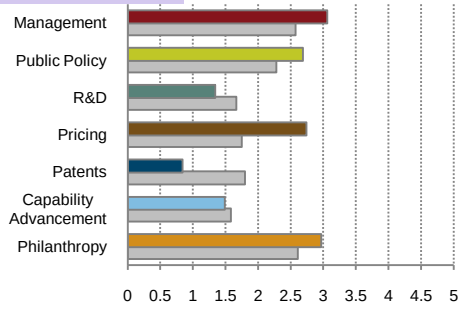
REPORT CARDS

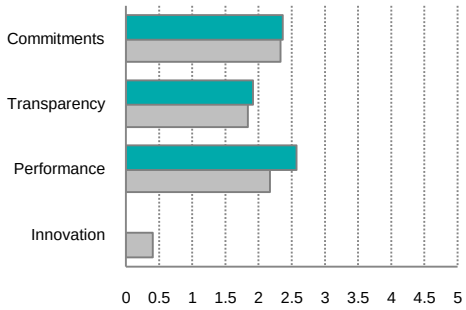
IN THIS SECTION

ABBOTT LABORATORIES INC.

Full Company Profile Available at: www.accesstomedicineindex.org/Abbott

HQ	Abbott Park, Illinois, USA	**Index Disease Focus**	**Existing Index Disease Commercial Products:** HIV/AIDS, Epilepsy , Diabetes Mellitus, Cerebrovascular Diseases, Ischemic Heart Disease
Employees	73,000 (as of 31 December 2009)		**Index Disease R&D Pipeline:** HIV/AIDS
Revenues	**2009**: USD 30,765 million **2008**: USD 29,528 million		





The grey bars represent industry average scores.

Leading Practices

- ***Abbott Laboratories*** (***Abbott***) has a transparent two-tiered inter-county pricing strategy for its HIV medicine Kaletra/Aluvia.
- ***Abbott*** ensures broad registration of its HIV medicines; Kaletra/Aluvia is the most widely registered HIV medicine in the world according to the WHO and was filed or approved in 170 countries by the end of 2009 (where 98% of the developing world's HIV population lives).
- ***Abbott*** is committed to carrying out adaptive R&D for HIV medicines (7 product combinations total for HIV).

Changes Compared to Index 2008

- Since Index 2008 was published, ***Abbott*** has worked to increase local research capacity within Index Countries; for example, ***Abbott*** renovated four regional laboratories in Tanzania in 2009 and has trained over 2,200 healthcare professionals to date.
- During 2008 and 2009, ***Abbott*** displayed an overall greater level of engagement with research organizations for screening of its compound library[20] for potential Index Disease candidates (e.g. with DNDi).
- During the period of analysis, ***Abbott*** opened a research center in China's Zhangjiang Hi-Tech Park; ***Abbott*** will partner with Chinese organizations and local academic centers.
- During the period of analysis, ***Abbott*** entered into dialogue with the Patent Pool Initiative of UNITAID (including senior level management).

Suggested Areas for Improvement

- ***Abbott*** has not engaged in non-exclusive voluntary licensing or full technology transfers to international generics companies.
- ***Abbott*** has received widespread criticism from stakeholders for its handling of compulsory licenses in Thailand's market. This approach to intellectual property protection can affect the company's stakeholder relations and have a negative impact on the company's future ATM related activities and collaborations.

[20] A compound library is a database of patented, small molecules with proven activity against a disease

- Unlike many of its peers, ***Abbott*** has no research collaborations with product development partnerships. Collaborative research activities can broaden its research activities beyond that of HIV (e.g. Neglected Tropical Diseases).

ASTRAZENECA PLC

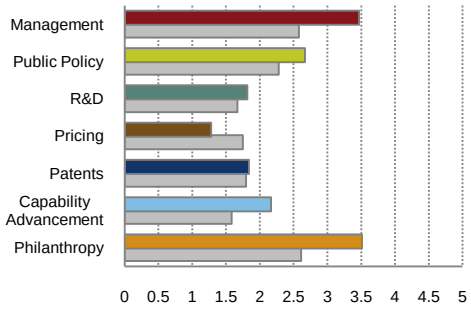
Full Company Profile Available at: www.accesstomedicineindex.org/AstraZeneca

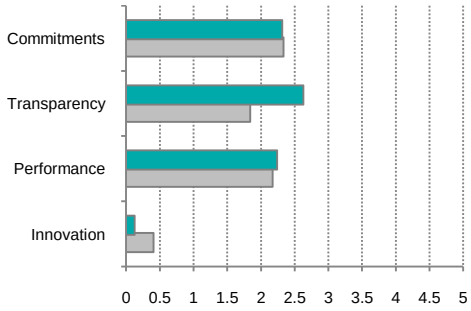
HQ	London, UK
Employees	62,700 (as of 31 December 2009)
Revenues	2009: USD 32,804 million 2008: USD 31,601 million

Index Disease Focus

Existing Index Disease Commercial Products: Asthma, Chronic Obstructive Pulmonary Disorder (COPD), Diabetes Mellitus, Epilepsy, Ischemic Heart Disease, Major Depressive Disorder, Meningitis

Index Disease R&D Pipeline: Lower Respiratory Infections, Tuberculosis





The grey bars represent industry average scores.

Leading Practices

- ***AstraZeneca*** has a clearly defined internal ATM management system, which includes both qualitative and quantitative targets.
- The company discloses several public policy positions on important ATM issues, such as product counterfeiting, pricing, donations, quality management, compulsory licensing, etc.

Changes Compared to Index 2008

- In December 2009, ***AstraZeneca***'s began Phase I clinical trials for its first drug candidate for tuberculosis (AZD5847), out of its Bangalore Research Institute in India.
- To address counterfeiting, AstraZeneca developed a hand-held device to detect counterfeit products, which can be used in Index Countries; in Colombia, the detector is being used as a legal instrument to detect counterfeit products.
- In 2009, AZ began working with Index Countries in sub-Saharan Africa to increase pharmacovigilance awareness and improve systems in that region.

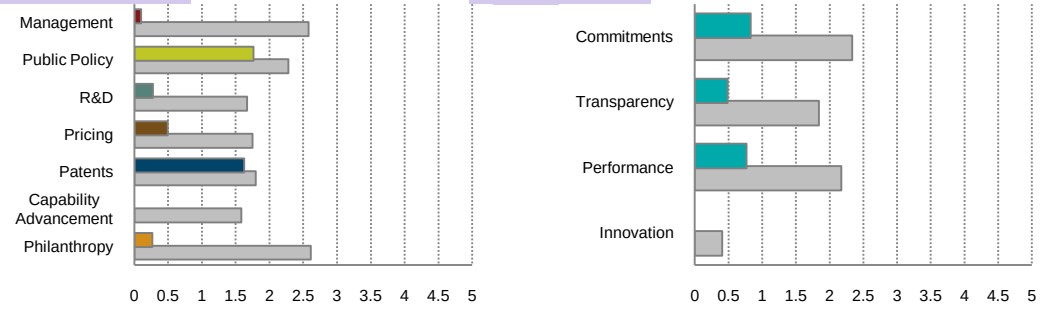
Suggested Areas for Improvement

- ***AstraZeneca*** is not transparent in its lobbying and advocacy activities (specifically financial contributions to relevant stakeholder groups) and marketing and promotional programs in Index Countries.
- The company has below average level of activity in tiered pricing and other equitable pricing mechanisms.
- The company has below average level of activity in non-exclusive licensing for its Index Disease products.

ASTELLAS PHARMA INC.

Full Company Profile Available at: www.accesstomedicineindex.org/Astellas

HQ	Tokyo, Japan	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Lower Respiratory Tract Infections, Asthma, Chronic Obstructive Pulmonary Disease, Diabetes Mellitus, Unipolar Depressive Disorder
Employees	13,666 (as of 30th of September 2009).		**Index Disease R&D Pipeline:** None
Revenues	2009: USD 10,236 million (JPY 974,87 billion) 2008: USD 10,428 million (JPY 965,6 billion)		



The grey bars represent industry average scores.

Leading Practices

No leading practice identified for this company.

Changes Compared to Index 2008

- ***Astellas*** was not evaluated in Access to Medicine Index 2008.
- ***Astellas*** has at least two philanthropic programs focusing on HIV and measles in Angola and Liberia. The company discloses the financial resources dedicated to these projects.

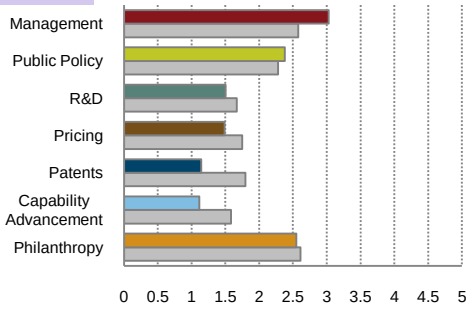
Suggested Areas for Improvement

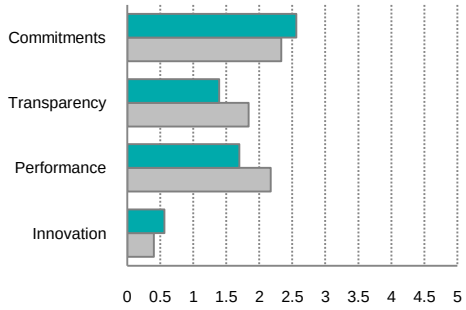
- ***Astellas*** is below average on ATM strategies, public reporting of policies, objectives & performance and formal representation of ATM issues at senior management level.
- The company has no R&D activities for neglected tropical diseases (NTDs), contrary to other Japanese companies such as ***Eisai.***
- ***Astellas*** has several products for non-communicable Index Diseases (e.g. diabetes, unipolar depressive disorder) in its portfolio, but no ATM initiatives aimed at more active registration and distribution of such products in the Index Countries.

BAYER AG

Full Company Profile Available at: www.accesstomedicineindex.org/Bayer

HQ	Leverkusen, Germany
Employees	Bayer AG: 108,400 (Bayer Healthcare: 53,400) as of December 31st, 2009
Revenues	Bayer AG: 2009: USD 44,6 million (EUR 31,168 million) 2008: USD 47,2 million (EUR 32,918 million) Bayer Healthcare: 2009: USD 22,9 million (EUR 16 million) 2008: USD 22,1 million (EUR 15,407 million)
Index Disease Focus	**Existing Index Disease Commercial Products:** Human African Trypanomiasis, Chagas, Schistomatosis, Malaria, Ischemic Heart Disease, Diabetes Mellitus, Neurological Index Diseases **Index Disease R&D Pipeline:** Tuberculosis





The grey bars represent industry average scores.

Leading Practices

- Drug donations to clinical trials, facilitated the approval of Nifurtimox-Eflornithine combination therapy for Sleeping Sickness in April 2009.
- ***Bayer*** has made a renewed five-year commitment to the WHO regarding its single-drug donation program for sleeping sickness and Chagas disease.

Changes Compared to Index 2008

- ***Bayer*** has made a renewed five-year commitment to the WHO regarding its single-drug donation program for sleeping sickness and Chagas disease.
- The company signed a collaborative agreement with USAID in September 2009 to ensure equitable pricing in 11 Index Countries for microgynon. For ranking, contraceptives are outside the disease scope of Index 2010.
- In 2008, ***Bayer*** implemented a new ATM strategy “Social Healthcare Programs” to place a greater emphasis on sustainability, on developing world needs and on Bayer’s areas of expertise.
- The company rolled out a new corporate compliance policy and systems plus a code for responsible lobbying during the period of analysis.
- There is evidence of new agreements with WHO to contribute to the strengthening of pharmacovigilance structures and capacity in India and China.
- ***Bayer*** continues its collaboration with the TB Alliance for clinical trial (in Phase III) of Moxifloxacin for drug-sensitive tuberculosis. There are provisions in the agreement for affordable delivery of the product in the developing world.
- During the period of analysis the company attempted to block the registration (obtaining marketing approval) of products by generics companies in an Indian court based on patent-registration linkage arguments. The company’s claim was rejected by the court.

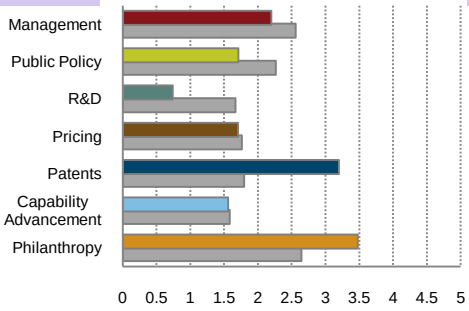
Suggested Areas for Improvement

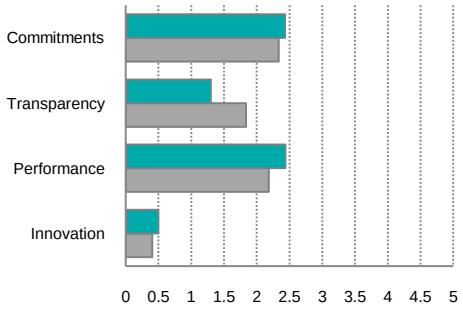
- ***Bayer*** has limited R&D activity for the neglected diseases compared to the leading companies under coverage.
- ***Bayer*** does not engage in non-exclusive voluntary licensing programs with generics companies.
- The company does not have short- and long-term, qualitative and quantitative targets, which would reflect the breadth of its current ATM practices and facilitate progress reporting.
- The company has limited public disclosure of program resources and output, advocacy activities, stance on patent-related issues (including TRIPS flexibilities) and post-trial access, which are all issues with potential ATM impact.

BOEHRINGER-INGELHEIM

Full Company Profile Available at: www.accesstomedicineindex.org/Boehringer-Ingelheim

HQ	Ingelheim, Germany
Employees	41,534 (as of 31 December, 2008)
Revenues	2009: USD 18,228 million (EUR 12,721 million) 2008: USD 16,614 million (EUR 11,595 million)
Index Disease Focus	**Existing Index Disease Commercial Products:** Ischemic Heart Disease, Chronic Obstructive Pulmonary Disease , HIV/AIDS **Index Disease R&D Pipeline:** HIV/AIDS





The grey bars represent industry average scores..

Leading Practices

- ***Boehringer-Ingelheim*** has established a non-assert declaration policy for its HIV/AIDS medication, Nevirapine (brand name Viramune), as an innovative option under voluntary licensing. Under this program non-exclusive royalty free voluntary licenses are offered to any WHO prequalified generic manufacturer and to date, six non-assert declarations have been issued and another six are in progress.
- ***Boehringer-Ingelheim*** has a stringent application and review (follow-up) process to ensure that donated products of its single-dose Nevirapine for the prevention of mother-to-child transmission (PMTCT) of HIV (Viramune Donation Program) reach target patients and are used appropriately.

Changes Compared to Index 2008

- ***Boehringer-Ingelheim*** was not evaluated in Access to Medicine Index 2008.
- In the area of research and development, ***Boehringer-Ingelheim*** is developing an extended release form of its HIV drug, Viramune® (Nevirapine), which is scheduled to be launched in 2010. Additionally, a pediatric version of its other antiretroviral (ARV), Aptivus® (Tipranavir), has been available since 2009.

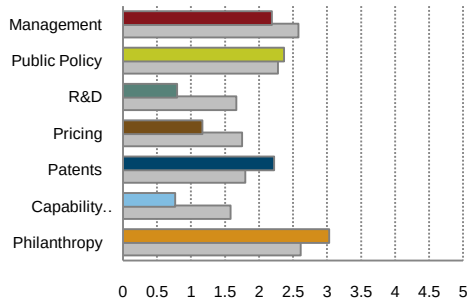
Suggested Areas for Improvement

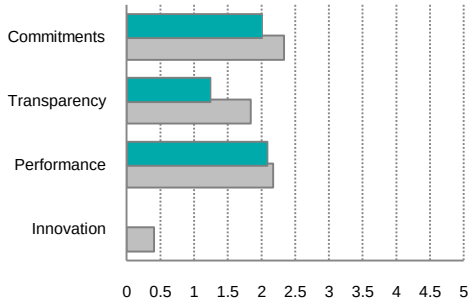
- ***Boehringer-Ingelheim*** provides little public disclosure across all technical areas, particularly on its ATM lobbying and advocacy activities (including public policy positions on key ATM issues), marketing and promotional programs in Index Countries as well as resource disclosure of ATM initiatives.
- ***Boehringer-Ingelheim*** does not have comprehensive ATM reporting, long-term or short-term targets at the project level.
- ***Boehringer-Ingelheim*** has limited R&D for Index Countries, either in-house or collaboratively.

BRISTOL-MYERS SQUIBB CO.

Full Company Profile Available at: www.accesstomedicineindex.org/Bristol-Myers-Squibb

HQ	New York, New York, USA	**Index Disease Focus**	**Existing Index Disease Commercial Products:** HIV/AIDS , Diabetes Mellitus
Employees	28,000 (as of 31 December, 2009)		**Index Disease R&D Pipeline:** HIV/AIDS
Revenues	2009: USD 20,555 million 2008: USD 19, 370 million		





The grey bars represent industry average scores.

Leading Practices

- ***Bristol-Myers Squibb*** accompanies its voluntary licensing activities with full technology transfer related to the manufacturing, testing, packaging and storage of the active pharmaceutical ingredient (API) in its second-line antiretroviral Reyatez.

Changes Compared to Index 2008

- Since Access to Medicine Index 2008 was published, ***Bristol-Myers Squibb*** has discontinued its project with Medicines for Malaria Venture (MMV) for its investigative anti-malarial candidate (protein franesyl-transferase inhibitors).
- As part of its flagship program 'Secure the Future', ***Bristol-Myers Squibb*** launched a technical assistance program in 2008, which provides technical assistance to governments and non-governmental organizations to increase support for HIV/AIDS care in seven African countries.
- During the period of analysis the company attempted to block the registration of its products by generics companies in India through the Indian courts based on patent-registration linkage arguments. The company's claim was rejected by the Indian court.

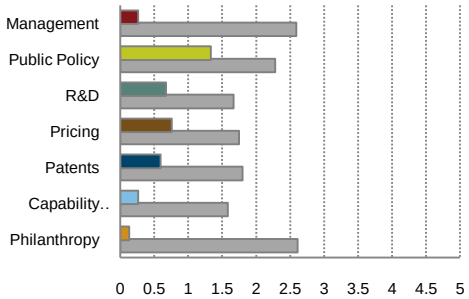
Suggested Areas for Improvement

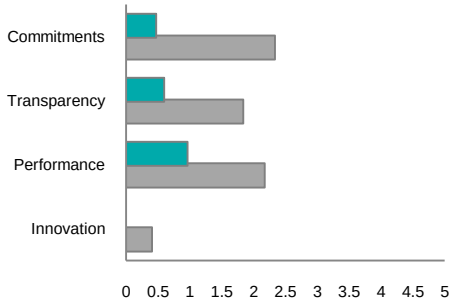
- ***Bristol-Myers Squibb*** is below average in the development and disclosure of its ATM program objectives and reporting on key performance indicators related to its ATM initiatives.
- ***Bristol-Myers Squibb*** does not disclose its financial contributions to third parties in the Index Countries; this limits its "Public Policy and Market Influence" performance.
- ***Bristol-Myers Squibb*** has low disclosure on areas such as channels (private and/or public) through which equitable pricing is offered and key performance measures such as number of doses sold within different price tiers.
- The company has little engagement in research collaborations such as product development partnerships (PDPs) for the Index Diseases (e.g. research for neglected tropical diseases). Its R&D focus is limited to HIV/AIDS.

DAIICHI-SANKYO CO. LTD

Full Company Profile Available at: www.accesstomedicineindex.org/Daiichi-Sankyo

HQ	Tokyo, Japan	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Diarrheal Diseases, Asthma, Chronic Obstructive Pulmonary Disease, Lower Respiratory Tract Infections, Tuberculosis
Employees	15,349		**Index Disease R&D Pipeline:** Tuberculosis
Revenues	2009: USD 10,314 million (JPY 955,09 billion) 2008: USD 9,505 million (JPY 880,120 million)		





The grey bars represent industry average scores.

Leading Practices

No leading practice identified for this company.

Changes Compared to Index 2008

- ***Daiichi Sankyo*** was not evaluated in Access to Medicine Index 2008.
- ***Daiichi Sankyo*** was actively involved in Ranbaxy's production quality improvement initiatives during the period of analysis.
- A range of philanthropic activities were introduced in Tanzania and other African countries during the period of analysis.

Suggested Areas for Improvement

- ***Daiichi Sankyo*** has no formal representation of ATM strategies at senior management level or annual reporting of policies, objectives and performance in this area.
- The company's R&D focus on Index Disease products, especially for NTDs, is lower than some other Japanese companies.
- ***Daiichi Sankyo*** has no intra-country tiered-pricing models in China, India and Thailand where its products are sold.
- The company's current disclosure on public policy positions in the Index Countries where it operates is low.
- ***Daiichi Sankyo***'s Index Country outreach for its existing two products relevant to the Index Diseases (an ischemic heart disease product and broad spectrum antibiotics) is lower than optimal, especially given ***Ranbaxy****'s manufacturing and distribution capacity.

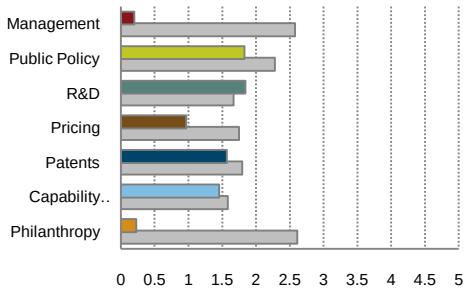
** **Ranbaxy**'s initiatives in this area are covered separately under the generics companies section of this report.*

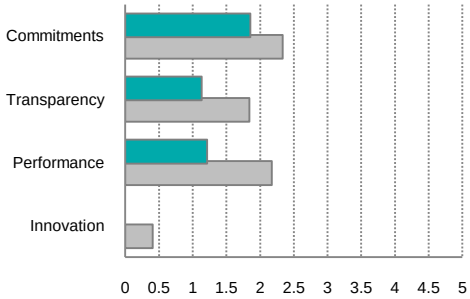
***Daiichi Sankyo** holds 63% of **Ranbaxy**'s shares.*

EISAI CO. LTD

Full Company Profile Available at: www.accesstomedicineindex.org/Eisai

HQ	Tokyo, Japan	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Epilepsy, Diabetes Mellitus **Index Disease R&D Pipeline:** Chagas Disease, Malaria
Employees	10,686 (as of 31 September, 2009)		
Revenues	2009: USD 8.442 billion (JPY 781.743 billion). 2008: USD 7.936 billion (JPY 734.286 billion)		





The grey bars represent industry average scores.

Leading Practices

- ***Eisai*** has dedicated a section of its new R&D center in India to Chagas disease and malaria. The company currently has two molecules for malaria and one for Chagas disease in its pipeline developed through collaborative research.
- ***Eisai*** has introduced an ATM Strategy in 2009 in which it disclosed ATM pricing policies based on affordability criteria, processes, standards, targets and has also defined the Index Countries covered by its program. This is a leading practice among the Japanese companies covered by Index 2010.

Changes Compared to Index 2008

- ***Eisai*** was not evaluated in Access to Medicine Index 2008.
- The company has stated that it plans to implement tiered pricing for an anti-epileptic product and has committed to implement tiered pricing for future Index Disease products especially for malaria and Chagas Disease.
- In 2008, the company launched research on malaria and Chagas disease.
- In 2009, the company significantly improved its ATM related policies and targets (please refer to the related leading practice).

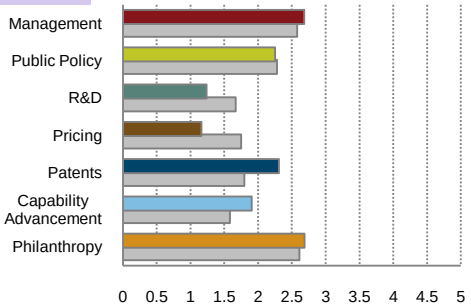
Suggested Areas for Improvement

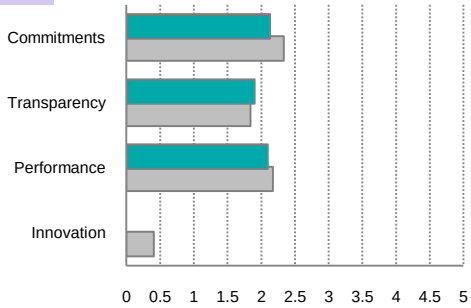
- The company has low public disclosure on public policy positions, lobbying activities and marketing activities in the Index Countries.
- Disclosure about existing ATM initiatives in areas such as resources dedicated and terms and conditions of collaborations is also low.
- ***Eisai*** is not transparent on the registration and patent status of Index Disease products in the Index Countries.

ELI LILLY & CO.

Full Company Profile Available at: www.accesstomedicineindex.org/Eli-Lilly

HQ	Indianapolis, Indiana, USA
Employees	40,360 (as of 31 December, 2009)
Revenues	2009: USD 21,836 million 2008: USD 20,372 million
Index Disease Focus	**Existing Index Disease Commercial Products:** Diabetes Mellitus, Ischemic Heart Disease, Unipolar Depressive Disorder, Tuberculosis **Index Disease R&D Pipeline:** Tuberculosis





The grey bars represent industry average scores.

Leading Practices

- ***Eli Lilly*** is recognized for its efforts in assisting local generic partners in Index Countries produce its (now off-patent) tuberculosis medicines and complying with Good Manufacturing Practices (GMP).
- ***Eli Lilly*** is one of the only companies in the sector that has established an equitable pricing scheme for its non-communicable Disease products. The company sells its diabetes product, Humulin (vials) to the public health system in Least Developed Countries (LDCs) at prices that do not exceed 20% of the average price in North America, Western Europe and Japan.

Changes Compared to Index 2008

- In November 2008, a shipment of Olanzapine (the generic version of Eli Lilly's treatment for schizophrenia, Zyprexa®) from Indian company Cipla was seized in the Netherlands on its way to Peru based on European intellectual property laws. The shipment was detained for about eight months based on company request.

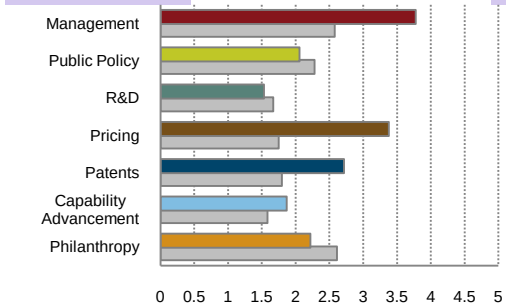
Suggested Areas for Improvement

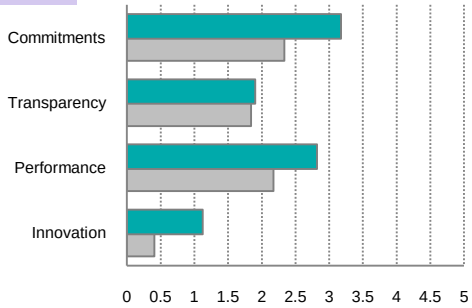
- ***Eli Lilly***'s ATM management system does not demonstrate comprehensive and systematic reporting of ATM initiatives, including the establishment of quantitative and qualitative targets at the project level.
- The company has limited in-house or collaborative R&D for Index Diseases other than tuberculosis.
- ***Eli Lilly*** has lower-than-average transparency on its ATM strategy in several areas, particularly registration data for Index Disease products in Index Countries, donation programs, lobbying and advocacy and marketing activities in, or related to, ATM in Index Countries and resources dedicated to and output information for all ATM activities.

GILEAD SCIENCES

Full Company Profile Available at: www.accesstomedicineindex.org/Gilead

HQ	Foster City, California, USA	**Index Disease Focus**	**Existing Index Diseases Commercial Products:** HIV/AIDS, Leishmaniasis, Ischemic Heart Disease **Index Disease R&D Pipeline:** HIV/AIDS
Employees	3,859 (as of January 31, 2010)		
Revenues	2009: USD 7,011 million 2008: USD 5,335.75 million		





The grey bars represent industry average scores.

Leading Practices

- ***Gilead*** has established an external advisory board, the Health Policy Advisory Board, as a platform for stakeholder engagement on ATM issues.
- The company has a high level of transparency in registration information for its HIV/AIDS medications, Viread and Truvada. It publicly discloses registration status at the country level.
- ***Gilead*** has established non-exclusive voluntary licensing agreements with 14 generics companies (13 in India and one in South Africa) for production of its HIV/AIDS products, covering a licensing territory of 95 developing countries including both least developed and developing countries.

Changes Compared to Index 2008

- Since Access to Medicine Index 2008 was published, ***Gilead***'s level of engagement and disclosure across all technical areas has increased.
- ***Gilead*** is developing two fixed-dose combinations (FDCs) for HIV/AIDS with Tibotec (a ***Johnson & Johnson*** subsidiary) and the "Quad", which combines four of Gilead's medicines).
- As of December 2009, ***Gilead***'s HIV/AIDS drugs, Viread and Truvada, were registered in 82 and 77 Access Program Countries, respectively, compared to Index 2008, where the two products were recorded as registered in 46 and 39 Access Program Countries, respectively (as of April 2008).
- In 2009, ***Gilead*** signed three new non-exclusive voluntary licensing agreements with Indian generics companies (Aptuit Laurus, Sequent and Cadila Healthcare) for production of its HIV/AIDS medicines.
- ***Gilead*** has begun monitoring and measuring the impact of its third-party generic licensees on ATM in areas such as number of patients receiving generic versions of ***Gilead***'s HIV medicines, price reductions, WHO prequalification and FDA tentative approvals received.
- In August 2009, the Indian Patent Office (IPO) rejected two patents sought by ***Gilead*** for Viread. The company has since filed an appeal. Rejection of the patent can have significant impact on the company's non-exclusive licensing practices.

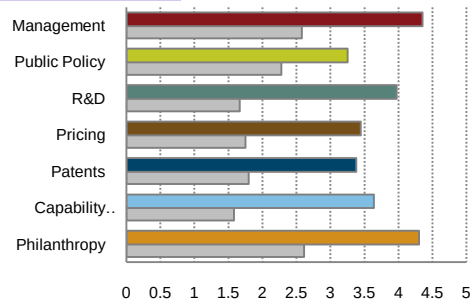
Suggested Areas for Improvement

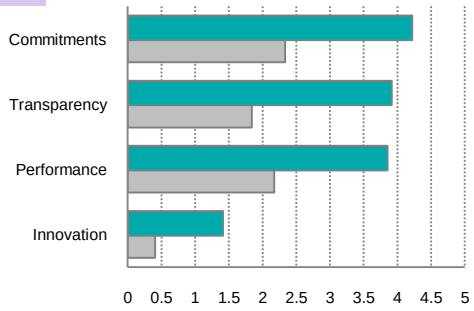
- While ***Gilead***'s transparency level has improved substantially since Index 2008, the company still has limited public disclosure in several areas, including ATM-relevant public policies (including the company's stance on specific competition practices), marketing and promotional activities in Index Countries.
- ***Gilead*** currently performs below average in collaborative research for Index Diseases compared to sector peers and its ATM related research scope is limited to HIV/AIDS.
- The company underperforms in capacity advancement in the Index Countries, compared to its performance in the other technical areas.

GLAXOSMITHKLINE PLC.

Full Company Profile Available at: www.accesstomedicineindex.org/GlaxoSmithKline

HQ	United Kingdom
Employees	99,003 (as of December 31st 2009)
Revenues	2009: USD 45, 810 million (GBP 28,368 million) 2008: USD 43,410 million (GBP 24,352 million).
Index Disease Focus	**Existing Index Disease Commercial Products:** HIV/AIDS, Malaria, Measles, Meningitis, Meningococcal Infection, Leishmaniasis (kala-azar), Diabetes Mellitus, Lymphatic Filariasis (elephantitis), Diarrheal Diseases, Ischemic Heart Disease, Lower Respiratory Diseases, Unipolar Depressive Disorders, Epilepsy. Plus multi-Index Disease vaccines i.e. Pertussis (Whooping Cough), Tetanus, Diphtheria **Index Disease R&D Pipeline:** Dengue, malaria, HIV, Meningitis, Diarrheal Diseases, Tuberculosis , Pneumonia, Multi-Index Disease Vaccines and early-stage research in: Leishmaniasis (Kala-azar), Chagas Disease, Human African Trypanosomiasis (Sleeping Sickness)





The grey bars represent industry average scores.

Leading Practices

- Significant price reduction of all patented products in LDCs, as no patented drug will be priced more than 25% of its price in the United Kingdom.
- Eight non-exclusive voluntary licensing agreements with local African manufacturers for HIV/AIDS products.
- The highest number of products in the research pipeline for the Index Diseases adjusted for company size.
- Numerous philanthropic programs aimed at improving the health infrastructure of Index Countries; in 2009 ***GlaxoSmithKline*** announced it will reinvest 20% of its profits in LDCs back into health infrastructure projects in these countries.
- The company has the highest number of single-drug donation programs in the sector.
- In November 2009, ***GlaxoSmithKline*** and ***Pfizer Inc***. launched ViiV Healthcare, a specialty HIV company; the new company is committed to a not-for-profit pricing strategy and non-exclusive voluntary licensing in sub-Saharan Africa to increase ATM. ***ViiV*** currently has seven HIV candidates in its pipeline, four of which were contributed by ***GlaxoSmithKline***.Changes Compared to Index 2008.

Changes Compared to Index 2008

- Since the release of the Access to Medicine Index 2008, ***GlaxoSmithKline*** has increased its intellectual property and molecules library sharing ; the company created a patent pool in April 2009 for Neglected Tropical Diseases (NTDs).
- The company has increased the scale and scope of its equitable pricing programs.
- In 2009, the company launched the HIV/AIDS focused company, ViiV, along with Pfizer.
- During the period of analysis, ***GlaxoSmithKline*** increased its level of engagement with the patent pool initiative of UNITAID for HIV medicines (through ***ViiV Healthcare***).

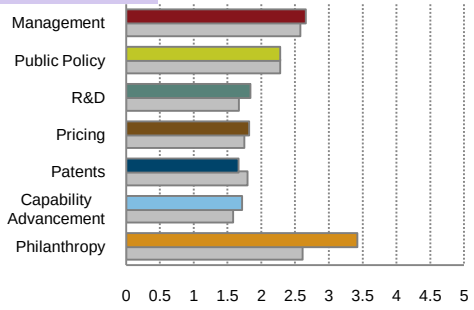
Suggested Areas for Improvement

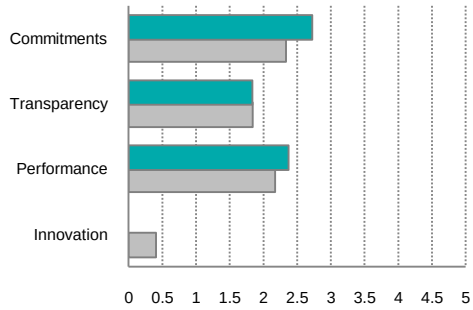
- ***GlaxoSmithKline***'s impact on ATM can be improved by expanding its voluntary licensing activities across Index Disease categories (outside of ARVs) and also in the Medium Human Development Countries.
- Most of ***GlaxoSmithKline***'s ATM initiatives do not include its non-communicable disease products.

JOHNSON & JOHNSON

Full Company Profile Available at: www.accesstomedicineindex.org/Johnson-Johnson

HQ	New Brunswick, NJ, USA	**Index Disease Focus**	**Existing Index Disease Commercial Products:** HIV/AIDS, Soil-transmitted Helminthiasis, Diabetes Mellitus, Epilepsy
Employees	115,500 (as of December 31, 2009)		**Index Disease R&D Pipeline:** HIV/AIDS, Tuberculosis, Measles
Revenues	2009: USD 61,897 million 2008: USD 63,747 million		





The grey bars represent industry average scores.

Leading Practices

- ***Johnson & Johnson*** has a long-term program (established in 2004) through the ***Johnson & Johnson*** Healthcare Training Fund that provides pharmaceutical supply chain management training for HIV/AIDS medicines to increase the local supply chain capabilities in the Index Countries.
- Since Access to Medicine Index 2008 was released, ***Johnson & Johnson*** has entered into a licensing and commercialization agreement with ***Gilead Sciences, Inc***. for the development of a novel fixed-dose combination (FDC) for HIV; the FDC consists of ***Johnson & Johnson***'s TMC278 and ***Gilead***'s Truvada and would be the first FDC that contains an antiretroviral from ***Johnson & Johnson***.

Changes Compared to Index 2008

- During the period of analysis, ***Johnson & Johnson*** entered into discussions with UNITAID about its patent pool; ***Johnson & Johnson***'s high level of engagement and dialogue with the patent pool initiative of UNITAID is considered a best practice across the sector (among companies with relevant product portfolio).
- In June 2009, ***Johnson & Johnson*** granted the Global Alliance for TB Drug Development a royalty-free license for the development of Tibotec Pharmaceutical's investigative candidate TMC-207, a novel anti-tuberculosis compound for drug sensitive tuberculosis. In addition, ***Johnson & Johnson /Tibotec*** are carrying out clinical trials for the same molecule for MDR-TB.
- In addition to its innovative R&D activities for tuberculosis, ***Johnson & Johnson*** has launched R&D for a heat-stable measles vaccine.

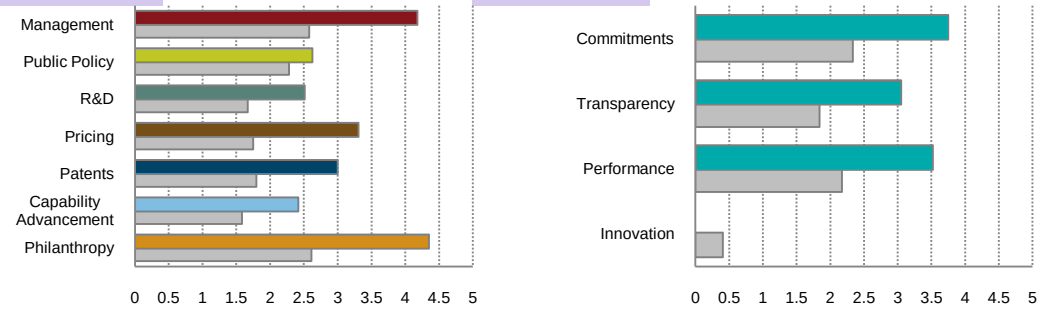
Suggested Areas for Improvement

- The company's disclosure of its pricing approach for its HIV medicine PREZISTA in middle-income countries is low. ***Johnson & Johnson***'s disclosed pricing model for PREZISTA only applies to least-developed countries and sub-Saharan Africa. Pricing for middle-income countries is negotiated on a case-by-case basis.
- ***Johnson & Johnson***'s overall ATM management system lacks time-bound, quantitative, short term ATM-related goals in addition, ***Johnson & Johnson***'s transparency on its financial contributions to third parties in the Index Countries is low.
- As many of its peers, ***Johnson & Johnson*** does not outline its public policy stance on ATM related issues such as patent extensions in Index Countries and data exclusivity.

MERCK & CO. INC.

Full Company Profile Available at: www.accesstomedicineindex.org/Merck

HQ	Whitehouse Station, New Jersey, USA	**Index Disease Focus**	**Existing Index Disease Commercial Products:** HIV/AIDS, Lower Respiratory Tract Infections, Diabetes Mellitus, Measles, Onchoceriasis, Diarrheal Diseases **Index Disease R&D Pipeline:** HIV/AIDS, Diarrheal Diseases
Employees	100,000 (as of 31 December, 2009)		
Revenues	2009: USD 27,428 million; 2008: USD 23,850 million		



The grey bars represent industry average scores.

Leading Practices

- ***Merck & Co. Inc***'s (***Merck & Co.***) extensive engagement in research collaborations for the Index Diseases during 2008 and 2009 is considered a leading practice across the sector.
- ***Merck & Co.*** has issued five non-exclusive voluntary licenses to local African generics companies.
- ***Merck & Co.*** has a transparent inter-country tiered pricing strategy for its four ARVs and vaccines; ***Merck & Co.*** accompanies this with broad registration of its products in the Index Countries.
- ***Merck & Co.*** has single-drug donation programs for four diseases. The company ensures that donated medicines reach intended recipients by requiring a certificate of receipt by the in-country organization.

Changes Compared to Index 2008

- Since Access to Medicine Index 2008 was published, ***Merck & Co.*** has significantly expanded the scale and scope of its research collaborations for Index Diseases.
- In November 2009, ***Merck & Co.*** launched MSD-Wellcome Trust Hilleman Laboratories with the aim of developing affordable vaccines; future objectives include the development of heat-stable vaccines.
- ***Merck & Co.***'s Rotateq vaccine program in Nicaragua was hailed as a public health success by the Bill and Melinda Gates Foundation 'Living Proof Project'. Approximately 81% of Nicaraguan infants were vaccinated with Merck's Rotateq vaccine in 2008.
- During the period of analysis, ***Merck & Co.*** entered into high level discussions with UNITAID patent pool;
- ***Merck & Co***. is one of the few Index 2010 companies currently carrying out discovery research for dengue and meningitis.
- In December 2008, Dutch customs authorities seized a shipment of a generic version of Losartan, ***Merck & Co***.'s antihypertensive medicine, as the ship was going through the Netherlands to Brazil where Merck has no patent rights for the drug. Based on company requests, the shipment was detained and then returned to India. Since, Merck has committed to prevent recurrence of such events.

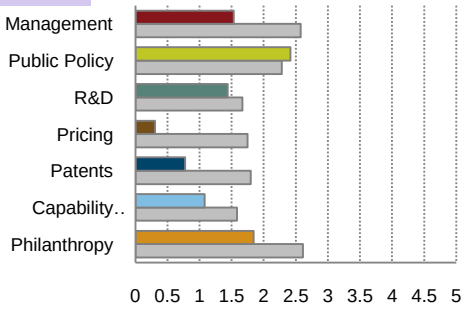
Suggested Areas for Improvement

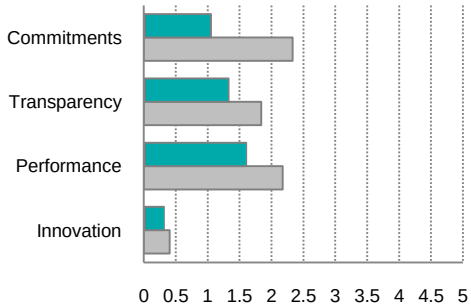
- Currently, the license territory of the voluntary licenses issued by ***Merck & Co.*** is limited to the sub-Saharan Africa. While non-exclusive voluntary licensing is a leading practice in the sector, the license territory for the company's licenses is smaller than most other companies with similar activities.
- ***Merck & Co.*** has less involvement in capacity advancement activities such as research collaborations with Index country institutions and supply chain management capacity building in the Index Countries.
- ***Merck & Co.*** 'does not publicly disclose its position on patent-related issues such as TRIPS+, patent extensions in Index Countries and TRIPS "flexibilities" such as parallel importation etc.
- The company's current access program does not cover its non-communicable disease products.

MERCK KGAA

Full Company Profile Available at: www.accesstomedicineindex.org/Merck-KGaA

HQ	Darmstadt, Germany (Merck-Serono: Geneva, Switzerland)	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Helminth Infections, Malaria, Ischemic Heart Disease and Respiratory Diseases **Index Disease R&D Pipeline:** Basic and early stage research occurring in Malaria, Shistosomiasis and Human African Trypanomiasis.
Employees	Merck KGaA: 33,062 (Merck Serono: approx. 17,500) as of 31 December, 2009		
Revenues	2009: USD 8,328 million(EUR 5,812 million) 2010: USD 7,818 million (EUR 5,456 million)		





The grey bars represent industry average scores.

Leading Practices

- ***Merck KGaA*** has a comprehensive approach to addressing the challenges of counterfeit products, which includes the introduction of new packaging technologies, an internal working group on the issue and a partnership with Global Pharma Health Fund e.V (GPHF) regarding the development and distribution of miniature quality testing laboratories (Minilab®) for product quality check in the Index Countries.
- The company has early stage research for three neglected diseases which is a sign of recent increased research focus in these areas.

Changes Compared to Index 2008

- Expansion of the resources dedicated to their in-house ("Medicinal Chemistry Workstation") collaboration with WHO-TDR to undertake R&D into malaria, Sleeping Sickness and Shistosomiasis.
- The molecule detection capability of the GPHF-Minilab® has been expanded since Index 2008 and can now identify the authenticity of about 43 products.
- ***Merck KGaA*** implemented the Merck–Praziquantel Donation Program (MPDP) as part of a 10-year agreement with WHO. The contract was signed in 2007.

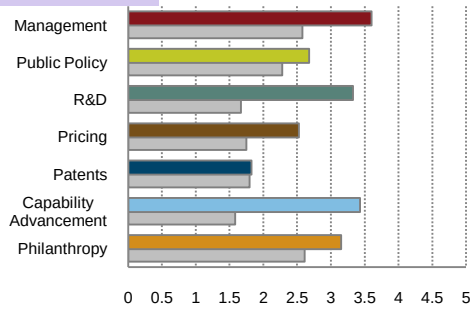
Suggested Areas for Improvement

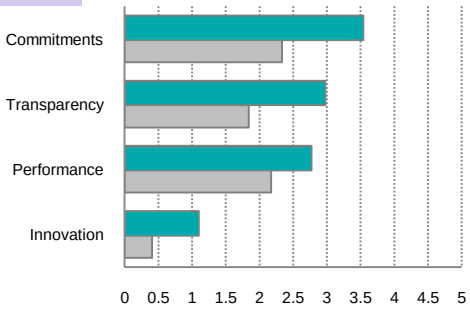
- Disclosure of the company's public policy positions relevant to ATM in areas such as competition practices, stance on TRIPS flexibilities etc. is lower than average.
- The company does not implement equitable pricing approaches or non-exclusive voluntary licenses for its Index Disease-relevant products despite its commitment to 'consideration of the lower purchasing power' in Index Countries.
- ***Merck KGaA***'s ATM management systems are below average because of its lacks of a dedicated ATM committee and low disclosure of its ATM business rationale and targets.

NOVARTIS AG

Full Company Profile Available at: www.accesstomedicineindex.org/Novartis

HQ	Basel, Switzerland	**Index Disease Focus**	**Existing Index Disease Commercial Products:** malaria, tuberculosis, Tetanus, Fascioliasis, Leprosy, Diarrheal Diseases, Meningitis, Lower Respiratory Tract Infections (LRTI's), Ischemic Heart Disease, Diabetes Mellitus, Unipolar Depressive Disorder, Lower Respiratory Tract Infections **Index Disease R&D Pipeline:** Tuberculosis, Malaria, Dengue, Lower Respiratory Tract Infections, Diarrheal Diseases, Meningitis, HIV, plus basic and early-stage research occurring in Malaria, Schistosomiasis, Human African Trypanomiasis, Dengue and Tuberculosis
Employees	99,834 as of 31 December, 2009 (23,423 in Sandoz Division).		
Revenues	2009: USD 44,267 million 2008: USD 41,459 million		





The grey bars represent industry average scores.

Leading Practices

- ***Novartis*** is active in discover' and early-stage R&D for new therapies for Index Diseases, including five priority Index Communicable diseases and was awarded the Medicine for Malaria (MMV) product of the year award 2009 for its Spirondolone anti-malarial.
- The company has one of the most comprehensive vaccine development programs, covering five communicable Index Diseases.
- ***Novartis*** is supporting Index Countries' local capacity for R&D through contributions to academic education programs and R&D collaborations with Index Country institutions.
- The company is among the highest performing companies in adopting innovative approaches to ATM challenges, such as its involvement in the "SMS for Life" initiative which uses mobile phones to report on inventory problems.
- ***Novartis*** has adopted innovative approaches to product packaging. Novartis was awarded the Healthcare Compliance in Packaging Council Award in 2009 for Coartem®, which was developed in consultation with Index Country populations.
- Through its subsidiary ***Sandoz***, the company has a strong long-term commitment to single-drug donation programs for leprosy and fascioliasis

Changes Compared to Index 2008

- ***Novartis*** has fulfilled some earlier commitments including the launch of a dispersible anti-malarial (Coartem®) and inauguration of the Novartis Vaccines Institute for Global Health (NVGH) dedicated to vaccine development for the developing world.
- The company has improved the breadth of disclosure of its public policy positions related to ATM in Index Countries.
- It has also provided price concessions acceptable to Thailand's Ministry of Health as an alternative to compulsory licenses issued for Glivec in 2008.

- Changes have been made to the Glivec donation program (GIPAP), which now has a co-payment-based equitable pricing program. The new approach is a financially sustainable model in contrast to donations.
- A shipment of the generic version of the company's product rivastigmine was seized in Netherland en route to Peru based on EU intellectual property laws. The shipment was detained for 5 months based on company request before being released for delivery.

Suggested Areas for Improvement

- ***Novartis*** does not extensively disclose the terms and conditions of its R&D Index Disease collaborations in areas such as pricing for the developed drugs across different geographical regions and supply channels.
- ***Novartis*** only uses equitable pricing approaches across a narrow range of countries and products.
- The company is not currently engaged in any non-exclusive voluntary licensing activity in the Index Countries.

NOVO NORDISK A/S

Full Company Profile Available at: www.accesstomedicineindex.org/Novo-Nordisk

HQ	Bagsværd, Denmark
Employees	29,329 (as of 31 December, 2009)
Revenues	2009: USD 7,212 million (DKK 37,502); 2008: USD 6,414 million (DKK 33,356 million)

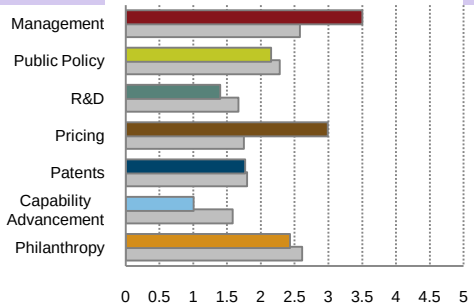
Index Disease Focus

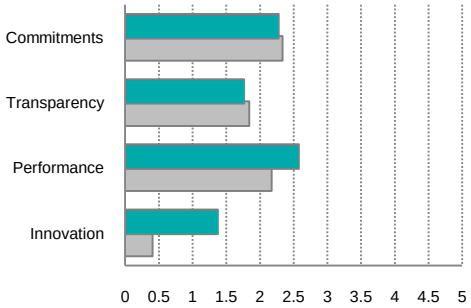
Existing Index Disease Commercial Products: Diabetes Mellitus (modern insulin; human insulin; protein-related products; oral anti-diabetic agents; devices [and other accessories]).

Biopharmaceuticals are currently out of Index Disease scope

Index Disease R&D Pipeline:

None





The grey bars represent industry average scores.

Leading Practices

- ***Novo Nordisk*** is among the highest performing companies in the area of innovative approaches to addressing ATM challenges.
- The company's ATM program priorities are determined by and developed in close collaboration with global health institutions.
- The company continues to expand the breadth of its equitable pricing programs for diabetes and has implemented 'pilot' schemes to ensure the equitable prices are passed on to patients.
- ***Novo Nordisk*** has undertaken significant activities through the "Changing Diabetes" umbrella and its World Diabetes Foundation, both of which aim at the "prevention and treatment of diabetes worldwide".

Changes Compared to Index 2008

- ***Novo Nordisk***'s "Changing Global Access to Diabetes Care" strategy was implemented in 2008 with the aim of making the company's diabetes related access programs more sustainable, global and affordable
- In April 2008, the company donated a license for its small molecule compound library for NTD screening to an Index Country institution, the National Center for Drug Screening (NCDS), at the Chinese Academy of Sciences. It does not hold patent rights on any product developed from the library.
- The firm has a partnership with the Danish Institute of Human Rights and Transparency International to develop a new methodology for supply chain mapping in the Index Countries.

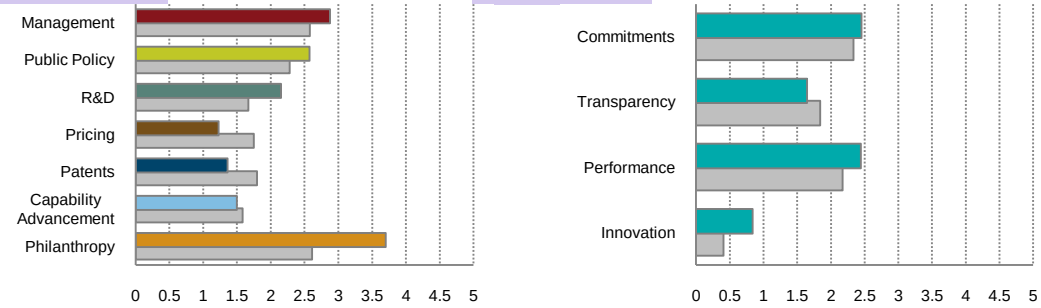
Suggested Areas for Improvement

- The company does not undertake adaptive R&D to address specific needs of populations living in Index Countries, e.g. heat-stable products, simple delivery devices, or Fixed Dose Combinations (FDCs).
- The company makes little disclosure on its intra-country tiered pricing programs that target specific groups (migrants, children and the poor).
- The company has limited activities aimed at increasing local capacity in the Index Countries.

PFIZER INC.

Full Company Profile Available at: www.accesstomedicineindex.org/Pfizer

HQ	New York, United States	**Index Disease Focus**	**Existing Index Disease Commercial Products:** HIV/AIDS, Trachoma, Soil Transmitted Helminthiasis, Malaria, Lower Respiratory Tract Infections, Meningitis, Epilepsy, Tuberculosis
Employees	116,500 (as of December 31, 2009)		**Index Disease R&D Pipeline:** Tuberculosis, HIV/AIDS, Malaria, Onchocerciasis (originally Wyeth)
Revenues	2009: USD 50,009 million; 2008: USD 48,296 million		



The grey bars represent industry average scores.

Leading Practices

- The company's rapid expansion of research collaborations for Index Diseases is a leading practice in the sector. In 2008, ***Pfizer*** signed a license agreement with IPM for development of an HIV microbicide an agreement with Medicines for Malaria Venture (MMV) to have ***Pfizer***'s chemical library screened for malaria treatments and an agreement with Drugs for Neglected Diseases Initiative (DNDi) to facilitate research efforts into sleeping sickness, visceral leishmaniasis (VL) and chagas disease.
- The company has above-average engagement in single-drug donation programs through the International Trachoma Initiative (ITI) for trachoma and the Diflucan Partnership Program (DPP) for cryptococcal meningitis and esophageal candidiasis.
- In November 2009, ***Pfizer*** (along with ***GlaxoSmithKline***) launched ***ViiV Healthcare***, essentially pooling ***Pfizer***'s and ***GlaxoSmithKline***'s HIV/AIDs medicines portfolio; the new company is committed to a not-for-profit pricing strategy and non-exclusive voluntary licensing in sub-Saharan Africa to increase ATM. ***ViiV*** currently has seven HIV candidates in its pipeline, three of which were contributed by ***Pfizer***.

Changes Compared to Index 2008

- Since the Access to Medicine Index 2008, the company has significantly expanded its research collaborations for Index Diseases.
- In April 2008, ***Pfizer*** restructured its ATM strategy to further prioritize this area through its Emerging Markets business unit; this was accomplished through extensive stakeholder outreach and feedback.
- In August 2009, ***Pfizer*** announced a partnership with the Clinton Foundation's HIV/AIDS Initiative (CHAI) to significantly reduce pricing for Rifabutin.
- During the period of analysis, ***Pfizer*** increased its level of engagement with the patent pool initiative of UNITAID for HIV medicines (through ***ViiV Healthcare***).

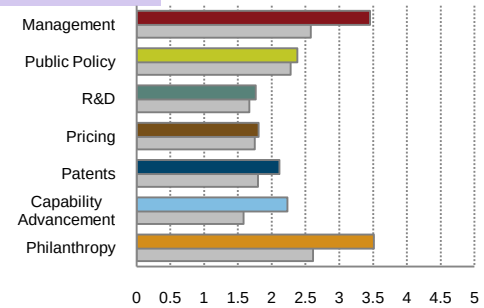
Suggested Areas for Improvement

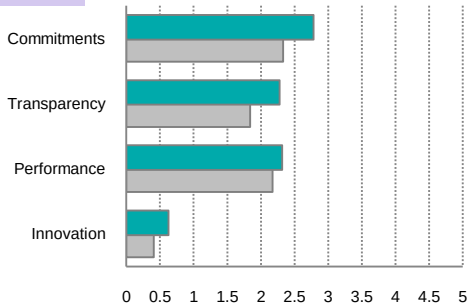
- ***Pfizer*** does not have a tiered pricing strategy for its Index Disease-related medicines in the Index Countries; currently it has not implemented a pricing approach that addresses affordability.
- ***Pfizer*** does not issue non-exclusive voluntary licenses for Index Disease-related medicines Index Country.
- ***Pfizer*** does not outline clear future objectives and short-term targets for its ATM program.

ROCHE HOLDINGS LTD

Full Company Profile Available at: www.accesstomedicineindex.org/Roche

HQ	Basel, Switzerland	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Diabetes Mellitus, Epilepsy, HIV/AIDS, Ischemic Heart Disease, Malaria, Osteoarthritis, Tuberculosis
Employees	81,507 (as December 31, 2009).		**Index Disease R&D Pipeline:** HIV/AIDS and Tuberculosis (Diagnostics)
Revenues	2009: USD 47,457 million (CHF 49,051 million) 2008: USD 44,1342,858.16 million (CHF 45,617 million)		





The grey bars represent industry average scores.

Leading Practices

- ***Roche*** has clearly defined public policy positions on several important ATM topics, including clinical trial conduct in developing countries, pricing, donations, counterfeiting, working with government officials and patient groups and patenting practices in Index Countries.
- Through its AIDS Technology Transfer Initiative, ***Roche*** provides local manufacturers in LDCs and Sub-Saharan Africa with the technical know-how to produce high-quality generic versions of its second-line anti-retroviral (ARV) Saquinavir for use in those countries; it also offers training on Good Manufacturing Practices (GMP); to date, 13 technology transfer agreements with local partners in five countries (South Africa, Ethiopia, Zimbabwe, Tanzania and Bangladesh) have been signed.

Changes Compared to Index 2008

- Since Access to Medicine Index 2008 was published, ***Roche*** has entered into research collaboration with the Institute for OneWorld Health (iOWH) to explore potential new treatments for diarrheal diseases in infants and young children in developing countries. The company has opened up its compound library of over 780,000 molecules for this partnership.
- ***Roche*** has begun integrating more objectives and goals for its ATM projects, including a select number of short-term targets for the coming business cycle.
- In 2008, ***Roche*** discontinued its HIV/AIDS R&D program; as a result, the company no longer has any in-house pharmaceutical research activity in HIV/AIDS or neglected diseases.

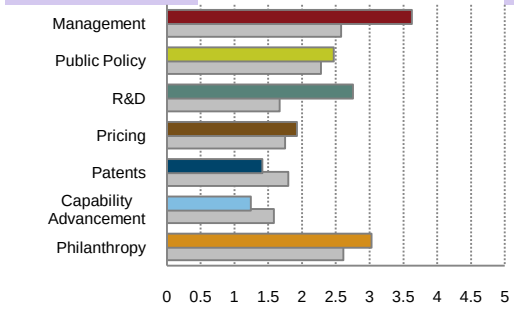
Suggested Areas for Improvement

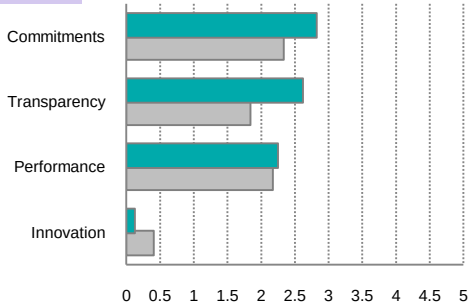
- ***Roche*** provides a low level of information on its R&D activities and equitable pricing approach for diagnostics relevant to Index Diseases and Index Countries.
- The company has below average activities in intra and inter-country pricing for Index Countries for its Index Disease products.
- The company has low levels of disclosure of lobbying and advocacy activities and marketing and promotional programs specifically in Index Countries.

SANOFI-AVENTIS

Full Company Profile Available at: www.accesstomedicineindex.org/Sanofi-Aventis

HQ	Paris, France	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Malaria, Tuberculosis , Meningitis, Lower Respiratory Tract Infections , Tetanus, Human African Trypanomiasis, Leishmaniasis, Diarrheal Diseases, Ischemic Heart Disease and Diabetes Mellitus and multi-disease vaccines **Index Disease R&D Pipeline:** Malaria, Lower Respiratory Tract Infections, Diarrheal Diseases, Meningitis, Dengue, HIV/AIDS and Tuberculosis - basic and discovery stage research occurring in Malaria, Tuberculosis, Human African Trypanomiasis and Leishmaniasis
Employees	104,867 (as of 31 December 2009)		
Revenues	2009: USD 20,452 million (EUR 29,306 million) 2008: USD 19,239 million (EUR 27,568 million)		





The grey bars represent industry average scores.

Leading Practices

- ***Sanofi-Aventis*** has instituted rapid registration programs in a large number of Index Countries in need and also instituted equitable pricing mechanisms for its 2007 anti-malarial (ASAQ) drug.
- Compared to peers, the company has one of the largest numbers of products in its R&D pipeline focused on communicable Index Diseases.
- ***Sanofi-Aventis*** is continuing one of the largest ever Phase IV trials (expected to enroll over 20,000 patients) in sub-Saharan Africa for ASAQ, with a stated objective of facilitating the strengthening of local pharmacovigilance infrastructures.

Changes Compared to Index 2008

- The company terminated the intra-country pricing initiative the “Anti-malarial Drug Access Card (CAP)” due to “administrative complexities” In six countries and over four years, the program had reached over 80,000 patients. The company states that it will instead deliver its malaria medicine through the Global Fund’s ‘Affordable Medicine Facility – malaria (AMFm)’.
- Since the release of Access to Medicine Index 2008, ***Sanofi-Aventis*** has continued to improve its ATM transparency with significant progress in disclosing comprehensive future ATM program targets and public policy positions relevant to ATM.
- The company was involved in one of the cases of seizure of generic drugs in the Netherlands based on the European intellectual property rules. The shipment of the product which is patented in the Netherlands by Sanofi-Aventis was detained based on company’s request and released after a few months.

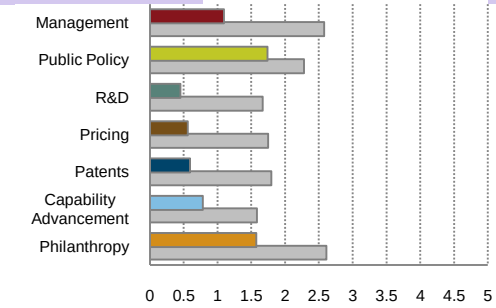
Suggested Areas for Improvement

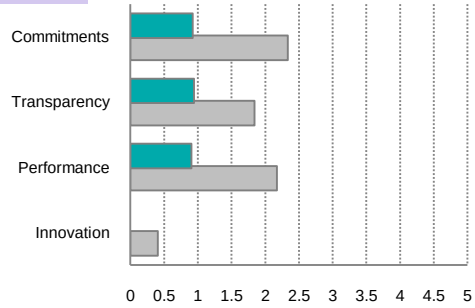
- The company makes no specific commitments or disclosure on quality management and capability advancement in the Index Countries, despite its expanding (20 to 25 sites) Index Country operations.
- The company has exhibited low transparency on the terms and conditions of its R&D collaborations in areas such as pricing for the products it has developed, across different geographies and supply channels.
- The company does not undertake any non-exclusive voluntary licensing activity.

TAKEDA PHARMACEUTICAL CO. LTD

Full Company Profile Available at: www.accesstomedicineindex.org/Takeda

HQ	Osaka, Japan	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Diabetes Mellitus **Index Disease R&D Pipeline:** Meningitis, Pertussis, Tetanus ; (combined vaccine for the three diseases)
Employees	15,717 (as of 31 September, 2009)		
Revenues	2009: USD 1,599 million (JPY 1,465 billion) 2008: USD 1,678 million (JPY 1,538 billion)		





The grey bars represent industry average scores.

Leading Practices

- The company has made efforts in local capacity advancement in Africa through financial support of Global Fund programs in this area.

Changes Compared to Index 2008

- ***Takeda*** was not evaluated by Index 2008.
- The company introduced technology transfer programs and quality checks for licensees in Jordan and Pakistan in 2007 and expanded them during the period of analysis.

Suggested Areas for Improvement

- ***Takeda***'s ATM strategies are not integrated into its business strategy and there is no senior management representation for ATM initiatives.
- The company commits to tiered pricing in the six Index Countries where it operates, without any indications that the company is putting it into practice.
- No R&D for Index Diseases targeting specific Index Country needs.
- The company has several non-communicable disease products relevant to Index Country needs but no Index Country access programs for such products.

RANKINGS BY TECHNICAL AREA

IN THIS SECTION

GENERAL ACCESS TO MEDICINE MANAGEMENT

As with any other company strategy, ATM policies and objectives need to be backed by a strong governance platform and management system in order to be translated into practice*. And as medicine delivery cannot happen in isolation, companies need to maintain positive dialogue with all stakeholder groups to achieve their ATM goals. Within this technical area, there are three important “drivers of access”: governance, ATM management systems and stakeholder engagement.

* OECD (2004). “OECD Principles of Corporate Governance" .http://www.oecd.org/dataoecd/32/18/31557724.pdf

WHAT WE MEASURE

Governance: A clear chain of accountability is essential to any corporate decision-making process. Board-level representation of ATM issues and having independent advisory boards focusing on ATM issues are considered best practices in this area.

ATM Management Systems: Index 2010 analyzes companies based on the clarity and comprehensiveness of their ATM management systems, whether they set specific ATM targets and whether they periodically measure their output and performance.

Stakeholder Engagement: Under this sub-area, Index 2010 evaluates companies’ efforts to engage with all relevant stakeholders, including universities, patient groups, local governments, employees, local and international NGOs and peers in order to establish dialogue and knowledge sharing with the goal of improving ATM.

HOW WE MEASURE

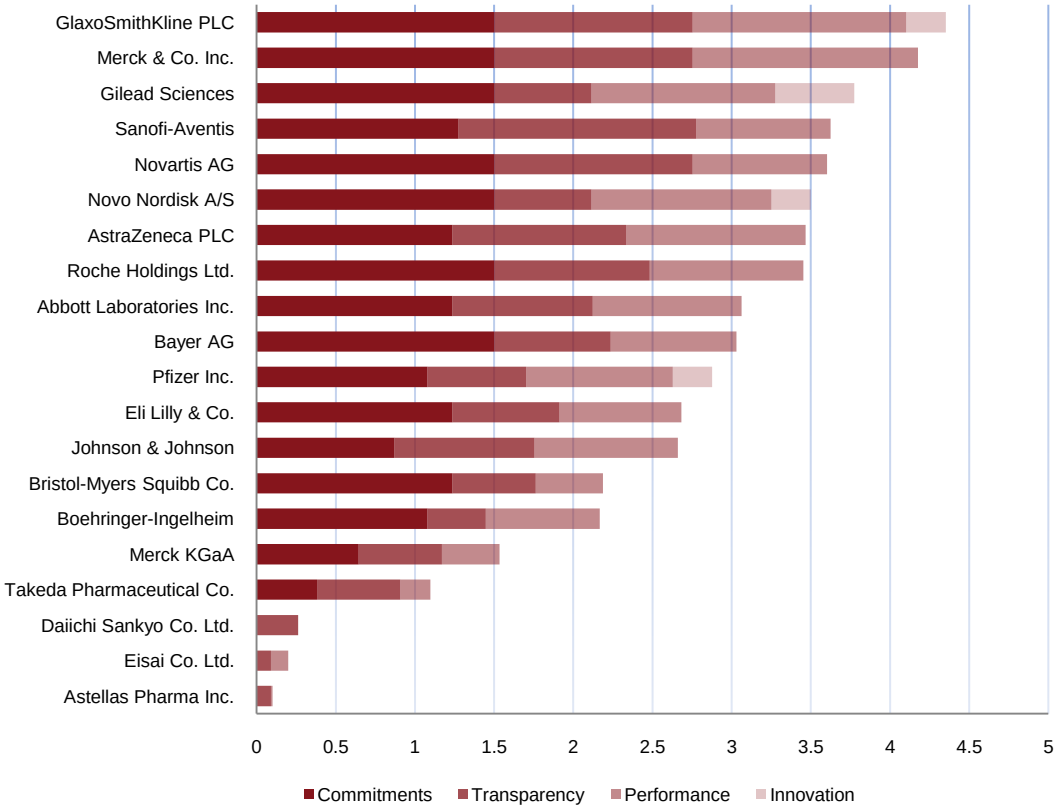
Indicators in this technical area include board-level representation as well as the existence of an ATM-specific management system which outlines detailed quantitative and qualitative targets. As part of this management system, companies are also rated on the quality and contents of their public annual ATM reporting. As a measure of companies’ stakeholder engagement, we assess the number of

multi-stakeholder ATM-related conferences the companies have sponsored/organized, during the period of analysis. For further information please refer Appendix D, Indicators and Scoring Guidelines.

Sources: The company analysis in this area is mostly based on companies' public disclosure, interview with companies' representatives and also the companies' response to our questionnaire.

COMPANY RANKINGS – GENERAL ATM MANAGEMENT

Figure 8. Originator Company Ranking - General ATM Management



The leading companies in this technical area are ***GlaxoSmithKline***, ***Merck & Co***. and ***Gilead***. All three companies have clear access to medicine (ATM) strategies that are grounded in a sustainable business rationale, demonstrate strong commitments in stakeholder engagement and have comprehensive management systems dedicated to managing their ATM activities.

Compared to Index 2008, two companies that have significantly improved are ***Gilead*** (13th to 3rd), ***Merck & Co***. (5th to 2nd) and ***Pfizer*** (14th to 11th). Since the last Index, ***Gilead*** has more clearly articulated its ATM strategy (embodied in its International Access Program), which has provided for a better understanding of its ATM management systems and governance structure. Additionally, the company has begun measuring the impact of its generic licensees on access by monitoring, among other items, the number of patients receiving generic versions of its medicines in developing countries. It has also established an

external advisory board as a platform for stakeholder engagement on ATM issues. All of these are considered innovations in the sector under this technical area.

Merck & Co. has sponsored and participated in a large number of ATM related conferences during the period of analysis, reports past performance and future targets for its ATM initiatives and has introduced a board committee focusing on "improving access to medicines, vaccines, and health care".

Pfizer, the company has organized and sponsored a number of conferences during the period of analysis aimed at promoting dialog on ATM in Index Countries. Additionally, the company entered into new partnerships with microfinance organizations such as PlaNet Finance. The goal of this work is to better understand barriers to access in resource-limited settings and in turn, tailor ATM strategies for these areas.

Three of the companies that have decreased significantly in ranking compared to Index 2008 are ***Merck KGaA*** (10th to 16th), ***Johnson & Johnson*** (J&J) (9th to 13th), ***AstraZeneca*** (3rd to 7th) and ***Novo Nordisk*** (2nd to 6th).

In the case of ***Merck KGaA***, this decrease is attributed to below-average practices across all strategic pillars. In particular, the company's short term target setting at the ATM project level is limited compared to sector peers and the company does not appear to have fully established a management system specific for its ATM efforts. Also, ***Merck KGaA's*** reporting on ATM is only bi-annual and the company has yet to articulate a clear business rationale behind its ATM strategy.

AstraZeneca and ***Novo Nordisk*** both have been overtaken by other companies which have expanded their stakeholder engagement initiatives improved their periodic ATM reporting and targets.

Johnson & Jonhson's decrease in rank is also due to the absence of a clear business case supporting its ATM approach and a lack of improvement in transparency or quantitative target-setting for its ATM activities since Index 2008.

Takeda is the leading Japanese company in this technical area. Although its efforts are largely philanthropic, the company has begun reporting on the implementation and progress of its ATM program.

OVERVIEW OF KEY METRICS

Table 7. Originator Company Practices - General ATM Management

		Abbott (ABT-N)	AstraZeneca (AZN-LN)	Bayer (BAY-FF)	Bristol-Myers Squibb (BMY-N)	Eli Lilly (LLY-N)	Gilead (GILD-O)	GlaxoSmithKline (GSK-LN)	Johnson & Johnson (JNJ-N)	Merck (MRK-N)	Merck KGaA (MRK-FF)	Novartis (NOVN-VX)	Novo Nordisk (NOVO'B-KO)	Pfizer (PFE-N)	Roche (ROG-VX)	Sanofi-Aventis (SAN-FR)	Astellas (4503-TO)	Daiichi Sankyo (4568-TO)	Eisai (4523-TO)	Takeda (4502-TO)	Boehringer-Ingelheim
Governance	Board Level Oversight of ATM	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes
ATM Management Systems	Publicly Disclosed, Time-bounded Quantitative Targets*	No	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No
	Annual Reporting on ATM	Policies	Policies	Policies and Objectives***	Policies	Not Annual	Policies	Policies and Objectives***	Policies	Policies and Objectives***	Not Annual	Policies and Objectives***	Policies	Not Annual	Policies and Objectives***	Policies and Objectives***	None	None	None	Policies	Policies
Stakeholder Engagement	Existence of Clear Strategy and Platform for Stakeholder Engagement **	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	No	No	No	Yes

*For one or more ATM initiative.

**Yes= Dedicated team and planning for stakeholder outreach No=None

*** Objectives: short term – time bound and measureable

ATM Governance: While for some companies in the sector, ATM in Index Countries still remains largely grounded in philanthropic endeavors, many others are beginning to position ATM as an integral part of their business strategy.

For the majority of the companies covered by Index 2010, ATM issues are overseen at the board level, consistent with good governance practice, while the direct management of day-to-day ATM activities typically resides with a non-executive director. For leading companies in this

area, direct management of ATM is the responsibility of an executive-level officer (e.g. Executive VP, Senior VP) or executive-level group (See Leading Practices below).

For the Japanese companies, however, where ATM strategies are still in early development, a clear governance structure for ATM has yet to be established.

ATM Management systems: Most companies do not have fully developed ATM management systems. Companies such as ***AstraZeneca***, ***Gilead***, ***GlaxoSmithKline***, ***Merck & Co.*** and ***Novo Nordisk*** have implemented internal mechanisms to monitor and record ATM activities. Such mechanisms may include central information databases, periodic project reviews and business "score cards".

The remaining companies provide little detail on how their internal ATM management systems actually function, which makes it difficult to fully assess performance in this area. Also, few companies publicly disclose short-term measurable quantitative targets for its activities.

Index 2010 evaluates companies' public reporting for its comprehensiveness and frequency. Most pharmaceutical companies do report on ATM annually and provide general information on the various types of activities they are engaged in. However, disclosure of output and achievements is minimal and as mentioned, detailed performance targets at the project level are largely absent for the majority of companies.

Stakeholder Engagement: Most companies in the sector make an explicit commitment to engage in constructive dialogue on ATM with all relevant stakeholders. Among the companies covered by the Index 2010, 11 out of 20 have established a platform and/or planning strategy dedicated to outreach and/or knowledge sharing between various stakeholders on access issues.

ATM issues have received greater attention from Japanese companies during the period of analysis. ***Eisai*** has begun to establish a formal ATM strategy for the Asia, Oceania, Middle East (AOME) region and ***Takeda*** has started to publicly report on its ATM-related philanthropic activities; both ***Astellas*** and ***Daiichi Sankyo*** make general commitments to supporting ATM. While overall, the ATM strategy and reporting practices of the Japanese companies are less developed than their Western peers, their actions signify increased awareness and strategic focus on ATM; Index 2010 hopes to build on this progress going forward.

Examples of Leading Practices

- **ATM Governance Structure with Responsibility and Accountability at the Board and Executive Levels:** The success and sustainability of a company's ATM strategy depends on support and effort from all management levels within the company. ***Abbott***, ***AstraZeneca***, ***Bayer***, ***Bristol-Myers Squibb***, ***Eli Lilly***, ***Gilead***, ***GlaxoSmithKline***, ***Novartis***, ***Novo Nordisk***, ***Roche*** and ***Sanofi-Aventis*** are among the companies under coverage demonstrating this type of governance structure for their ATM programs.
- **Clear and Comprehensive ATM Reporting:** The criteria by which Index 2010 evaluates comprehensiveness in company ATM reporting include annual and systematic disclosure of inputs (i.e. resources and specific actions), impact (i.e. progress and achievements) and future targets. Among the companies covered by Index 2010, ***GlaxoSmithKline***, ***Merck & Co***. and ***Sanofi-Aventis*** demonstrate leading practices in systematic and annual public ATM reporting.

Suggested Areas for Improvement

- **Commitment to Future Targets:** Targets can be product-related (e.g. R&D pipeline targets for Index Disease products, price targets, etc.) or patient-related (e.g. targets for number of patients reached). They may also include, for example, investment targets and the number of future collaborations and should be made publicly available. While a few companies in the sector have begun to develop and publish concrete targets for a limited number of their ATM initiatives, generally this is an area where disclosure across all ATM activities is low.
- **Disclosure of Resources Dedicated to ATM Activities:** The majority of companies covered under Index 2010 disclose little information about the resources (human, financial and technical) dedicated to their ATM activities. Greater disclosure would enable more accurate assessment of each company's efforts.

RECENT INNOVATIONS - GENERAL ATM MANAGEMENT

Topic	Working with Local Stakeholder to Better Tailor ATM Strategy
Company	***Pfizer***
Description	In 2009, ***Pfizer*** entered into a partnership with PlaNet Finance – an NGO dedicated to alleviating poverty through microfinance and micro insurance – to conduct an extensive market survey of six different rural and urban areas in China. The purpose of the project is to help identify and understand the nature of the health market and the typical health access issues faced by low-income populations. Through this collaborative effort, ***Pfizer*** and PlaNet Finance have engaged in over 3,000 interviews, assessing issues such as existing sources and availability of medicine, patient purchasing patterns and the level of access to medical services among the working poor in China. With the findings of this research endeavor, which are expected in Spring 2010, ***Pfizer*** and PlaNet Finance hope to identify sustainable models that will improve ATM and healthcare services in China. An initiative such as this allows ***Pfizer*** to develop a more needs-based ATM strategy and set specific objectives and targets at the project level. This is also a way for ***Pfizer*** to better understand and thus better penetrate emerging markets in a way that is both sustainable to the business and beneficial to ATM for those in need.

Topic	Expanding ATM Monitoring to Include Impact of Third Party Partners
Company	***Gilead*** and ***GlaxoSmithKline***
Description	***Gilead*** and ***GlaxoSmithKline*** have begun to extend their ATM monitoring practices beyond internal activities to include measuring performance of third-party actors. This signifies a shift towards a more sophisticated ATM management system. As part of its ATM program, ***Gilead***, for example, tracks the number of patients receiving generic versions of its HIV medications in developing countries, as well as the number of WHO Prequalification's and FDA Tentative Approvals received by its generics company licensees for these products. Both ***Gilead*** and ***GlaxoSmithKline*** also monitor and measure their licensees' sales of anti-retrovirals. In measuring and monitoring these performance indicators, both companies are better able to identify the impact their licensees are having on ATMs in Index Countries, which can affect how the companies structure their overall ATM strategy.

Topic	Establishing Multi-Stakeholder Corporate Advisory Board on ATM
Company	***Gilead***
Description	***Gilead***'s Health Policy Advisory Board is an innovative practice in the sector as a platform specifically dedicated to dialogue on ATM issues in Index Countries. The Health Policy Advisory Board is made up of external experts from non-governmental organizations, academia and other stakeholder representatives who advise and assist ***Gilead*** on ATM-related issues. Such issues include, but are not limited to, global health policy, access to healthcare, ways to improve healthcare systems, advocacy for effective disease prevention and education, interactions with global institutions (e.g. UN, WHO, UNIAIDS, Global Fund, World Bank, etc), intellectual property, communication with media and key opinion leaders, health economics and pricing and trade issues.

PUBLIC POLICY AND MARKET INFLUENCE

Due to their size and global presence, pharmaceutical companies have significant leverage to influence markets with potential positive or negative implications for ATM. Under this area, the influence of pharmaceutical companies on ATM through lobbying and advocacy, behavior towards competition and marketing practices are analyzed.

WHAT WE MEASURE

Lobbying and Advocacy: Public policy lobbying and advocacy in areas such as intellectual property rights, pricing, counterfeit products, quality, etc. can have a direct impact on ATM. While there are several ways that lobbying and advocacy activities can improve ATM (e.g. advocating for more stringent regulatory standards for drug quality in Index Countries), other lobbying practices could inhibit access.

Competition Behavior: Competition between multiple sources for pharmaceutical products can result in both increased supply and decreased prices. Below are examples of areas covered under this subtopic:

- Disclosure of public policy positions on competition related issues such as data exclusivity for clinical trial data and discouraging competitors from entering a market
- Facilitation of competition in the Index Countries by choosing multiple non-exclusive distributors for products
- Involvement in significant competition related litigations and/or controversies

Marketing Behavior: The marketing and promotion of drugs can have a significant influence on the type of medicines that patients receive. Particularly in Index Countries with less robust regulatory enforcement and consumer protection, the marketing behavior of pharmaceutical companies can shape access to both appropriate and affordable medicines[21]. Unethical marketing can lead to suboptimal clinical decisions, prescription

[21] Bala-Miller, Priya, Justin Macmullan and Luke Upchurch. (2007) "Drugs, Doctors and Dinners: How drug companies influence health in the developing world." Consumers International.
WHO (2004). "Promoting rational use of medicines saves lives and money, WHO experts say." WHO news brief. Available online: http://www.who.int/mediacentre/news/notes/2004/np9/en/index.html (Accessed April 4, 2010).

of more expensive drugs and irrational use of medicines by consumers, which can result in reduced treatment efficacy and other complications, such as adverse drug reaction and drug resistance[22].

Under this area, we evaluate the companies' level of transparency about their marketing activities in the Index Countries. In addition, we evaluate companies' initiatives to ensure ethical marketing policies and practices in Index Countries.

HOW WE MEASURE

Compared to Index 2008, this technical area has expanded to include coverage and analysis of company competition practices and marketing behavior in addition to lobbying and advocacy activities. Therefore, it has been more appropriately titled "Public Policy and Market Influence".

The indicators under this technical area cover the companies' commitments and transparency related to Public Policy and Market Influence. In addition the companies' performance is evaluated through analysis of related practices.

Our analysis of commitments is focused on the public policy stance of the companies on lobbying and competition issues. For marketing behavior, the marketing codes and standards to which the companies have committed are evaluated.

Analysis of transparency for lobbying and also competition issues is based on level of disclosure of public policy positions and advocacy activities in the Index Countries. As for marketing behavior, we focus on disclosure on marketing policies for the Index Countries and also the level of disclosure of mechanisms used to promote products in the Index Countries such as payments to healthcare providers, physicians etc.

Analysis of performance is based on both company disclosure and analysis of data from external sources. In addition, any major litigation or controversies the company has been involved in are covered in this analysis.

Litigations have been considered that relate to practices in the Index Countries without consideration of disease scope. The focus has been primarily on litigations with a final ruling related to practices during the last five years. In addition, recent unresolved controversies with potential impact on ATM have also been captured in the analysis but have affected the score to a lesser extent than litigations with negative ruling. (For more information, please refer to Appendix D: Indicators and Scoring Guidelines).

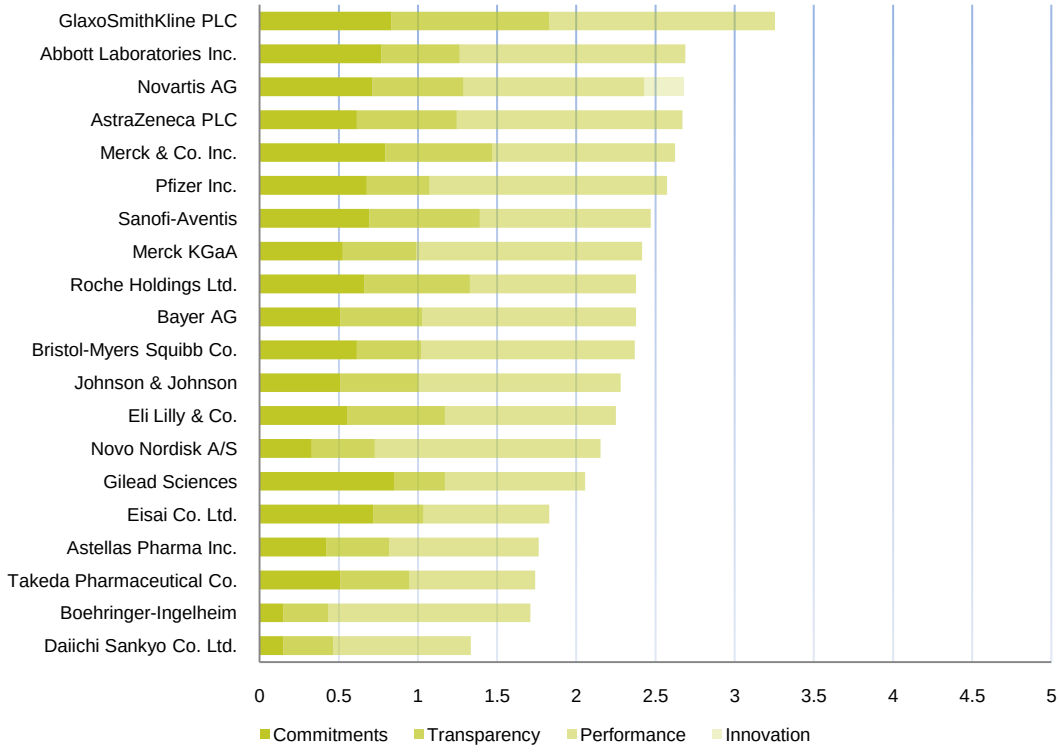
[22] Bala-Miller, Macmullan and Upchurch (2007); DFIndex Disease (2006). Access to Medicines Factsheet. Available online: www.dfid.gov.uk/pubs/files/atm-factsheet0106.pdf (Accessed March 10, 2010)

Sources

Along with company data, the analysis behind this chapter was conducted through input from external sources such as Factiva and Lexis/Nexis (news and litigation databases) and an interview with the European Commission regarding competition practices.

COMPANY RANKINGS – PUBLIC POLICY & MARKET INFLUENCE

Figure 9. Originator Company Ranking - Public Policy & Market Influence



In Index 2010, marketing practices and competition practices have been added to this technical area. The ranking under this technical area can be explained by both changes in policy and practices during the period of analysis and the increased scope of the technical area.

The leading company in this technical area is ***GlaxoSmithKline.*** This company has clear public policy disclosure, including policies related to competition issues that may impact ATM. In addition the company has faced no apparent litigations or major controversies in Index Countries during the past 5 years in the areas of lobbying and advocacy, anti-competitive behavior and marketing behavior. Yet the ranking is very close among the remaining companies within the top 5, which include ***Abbott***, ***Novartis, AstraZeneca*** and ***Merck & Co***. Compared to sector peers, these companies are all strong in at least two strategic pillars. For ***Novartis***, its innovative approach in promoting competition stands out.

Compared to the Index 2008, four companies have experienced a significant improvement in ranking: ***Abbott*** (14th to

2nd), ***Sanofi-Aventis*** (16th to 7th), ***Pfizer*** (13th to 6th) and ***Merck KGaA*** (15th to 8th).

Abbott's large increase in rank is mainly attributed to its above average practice under the performance pillar, which is an area more heavily emphasized in Index 2010. In particular, the company performs well in ethical marketing behavior, a new issue being covered under this technical area. ***Abbott***'s patent related cases are captured under Patents and Licensing.

Sanofi-Aventis has significantly improved transparency in public policy and. Since the last Index, the company has disclosed its public policy positions on many issues related to ATM publicly on its website.

For both ***Pfizer*** and ***Merck KGaA***, increase in ranking is largely due to their well above average practices under the performance pillar, as both companies have not been involved in any related litigation or controversies in Index Countries in the past 5 years.

Three companies have decreased significantly in ranking compared to the Index 2008: ***Eli Lilly*** (1st to 13th) and ***Novo Nordisk*** (4th to 14th).

Eli Lilly's ranking decrease is primarily because in Index 2010, only disclosure of lobbying activities in Index Countries is rewarded. ***Eli Lilly*** has strong reporting of lobbying activities only for the developed countries. The expansion of this technical area to include coverage of competition practices and marketing behavior has also impacted the company's rank as its practices in these areas are not at the level of leading companies. ***Eli Lilly***'s involvement in two of the drug seizure cases in 2008 in the Netherlands has also contributed to its ranking change.

Novo Nordisk's decrease is also primarily due to the focus of its disclosure on lobbying activities to the developed countries***.*** ***Novo Nordisk*** has limited public disclosure on policy positions on competition related issues relevant to ATM, such as data exclusivity and pay for delay[23] practices.[24]. The company does not disclose its financial support (i.e. actual figures) to various organizations and other stakeholders through which it may advocate on ATM issues in Index Countries.

Among the Japanese companies, ***Eisai*** is leading the group in this technical area, mainly due to its clear commitment to not pursue data exclusivity in Index Countries (with the sole exception of Bangladesh) for any treatments.

[23] Pay for delay involves a generics company accepting an economic compensation from an originator company, in exchange for delaying its entry into the market (for example as part of a settlement of a patent infringement lawsuit with an originator company).
[24] TRIPS+ is an amended version of TRIPS which limits the use of TRIPS flexibilities. TRIPS+ is not a WTO ratified set of requirements and is adopted by some Index Countries only based on bi-lateral or regional trade agreements.

OVERVIEW OF KEY METRICS

Table 8. Originator Company Practices - Public Policy and Market Influence

		Abbott (ABT– N)	AstraZeneca (AZN-LN)	Bayer (BAY-FF)	Bristol-Myers Squibb (BMY-N)	Eli Lilly (LLY-N)	Gilead (GILD-O)	GlaxoSmithKline (GSK-LN)	Johnson & Johnson (JNJ-N)	Merck (MRK-N)	Merck KGaA (MRK-FF)	Novartis (NOVN-VX)	Novo Nordisk (NOVO'B-KO)	Pfizer (PFE-N)	Roche (ROG-VX)	Sanofi-Aventis (SAN-FR)	Astellas (4503-TO)	Daiichi Sankyo(4568-TO)	Eisai (4523-TO)	Takeda (4502-TO)	Boehringer-Ingelheim
Governance	**Level of Public Policy Disclosure on ATM related Issues***	MEDIUM	HIGH	MEDIUM	MEDIUM	MEDIUM	MEDIUM	HIGH	MEDIUM	MEDIUM	MEDIUM	HIGH	MEDIUM	MEDIUM	HIGH	HIGH	MEDIUM	LOW	LOW	MEDIUM	MEDIUM
Marketing Behavior	**Public Disclosure of Marketing Activities in the Index Countries****	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Competition Behavior	**Public Disclosure of Competition-related Policies *** **	MEDIUM	MEDIUM	MEDIUM	LOW	LOW	LOW	MEDIUM	LOW	MEDIUM	LOW	LOW	LOW	LOW	LOW	MEDIUM	LOW	LOW	LOW	LOW	LOW	LOW

*ATM issues include, but are not limited to, counterfeiting, clinical trial conduct, pharmacovigilance, pricing and product donations.

** E.g. payments to physicians and other methods of promotion for healthcare providers.

***Competition-related policies include patent extensions, arrangements with generics companies which might delay market entry ('pay-for-delay'), data exclusivity, TRIPS+ (and any major components) and compulsory licensing).

N.B. High=disclosure of ≥ 5 Medium=disclosure of 1-4 policy positions Low= no policy positions disclosed.

Lobbying and Advocacy

AstraZeneca, ***GlaxoSmithKline***, ***Roche***, ***Novartis*** and ***Sanofi-Aventis*** have had the highest levels of disclosure of public policy positions related to ATM among the companies under coverage. The majority of companies make a commitment to transparency in their ATM-related lobbying and advocacy activities. In practice, however, detailed disclosure of public policies related to ATM is limited. Overall, company policies on issues such as counterfeiting and intellectual property rights are the two most commonly disclosed areas, while public policy positions on other ATM-related issues, such as clinical trial conduct in Index Countries, pricing policies and marketing regulations are often not provided. Based

on regulatory requirements, most firms disclose their financial support to US and European institutions, patient and trade associations, individuals and political parties. In Index Countries, however, disclosure of the companies' lobbying activities and contributions remains very limited.

Examples of Leading Practices

- **Transparency in Public Policy Positions:** ***AstraZeneca***, ***GlaxoSmithKline***, ***Novartis***, ***Roche*** and ***Sanofi-Aventis*** all publish a number of formal corporate policies directly related to ATM in Index Countries, including, but not limited to, intellectual property rights, compulsory licensing, pricing, clinical trial practices in developing countries, counterfeiting and donations. ***GlaxoSmithKline*** is the only company in the sector to clearly disclose its position on issues such as patent extensions and data exclusivity.

Suggested Areas for Improvement

- **Greater Disclosure of ATM-specific Lobbying and Advocacy Activities in the Index Countries:** Disclosure of lobbying and advocacy activities in Index Countries is generally weak across the sector, which makes it difficult for external actors to adequately assess how such activities impact ATM. Few companies go beyond legal disclosure requirements (i.e. reporting of activities/contributions inside the US and Europe). No companies currently disclose financial contributions provided to governments, NGOs, patient groups, trade associations and other third party institutions in Index Countries.

Competition Behavior

The majority of companies commit to fair and ethical competition within pharmaceutical markets. In practice, disclosure of actual policies on specific competition practices is often limited.

On the positive side, more companies have undertaken non-exclusive voluntary licensing activities. Such activities facilitate generic competition for patented products. For more information, please refer to the Patents and Licensing technical area.

Another example of company behavior that is conducive to more competitive prices for the patients is demonstrated by ***Novartis.*** The company has committed to choosing multiple non-exclusive distributors in the Index Countries, when feasible, with the goal of enabling local competition between distributors.

One key competition issue within the ATM debate is data exclusivity, which refers to the fixed period of time (which can range from 5-10 years) during which regulatory authorities do not allow the registration files of an originator company to be used to register a pharmaceutically equivalent generic version of that medicine[25]. While

[25] Médecins Sans Frontières (MSF) (2004). "Data exclusivity in international trade agreements: What consequences for access to medicines?" MSF technical brief. Available online:

Index Country governments hold ultimate responsibility for data exclusivity of clinical trial data, the company can choose to share its clinical trial data, where it sees fit.

The pursuit of data exclusivity can delay the introduction of more affordable generic products. Note that data exclusivity and the barrier to market entry that it creates are independent of the patent status of the product[26].

Gilead and Eisai are the only companies with commitments in this area. ***Gilead*** has committed to permit its clinical trial data to be used by its non-exclusive licensees for the registration of generic equivalents of its ARV products. ***Eisai*** has committed to let its clinical trial data to be used by generics companies for registration in Index Countries, with the sole exception of Bangladesh.

During the period of analysis another significant competition related case came to light. Under new European laws, numerous drug shipments from Indian generics companies en route to other developing countries were blocked in the Netherlands. The drugs were held by the Dutch customs on the grounds that they infringe EU intellectual property laws, even though they were not manufactured or intended for sale in the Netherlands or elsewhere in Europe. The drugs were not patented in the destination countries either. In such cases it was up to the pharmaceutical companies to decide to release the medications or push for more legal action.

The first case to receive wide public attention was the detention by Dutch customs in December 2008 of a shipment of Losartan, a blood pressure medication, in transit from India to Brazil. While Losartan is not patented in India or Brazil, ***Merck & Co.*** holds patent rights in the Netherlands. Lawyers acting on behalf of ***Merck & Co.*** demanded that the manufacturer, ***Dr. Reddy's***, consent to the destruction of the shipment. ***Merck & Co.*** eventually authorized the release of the goods back to India in exchange for ***Dr. Reddy's*** acknowledgement of the Dutch patent[27]. Since then, on more than 20 occasions, shipments of generic medicines from India for the treatment of a variety of ailments such as HIV/AIDS, Alzheimer's disease and cardiovascular diseases have been held at the request of originator companies including ***Sanofi-Aventis***, ***Novartis*** and ***Eli Lilly*** for periods as long as eight months on accusations of patent infringement in EU member states[28]. In most of the cases the drugs are finally released to be delivered to the destination or to be returned to origin.

http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/DataExclusivityInInternationalTradeAgreementsMSF.pdf (Accessed April 5, 2010).

[26] MSF (2004)

[27] Abbott, Frederick M. (2009). "Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare." W.I.P.O.J no.1: 43-50.

[28] Miller, John W. Miller and Geeta Anand. (2009). "India prepares EU trade complaint." Wall Street Journal. Available online: http://online.wsj.com/article/SB124949598103308449.html (Accessed April 2, 2010).

Following these cases, India and Brazil requested consultations with the EU in May 2010, the first step in WTO dispute settlement procedures. The European Commission is now reviewing the relevant regulations under which the detentions were made.

It should be noted that one of the shipments detained in the Netherlands was an ARV, Abacavir produced by Aurobindo, an Indian generics company. The product is patented in the Netherlands by ***GlaxoSmithKline***. The shipment was destined for Africa. In this case, ***GlaxoSmithKline*** advised the Dutch customs that it does not wish to initiate legal action against Aurobindo[29].

Under the current EU laws, it is the legal right of the originator companies to take legal action in such cases. However, the type of action that some companies have pursued has resulted in a strong reaction from civil society actors and Index Country governments. Such practices can affect a company's image in the Index Countries and render future operations in such markets more difficult. They can hamper stakeholder dialogue and engagement around ATM issues.

For more coverage of competition issues concerning intellectual property and patents please refer to the "Patents and Licensing" chapter of this report.

[29] Frederick M. Abbott (2009); Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare

Examples of Leading Practices

- **Strategies to Improve Competition in Index Country Markets:** Among the companies under coverage, ***Novartis*** is implementing potential pro-competition mechanisms. Please see "Recent Innovations" below.

Suggested Areas for Improvement

- **More Constructive Approaches to Facilitate Competition:** Competition-related cases remain a persistent obstacle for ATM. More constructive business approaches to competition, which combine the competitive advantage of originator and generics companies such as non-exclusive licensing, can facilitate access.

Marketing Behavior

All the originator companies covered by the Index commit to complying with at least one internationally recognized code for the ethical marketing of pharmaceutical products. In most cases this is the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Pharmaceutical Marketing Practices or the WHO Ethical Criteria for Medicinal Drug Promotion, or both. Many companies also abide by a number of standards at regional levels. Examples include European Federation of Pharmaceutical Industries Association, the Pharmaceutical Research and Manufacturers of America, or the national level such as the Association of the British Pharmaceutical Industry (ABPI) and Japan Pharmaceutical Manufacturers Association (JPMA). Some company have developed their own internal marketing codes and policies based on the principles of the aforementioned guidelines.

In 2009, ***AstraZeneca***, ***Eli Lilly*** and ***Pfizer*** each settled major whistleblower litigations concerning the off-label promotion of drugs in the US.[30] Index Countries off-label drug promotion is defined as the promotion of a pharmaceutical product for indications for which the product has not been approved. This practice has the potential to reduce treatment efficacy and create higher financial burdens for patients

Currently, these cases are mostly specific to the US market. But if replicated in the Index Countries they can have significant implications for ATM. This risk is more significant in Index Countries with weak regulatory enforcement capacity, where such cases might go unreported.

In addition to off-label marketing, there is growing concern over the relationship between pharmaceutical companies and healthcare providers, particularly the industry's influence on prescribing and

[30] AstraZeneca reached a USD 520 million agreement to settle lawsuits over the sale and marketing of its blockbuster psychiatric drug, Seroquel; Eli Lilly paid USD 1.4 billion over its off-label marketing of its own antipsychotic drug, Zyprexa; Pfizer settled to pay USD 2.3 billion for the off-label marketing of a number of drugs, including its painkiller Bextra

dispensing decisions. This influence is administered through a range of promotional tools[31]. These can include advertising, gifts, financial incentives, continuing medical education, etc. In some Index Countries, where independent sources of medical information are weak, healthcare professionals must rely to a greater extent on companies' marketing material. In such cases, information that is misleading, inaccurate, or biased can have serious implications for clinical decisions and quality of healthcare delivery[32].

In the US, some companies have started to report their promotional activities and payments to healthcare providers and patient groups. No company has disclosed such data for the Index Country markets. ***GlaxoSmithKline, Merck and Roche*** are the only companies which have committed to start disclosing payments related to marketing activities in the Index Countries in the near future.

While during the period of analysis there has been no major litigation in the Index Countries in this area, some independent reports have raised issues about pharmaceutical marketing practices in the Index Countries, especially regarding clear mention of product's adverse side effects[33].

[31] WHO and HAI. (2009). "Understanding and Responding to Pharmaceutical Promotion: A Practical Guide (1st edition)." WHO and HAI Collaborative Project. Draft Manual.
[32] Bala-Miller, Macmullan and Upchurch (2007) – For Consumer International

[33] Ibid

Examples of Leading Practices

- **Implementation of Marketing Code Commitments:** While most companies do include ethical marketing provisions in their employee codes of conduct, these codes should be accompanied by training and reporting mechanisms for breaches of such codes in the Index Countries. ***Abbott, Astellas***, ***AstraZeneca***, ***Bayer***, ***Daiichi Sankyo***, ***Eisai***, ***Gilead***, ***GlaxoSmithKline***, ***Merck & Co. Novartis, Novo Nordisk, Roche and Sanofi-Aventis*** are among the companies under coverage that have established detailed policies and stringent procedures to monitor employee compliance with company marketing standards, including mechanisms for reporting breaches globally (e.g. an ethics hotline available to employees in the Index Countries). ***AstraZeneca*** also makes this hotline available to healthcare professionals and the public and it commissions external reviews of its sales and marketing activities by specialized auditors.

- **Commitment to Demand Ethical Marketing Behavior from Local Distributors and Other Third Parties in Index Countries:** Companies should not only internally subscribe to an ethical marketing code such as the ones outlined by the WHO and IFPMA, but also demand that these standards be adhered to by all of its third-party distributors, contractors and local sales agents in Index Countries. These parties can play a large role in marketing and promoting company products in Index Countries, particularly in areas where companies do not have their own sales forces on the ground. Among the companies under coverage, ***Merck KGaA, Novartis, Pfizer and Roche*** have established a clear policy and audit function for all their contractors, including marketing and promotional activities in Index Countries.

Suggested Areas for Improvement

- **Disclosure of Marketing Activities in Index Countries:** Since direct-to-consumer advertising (DTCA) is banned in most countries (with the exception of the US and New Zealand), healthcare professionals are the primary marketing targets for pharmaceutical companies[34]. However, no companies systematically disclose information on their marketing and promotional activities outside of the US and European markets. Companies could improve their disclosure in their Index Country marketing and promotional programs including payments, gifts and other incentives provided to healthcare professionals and other providers and intermediaries.

RECENT INNOVATIONS - PUBLIC POLICY AND MARKET INFLUENCE

Topic	Multiple Distributors to Promote Local Competition in Index Country Markets
Company	***Novartis***
Description	***Novartis*** has stated that, where possible, it appoints multiple local distributors in each country market as a means to create local competition and facilitate competitive pricing. Such efforts, while demanding minimum resource commitments from the pharmaceutical firms, can have a positive impact on the accessibility and affordability of products in the Index Countries. (More information about the extent and impact of these efforts would be welcome.)

[34] Bala-Miller, Macmullan and Upchurch (2007) - For Consumer International

RESEARCH AND DEVELOPMENT FOR INDEX DISEASES

Research and Development remains a key bottleneck for ATM in the Index Countries. This gap is especially significant for the neglected diseases. As there is a lack of developed world markets for these products, there is currently a weak business case for R&D in this area. There is also insufficient R&D directed toward product adaptation needs for specific demographics (e.g. pediatric formulations), environmental factors (e.g. heat-stable formulations) and social factors (e.g. fixed-dose combinations). Under this technical area, the companies' efforts in Innovative R&D for Index Diseases, Adaptive R&D and Intellectual Property Sharing are analyzed.

WHAT WE MEASURE

Innovative R&D

The WHO's 2001 Commission on Macroeconomics and Health distinguished three classes of diseases[35]. Class III, or "very neglected diseases", are those diseases "overwhelmingly or exclusively prevalent in the developing world"[36].

These include the diseases on the WHO's list of 14 neglected tropical diseases (NTDs) such as Chagas disease, sleeping sickness (human African typanosomiasis), kala-azar (leishmaniasis), river blindness (onchoceriasis) and shistosomiasis. For such diseases, due to the absence of individual purchasing power or institutional payers in many Index Countries, the companies have insufficient economic incentives to invest in research. This sustained, long-term market failure helps prolong the shortage of suitable products

[35] WHO (2001) Macroeconomics and Health: Investing in Health for Economic Development. Report of the Commission on Macroeconomics and Health. Geneva: World Health Organization. p.89. Available: http://whqlibdoc.who.int/publications/2001/924154550x.pdf. Accessed 25 January 2010

[36] Ibid

for prevention, diagnosis and treatment of these diseases.

Class II diseases are termed “neglected diseases (NDs)" and occur in both rich and poor countries, but with a substantial proportion of cases (>90%) occurring in poor countries. Examples include HIV/AIDS and tuberculosis. For those diseases the market failure is incomplete due to the presence of some developed world demand or overlapping R&D goals. Nevertheless, the level of R&D is “not commensurate with the disease burden”[37]. As these are all communicable diseases, new treatments are needed to replace those whose efficacy has waned due to microbial resistance. To address this need, R&D for new chemical entities (NCEs) can play a significant role.

Another major area of need for new products is prevention. The industry’s pipeline for vaccines has expanded during the past few years. However, there are still no vaccines for many neglected diseases.

Index 2010 assesses companies’ efforts to meet these needs. Both in-house research and the use of innovative, collaborative business models, such as product development partnerships (PDPs) are covered by Index 2010.

[37] Ibid.

Adaptive R&D

Adaptive R&D or “incremental innovation” offers significant advantages to the people of Index Countries. By making small adaptations to existing molecules or products, they can sometimes be made more suitable for certain Index Country environments. Such changes may include: creating soluble forms for small children; extending indications to other diseases (label-extensions); capturing new target groups (such as pregnant women) or age-groups (such as pediatric formulations). Adaptive research can also simplify dosing regimens through developing Fixed Dose Combinations (FDC) which can delay or prevent emergence of resistance through more rational medicine use. Adaptive R&D can also lead to more stable molecules with a longer shelf life and better environmental resistance.

The lack of Index Country-tailored products is a major source of health burden and mortality, especially in the case of pediatric formulations of anti-retroviral (ARV) medicines. Note that challenges related to pediatric formulations are not limited to Index Countries. The ethical sensitivities of carrying out clinical trials for pediatric formulations make them a pharmaceutical challenge in developed markets as well[38].

[38] European Commission (2008) ETHICAL CONSIDERATIONS FOR CLINICAL TRIALS ON MEDICINAL PRODUCTS CONDUCTED WITH THE PAEDIATRIC POPULATION

Under this topic, we provide an evaluation of companies' policies and practices in adapting existing medicines to meet the needs of the Index Countries.

Intellectual Property (IP) Sharing

Proprietary knowledge (primarily protected through the patent system) is the engine of the pharmaceutical sector and as soon as a company has proven that a new entity "is novel, non-obvious and has utility" it also becomes an asset that can be bought, sold and licensed. Some of the trends we note in Index 2010 are:

- The industry's flexibility in IP management in collaboration with the PDPs and bi-lateral private-private partnerships
- Enabling third-party access to "compound libraries"

HOW WE MEASURE

Access to Medicine Index 2010 evaluates the companies' R&D activities for the Index Countries, be it in-house or collaborative. The products areas covered under this technical area are: drugs, vaccines, microbicides, diagnostics, adjuvants and platform technologies. The Index 2010 distinguishes 'Innovative (breakthrough)' efforts and 'Adaptive' R&D for Index Diseases to acknowledge the distinct needs these activities fulfill.

In establishing the research needs to be covered by the Index 2010, extensive stakeholder dialog was conducted. In addition, the G-FINDER project of the George Institute for International Health which tracks ND investments has been an important reference in this area[39]. As such, the main criteria for inclusion are detailed below:

- The disease should be causing significant health burden in the Index Countries.
- Investment in research should have the potential to significantly decrease the social burden.
- The market incentives for developing the needed product should be deficient.

Note that research for non-communicable diseases (such as diabetes, ischemic heart disease, etc.), whose treatments have developed-world applications are not covered by this portion of the Index. Also note that some exclusions have been applied which are consistent with the exclusions of the G-Finder project for communicable diseases. For further information about the R&D exclusions of Index 2010, please refer to the 2010 Methodology and Stakeholder Review.

[39] Moran M, Guzman J, Ropars AL, McDonald A, Sturm T, Jameson N, Wu L, Ryan S, Omune B (2009). "Neglected disease research and development: how much are we really spending?" The George Institute for International Health. Available at: http://www.thegeorgeinstitute.org/shadomx/apps/fms/fmsdownload.cfm?file_uuid=409D1EFD-BF15-8C94-E71C-288DE35DD0B2&siteName=iih

To measure the performance of R&D initiatives of the companies, Index Disease-relevant molecules at different stages of product development are evaluated. The development stages considered for analysis are listed below:

- Pre-clinical (from lead identification to Investigational New Drug Application [iNDAs])
- Clinical (from phase 1 to regulatory filing or licensure)
- Post-registration (approvals within the last three years)

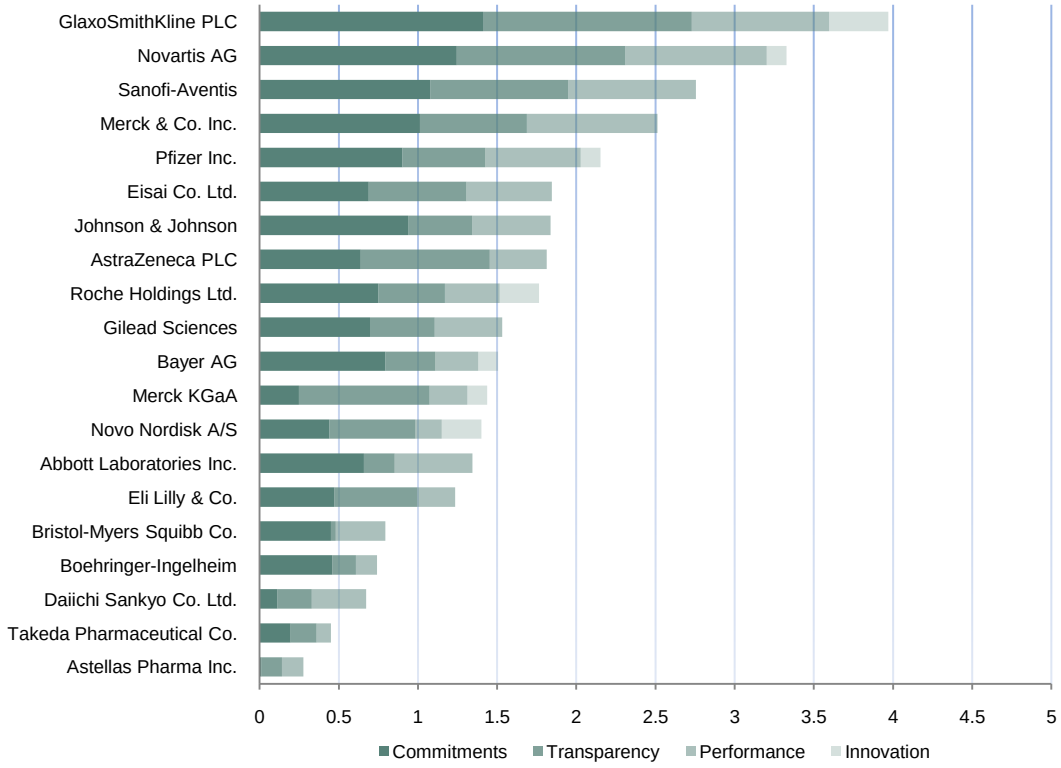
For the purpose of scoring, the number of molecules in the companies' pipeline was adjusted for the company size based on pharmaceutical revenues.

Additionally R&D resource inputs such as financial investments were evaluated. Both R&D investments and 'discovery stage' activities enable an insight into more recent company initiatives and how current commitments are supported with the necessary resources. This is because it can take around six years for a compound to reach Phase I clinical trial. Measurements in this area were at times hampered by low levels of company disclosure. Still, this exercise in measuring and comparing inputs and outputs of R&D for Index Disease has yielded highly pertinent and valuable insights. Multi-disease vaccines in most of the cases also have viable developed markets. In such cases, only such vaccines developed with explicit Index Country motives were considered for inclusion. For more details about the methodology and how scoring was carried out, please refer to Appendix D: Indicators and Scoring Guidelines.

Sources: For analysis of R&D pipelines, the company's public and engagement based disclosure was used. For analysis of collaborations, news, interviews with PDPs and companies' disclosure were used. For analysis of investments, a mix of company disclosure and the data kindly provided by the George Institute were used (upon approval by the companies).

COMPANY RANKINGS– RESEARCH AND DEVELOPMENT

Figure 10. Originator Company Ranking - Research & Development



GlaxoSmithKline, ***Novartis***, ***Sanofi-Aventis*** and ***Merck & Co*** all have detailed commitments to research for the Index Diseases, are involved in several research collaborations and have several molecules for the Index Diseases with specific Index Country purpose in their pipelines.

Compared to Index 2008, three companies whose rankings have significantly improved are ***Merck & Co.*** from 13th to 4th, ***Pfizer*** from 17th to 5th and ***Gilead*** from 15th to 10th.

During the period of analysis ***Merck & Co.*** has undertaken new research collaborations, has launched a new vaccine institute with special focus on the Index Country needs. The company has an above-average number of Index Disease-related molecules in its pipeline (after adjustment for size and exclusions).

Pfizer has started three new research collaborations during the period of analysis. In addition, ***Pfizer*** has launched ViiV Health along with ***GlaxoSmithKline*** which is undertaking Index Country focused research activities for HIV/AIDS (For more information on company practices please refer to their respective Report Cards and Profiles).

During the period of analysis, in collaboration with Tibotec, ***Gilead*** has engaged in adaptive research aimed at developing two HIV/AIDS FDCs. Taking into the size of the companies in our analysis has resulted in more reward for R&D initiatives of smaller companies such as ***Gilead.***

Three of the companies whose ranking has decreased significantly compared to Index 2008 are ***Roche*** (4th to 9th), ***Abbott*** (7th to 14th) and ***Eli Lilly*** (11th to 15th).

During the period of analysis ***Roche*** terminated its R&D activities for HIV/AIDS drugs. As for ***Abbott*** and ***Eli Lilly***, neither of them appear to have undertaken any new Index Disease-related R&D activities during the period of analysis. Such companies have been overtaken by several companies which have expanded their R&D activities for the Index Diseases. Also, Index 2010 covers both breadth and depth of R&D activities which results in a lower score for companies with single disease R&D focus such as ***Abbott***.

Eisai leads the Japanese companies in this technical area. The company is involved in innovative research for Chagas disease and malaria and has dedicated part of its research centre in India to neglected disease research.

OVERVIEW OF KEY ATM INDEX 2010 METRICS

Table 9. Originator Company Practices – In-House and Collaborative Research Pipeline

NB: This table attempts to illustrate the 'breadth' of originator companies Index Disease R&D activity (generic companies contribution to R&D is captured in the Generic Pharmaceutical Companies chapter). Hence, this does not illustrate 'depth' i.e. a single highlighted cell may represent one or many molecules. The data has been impacted by both our methodology (see inclusions/exclusions as detailed in methodology report) and data capture or disclosure constraints (see 'How We Measure'). For example Innovative HIV/AIDS work is excluded due to presence of developed market incentives.

The diseases shaded grey are the WHO NTDs.

* Bayer CropScience work on insecticides # Specific diseases (or breadth) unverifiable ** Discontinued program in 2008 † Data may be incomplete (due to disclosure constraints)

Innovative R&D

Five of the 20 companies undertake innovative R&D for three or more Index Diseases (after applying exclusions). These companies are: ***GlaxoSmithKline***, ***Merck & Co***., ***Novartis, Pfizer*** and ***Sanofi-Aventis***. Four other companies reportedly have at least one innovative candidate for Index Diseases in their pipelines. These companies are ***AstraZeneca***, ***Daiichi***, ***Eisai*** and ***Johnson & Johnson***.

Despite adjustments for company size, the level of activity remains highest among the largest companies.

There is an encouraging trend towards launching dedicated developing-world R&D institutes that focus on neglected disease drug development.

Currently ***AstraZeneca*** (tuberculosis), ***Eli Lilly*** (tuberculosis), ***GlaxoSmithKline*** (malaria, tuberculosis, kinetoplastids[40]) and ***Novartis*** (dengue fever, malaria, tuberculosis and diarrheal diseases) have dedicated R&D centers for neglected diseases.

Most of the sectors' innovative R&D efforts are concentrated on the 'big 3' (HIV/AIDS, tuberculosis and malaria) as illustrated in the table 5.

Innovative research pipelines for NTD drugs (in Phase I to III) are currently limited to three molecules. A collaboration between ***Eisai*** and DNDi is investigating E1224 (Phase II) for Chagas disease; ***Pfizer*** is investigating moxidectin (Phase III) for river blindness and ***GlaxoSmithKline*** is investigating sitamaquine (Phase II) for treatment of kala-azar (for more details please refer to Table 9).

There are some signs of an increase in early stage R&D activity which indicates new programs begun within the last five years. Basic R&D for NTDs is currently being undertaken by ***Merck & Co***. for Chagas disease, Novartis for dengue and ***Sanofi-Aventis*** for sleeping sickness. When looking at the even earlier "discovery" stages (see Intellectual Property Sharing) it is heartening to note the increased disease coverage and activity for NTDs. This development is largely due to the new trend of sharing and screening of compound libraries by the originator companies for effectiveness against neglected diseases. For more information, please refer to the following section on Intellectual Property Sharing.

A number of firms have new vaccines for NTDs under development. These efforts are largely focused on dengue, for which there are market incentives, such as vaccination of Western travelers. For a list

[40] A range of insect transmitted protozoa causing diseases such as Chagas and sleeping sickness

of companies active in this area please refer to Table 9.

Outside the NTD area, there has been significant research of new vaccines for diseases that also threaten the developed world. The pipeline of many companies' vaccine divisions (such as ***GlaxoSmithKline Bio*** and ***Sanofi-Pasteur***) is a significant portion of their overall Index Disease-related pipeline. ***AstraZeneca, GlaxoSmithKline***, ***Johnson & Johnson, Merck & Co***., ***Novartis***, ***Pfizer and Sanofi-Aventis*** all showed evidence of conducting R&D for new Index Disease-specific vaccines during the period of analysis.

This observation is corroborated by investment data which show that vaccine investments now dwarf all other R&D areas by a factor of three. [41]

Most vaccine R&D focuses on multi-disease vaccines, lower respiratory tract infections (LRTIs), diarrheal diseases and meningitis (please refer to table 5). Outside of these areas, highlights of the sector's current innovative vaccine pipelines include: malaria (***GlaxoSmithKline***), HIV (***GlaxoSmithKline***, ***Novartis*** and ***Sanofi-Aventis***), tuberculosis (***Sanofi-Aventis***, ***GlaxoSmithKline***), dengue (***Sanofi-Aventis***, ***Novartis***, ***GlaxoSmithKline***) and rotavirus (***Novartis***, ***Sanofi-Aventis***, ***Merck & Co***.).

Leading companies in this area either already have launched dedicated divisions/institutions or have added R&D capacity or investments for vaccines during the period of analysis. Examples of the latter include the ***Novartis Vaccine Institute for Global Health*** (NVGH) in Italy and the ***Merck-Wellcome Trust Hilleman Laboratories*** in India.

[41] Data provided by the George Institute

Examples of Leading Practices

- **Innovative R&D Activity in Multiple Communicable Index Diseases:** ***GlaxoSmithKline***, ***Merck & Co***., ***Novartis*** and ***Sanofi-Aventis*** have the richest pipeline for innovative R&D for Index Diseases. Excluding multi-disease vaccines, ***GlaxoSmithKline*** has drugs in development for five Index Diseases. While ***GlaxoSmithKline*** and ***Novartis***' efforts are across a broader range of therapeutic areas (six and five respectively), ***Sanofi-Aventis*** maintains a similar number of products but has focused on fewer Index Diseases. Based on our analysis, ***Novartis*** has innovative drugs and vaccines in development for eight of our 23 Index Diseases. While ***GlaxoSmithKline*** and ***Sanofi-Aventis*** efforts are across seven Index Diseases and ***Merck & Co***. across six. However, ***GlaxoSmithKline*** and ***Sanofi-Aventis*** also support this breadth with depth – both having greater than ten drug and vaccines candidates in current development.

- **High Level of Transparency in R&D Activities:** The best performers in the sector support their commitments with a high level of disclosure both with respect to the R&D outputs (molecules in development pipelines and preclinical research) and the dedicated resource inputs and investments. Especially notable in this area are the Japanese companies. While they have limited Index Disease R&D initiatives compared to their Western peers, they have been very transparent about input and structure of their R&D initiatives. ***Novartis*** should be commended for its high level of public disclosure regarding its human resources dedicated to its Index Disease R&D and also for disclosing the molecules in early development stages. While we acknowledge some improvements since the last Index (especially ***Pfizer*** and ***Merck & Co***.), the average level of disclosure in this area remains low, notably from the US and non-listed companies.

Suggested Areas for Improvement

- **Several NTDs Underrepresented in the Industry's Current Portfolio:** Despite efforts in the last 10 years at securing funding and adopting innovative approaches to NTD R&D, there remain significant treatment (and hence R&D) gaps for NTDs (please refer to Table 9).Whilst the Index 2010 has attempted to capture all of the company's efforts and approaches in this area, it is apparent that significant gaps remain. For example some of the diseases in this group such as the helminth infections – a group of six worm-based diseases – are currently notable for their absence from the sector's R&D efforts. Additionally, diseases such as Buruli ulcer, leprosy and yaws continue to be neglected. These results from our pipeline analysis are corroborated by investment data showing that 2008 investment into kinetoplastid diseases was less than USD 1.5 million across the sector and that zero investment was disclosed for all helminth infections. Investments were highest for malaria, HIV, tuberculosis and dengue.

- **Insufficient 'Truly Innovative' Efforts to Develop Needed Medications in a Large Portion of the Companies:** R&D for adaptive research is attractive because of its shorter development timeline, lower cost and risk profiles and ready availability of public and philanthropic (upfront) funds. However, this leads to unmet needs for higher cost innovative R&D – for both drug and vaccines[42] (see Table 9). Innovative R&D is important for a number of reasons, not least the inevitable development of resistance for communicable disease products. Seven of the twenty originator companies surveyed have no new molecules for Index Diseases in their pipeline (after applying R&D exclusions) and eight are not currently demonstrating signs of activity in earlier R&D stages, such as support for discovery-stage activity by providing third-party access to compound libraries.
- Increased Peer-Engagement for Better Co-ordination of Priorities: PDPs help improve dialogue and co-ordination between developers, but most tend to be disease and product specific. Broader dialogue across sectors, functions and diseases can lead to improved knowledge sharing and priority setting[43]. The WHO Special Program for Research and Training (TDR) plays an admirable role in this area. With some exceptions, such as the ViiV initiative of GSK and Pfizer, pharmaceutical companies have not engaged in needed dialogue and collaboration with their peers about R&D priorities during the period of analysis. More

[42] Sheridan M. (2005). The Business of Making Vaccines. Nature Biotechnology Volume 23 (11)
[43] For example PDPs, companies, funders, endemic Index Country countries and global health institutions (such as WHO)

peer collaboration and sector-wide coordination can be a potent means of resource pooling and prioritization (to prevent duplication).

Adaptive R&D

Currently only ***GlaxoSmithKline***, ***Pfizer***, ***Sanofi-Aventis*** and ***Eisai*** make a strategic commitment to undertake adaptive research in more than one disease area.

Most adaptive R&D activity undertaken by the industry attempts to address two main Index Country needs. The first is to facilitate dosing and patient compliance through the development of Fixed Dose Combinations and the second is to adapt products to (or to register existing products for) specific population groups, mostly pediatric formulations.

Both of these represent areas of high therapeutic need. During 2008 and 2009, 10 of the 20 originator Index 2010 companies were undertaking adaptive R&D for Index Diseases.

Collaborations or PDPs play an important role in the current adaptive research activities in the sector. Significant and frequent partners to the private sector include: Medicines for malaria Venture (MMV), PATH and the Drugs for Neglected Diseases Initiative (DNDi).

The current adaptive research activities of the originator companies cover six out of the 23 communicable Index Diseases. None of the companies' current adaptive R&D for Non-Communicable Index Diseases was directed specifically at the Index Countries. Examples of some of the adaptive remedies which received marketing approval during the period of analysis are detailed in Table 10.

Table 10. A selection of adaptive products for Index Diseases, developed with industry involvement filed or launched since 2007

This list aims to provide examples only. Coverage was constrained by company disclosure levels

Disease	Product	Type of adaptation	Company/ PDP
Malaria	Coarsucam® / Winthrop® Artesunate-Amodiaquine ASAQ	Pediatrics	***Sanofi-Aventis*** / DNDi
	Eurartesim® dihydroartemisinin / piperaquine	FDC	***Pfizer*** (Sigma-Tau) / MMV
	Camoquine Plus® Children amodiaquine / artesunate	Pediatrics	***Pfizer***
	Metakelfin® Sulphamethopyrazine + Pyrimethamine	Pregnant women	***Pfizer***
	Pediatric Coartem® Dispersible artemether / lumefantrine	Pediatrics	***Novartis*** / MMV
Sleeping Sickness	NECT® / co-administration schedule of oral nifurtimox and intravenous eflornithine	FDC	***Sanofi-Aventis***/***Bayer*** (TDR, DNDi & others)
HIV/ AIDS	Norvir / Aluva®	Heat Stable	***Abbott***
	Norvir / Aluva®	Pediatrics	***Abbott***
	Aptivus® (tipranavir) oral solution	Pediatrics	***Boehringer-Ingelheim***
	Prezista® darunavir	Pediatrics	***Johnson & Johnson***
	Lexiva® fosamprenavir calcium oral suspension & dose	Pediatrics	***GlaxoSmithKline***

Examples of Leading Practices

- **Adaptive Research for Pediatric Formulations:** Leading companies are contributing further resources to ensure their products, once developed, are also being licensed for use in, or adapted to better suit, pediatric populations. Table 10 gives an indication of some recent successful outputs from these activities. Ongoing development projects aimed at achieving pediatric registrations of, or formulations for, existing HIV compounds were being undertaken during the period of analysis by companies such as: ***GlaxoSmithKline***, ***Gilead***, ***Johnson & Johnson***, ***Abbott*** and ***Bristol-Myers Squibb***. With respect to tuberculosis, the pipeline is dominated by ***GlaxoSmithKline*** (and formerly ***Novartis*** through ***Sandoz***). This is a significant and welcome development, as children differ significantly from adults in the way they absorb, metabolize and

excrete drugs and the significant health burden resulting from unavailability of pediatric formulations in several disease areas.

- **Adaptive Research to Decrease Dosing Burden:** FDCs and product developments that simplify dosing have many advantages, especially for certain age groups (senior patients and children). Such activities are currently concentrated on FDC development for HIV/AIDS and tuberculosis. Development projects aimed at new combinations or FDC for existing HIV compounds were being undertaken by ***GlaxoSmithKline***, ***Merck & Co***., ***Gilead***, ***Johnson & Johnson***, ***Abbott***, ***Pfizer***, ***Boehringer-Ingelheim*** and ***Bristol-Myers Squibb***. Additionally, extended release (or long acting) formulations, vaccine adjuvants and boosters can also contribute to further reducing dosing burdens in Index Countries. Examples include ***Boehringer-Ingelheim***'s extended-release version of Viramune® (Nevirapine), ***Novartis*** for its vaccine adjuvant MF-59 (which it out-licensed to ***Sanofi-Aventis*** / Medimmune) and ***Gilead***'s PK-enhancer Cobicistat® (GS 9350) for HIV/AIDS.
- **Adaptive R&D for Vaccines:** Vaccines need to be adapted to the environmental and socioeconomic attributes of Index Countries. For example, refrigeration can be a major limitation in Index Countries. Some companies in the sector play a leading role in adapting vaccines to Index County environments. Examples include ***Johnson & Johnson*** in development of a heat-stable measles vaccine (Phase II-III), ***Merck & Co***'s pediatric rotavirus vaccine (Phase III) and notably ***GlaxoSmithKline*** who has five pediatric-specific vaccines in the pipeline for diseases such as (HIV, tetanus, Pertussis and meningitis).

Suggested Areas for Improvement

- **More Transparency in Research Collaborations:** As products progress through the R&D pipeline, the contracts which bind the parties together increasingly include "downstream provisions", or terms that determine IP-management issues following successful product approval. These can include items such as minimum supply commitments, market segmentation arrangements (public vs. private distribution), quality control guarantees, price commitments, regulatory responsibilities, pharmacovigilance and product liability. Greater transparency surrounding these provisions would likely contribute a clearer picture of the sector's IP management arrangements in this area.
- **Adaptive Research for Non-Communicable Diseases:** There is almost no adaptive research in diagnostic, preventive and therapeutic areas for the Non-Communicable Diseases. FDCs for diseases such as diabetes and ischemic heart diseases have been cited as crucial to some Index Country socio-economic environments[44]. A WHO report published in 2005 indicated that 80% of deaths from Non-Communicable Diseases occur in low and middle income countries and the rapidity of their growth exceeds those from Communicable Diseases by around 20%[45]. The idea of a "polypill" was first advocated by the WHO in 2001. The concept is gathering momentum, but there remains an absence of evidence to support this approach, compounded by the fact that the priorities in this area have not been fully established. The only existing non-communicable chronic disease polypill has been developed by the Indian generics company, ***Dr Reddy's*** for ischemic heart disease.
- **Adaptive Development to Address a Broader Range of Index Country Needs:** Aside from a small number of vaccines (highlighted previously), our pipeline analysis (Table 9) indicates an absence of adaptive efforts outside of the 'Big 3' diseases. As an example of the needs for adaptive research outside the "Big 3", the WHO has recently highlighted how a dearth of manufacturers for pediatric products for NTDs is compounded by an absence of specific and suitable formulations[46]. Currently only ***GlaxoSmithKline*** makes a public commitment to consider issues such as heat, humidity resistance and ease of use in the development of all its products aimed at Index Countries. Needle-free delivery devices, pre-filled syringes, products with proven safety for pregnant-women and vaccines that do not require refrigeration are examples of valuable adaptive efforts.

[44] Wise. J. (2005). Polypill holds promise for people with chronic disease, Bulletin of the World Health Organization | December 2005, 83 (12)
[45] Ibid
[46] WHO (2010) Sources and prices of selected medicines for children

Intellectual Property Sharing

An important new ATM trend is companies sharing or providing third-party access to their Index Disease-related Intellectual Property for research purposes. This occurred most commonly through two mechanisms: Product Development Partnerships or providing access to relevant compound libraries. A compound library is a database of patented, small molecules with proven activity against a disease.

While a relatively new trend, this practice has been broadly adopted across the sector. It is too early to tell if this will result in successful products developed for Index Diseases but it is a new and promising approach. The majority of companies during the period of analysis have enabled third (public)-party access to at least one of their 'compound libraries'. This reflected at least 15 new arrangements signed across the sector by 11 of the originator companies.

No new examples of companies licensing-out individual molecules at later stages of the product development cycle have emerged for Index 2010. Prior examples include ***Gilead***, ***Merck & Co***. and ***Bristol-Myers Squibb,*** who have all out-licensed their HIV drugs to the International Partnership for Microbicides (IPM) through royalty-free licenses and Eisai's out-licensing for Chagas Disease to academic institutions in Venezuela.

Examples of Leading Practices

- **Strong Commitments to Pursuing More Flexible Approaches to Intellectual Property Management:** For Index 2010, the only public general commitment of this kind came from ***GlaxoSmithKline***'s CEO Andrew Witty in February 2009, when he committed to adopting a more "flexible approach to IP management"." Other leading companies make a similar commitment that "flexible approaches may be adopted, or considered on a case-by-case basis". Many of the originator companies make advanced, public commitments with respect to the 'access' terms of specific products before they are successfully launched. Examples during the period of analysis include ***Novartis*** and ***Merck & Co***., who have both stated that they will make any outputs from all their dedicated institutions available at 'not-for-profit' pricing terms (as mentioned earlier). These commitments, which are made possible due to the public and philanthropic funding that is used to facilitate R&D, are a positive trend in the sector. Additionally, ***ViiV Healthcare*** (***GlaxoSmithKline*** /***Pfizer***) and ***Eli Lilly***'s (2007) TB Drug Discovery Initiative operate under a similar commitment.
- **Facilitate Access to Dormant Intellectual Property for Index Disease Applications:** The majority of the companies have enabled third-party access to (at least) one of their compound libraries for screening against single or multiple Index Diseases in the last five years. During the period of analysis a majority (60%) of the originator companies made such agreements. Best practice is currently defined as those companies who provided access to multiple parties or for the investigation of multiple diseases. Such companies include: ***Pfizer***, ***Merck & Co***, ***Novo Nordisk***, ***Eisai*** and ***Sanofi-Aventis***. In terms of the impact on R&D activities, at the very earliest stages of the R&D pipeline for Index Diseases, based on our analysis, this practice has led to 18 'discovery stage' projects: three for sleeping sickness; five for Leishmaniasis; three for dengue; one for onchoceriasis; three for Chagas disease, two for shistosomiasis and one for diarrheal diseases. A number of

companies indicated to us that they were currently 'in negotiations' regarding compound library access. This is a relatively low-cost and potentially high impact contribution to ATM.

- **Intellectual Property Sharing with Index Country Research Institutions:** Despite a number of companies now having dedicated developing world research institutes in the Index Countries and others engaging in PDPs or R&D-related technology transfer activities (see chapter on Capability Advancement), there was only one example during the period of analysis of a company sharing IP with institutions in Index Countries. ***Novo Nordisk***'s contribution was an IP transfer through the donation of a license to its small molecule compound library to the National Center for Drug Screening (NCDS) affiliated with Shanghai Institute of Materia Medica, the Chinese Academy of Sciences, for the discovery of therapies for the treatment of NTD. Index Country partners may possess specialist knowledge and expertise inaccessible in the developed world, for example clinical and scientific NTD expertise; they may have better understanding of product needs, local market conditions and development constraints; and they may have better knowledge and ability to access and navigate health authorities as well as support locally run clinical trials.

Suggested Areas for Improvement

- **Greater Engagement in Collaborations and Intellectual Property Sharing across the Sector**: Currently 40% of covered companies do not have a current agreement with a third-party enabling access to their current compound libraries. Additionally 13 companies are currently involved in less than 2 Product Development Partnerships for Index Diseases. The former is a relatively inexpensive way of contributing to R&D for communicable Index Diseases which can potentially maximize the value from existing intellectual property. The latter can be a low cost (due to the funding that the partner brings and resource pooling) method of contributing to research for Index Diseases and can help companies acquire research expertise in new areas. This is especially valid for smaller firms or the ones with limited Index Disease in-house research capacity.

RECENT INNOVATIONS - RESEARCH AND DEVELOPMENT

Topic	Supporting 'Open-Source' Access to Knowledge
Company	***GlaxoSmithKline***
Description	***GlaxoSmithKline's*** commitment during the period of analysis to pursue more open and flexible approaches to addressing developing world health needs has recently been supported by a number of innovative and unique proposals. The 'Open Lab' provides 60 external researchers access (and USD 8 million in funding) to ***GlaxoSmithKline***'s dedicated developing world research institute in Tres Cantos, Spain. An 'open-access malaria compound library' will enable free, public access (including the chemical structures and associated assay data) via leading scientific websites to 13,500 screened compounds. In addition, the company has launched a 'knowledge pool' which was originally a collaborative initiative and now is independently run by BIO Ventures for Global Health (BVGH). The ***GlaxoSmithKline*** knowledge pool places approximately 80 patent families (over 500 granted patents and over 300 pending applications) in a pool to help others develop new medicines for neglected diseases. All of these efforts are in-line with the 'open source' principle – most well known in the computer software industry – in which, access to knowledge, information and tools are increased as a method of facilitating innovation.

Topic	Innovation in R&D Funding
Company	***GlaxoSmithKline*** and ***Novartis***
Description	***GlaxoSmithKline*** has recently adopted a new model aimed at increasing the sustainability of its Index Disease R&D funding. The company has announced that the price for its RTS,S malaria vaccine will be defined at cost plus a small return and the returns will be earmarked for reinvestment into developing world vaccines. ***Novartis*** is also championing an innovative funding mechanism, which is looking at a way of channeling and optimizing public funds to the most promising NTD development projects. The Fund for R&D in Neglected Diseases (FRIND) model would facilitate oversight and improve research portfolio management and coordination for NTD R&D. FRIND would own the exclusive licenses, with an obligation that medicines developed will be made available at not-for-profit prices and it would take central responsibility for initial and ongoing evaluation by a portfolio management team, ensuring selection and funding allocation to only the most promising compounds. This is currently a proposal only and has not yet been backed by concrete future commitments or funding.

Topic	R&D Collaboration with Peers
Company	***GlaxoSmithKline*** and ***Pfizer***
Description	Collaboration and intellectual property sharing between peers can be a valuable approach to prioritizing and coordinating R&D efforts within the sector, combining the relative research strengths of each partner to find the most efficient and effective methods in developing new treatments. ***GlaxoSmithKline*** and ***Pfizer's*** new company named ViiV focusing on HIV/AIDS, launched in November 2009, is an example of innovative peer-collaboration in R&D for an Index Disease.

EQUITABLE PRICING, MANUFACTURING AND DISTRIBUTION

This technical area covers company efforts in manufacturing, pricing and distribution of the products related to the Index Diseases and their impact on ATM in the Index Countries. The three main topics of this technical area have a direct impact on the quality, affordability and accessibility of pharmaceutical products in the Index Countries.

WHAT WE MEASURE

Equitable Pricing

According to the WHO, in the Least Developed Countries (LDCs), medicine costs account for the largest share of household expenditures after food. This can cause severe financial hardship, as 90% of individuals in these countries pay for medicines through "out of pocket" payments[47]. Equitable pricing is defined as a pricing mechanism that is intended to lower financial barriers to pharmaceutical access[48].

In several situations competitive pricing mechanisms cannot work. Some examples include patented products, exclusive voluntary licensing, "authorized generic"[49] and exclusive third party distribution contracts.

In such cases equitable pricing initiatives can be used to ensure affordability and access to medicine for the underprivileged individuals and communities.

Through tiered pricing, companies adjust prices to assure affordability of products in different social segments[50]. When tiered pricing includes special provisions for the poor countries and/or communities, it is a prime example of equitable pricing. Price tiers can be defined at the country level (inter-country tiered pricing) or for different

[47] World Health Organization (2004) Equitable Access to Essential Medicines: A Framework for Collective Action - WHO Policy Perspectives on Medicines, No. 08 Available at http://apps.who.int/medicinedocs/en/d/Js4962e/1.1.2.html ; accessed on 03/03/2010

[48] WHO (2004)

[49] An authorized generic (AG) is a pharmaceutical product that was originally marketed and sold by an originator company, but following patent expiry, is relabeled and marketed under a generic product name by the same company or in arrangement with a generics manufacturer.

[50] P.Yadav (2009) Differential Pricing. The interface of economics and supply chains. DFD - Industry Government Forum on Access to Medicines, October 12, 2009

supply channels and target groups in the country (intra-country tiered pricing). Inter-country tiered pricing can be extremely useful for Low Human Development Countries (LHDC) where most of the population remains poor. In contrast, intra-country tiered pricing can be better suited to countries where an expanding middle class co-exists with poor communities such as most of the Middle Human Development Countries (MHDCs), for example China, India).

An effective tiered pricing program would address the following issues[51]:

- Price tiers should accommodate those individuals and nations that face the highest financial barriers to access.
- Medicine prices for individuals and nations with high financial barriers to access should be set at or close to the marginal cost of medicine. Fixed costs such as R&D and marketing should be excluded from the price.
- Distribution and packaging of products under a tiered pricing program should include features to minimize the risk of product diversion. Product diversion is the redirection of products destined for poor countries or communities to other countries or communities
- Companies should work with their local distributors to guarantee that price-adjusted medicines reach their intended targets.

Considering the heterogeneity of countries and distribution channels, intra-country tiered pricing might not always be feasible or effective. Challenges arise when distribution channels for different social segments are not sufficiently isolated to minimize the risk of product diversion. In such cases, methods such as non-exclusive voluntary licensing, which decrease prices through generic competition, can be effective alternatives. For demonstrative examples please refer to the “Patents and Licensing” chapter.

To avoid repetition, this report, uses the term “tiered pricing” to refer to all efforts with special provisions and equitable prices for the countries or individuals with financial barriers to access.

Marketing Approval (Registration)

Registration is the regulatory process of verifying the quality, safety and efficacy of pharmaceutical products for different markets. Companies must carry out trials and submit documents to qualify for marketing approval in each country where they market their products. Index 2010 covers registration practices that are conducive to improved access:

[51] Ridley (2005). Price Differentiation and transparency in the global pharmaceutical market. Pharmaeconomics, 23(7): 651-658

- Registering medicines for high-priority need areas regardless of the viability of the target Index Country markets
- Collaboration with international mechanisms that speed the introduction of pharmaceutical products in the Index Countries, such as the WHO prequalification process and the FDA tentative approval process
- Committing not to seek or advocate for exclusivity of clinical trial data submitted for registration in the Index Countries. This would facilitate competition and lead to increased supply and lower prices for much-needed medications following the expiration of patents

Manufacturing & Distribution

Product quality issues and unsuitable packaging are both important barriers to ATM[52]. While most international pharmaceutical producers comply with international and regional quality standards such as FDA, EMA and WHO Good Manufacturing Practices, it is important that these standards apply to drugs sold in the Index Countries. Also, product packaging must be tailored to the needs of the target communities.

[52] World Health Organization (2010) Fact sheet Counterfeit medicines: a public health challenge. Available at http://www.who.int/mediacentre/factsheets/fs275/en/ accessed 02/03/2010

Companies play an important role, especially in countries with weak regulatory enforcement regimes. For this topic, the following principles have guided our analysis:

- Products sold in Index Countries should meet the same quality standards as those of the developed world.
- Product packaging, including product labeling, should be adapted to Index Country needs and languages.
- Product packaging should be designed to minimize the risk of product counterfeiting.
- The company should maintain the capacity to carry out effective product recalls in Index Countries.

HOW WE MEASURE

For Index 2010, this technical area has been expanded to include in-house manufacturing and distribution efforts of the companies as related to ATM. The name of this area has been changed to “Equitable Pricing, Manufacturing and Distribution”. In Index 2008, manufacturing and distribution efforts of the companies were covered under Drug Manufacturing, Distribution and Capability Advancement. This change is to differentiate pricing and manufacturing efforts from the companies’ capability advancement efforts in the Index Countries. To measure performance in this area, we have evaluated what portion of

the companies' Index Disease related product portfolio is covered by tiered pricing. Index 2010 also notes how many Index Countries benefit from each firm's tiered pricing efforts.

We evaluated the companies' registration efforts by measuring the number of LHDCs in which Index Disease products are registered or registration is attempted. Other indicators measure companies' quality standards, packaging adaptation efforts and their capacity for managing product recalls in the Index Countries. For more information about the indicators used for measurement, please refer to Appendix D: Indicators and Scoring Guidelines.

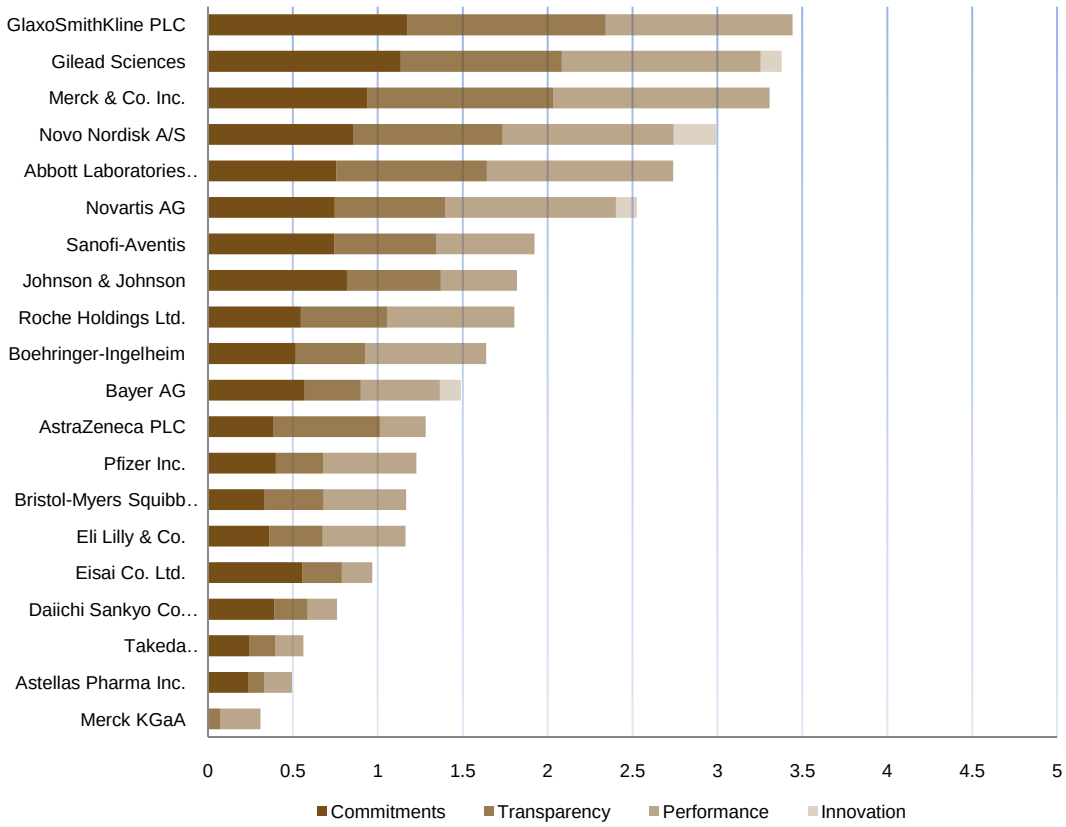
Sources

For company analysis on this technical area, the following sources of data have been used:

- Companies' reporting on their product portfolio and pricing mechanisms
- Input from pricing experts from Harvard University and DFID
- Pricing reports and databases of WHO and Health Action International.

COMPANY RANKINGS– EQUITABLE PRICING, MANUFACTURING AND DISTRIBUTION

Figure 11. Originator Company Ranking- Equitable Pricing, Manufacturing & Distribution



Note that manufacturing and distribution were covered under “Drug Manufacturing, Distribution and Capacity Advancement” in Index 2008.

The top companies under this technical area are ***GlaxoSmithKline***, ***Gilead*** and ***Merck & Co***. All have established inter-country tiered pricing policies based on affordability, for a number of Index Disease products in Index Countries.

These companies have strong commitment to high quality manufacturing for products destined for Index Countries and have implemented special packaging to both address the local needs of target communities as well as prevent drug diversion from Index Countries to more affluent markets.

Compared to Index 2008, four of the companies that experienced significant

increases in ranking include ***Abbott*** (16th to 5th), ***Novartis*** (13th to 6th), ***Bayer*** (17th to 11th), ***Gilead*** (7th to 2nd) and ***Pfizer*** (18th to 13th).

Abbott's ranking improvement is due to implementing inter-country tiered pricing strategies for two of its HIV/AIDS medicines, the introduction of intra-country tiered pricing and broad registration and WHO prequalification of its Index Disease products.

Similarly, in the case of ***Novartis***, its increase in rank is largely attributed to its performance in both inter- and intra-country tiered pricing and use of needs-based packaging, such as pictograms, in the distribution of its Index Disease products in Index Countries. The company's use of multiple distributors to encourage competition in local markets is considered an innovative approach under this technical area and has contributed to the company's ranking improvement.

Bayer's improved disclosure compared to Index 2008 has allowed for a better assessment of its pricing and distribution policies.

Gilead's move into the top two companies under this technical area is a reflection of its above average commitments, transparency and performance in equitable pricing policies, Index Disease product registration in Index Countries, quality management and special packaging tailored to local needs. The size adjustments used in Index 2010, have also helped ***Gilead,*** which is one of the smallest originator covered by the Index 2010, achieve its improved ranking.

The improvement of ***Bayer*** (17th to 11th) and ***Pfizer*** (18th to 13th) is partly because of coverage of generics companies under a separate list in Index 2010 (***Cipla*** was ranked 6th and ***Ranbaxy*** 9th in Index 2008) and removal of ***Wyeth*** (ranked 15th in Index 2008) from the Index due to its acquisition by ***Pfizer.***

Two companies that have experienced a significant decrease in ranking compared to Index 2008 are ***Bristol-Myers Squibb*** (***BMS***) (5th to 14th) and ***Johnson & Johnson*** (***J&J***) (3rd to 8th). In the case of ***BMS***, the company's commitments and transparency under this technical area are below sector peers. Furthermore, whereas several other companies under coverage have begun to introduce new equitable pricing strategies, it does not appear that ***BMS*** has expanded its access program and equitable pricing model during the period of analysis and thus has been overtaken in rank by many peers. For ***J&J***, compared to sector peers, its performance in equitable pricing is below average as its strategy is not well defined and the company has had little improvement in its overall disclosure of pricing policies since the last iteration.

Eisai leads the Japanese companies in this technical area. While the company has yet to establish any pricing models based on affordability in Index Countries, it is the only Japanese company to make any future commitments in this area for both inter- and intra-country tiered pricing and not pursuing data exclusivity in the Index Countries.

OVERVIEW OF KEY ATM INDEX 2010 METRICS

Table 11. Originator Company Practices - Equitable Pricing, Manufacturing & Distribution

		Abbott (ABT-N)	AstraZeneca (AZN-LN)	Bayer (BAY-FF)	Bristol-Myers Squibb (BMY-N)	Eli Lilly (LLY-N)	Gilead (GILD-O)	GlaxoSmithKline (GSK-LN)	Johnson & Johnson (JNJ-N)	Merck (MRK-N)	Merck KGaA (MRK-FF)	Novartis (NOVN-VX)	Novo Nordisk (NOVO'B-KO)	Pfizer (PFE-N)	Roche (ROG-VX)	Sanofi-Aventis (SAN-FR)	Astellas (4503-TO)	Daiichi Sankyo (4568-TO)	Eisai (4523-TO)	Takeda (4502-TO)	Boehringer-Ingelheim
Marketing approval	**Products Prequalified Under WHO pre-qualification / FDA tentative approval *1***	X		X	X		X	X	X	X		X		X	X	X					X
Pricing	**Inter-country tiered pricing**	X		X *3*	X	X	X	X	X	X		X	X		X	X					X
	Intra-country tiered pricing *2*	X		X *3*				X		X		X	X			X					

1 At least one product found on the WHO pre-qualification list or FDA tentative approval

2 At least one example found for at least one product

3 Outside the scope of Index 2010.

Equitable Pricing

There has been an increase in the number of originator companies that have engaged in tiered pricing since Index 2008. In total, thirteen originator companies have implemented tiered pricing programs and three more have a clear long-term future commitment to this practice. ***Abbott***, ***Bayer***[53], ***Boehringer-Ingelheim***, ***Bristol-Myers Squibb***, ***Gilead***, ***GlaxoSmithKline***, ***Johnson & Johnson***, ***Eli Lilly***, ***Merck & Co***., ***Novartis***, ***Novo Nordisk***, ***Roche*** and ***Sanofi-Aventis*** have introduced inter country/regional tiered pricing, taking into consideration the economic differences between Index Countries and developed countries and their ability to pay and/or the burden of disease in those countries. Nonetheless, the implementation of tiered pricing has mostly been limited to relatively small subset of companies' Index Disease products and only to the poorest countries.

As a leading practice in the sector, ***GlaxoSmithKline*** committed to reducing prices for several of its patented medicines for a wide range of Index Diseases such as asthma, diabetes, COPD and malaria for a large subset of Index Countries. However, the price reductions are set as a percentage of a drug's price in the developed markets, rather than a price based on LDC residents' ability to pay or production costs.

Novo Nordisk is another company which has expanded its tiered pricing scope since Index 2008. The company's access program for Novolin (an insulin formulation) reached 38 LDCs in 2009. ***Merck & Co***. also stands out as, since Index 2008, it has extended its equitable pricing model by adding two vaccines to its existing HIV inter-country tiered pricing program.

Of the companies that have already implemented tiered pricing, six (***Abbott***, ***Bayer****, ***Gilead***, ***GlaxoSmithKline***, ***Novartis*** and ***Merck & Co***.) have set performance indicators and evaluate the outcomes of their equitable pricing practices. ***Gilead***, ***Merck & Co***. and ***Novartis*** measure and disclose the number of patients who received products through their tiered pricing program, while ***Roche*** provides an aggregated evaluation of patients' access to their not-for-profit products.

In terms of transparency, only six of the Index companies, ***Bayer****, ***Eli Lilly***, ***Gilead***, ***GlaxoSmithKline***, ***Merck & Co***. and ***Novo Nordisk*** have publicly defined their criteria for identifying price tiers. ***Eli Lilly***, ***GlaxoSmithKline*** and ***Novo Nordisk*** have published their baseline prices and have disclosed the maximum price for some of their patented products

[53] Bayer's tiered pricing for family planning products has not been taken into consideration in the ranking as it is outside the scope of Index 2010 (see Appendix A, Access to Medicine Index 2010 Scope).

for a subset of Index Countries. For ***Eli Lilly*** and ***Novo Nordisk*** the Index Country price is at 20% and for ***GlaxoSmithKline*** at 25% of the price for the same product in developed countries.

Regarding the introduction of intra-country tiered pricing mechanisms, some companies stated that they face difficulties implementing a tiered price for sub-populations. It can be difficult to find distribution channels that are sufficiently isolated to implement tiered pricing without risking significant drug diversion. Intra-country tiered pricing initiatives have been undertaken by ***Abbott***, ***Boehringer-Ingelheim***, ***GlaxoSmithKline***, ***Merck & Co***. and ***Novartis***, alongside the diabetes program of ***Novo Nordisk,*** which was acknowledged in Index 2008. ***Abbott***, ***GlaxoSmithKline*** and ***Merck & Co*** have developed their own mechanisms aimed at ensuring different prices for different socio-economic groups, by accounting for such groups' levels of income and health burden.

As companies find it difficult to implement intra-country pricing independently, some firms are joining forces with other organizations that have a strong presence in Index Countries.

For example, in 2008, ***Sanofi-Aventis*** terminated its four-year-old "Anti-malaria Drug Access Card (CAP)," an intra-country pricing initiative in six countries due to "administrative complexities". But ***Sanofi-Aventis*** plans to make its product available at affordable prices through the Global Fund's "Affordable Medicine Facility (AMFm)". This program will subsidize the malaria products of ***Sanofi-Aventis***, ***Novartis*** and others for several countries in need.

Novartis's "Patient Access Program" also offers a wide spectrum of pricing mechanisms, including discounts to governments and co-payments that reflect customers' economic status (see Examples of Leading Practices below).

AstraZeneca made commitments in both Index 2008 and Index 2010 to implement intra-country tiered pricing, but so far, no related initiatives have been found.

Médecins Sans Frontières has signaled – and our analysis confirms – that companies are focusing their pricing programs on HIV, tuberculosis and malaria, while less attention is being paid to other communicable and non-communicable Index Diseases.

Also, only five companies, ***Abbott***, ***Gilead***, ***GlaxoSmithKline***, ***Merck & Co***. and ***Novartis*** (only for Coartem Dispersible, its anti-malaria product) have been willing to disclose the percentage of units supplied at not-for-profit prices in Index Countries. More disclosure in this area and also the

method of determining the not-for-profit prices would be welcome.

Examples of Leading Practices

- **Measuring Output in Tiered Pricing Programs:** Several companies have introduced tiered pricing programs. However, most of them fail to measure the key indicator of success, which is the number of patients in each tier who have received needed products. ***Abbott***, ***Gilead***, ***GlaxoSmithKline***, ***Novartis*** and ***Merck & Co***. have disclosed the impact of their tiered pricing mechanism by reporting the number of patients that received the product at cost. More measurement and disclosure of output would promote more accurate evaluation of tiered pricing programs.
- **Disclosing the Basis for Calculation of Not-for-Profit Prices for the Lowest Tier:** In defining product pricing for the lowest tier, several companies commit to providing the product "at cost" or at "not-for-profit" prices. How the firms arrive at their cost figures, though, remains mostly unknown. One study[54] indicates that "variable costs" (manufacturing costs excluding R&D, capital and marketing) tend to comprise around 15% of the total cost of producing a pharmaceutical product. This is a useful benchmark for evaluating the actual discount given to the poorest customers. Among the companies under analysis, ***GlaxoSmithKline***, ***Novo Nordisk*** and ***Eli Lilly*** have disclosed the basis for calculation of cost in some cases. ***Boehringer-Ingelheim*** has committed to excluding marketing and R&D costs for the lowest price tier in its tiered pricing programs.
- **Collaboration with International Organizations in Implementation of Intra-Country Tiered Pricing:** Distribution challenges may interfere with tiered pricing efforts in Index Countries. Collaboration with specialized global organizations can help with implementation. ***Novartis*** malaria initiatives suggest that joint distribution arrangements can help both intra- and inter-country tiered pricing. The firm has defined different prices and brands for developed and Index Countries. Also, within Index Countries it has developed different prices and packaging for public-private sector distribution, with a not-for-profit price set for the public sector; this price is established in collaboration with the WHO. In countries where distribution channels are not regulated, ***Novartis*** is considering a partnership with Affordable Medicines Facility - malaria (AMF-m) which offers subsidized prices through the private sector. ***Sanofi-Aventis*** is undertaking similar collaboration with AMF-m.

Suggested Areas for Improvement

- **More Utilization of Equitable Pricing to Reach the Poorest in MHDCs:** Intra-country tiered pricing is still used by only a few companies in the sector (please refer to the related best practice section). Despite the challenges of implementing intra-country equitable pricing, the Medium Human Development Countries in particular would benefit from such programs. More collaborative and innovative intra-country pricing models would be welcome.
- **More Focus on Non-Communicable Diseases:** Most tiered-pricing products address HIV, tuberculosis or malaria. Index companies should do more regarding non-communicable diseases, as these are an increasing health burden in Index Countries[55].
- **More Transparency about Equitable Pricing Mechanisms and their Output:** Currently, companies' disclosure regarding their equitable pricing mechanisms and the impact of such programs is low. Sharing more detail about tiered pricing programs could promote accountability and widespread adoption of best practices.

[54] C. Grace (2003). Equitable pricing of newer essential medicines for developing countries: evidence for the potential of different mechanisms, Department for International Development, UK, internal report
[55] Abergunde DO, Mathers CD, Adam T, Ortegon M, Strong K. (2007). The burden and costs of chronic diseases in low-income and middle-income countries. Lancet 370: 1929–38

Marketing Approval

Currently, nine out of 20 companies commit to register at least some of their products in countries where there is a need, even if those nations' markets might not be profitable. ***Abbott***, ***Boehringer-Ingelheim***, ***Eisai***, ***Gilead***, ***Johnson & Johnson***, ***Merck & Co***, ***Novo Nordisk*** and ***Roche*** have committed to registering a subset of their products based on need. However, the scope of such commitments is mostly limited to a few products in their portfolio. Only two companies, ***GlaxoSmithKline*** and ***Eisai*** (though this company has very few Index Disease products***)***, have recently committed to Index Country registration of all their needed products where the regulatory infrastructure permits.

To overcome regulatory bottlenecks, ***Gilead*** has developed a standard registration dossier and collaborates with local partners and regional leaders in order to speed up the registration process for its HIV products.

Public disclosure of the registration status of pharmaceutical products in the Index Countries is low, with nine of the 20 companies disclosing their registration status in Index Countries. Also, there is little public reporting on the criteria used to establish overall drug registration priorities. ***GlaxoSmithKline***, ***Gilead*** and ***Merck & Co***. provide extensive information in this area for some of their HIV products.

On a more positive note, the majority of the originator companies with eligible products are participating in international quality assurance processes such as the WHO prequalification process and the FDA tentative approval process. These processes have both centralized and simplified quality verification of medicines. In addition, they facilitate procurement by international organizations and registration by some national regulators. Nine originator companies evaluated by Index 2010 already have a WHO prequalified product.

Examples of Leading Practices

- **Introducing and Disclosing Targets for the Registration of New Products:** ***Johnson & Johnson*** has committed to specific timelines and number of countries for registration of its anti-retroviral products in particular countries.

Suggested Areas for Improvement

- **More Flexibility With Regard to Data Exclusivity in the Index Countries:** Following the expiration of a patent, the introduction of generic competition is a major driver for increased affordability and accessibility. Sharing of clinical trial data by originator companies would enable generic firms to introduce drugs more

quickly. Even when a national regulator has adopted data exclusivity regulations, the originator companies could still choose to share their clinical trial data with generics companies on an as-needed basis. Most of the originator companies either do not make a statement in this area or make it explicit that they advocate for data exclusivity.

- **Faster Market Approvals for a Wider Range of Index Diseases:** Médecins sans Frontières and Oxfam have called for pharmaceutical companies to provide better access to new treatments for all high-priority diseases, not only The Big Three. Non-communicable diseases in particular need greater attention from drug firms and regulators.

Manufacturing Quality & Distribution

All Index 2010 originator companies declare their compliance with international manufacturing guidelines and standards. Therefore, any products destined for use in the Index Countries are held to the same standards as products sold in developed countries. Overall public disclosure of the companies about product recalls in the Index Countries is low.

However, environmental requirements and storage conditions in Index Countries demand customized products, packaging and distribution methods. This has led the WHO to introduce new stability guidelines for Zone IVb climates. These are hot and humid areas, such as China, Brazil, Cuba, India and the ASEAN nations). However, the application of such standards is left up to individual drug companies. Only a few companies, such as ***GlaxoSmithKline*** and ***Novartis,*** have been found to invest in the development of tropical climate-appropriate packaging.

To meet national regulatory requirements, all companies have provided product documentation in the local language(s) for some Index Countries. However, in many Index Countries, regulations in this area are weak and in such cases providing local language documentation for the products is left to the companies.

In addition many Index Countries have high levels of illiteracy. For these countries, initiatives to use pictograms and other forms of visual instructions as ***Pfizer***, ***Novartis*** and ***Sanofi-Aventis*** do for their malaria products are critically important.

In the area of product counterfeiting, multiple companies work with international organizations like the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT). ***Pfizer*** and ***Merck KGaA,*** have introduced special bar-coding or holograms on their external packaging to make it more difficult for the products to be counterfeited.

As for distribution, ***Gilead***, ***Novartis*** and ***Novo Nordisk*** have emerged as leaders in their attempts to control the pricing practices of local distributors. Gilead has set a maximum mark-up of 10-15% for its

11 Index Country ARV distributors. ***Novartis*** has committed to choosing multiple non-exclusive distributors in Index Countries. Also, in 2008, ***Novo Nordisk*** introduced a pilot program to evaluate whether patients with diabetes actually benefit from the company's tiered pricing programs (see "Recent Innovations").

Examples of Leading Practices

- **Different Brands for Different Distribution Channels:** Drug diversion can interfere with companies' efforts to implement tiered pricing mechanisms. ***Bayer***, ***GlaxoSmithKline***, ***Novartis*** and ***Sanofi-Aventis*** have initiatives to thwart the diversion of their tiered-priced products from the intended distribution channels. These companies have introduced new brands that are only available through public distribution channels, while the same product, under an existing brand, is made available through in private market.

Suggested Areas for Improvement

- **More Influence on Local Distributors:** Several pricing reports[56] cite the high mark-ups added by local distributors and private sector retail outlets as a major driver of the final price of the products. The pharmaceutical companies are in a good position to help address this issue. They can choose multiple non-exclusive distributors and monitoring the final price of the products to the patients (for a demonstrative example please refer to the following section, "Recent Innovations").

[56] Health Action International (2009) Medicine Prices a new approach to measurement

RECENT INNOVATIONS - EQUITABLE PRICING, MANUFACTURING AND DISTRIBUTION

Topic	Ensuring Affordable Prices at the Point of Access
Company	***Novo Nordisk***
Description	Despite companies' engagement in tiered pricing, there is a risk that price cuts may not reach the consumer as a result of distribution markups and wholesalers' margins. Novo Nordisk has implemented a pilot program in Tanzania of engaging with local distributors to reduce the price paid by consumers. The program has led to a 50% price reduction below the previous LDCs price.

Topic	Controlling Distributors' Mark-ups
Company	***Gilead*** and ***Novartis***
Description	***Novartis*** used multiple non-exclusive distributors to spur competition between local distributors. Gilead sets maximum mark-up for its Index Country distributors. Holding down distributors' mark-up through direct controls or facilitating competition between distributors helps ensure that patients benefit from tiered pricing programs.

Topic	Tailored Packaging for Environmental and Social Needs
Company	***Novartis***
Description	For its malaria program, ***Novartis*** has engaged with local health workers and also community members (both literate and illiterate) to develop appropriate packaging. The company has already applied a similar process for its leprosy blister packs, which use multiple languages & pictograms, color coding for different formulations and are resistant to humidity and harsh environments.

PATENTS AND LICENSING

Originator companies view patents as a crucial means to recoup R&D costs and foster further innovation. The companies' approach to intellectual property protection can have significant impact on ATM in the Index Countries. Under this technical area, the companies' policies and practices related to patents and intellectual property are analyzed under "Trade Aspects of Patents" and "Non-Exclusive Voluntary Licensing."

WHAT WE MEASURE

Trade Aspects of Patents

Index Country markets can be as large as or larger than developed-nation markets, but the typical customer has lower ability to pay. Consequently, success in such markets requires an approach that is based on selling higher volumes of products at lower prices. This is in contrast to the Western markets price-based approach, which charges higher prices recoup of fixed costs such as research (through patents) and marketing.

Following the introduction of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, the issue of patent protection in lower income countries has been a topic of great debate, conflicts and litigations.

The 2001Doha Declaration on the WHO TRIPS and Public Health, clarified exceptions to the IP protections outlined in the TRIPS agreement. These exceptions (or flexibilities) include countries' ability to use compulsory licensing[57] and parallel importation[58], as well as the right of LDCs not to grant or enforce pharmaceutical product patents until 2016.

Pharmaceutical company approaches to patent related issues can have far-reaching influence on ATM in the Index Countries. Under "Trade Aspects of

[57] Compulsory licensing enables a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder.
[58] Parallel importation is importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder's consent. http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html

Patents" some of the key areas that are analyzed are:

- The companies' stance on TRIPS flexibilities and the Doha Declaration on TRIPS and Public Health
- The level of transparency on status of product patents in different countries
- The level of transparency with regard to controversial patent-related issues, controversies and litigations relevant to ATM and in the Index Countries
- Whether companies refrain from applying for or enforcing product patents in the LDCs, as called for by the Doha Declaration on TRIPS and Public Health
- Whether companies have been supportive of the concept of patent pools[59] (such as the UNITAID patent pool) which could be an effective mechanism to decrease the cost of patented products for the Index Countries.

Non-Exclusive Voluntary Licensing:

More non-exclusive voluntary licenses to multiple generics companies would spur competition, lowering prices and increase supply, while still allowing the patent holder to receive license fee. The impact of voluntary licenses depends on the license territory (number of the countries covered by the license) and the number of licensees[60].

Non-exclusive voluntary licensing can help the originator companies focus on their competitive advantage of innovative research while benefiting from the low cost and increasingly high quality production capacity and distribution channels of the generics companies. In addition, such business models can shift the originator-generic relationship to a more constructive and collaborative one with potential positive consequences for access.

For this topic, the following policies and practices of originators are analyzed:

- Whether companies engage in non-exclusive voluntary licensing across their Index Disease-related market portfolio
- The number of products for which companies have granted non-exclusive voluntary licenses to international generics companies
- Whether companies commit to charging moderate license fees
- Whether voluntary licenses are accompanied by comprehensive technology transfer from the originator companies to their licensees

[59] A patent pool is a mechanism that pools the patents for a set of products from different companies with the aim of facilitating licensing and research.

[60] A voluntary License is where a pharmaceutical company that holds patents on a product (patentee) offers on his own accord a licence to a third party (usually a generic producer) to produce, market and distribute the patented product. (for company practices related to sharing of IP prior to product approval see Research & Development for Index Diseases)

- The geographical scope of the licenses or license territory

HOW WE MEASURE

Commitments of the companies are analyzed based on their public policy stances on different intellectual property topics such as TRIPS flexibilities, patent extensions in Index Countries, In the area of transparency, we analyzed companies' level of public policy disclosure regarding TRIPS, TRIPS+[61] and the usage of TRIPS flexibilities by the Index Countries.

To capture companies' performance, we assessed their patenting practices in Index Countries in the context of TRIPS and the Doha Declaration on TRIPS and Public Health. We examined patent-related IP litigations and controversies most significant to ATM. For the purpose of analyzing litigations and controversies any cases in the Index Countries were captured regardless of whether they are covered by the disease scope of Index 2010. We also evaluated whether the companies have filed for or enforced patents in the LDCs.

Regarding voluntary licensing activities, we considered the total number of products covered by such licenses, their geographical scope and the extent to which companies accompanied licenses with technology transfer. Companies that granted broader license territories, including MHDCs, received higher scores. We only counted in "active" voluntary licenses those under which production is currently occurring, or else the licensee is actively pursuing production. Companies receive credit for voluntary licenses granted without global or regional marketing exclusivity. For more information on the methodology used in this area, please refer to Appendix D: Indicators and Scoring Guidelines.

Sources

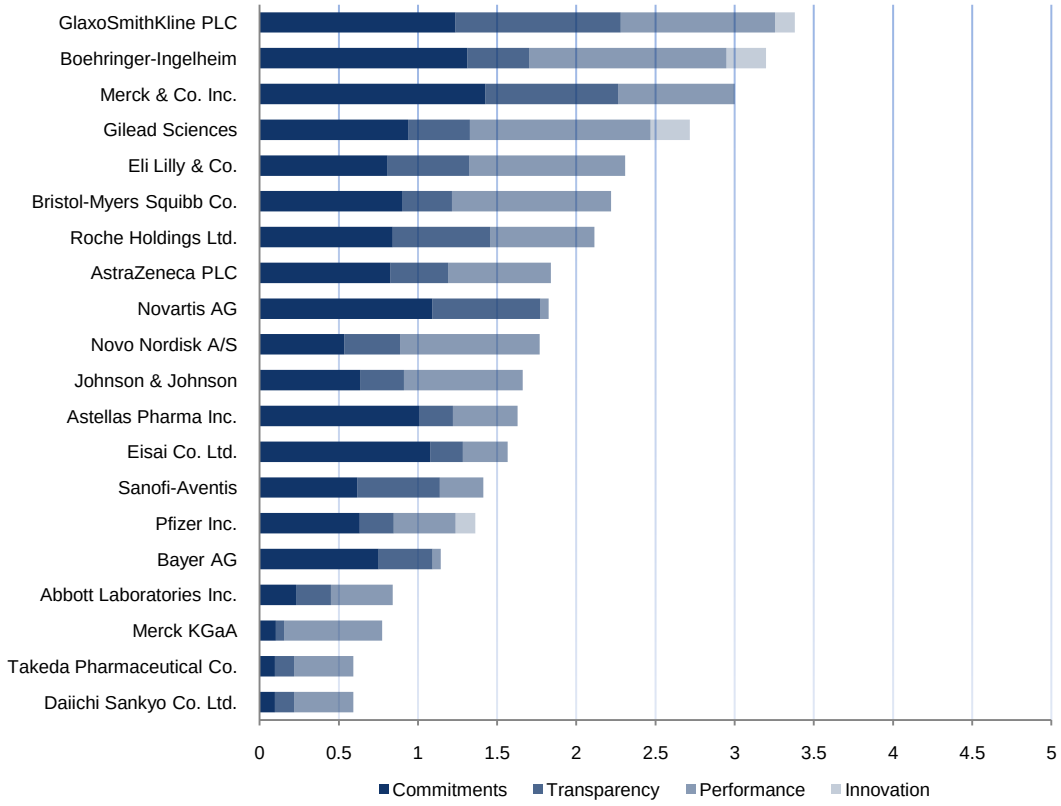
External sources for this technical area included Factiva and LexisNexis searches for litigations, company interviews/data submissions and input from UNITAID.

For checking the status of product patents in Index Countries WHO and other third party patent databases were used.

[61] TRIPS+ is an amended version of TRIPS which limits the use of TRIPS flexibilities. TRIPS+ is not a WTO ratified set of requirements and is adopted by some Index Countries only based on bi-lateral or regional trade agreements.

COMPANY RANKINGS– PATENTS AND LICENSING

Figure 12. Originator Company Ranking - Patents & Licensing



The leading companies in this technical area are ***GlaxoSmithKline***, ***Boehringer-Ingelheim***, ***Merck & Co***. and ***Gilead.*** All four companies are involved in non-exclusive voluntary licensing or similar activities with generics companies for at least one Index Disease-related product. Both ***GlaxoSmithKline*** and ***Gilead*** define wide licensing territories for their generics company licensees and accompanies its non-exclusive voluntary licensing activities with detailed technology transfer. ***GlaxoSmithKline***, ***Boehringer-Ingelheim*** and ***Gilead*** are also the leading three of the four companies undertaking innovative initiatives related to patents & licensing.

Three companies that have significantly improved in ranking compared to Index 2008 are ***AstraZeneca*** (14th to 8th), ***Novartis*** (18th to 9th) and ***Roche*** (16th to 7th).

AstraZeneca's improved ranking is primarily a result of its increased levels of transparency on patent-related issues such as TRIPS, TRIPS flexibilities and

patent extensions for Index Disease products.

Although ***Novartis*** has received widespread criticism for its Gleevec case in India, it has increased its level of disclosure compared to the last Index and has made strong commitments in this technical area. For example, ***Novartis*** commits to respect the rights of Index Countries to use the TRIPS flexibilities, commits not to seek, maintain, or enforce patents in the least-developed countries (LDCs) and states that it will consider non-exclusive voluntary licenses on a case-by-case basis.

Roche's improved ranking was driven by its increased level of transparency on patent-related issues in the Index Countries such as TRIPS and TRIPS flexibilities (e.g. compulsory licensing).

Companies that have had significant decreases in ranking under patents & licensing are ***Bayer*** (7th to 16th), ***Merck KGaA*** (5th to 18th), ***Sanofi-Aventis*** (6th to 14th) and ***Johnson & Johnson (***4th to 11th). During the period of analysis, ***Bayer*** has been involved in a significant patent-related case in India for its cancer therapy. While several Index 2010 companies were involved in patent-related controversies and litigations in the Index Countries, ***Bayer***'s lower ranking in performance coupled with its relatively low ranking in commitments and transparency has resulted in a decreased ranking compared to other companies that have improved in these areas since the last Index.

In ***Johnson & Johnson***'s case, the decrease in ranking is mainly due to the company's lack of patent-related commitments compared to sector peers, such as the absence of a commitment not to file or enforce its patents in the LDCs. ***Sanofi- Aventis*** has also had below average commitments in this area and has been involved in controversies related to the use of TRIPS flexibilities in Thailand.

Merck KGaA's lower rank compared to the Index 2008 is driven by a number of factors, such as an absence of commitment to respect the rights of the Index Countries to use the TRIPS flexibilities and the company's relatively low level of public disclosure on patent-related issues such as TRIPS, TRIPS flexibilities and patent extensions. Companies such as ***Bayer***, ***Johnson & Johnson*** and ***Merck KGaA*** that have a relatively low level of public disclosure on their positions related to TRIPS and the TRIPS flexibilities generally ranked lower compared to industry peers.

OVERVIEW OF KEY ATM INDEX 2010 METRICS

Table 12. Originator Company Practices - Patents and Licensing

		Abbott (ABT-N)	AstraZeneca (AZN-LN)	Bayer (BAY-FF)	Bristol-Myers Squibb (BMY-N)	Eli Lilly (LLY-N)	Gilead (GILD-O)	GlaxoSmithKline (GSK-LN)	Johnson & Johnson (JNJ-N)	Merck (MRK-N)	Merck KGaA (MRK-FF)	Novartis (NOVN-VX)	Novo Nordisk (NOVO'B-KO)	Pfizer (PFE-N)	Roche (ROG-VX)	Sanofi-Aventis (SAN-FR)	Astellas (4503-TO)	Daiichi Sankyo (4568-TO)	Eisai (4523-TO)	Takeda (4502-TO)	Boehringer-Ingelheim
Trade aspects of patents	**Public disclosure on TRIPS and/or "TRIPS flexibilities"**	Medium	Medium	Low	Low	Medium	Low	Medium	Low	Yes	Low	Medium	Medium	Low	Medium	Medium	Low	Low	Low	Low	Low
	General commitment to respect TRIPS "flexibilities"	-	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	-	Yes	-	Yes
	Commitment not to file or enforce patents in Least Developed Countries	Yes[I]	Yes	Yes	Yes[II]	Yes	-	Yes[II]	-	Yes	-	Yes	-	Yes[I]	Yes	-	Yes	-	Yes[III]	-	Yes[I]
Non-Exclusive Licensing	**Senior-level company engagement with UNITAID patent pool (to date)**	-	-	-	-	-	Yes	-	Yes	Yes	-	-	-	-	-	-	-	-	-	-	-
	Grants multiple, non-exclusive, voluntary licenses to generics companies for Index Disease medicines	-	-	-	Yes	-	Yes	Yes	-	Yes	-	-	-	-	-	-	-	-	-	-	No[IV]
	Accompanies voluntary licenses with detailed technology transfer	-	-	-	Yes	-	Yes	If requested	-	-	-	-	-	-	Yes	-		-	-	-	-

H =Stance disclosed on the majority of issues: TRIPS, compulsory licenses, patent extensions, parallel imports etc.

M = Partial disclosure on 1-2 of the above issues

L = Minimal/no disclosure on the above issues

I Only for HIV medicines only or in Sub-Saharan Africa

II File in LDCs on occasion; company claims it supports the capacity of IP offices in LDCs

III Eisai does not seek patent protection in LDCs with the exception of Bangladesh

IV Issues non-assert declarations (substitute for granting voluntary licenses)

Trade Aspects of Patents

Our research found that nine of the 20 originator companies publicly disclose some of their positions toward TRIPS and/or the TRIPS flexibilities. These companies are ***Abbott***, ***AstraZeneca***, ***Eli Lilly***, ***GlaxoSmithKline***, ***Merck & Co***., ***Novartis, Novo Nordisk, Roche*** and ***Sanofi-Aventis***.

Despite this lack of public reporting, most companies provided our research team with full disclosure on their stance on TRIPS, TRIPS flexibilities and various other patent and competition-related issues such as patent extensions and data exclusivity (see Public Policy & Market Influence). 13 of the 20 originator companies made a general commitment not to file or enforce patents in the LDCs for some products, although the scope of the commitment varied. Of the companies that made a commitment in this area, seven extended this commitment broadly across their entire operations, while three of the 13 companies committed not to enforce patents for specific medicines, such as those used to fight HIV, or in specific geographic regions such as sub-Saharan Africa.

Most of the companies support the use of TRIPS flexibilities, although some say that they believe certain flexibilities, such as compulsory licensing, should be limited to particular countries, diseases, or emergency situations.

During the period of analysis, originator companies have been involved in a number of patent related lawsuits and controversies most of which fall under one of the following categories

- *Applications for patents or extensions rejected by Index Country intellectual property offices, appealed by the company*: Examples include India's rejection of **Novartis**'s patent application for Gleevec, which was appealed by the company; the case is on-going. India also rejected **Gilead's** patent application for its HIV drug, Tenofovir Disoproxil Fumarate; the company plans to appeal. Rejection of this patent can endanger the company's related non-exclusive licensing.
- *Legal action or advocacy against use of TRIPS flexibilities by Index countries (especially Medium Income Countries):* Examples include ***Abbott***'s fight against Thailand's 2008 demand for a compulsory license for its HIV medicine Kaletra/Aluvia. ***Sanofi-Aventis*** has been involved in a similar case for a cancer drug.

- *Patent infringement lawsuits between originator and generics companies:* These cases are common, involving a majority of the originator companies.
- *Advocacy efforts by companies to link product registration to its patent status (a TRIPS+ requirement):* During the period of analysis **Bayer** and **Bristol-Myers Squibb** attempted to block the registry of generic versions of their products in India based on patent infringement claims; the claims were rejected by an Indian court.

Such significant cases highlight the differences between the originators, generic and Index Country governments over their interpretation of TRIPS and intellectual property protections.

Regardless of their result, such litigations and controversies compromise the regulatory environment for the companies and can make stakeholder engagement and collaboration more difficult.

One promising initiative that can help decrease the cost of patents for the Index Countries is the patent pool initiative of UNITAID. The idea of patent pools in other sectors dates back to 1856, when a patent pool for sewing machines was established by five American manufacturers[62]. A patent pool is a mechanism that pools the patents for a set of products from different companies with the aim of facilitating licensing and research.

For example, if a generics company were seeking to produce an FDC consisting of three patented medicines held by three separate patent holders, the generics company would be required to seek licensure from only one patent-pool holding organization rather than seeking licensure from all three patent holders[63]. In addition, voluntary licensing of products by the generics companies would be facilitated by the patent pools.

The first patent pool for pharmaceutical products is still being established by the UNITAID. This patent pool will initially cover only HIV medicines.

Most of the companies with a relevant product portfolio have entered into dialogue with UNITAID about its proposed patent pool. However, only ***Gilead***, ***Johnson & Johnson*** and ***Merck & Co***. have engaged in high-level dialogue with UNITAID. As the pool has not yet been established, no company has yet made an official commitment.

[62] Moser , Lampe (2010) Do Patent Pools Encourage Innovation? Evidence from the 19th-Century Sewing Machine Industry, Working paper

[63] Mueller, J (2007). "Taking TRIPS to India-Novartis, Patent Law and Access to Medicines". New England Journal of Medicine 356;6

Examples of Leading Practices

- **Clear, Detailed Company Positions on TRIPS and TRIPS "flexibilities":** ***GlaxoSmithKline*** has the highest degree of public disclosure. The company discloses its position on TRIPS, its usage of TRIPS flexibilities (e.g. compulsory licensing) and patent extensions. ***Abbott***, ***AstraZeneca***, ***GlaxoSmithKline***, ***Merck & Co***., ***Novartis*** and ***Sanofi-Aventis*** also publicly disclose their positions on TRIPS and/or TRIPS flexibilities. ***Merck & Co***., ***GlaxoSmithKline***, ***Abbott*** and ***AstraZeneca*** publicly disclose their stance on compulsory licensing.
- **Commitment Not to File or Enforce Patents in the LDCs in line with the Doha Declaration on TRIPS:** Through its collaboration with DNDi, ***Sanofi-Aventis*** foregoes all patent rights, in any country, for its anti-malarial FDC of artesunate + amodiaquine (ASAQ).This commitment extends beyond stipulations outlined in the Doha Declaration, which only includes LDCs. ***Roche*** commits not to file patents for any medicines in the company's portfolio in the UN LDCs and to forego legal action against infringement for any generic manufacturing company that supplies medicines to LDCs.
- **Engagement with Patent Pools:** ***Johnson & Johnson/Tibotec, Merck & Co***. and ***Gilead*** agreed to collaborate with the Patent Pool Initiative of UNITAID and have had several high-level meetings with the group. ***GlaxoSmithKline*** has supported the formation of a pool for intellectual property (including patents and molecule sharing) for 16 NTDs. ***GlaxoSmithKline***'s patent pool differs from the Patent Pool Initiative of UNITAID in that it is mainly focused on promoting R&D for NTDs. In contrast, the UNITAID Patent Pool emphasizes increased affordability and facilitation of non-exclusive licensing of ARVs as one of its primary objectives.

Suggested Areas for Improvement

- **Commitment to More Transparency on Company Positions Related to Patents:** Index 2010 encourages greater public disclosure on the companies' patent-related stances, particularly, regarding TRIPS and the TRIPS "flexibilities" outlined in the Doha Declaration, which are relevant to ATM.
- **Commitment Not to File or Enforce Patents in the LDCs:** In-line with the Doha Declaration on TRIPS and Public Health, the LDCs are exempt from patent enforcement till 2016. Currently many companies do not make to commitment to respect this and some have enforced patents in some LDCs.
- **More Transparency on Products' Patent Status:** None of the companies have been fully open about patent status for Index Disease products in the Index Countries. Generally, public disclosure of patent status in the Index Countries is limited to drugs under ATM programs. Although this information should be publicly available from local regulatory authorities in the Index Countries, companies are better placed to systematically report this information. More disclosure in this area can help increase accountability and more sustainable patenting practices.

Non-Exclusive Voluntary Licensing Practices

At the time of this analysis, only four out of 20 companies, ***Bristol-Myers Squibb***, ***Gilead***, ***GlaxoSmithKline*** and ***Merck Co***., have formally incorporated non-exclusive voluntary licensing into their ATM strategies. These firms granted licenses only for HIV medicines and the license territories in most of the cases were limited to a small subset of Index Countries. ***Gilead*** has been leading the other companies in this area by licensing its HIV products to 14 generics companies for a license territory covering 95 countries. For all the four companies, royalty fees have been moderate at 5% or have been

waived. Several Index 2010 companies expressed willingness to engage in more non-exclusive voluntary licensing in the future.

Roche and ***Boehringer-Ingelheim*** have had a unique approach in this area. As called for by the Doha Declaration on TRIPS and Public Health, ***Roche*** has committed not to enforce patents for its HIV products in the LDCs and sub-Saharan Africa. In addition, the company provides technology transfer to any generics company that will produce drugs for the LDCs (see Capability Advancement in Product Development and Distribution).

Boehringer-Ingelheim has committed to not charging license fees in 78 countries and to granting "non-assert declarations" to generics companies. It does require that licensees obtain WHO pre-qualification to ensure product quality. For more information please refer to the "Recent Innovations" section at the end of this chapter.

Examples of Leading Practices

- **Granting Multiple, Non-Exclusive, Voluntary Licenses in the Index Countries Combined with Effective Quality Standards and Technology Transfer:** As of December 2009, ***Gilead*** had issued a total of 14 non-exclusive voluntary licenses. Licensees are able to establish their own sales prices for their generic products, yet are required to pay ***Gilead*** a royalty fee of 5% on net sales of products. ***Gilead*** outlines an extensive licensing territory (95 developing countries) which also includes MHDCs. ***Gilead***'s licensing practices are well above average compared to sector peers. As of 2009, ***GlaxoSmithKline*** has granted nine non-exclusive voluntary licenses to local African manufacturers, the most recent in July 2009, when the company entered into a royalty-free, non-exclusive voluntary license with Aspen PharmaCare (South Africa) for the company's ARV Abacavir. ***GlaxoSmithKline*** publicly discloses the status of its voluntary licenses, as well as the output, i.e. the number of Combivir and Epivir tablets produced by the licensees.
- **Effective Technology Transfer and Monitoring of Production Performance of the Licensees:** ***Gilead*** accompanies voluntary licenses with technology transfer agreements, including descriptions/specifications related to the product manufacturing process, stability data, analytical method validation and details of impurities. ***Gilead*** also assists licensees in applying for WHO prequalification. ***Bristol-Myers Squibb*** engaged in detailed technology transfer agreements with its two licensees, Aspen PharmaCare (South Africa) and Emcure Pharmaceuticals (India), for its HIV medicine Atazanivir (Reyatez) in 2006. Technology transfer included transfer of expertise related to the manufacturing process, handling, storage, testing and packaging of the API in Reyatez.

Suggested Areas for Improvement

- **More Non-Exclusive Voluntary Licenses:** Only four out of the 20 originator companies covered by Access to Medicine Index 2010 currently have non-exclusive voluntary licensing activities. Several generics companies support and are ready to engage in non-exclusive voluntary licensing activities (for more information, please refer to the Generic Manufacturers section of this report).
- **Increase in Scale and Effectiveness of Non-Exclusive Licensing:** Companies can improve in this area by increasing the number of voluntary licenses for Index Disease-related products in the Index Countries and permitting relevant licensees to sell within a large number of Index Countries (including MHDCs). In addition, more detailed public disclosure related to 1) the number of supply units produced under license 2) the scope

of the licensing territory and 3) details of any technology transfer that accompanied the licenses would help achieve better evaluation of companies' practices and more learning.

RECENT INNOVATIONS - PATENTS AND LICENSING

Topic	Non-assert declarations
Company	***Boehringer-Ingelheim***
Description	As part of its ATM strategy ***Boehringer-Ingelheim*** issues non-assert declarations. Non-assert declarations, which are royalty-free, combined with training and quality checks, can be a sustainable solution to improving ATM in the Index Countries. Under ***Boehringer-Ingelheim***'s policy, any company that is WHO-prequalified automatically qualifies for non-assert declarations for Nevirapine. Generics companies can then begin producing Nevirapine-containing HIV medicines for eligible countries (78 in total). Prior to 2007, ***Boehringer-Ingelheim*** granted voluntary licenses to generics companies in Africa. However, due to the difficulty associated with assessing the production capabilities of these companies, ***Boehringer-Ingelheim*** began granting non-assert declarations as a better means of facilitating access to its HIV medicines.

CAPABILITY ADVANCEMENT IN PRODUCT DEVELOPMENT AND DISTRIBUTION

The WHO cites* six main barriers to the improvement of ATM, two of which are covered in this section – the unreliable supply of medicines to Index Country markets and the inconsistent quality of products sold in Index Countries. This technical area covers the companies' initiatives to improve local capacity in Supply Chains, Research & Development and Manufacturing Quality.

* World Health Organization. (2004) *WHO Medicines Strategy Countries at the Core 2004-2007*

WHAT WE MEASURE

Capability Advancement in the Pharmaceutical Supply Chain

Improving local supply chain capabilities in the Index Countries is essential to enhancing ATM[64]. Drug supply chain problems in Index Countries include drug diversion, depleted inventories, inadequate cold chains[65] and counterfeit products. While advancements in several of these areas fall outside the contractual responsibilities of the companies, they would directly benefit from better distribution networks in Index Countries. International efforts to address such challenges include work by the WHO through the International Medical Products Anti-Counterfeiting Task Force (IMPACT) and the work of Medicines Transparency Alliance (MeTA) in improving the capacities and transparency of several Index Country governments.

Stock-outs in health dispensaries and hospitals are a frequent occurrence, especially in more rural areas of the Index Countries. For example, in Malawi, it is estimated that only 10% of health dispensaries and government facilities are well-stocked with anti-malaria and HIV medicines[66].

[64] Department for International Development (2010). Available at: http://www.dfid.gov.uk/Documents/publications/atm-factsheet0106.pdf Accessed April 28, 2010

[65] Cold chain is a supply chain with refrigeration capacity for products with low heat stability.

[66] Oxfam International (2010). Available at: http://www.oxfam.org/campaigns/health-education/stop-stock-outs. Accessed April 29, 2010.

Along with weak supply chains, Index Countries also lack sufficient monitoring of adverse drug reactions (ADR) and effective pharmacovigilance systems. Only about 27% of LDCs have national pharmacovigilance programs registered with the WHO, compared to approximately 96% of OECD countries[67]. Originator companies can contribute both resources and expertise to improve Index Country pharmacovigilance systems.

Capability Advancement in Manufacturing Quality

Pharmaceutical companies can help ensure the quality of medicines in Index Countries through different mechanisms. Such mechanisms include:

- Demanding high standards licensees and contract manufacturers
- Engaging in effective technology transfer
- Assisting licensees in obtaining quality management systems that conform to international quality standards; such standards include FDA, EMA and WHO Good Manufacturing Practices.

The WHO's Global Strategy on Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) brings together a number of strategies to support better manufacturing and distribution in Index Countries. Under this area the contributions of the companies to addressing the challenge of low quality production in the Index Countries are evaluated.

Capability Advancement in R&D

Improving the local R&D capabilities of Index Countries can play a significant role in the development of tailored remedies for Index Country environments through adaptive research. Pharmaceutical companies can help build capacity in this area by engaging in public private partnerships with Index Country research organizations, supporting the R&D capabilities of university students through grants and partnering with academic institutions. Such efforts may not only improve ATM in the Index Countries but could also help hold down R&D costs for Index Country needs and help companies better understand Index Country market conditions.

HOW WE MEASURE

For Index 2010, originators' in-house manufacturing and distribution indicators have been moved under the "Equitable Pricing, Manufacturing and Distribution" technical area. "Capability Advancement in Product Development and Distribution" focuses on the capacity-building efforts of companies in the Index Countries.

[67] Pirmohamed, Munir; Atuah, Kwame N; Dodoo, Alex N O; Winstanley, Peter (2007). "Pharmacovigilance in developing countries", BMJ 2007;335:462

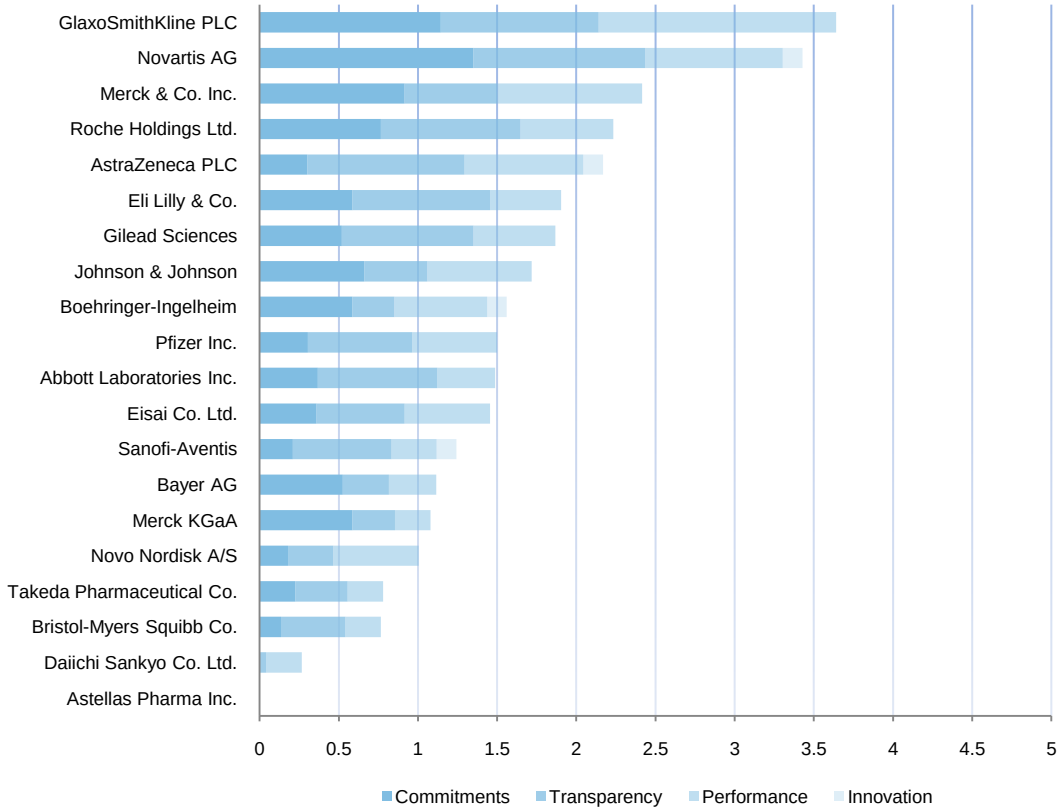
Index 2010 examines companies' collaborations with local governments, regulatory authorities and institutions to improve supply chain systems and R&D capacity. We also considered the content of technology transfer agreements between originators and Index Country manufacturing partners. For the list of indicators under this technical area, please refer to Appendix D, Indicators and Scoring Guidelines.

Sources

Sources for this technical area included news searches, company interviews/data submissions and independent reports.

COMPANY RANKINGS– CAPABILITY ADVANCEMENT IN PRODUCT DEVELOPMENT AND DISTRIBUTION

Figure 13. Originator Company Ranking - Capability Advancement in Product Manufacturing and Distribution



In Index 2010, in-house manufacturing and distribution have been moved to Equitable Pricing, Manufacturing and Distribution. Consequently, in Index 2010, this technical area purely focuses on the capability advancement efforts of the companies. Some of the ranking changes under this technical area are due to this structural change.

Leading companies in this technical area are ***GlaxoSmithKline***, ***Novartis***, ***Merck & Co.*** and ***Roche***. All four companies display strong commitments toward improving the capacity of Index Countries are actively engaged in research collaborations with local Index Country institutions and have detailed initiatives devoted to improving the local supply chain or quality management systems in

the Index Countries. Both ***GlaxoSmithKline*** and ***Novartis*** are ranked as leading companies under at least three of the four strategic pillars and each have strong commitments, a high level of disclosure and key initiatives aimed at improving the capacity of Index Countries. ***Novartis*** also had innovative initiatives under this technical area.

Three companies that have significantly improved since the Index 2008 are ***AstraZeneca*** (14th to 5th), ***Gilead*** (15th to 7th) and ***Roche*** (10th to 4th). All three companies have increased their level of disclosure in this technical area since the last Index and have expanded their existing capacity advancement initiatives in the Index Countries. ***AstraZeneca*** enhanced its activities related to improving the local supply chain by providing training and assistance to Ministries of Health and regulatory authorities in Index Countries such as India, Kenya and Egypt and additionally worked to develop a hand-held device that is being used as a legal instrument to identify counterfeit products in several countries. ***Gilead*** has expanded its activities toward improving the local research capabilities in both Uganda and Mozambique. Lastly, ***Roche*** significantly expanded its AIDS Technology Transfer Initiative to include agreements with seven new local partners, increasing the total number of partnerships to 13, during the period of analysis. These new partnerships are aimed at improving the quality management systems of Index Countries through long-term technology transfer programs.

Since the Index 2008, companies that have significantly decreased in ranking are ***Bayer*** (1st to 14th), ***Bristol-Myers Squibb*** (6th to 18th) and ***Merck KGaA*** (9th to 15th). During the period of analysis, all three companies ranked poorly in the performance pillar and had minimal to no initiatives related to improving quality management systems in the Index Countries and engaging in public-private partnerships (PPPs) or collaborations with academic institutions to improve research capabilities. The addition of research capacity indicators to this technical area was one of the main reasons for the changes in ranking. All three companies also had below average transparency compared to the majority of sector peers.

Leading among the Japanese companies is ***Eisai***. In 2009, ***Eisai*** began its first "TDR Clinical R&D Career Development Fellowship" to support the research capabilities of students from Index Countries. ***Eisai*** is also collaborating with the Institute of Clinical Research India to provide training to students and support research in that country.

Capability Advancement in the Supply Chain

Most companies' efforts to improve local supply chains are aimed at preventing counterfeiting and drug diversion in the Index Countries. Companies active in this area, often in partnership with global initiatives, are ***Abbott***, ***Johnson & Johnson***, ***GlaxoSmithKline***, ***Pfizer***, ***Merck & Co***. and ***AstraZeneca***. Companies that have partnered with local regulatory authorities and law enforcement agencies to help prevent counterfeiting in the Index Countries include ***AstraZeneca, Merck KGaA and Pfizer***.

AstraZeneca and ***Merck KGaA*** both have been active in capacity building for addressing local counterfeiting. These companies have developed test units which are used by local regulatory authorities to detect whether medicines are counterfeit. Merck KGaA states that more than 350 of its test units are now used in about 70 African and Asian countries.

Novartis is one of the few companies to launch an initiative to help dispensaries detect stock-outs and maintain sufficient inventories of much-needed drugs. For more information please refer to Examples of Leading Practice.

While these programs are encouraging, few companies have devoted significant resources to any supply chain programs. Other than anti-counterfeiting initiatives, most companies have done little to address supply chain issues, including the elimination of stock-outs, better forecasting of supply needs and assistance with establishing cold chains.

Examples of Leading Practices

- **Knowledge Sharing and Training on Supply Chain Management:** Since 2004, ***Johnson & Johnson***'s Health Care Training Fund has focused on building capacity related to HIV/AIDS supply chain management throughout Africa. Initiatives include training in monitoring & evaluation to identify limitations in supply-chain activities, the development of a web-based platform for health care professionals involved in supply-chain management and training activities related to supply and warehouse management.

Suggested Areas for Improvement

- **More Engagement in Capacity Building for Control of Low Quality or Counterfeit Products:** Counterfeiting is a global problem that affects countries at all income levels, although counterfeit medicines are generally more prevalent in countries where supply and distribution channels, importation and sale of medicines are less regulated and where enforcement is limited. In addition, genuine but substandard products are also a major barrier to ATM in the Index Countries. Few companies currently collaborate with local governments and distributors to improve the integrity of local supply chains and to better detect substandard products in the Index Countries.

- **Capacity Building to Maintain Drug Inventories:** Companies can help Index Countries establish improved feedback channels and better systems to help eliminate stock-outs. Only one company under coverage has been found to be active in this area.
- **Capacity Building in Environmental Adaptation of Local Supply Chain:** Securing strong cold chains is vital for the transportation of temperature-sensitive medicines such as vaccines, which lose their effectiveness outside of narrow temperature ranges. Maintaining proper temperature ranges from the site of production to beneficiaries in the Index Countries is challenging because of limited resources, high temperatures and unreliable electricity supply. No companies were found to have undertaken significant initiatives in this area.

Capability Advancement in R&D

Of the originator companies examined, 16 out of 20 were engaged in at least one Public-Private Partnership (PPP) aimed at increasing local research capacity within the Index Countries. The extent and long-term level of commitment to PPPs varied across the sector. Most of them provide financial support on a request-for-proposal (RFP) basis to support research efforts in Index Countries. These efforts include grants/fellowships for students in developing countries, collaboration with academic institutions and the establishment of contract research programs.

Abbott, AstraZeneca, ***Eisai, Novartis*** and ***Pfizer*** have research centers or research collaborations in the Index Countries which employ local staff and scientists.

Companies' efforts under this technical area consist mostly of support for students and clinical research programs. Some companies fostered research through the creation of collaborative programs and institutes in the Index Countries. Activities in this area were generally limited. Please refer to "Examples of Leading Practices".

Examples of Leading Practices

- **Collaborative Research with Index Country Academic Institutions:** ***Pfizer***'s Infectious Diseases Institute (IDI) in Kampala, Uganda focuses on improving the delivery of HIV/AIDS care through research, training, clinical care and prevention at African academic institutions. The IDI currently sponsors approximately 20 ongoing research projects. Pfizer's partners in the IDI program include the Ugandan Ministry of Health and Mulago Hospital, Makerere University, the Academic Alliance, Accordia Global Health Foundation and the Infectious Diseases Society of America Impact on Society program. ***Abbott*** recently finished renovation of a Research Center in China's Zhangjiang Hi-Tech Park located near Shanghai. The Center will serve as a platform for ***Abbott***'s team to partner with Chinese organizations and local academic centers.
- **Launching Index Country Collaborative Research Organizations:** ***Novartis***' NEHCRI (the Novartis Institute for Tropical Diseases NITD - Eijkman Institute - Hasanuddin University Clinical Research Initiative) is a joint research partnership that aims to support the clinical research capabilities for research into dengue, tuberculosis and malaria in Indonesia. Novartis provides expertise and training related to drug discovery, development, technologies and financial support for students, post-docs and healthcare professionals.

Suggested Areas for Improvement

- **More Partnerships with Index Country Research Organizations:** Local research organizations could help originators learn more about each country's product needs. Currently, however, only four companies have active research collaborations with local academic institutions and research organizations.

Capability Advancement in Quality Management

Although several companies select licensees based on stringent quality and manufacturing standards, few companies assist local licensees achieve such standards. ***Gilead*** and ***Roche*** assist Index Country manufacturers in acquiring WHO prequalification. ***AstraZeneca*** provides education and technology transfer to licensees in China and India.

Pfizer and ***GlaxoSmithKline*** state that transfer technical know-how to local manufacturers. At ***GlaxoSmithKline***, this transfer generally mostly takes place post-patent expiry when the company starts outsourcing production of its products.

Companies typically conduct audits at the outset of transfer and periodically every few years. However, companies mostly view improvements in quality management as the responsibility of the licensee and local regulatory authorities. Companies with leading practices in this area, such as ***Roche*** and ***Eli Lilly,*** have long-term technology transfer initiatives that permit Index Country generics companies to independently manufacture high-quality medicines. See Leading Practices in this area for more information.

Examples of Leading Practices

- **Public Private Partnerships for Improving Local Manufacturing Quality:** Through the MDR-TB Partnership, ***Eli Lilly*** (in conjunction with Purdue University) assists licensees of its two anti-tuberculosis drugs Cycloserine and Capreomycin comply with Good Manufacturing Practices (GMP) and assists them in raising the overall quality of their production standards. This assistance is provided to four generics companies: Aspen PharmaCare (South Africa), Hisun Pharmaceuticals (China), Shasun Chemicals and Drugs (India) and SIA International (Russia). In addition to training, the company provides financial assistance to licensees for the purchase of equipment necessary to manufacture the medications.
- **Extensive Quality Management Technology Transfer to Local Licensees:** In 2006, ***Roche*** began its AIDS Technology Transfer Initiative (TTI) and in 2008 expanded it to assist local manufacturers in LDCs and sub-Saharan Africa in the production of generic versions of ***Roche***'s second-line ARV Saquinavir. ***Roche*** works on site with local manufacturers to facilitate technology transfer agreements that help companies meet international manufacturing standards. Since 2006, ***Roche*** has entered into a total of 13 licensing agreements. During 2008 and 2009 alone, the company signed agreements with seven new local partners.

Suggested Areas for Improvement

- **More Quality Management Technology Transfers and Quality Audits:** Companies could do more to support drug manufacturing in the Index Countries. In addition to auditing licensees, companies could work with them to rectify weaknesses identified by the audit process.

RECENT INNOVATIONS - CAPABILITY ADVANCEMENT

Topic	New technology to Help Improve Local Storage and Supply Chain Capacities
Company	***Boehringer-Ingelheim***
Description	Through the Boehringer/UTI Central Medical Stores Logistics Project, ***Boehringer-Ingelheim*** developed a tool to improve local supply chain management in Africa. ***Boehringer-Ingelheim*** has worked with the government of Botswana to improve the supply and delivery of medicines throughout that country. The project aims to transform the country's Central Medical Stores into a world class distribution center. The firm aims to replicate this system in other African nations, including Rwanda. Primary objectives include monitoring and improving warehouse lay-out and workflow, identifying inefficiencies and strategies related to ARVs and improving distribution networks within countries.

Topic	R&D Partnership in Africa Aimed at Capacity Building in Multiple African Countries
Company	***Sanofi-Aventis***
Description	In May 2009, ***Sanofi-Aventis*** and the not-for-profit product development partnership DNDi entered into R&D collaboration for Fexinidazole for human African trypanosomiasis (sleeping sickness). The partnership also commits to working with local stakeholders to improve clinical research capabilities in several African countries and will also focus on building the capacity of the countries' regulatory agencies.

Topic	Handheld Counterfeit Detection Units
Company	***AstraZeneca and Merck KGaA***
Description	To address counterfeiting, ***AstraZeneca*** developed a hand-held counterfeit detector based on laser spectroscopy. A number of pharmaceutical companies are using this device to detect counterfeit products and in Colombia, the detector is used as a legal instrument for detecting counterfeit products. ***Merck KGaA***, in partnership with the Global Pharma Health Fund (GPHF), developed a portable anti-counterfeiting laboratory known as the "GPHF-Minilab". This portable device can detect 43 compounds to determine their authenticity. ***Merck KGaA*** has introduced the GPHF- Minilab in both Gambia and Haiti.

Topic	**Working with Index Country Governments to Improve Forecasting Capabilities to Prevent Stock-Outs**
Company	***Novartis***
Description	Through its "SMS for Life" program, Novartis is collaborating with the Ministry of Health in Tanzania to develop a system that collects up-to-date, on-hand stock level information on Artemisin-based combination therapy (ACT) from 4,600 public health systems and dispensaries. This information will help maintain sufficient supplies of anti-malarial drugs. Inventory info for the drugs will be collected centrally via a web-based system and made available by zone, region, district and at individual health centers.

PRODUCT DONATIONS AND PHILANTHROPIC ACTIVITIES

Product donations and philanthropic activities can have a meaningful impact on global ATM. Examples include philanthropic campaigns for disease eradication and corporate responses to natural or human-made disasters. This chapter provides an analysis of current originator company practices regarding product donations and philanthropic activities.

WHAT WE MEASURE

Product Donations

Donations are typically made by companies in response to governments and/or NGO requests during emergencies. Such donations are generally taken from available company stock, are supply-driven and are referred to as "multi-drug donations". Some companies also attempt to target specific diseases and geographical areas through ongoing donation programs. These "single-drug donations," are typically need-driven targeted programs with a defined strategy as to the type, volume and destination of donated products. These sustained single-drug donation programs are believed to be more effective in addressing health issues than multi-drug inventory driven programs[68].

It is important that all donations be carried out responsibly and in accordance with internationally recognized standards, such as the WHO Inter-Agency Guidelines for Drug Donations. Unwanted or inappropriate donations (e.g. near- expiry products, improperly labeled products, etc.) place an additional burden on Index Country health systems, as mechanisms and resources for safe and effective drug disposal may be lacking or costly[69].

[68] Department for International Development (DFID) (2005). "Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry." DFID-UK Government Policy Paper.
[69] Pinheiro, Cristina P. (2008) - Drug Donations: what lies beneath." Bulletin of the World Health Organization 86(8): 580-581; Snell, Beverly. (2001). "Inappropriate drug donations: the need for reforms." The Lancet 358: 578-580

Philanthropy

Index 2010 considers philanthropic activities focused on building health infrastructure and local health delivery systems in Index Countries. Health infrastructure deficiencies such as lack of effective healthcare financing, or healthcare delivery infrastructure are major barriers to ATM in most of the Index Countries. Especially in the case of Chronic Diseases, due to the long-term need for therapy, strong health infrastructure is indispensible to successful care.

While such activities are not the primary responsibility of the pharmaceutical industry, there is a business incentive for companies to invest in this area. Not only does strengthening health infrastructure facilitate greater ATM at the local level, it also allows companies to deliver their products in the target markets more effectively. Such initiatives also help build better relationships with local authorities and communities.

HOW WE MEASURE

Under product donations, Index 2010 measures companies' commitments to ethical drug donation programs through compliance with the WHO Inter-Agency Guidelines for Drug Donations and their disclosure level of the type, volume and destination of products for each donation program. We evaluated the scale and scope of companies' donation programs by assessing their drug donations (i.e. single-drug or multi-drug) and the quality of disclosure for each program.

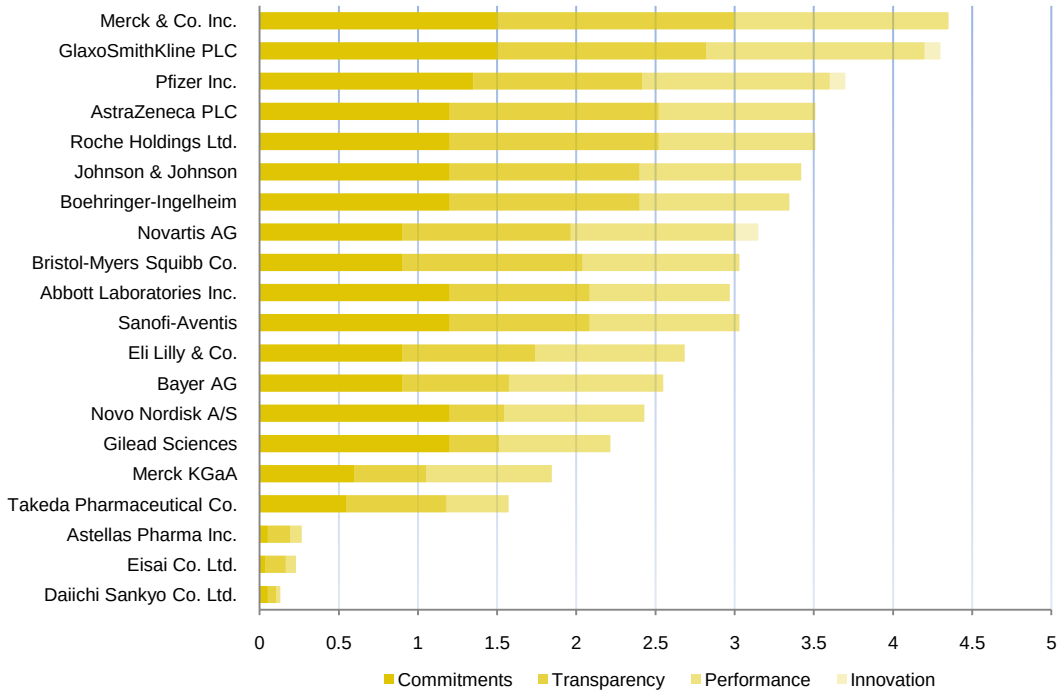
Under philanthropy, the Index seeks to highlight not only a company's commitment to pursue health infrastructure-related philanthropic projects, but also the rationale behind each endeavor and the resources dedicated to these activities. For Index 2010, Drug Donations (as it was formerly titled) and Philanthropic Activities have been merged into one technical area. For more information, please refer to the 2010 Methodology and Stakeholder Review.

Sources

In addition to data provided directly from companies, external sources used for this chapter include Factiva and Lexis/Nexis, as well as an interview conducted with an international donations management agency.

COMPANY RANKINGS - PRODUCT DONATIONS AND PHILANTHROPIC ACTIVITIES

Figure 14. Originator Company Ranking - Product Donations and Philanthropic activities



Note that In Access to Medicine Index 2010, Product Donations and Philanthropy are ranked under the same technical area. In Index 2008, they were ranked separately.

The leading companies in this technical area are ***Merck & Co.***, ***GlaxoSmithKline*** and ***Pfizer***. All top companies operate at least one long-term targeted drug donation program (single-drug donations) and have several ongoing health infrastructure building philanthropic activities. In addition to a strong performance in this area compared to sector peers, ***Merck & Co.*** and ***GlaxoSmithKline*** also have clear and detailed commitments to and public disclosure of such activities.

Compared to Index 2008, two companies that have significantly increased in ranking are ***Pfizer*** (13th in Donations and 11th in Philanthropy to 3rd) and ***Johnson &***

Johnson (11th in Donations and 6th in Philanthropy to 6th).

Pfizer's move up in ranking is largely due to its two single drug donation programs and its innovative partnership with Grameen Health – a health delivery network affiliated with Grameen Bank – to discover and build more sustainable drug delivery systems in resource-limited settings.

J&J is also involved in a single drug donation program in Index Countries and has improved the transparency of its drug donation programs. Given the Index 2010's greater emphasis on analyzing the scale and scope of drug donation programs, both companies' involvement in strategic and more sustainable single-drug donation programs is a key contributing factor to their increase in rank.

Three companies that have decreased in ranking significantly since Index 2008 are ***Eli Lilly*** (7th in Donations and 2nd in Philanthropy to 12th), ***Bayer*** (6th in Donations and 4th in Philanthropy to 13th) and ***Novo Nordisk*** (9th in Donations and 8th in Philanthropy to 14th).

Unlike Index 2008, in Index 2010, insulin manufacturers are ranked based on the same indicator weights as the other companies. This has had negative impact on the ranking of insulin manufacturers such as ***Eli Lilly*** and ***Novo Nordisk***.

Eli Lilly's commitments and process to ensure that product donations reach intended patients is not as explicit as those of sector leaders. Both factors contributed to ***Eli Lilly's*** move downwards in ranking in Index 2010.

In the case of ***Bayer***, while the company's single drug donations programs for human African trypanomiasis (sleeping sickness) and Chagas disease are recognized, it is not apparent how the company ensures that these and its multi-drug donations reach intended patients. Additionally there is low transparency on the company's donation decision making process on type, volume and destination of donations. As a result the company's score on commitments and transparency is lower than its performance score in this technical area. Exclusion of the company's donation of contraceptives from Index 2010 has also contributed to the decrease of its ranking. For

Novo Nordisk, although the company is involved in a number of philanthropic activities in Index Countries, the company does not appear to have any single-drug donation programs and compared to sector peers, its transparency in donations in general is well below average.

Among the Japanese companies, ***Takeda*** is the leader in the group for this technical area. In 2009, the company established the ***Takeda***-Plan Healthcare Access Program and has begun to implement various healthcare projects specifically targeting children in Indonesia, China, the Philippines and Thailand.

OVERVIEW OF KEY METRICS

Table 13. ORIGINATOR COMPANY PRACTICES – Product Donations and Philanthropic Activities

		Abbott (ABT-N)	AstraZeneca (AZN-LN)	Bayer (BAY-FF)	Bristol-Myers Squibb (BMY-N)	Eli Lilly (LLY-N)	Gilead (GILD-O)	GlaxoSmithKline (GSK-LN)	Johnson & Johnson (JNJ-N)	Merck (MRK-N)	Merck KGaA (MRK-FF)	Novartis (NOVN-VX)	Novo Nordisk (NOVO'B-KO)	Pfizer (PFE-N)	Roche (ROG-VX)	Sanofi-Aventis (SAN-FR)	Astellas (4503-TO)	Daiichi Sankyo(4568-TO)	Eisai (4523-TO)	Takeda (4502-TO)	Boehringer-Ingelheim
Product Donations	Single-Drug Donation Programs for Neglected Tropical Diseases			Sleeping Sickness - Chagas				Lymphatic Filariasis (elephantitis)	Hookworms/Roundworms	River blindness-Lymphatic Filariasis	Shistosomiasis (and other helminth (worm) infections	Leprosy - Fascioliasis		Trachoma		Sleeping Sickness - Leishmaniasis					
Philanthropic Activities	Philanthropic Activities Focused on Index Country Health Infrastructure	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Public Disclosure of Resources and/or output*	Partial	Full	Partial	Partial	Partial	Partial	Full	Partial	Full	Partial	Partial	Partial	Partial	Partial	Partial	None	None	None	Full	Partial

*Full=disclosure at the project level for all activities Partial = partial disclosure (for some activities) None= no disclosure or not engaged in healthcare infrastructure activities

Product Donations

Our research found that almost all originator companies are engaged in multi-drug donations to Index Countries. Products are generally donated from existing stocks and in response to requests made by governments or international donation agencies. Several companies make product donations to third-party research institutions to support clinical research. For ***Gilead***, this type of contribution makes up the bulk of its product donations in Index Countries.

Most researched companies have made a commitment to comply with the WHO Inter-Agency Guidelines on Drug Donations. Many companies work in partnership with third parties (e.g. International Health Partners, Americares, MSF, etc.) – typically non-governmental organizations – to manage product donation programs. No breaches of WHO Guidelines or controversies related to cases of premature termination of donations programs were found in Index Countries for any of the originator companies under coverage in the past five years.

For 2010, eight out of twenty originators, ***Bayer***, ***GlaxoSmithKline***, ***Johnson & Johnson***, ***Merck & Co***., ***Merck KGaA***, ***Novartis***, ***Pfizer*** and ***Sanofi-Aventis*** are engaged in single-drug donation programs focused on neglected tropical diseases (NTD) (Please see Table 13 above). Many NTD control programs depend in large part on donations by companies.

Examples of Leading Practices

- **Commitment to Single Drug Donations:** Currently, ***Bayer***, ***Boehringer-Ingelheim***, ***GlaxoSmithKline***, ***Johnson & Johnson***, ***Merck & Co***., ***Merck KGaA***, ***Novartis***, ***Pfizer*** and ***Sanofi-Aventis*** are engaged in single-drug donation programs. In Index 2010 methodology, targeted programs based on Index Country disease priorities are considered the most effective type of donations. While this strategy is not suitable to address all Index Diseases, specifically non-communicable diseases, long-term targeted programs have been effective in tackling neglected diseases such as lymphatic filariasis, malaria, onchoceriasis (river blindness), human African trypanosomiasis (sleeping sickness), trachoma, Chagas disease and shistosomiasis. The donation of single-dose Nevirapine by ***Boehringer-Ingelheim*** for the prevention of mother-to-child transmission (PMTCT) of HIV is another valuable program.
- **Ensuring Donated Products Reach Target Patients:** Product donations to Index Countries are generally carried out in partnership with third-party organizations, rather than directly by the pharmaceutical companies. While many of these external organizations are reputable and qualified, some companies establish stringent monitoring and reporting with such organizations to ensure that products reach intended Index Country patients. An example of best practice in this area is ***Merck & Co***., who requires a certificate of receipt be signed by receiving in-country organizations as part of its Mectizan donation program.

Suggested Areas for Improvement

- **Transparency in Drug Donations:** The majority of companies disclose little about their drug donation programs. Very few companies publicly report on the type, volume, or destination of annual donated products. Most companies disclose donation information on an aggregate basis. Some refer to the product type and volume, but not the destination, while others disclose the destination and type, but not the specific volume of each donation.

Philanthropic Activities

A majority of originators are involved with health infrastructure-related philanthropic projects in Index Countries. These initiatives are generally focused on education and disease awareness and training of local doctors, nurses and other traditional healthcare practitioners in treatment and diagnosis. Another common area of activity is building and repair of community clinics and hospitals. Many of these projects are executed in collaboration with national, regional and local governments and NGOs. In constructing the Index, we assign more value to training for genuine healthcare capacity purposes, rather than training driven by sales and marketing motivations.

Examples of Leading Practices

- **Collaborations with Local Governments Aimed at Better Addressing National Healthcare Priorities:** Since 2007, ***AstraZeneca***, African Medical and Research Fund (AMREF) and the Ministry of Health in Uganda have been working together to develop a model for integrated management of malaria, HIV/AIDS and tuberculosis. The program seeks to enhance the capacity of health centers, improve community-based prevention, treatment and care for the three diseases and strengthen links between formal health systems and informal community-based capabilities.
- **Collaborations with Local Governments Aimed at Improving Healthcare Organizations, Financing and Delivery:** In Mali, the ***Novartis*** Foundation for Sustainable Development has worked with the Ministries of Health and Social Development to improve primary healthcare services in rural areas. This three-year program (2007-2009), called Initiative Accès, aims to provide better basic health services in rural villages. The program also works to strengthen existing community-based health insurance schemes through access to credit and jobs. ***Pfizer*** also has a health financing-focused project which is covered under “Recent Innovations” at the end of this chapter.
- **Global Collaborations Aimed at Improved Patient Awareness and Education:** In December 2008, ***Novo Nordisk*** announced “Changing Diabetes in Children”, a five-year program in partnership with the World Diabetes Foundation (WDF), to build healthcare management capacity in diabetes in sub-Saharan Africa. ***Roche*** joined these efforts in 2009. The partnership is working with local and national governments to develop tailored diabetes education, diagnosis and self-management programs for patients and their families. To date, pilot projects have begun in Tanzania, Uganda, Cameroon, Guinea-Conakry and the Democratic Republic of Congo.

Suggested Areas for Improvement

- **Disclosure of Resources and Outcome:** Very few companies publicly disclose the resources (human or financial) or investments dedicated to their philanthropic activities. Many of those that do disclose resources do so on an aggregate basis, which makes it difficult to evaluate the degree of commitment or scope of each project, or whether they are long-term or short-term endeavors. More information on the impact or outcomes of companies' philanthropic activities would allow for better evaluation of these projects.

RECENT INNOVATIONS - PRODUCT DONATIONS AND PHILANTHROPY

Topic	Creating Models for Healthcare Delivery
Company	***Pfizer***
Description	In 2008, ***Pfizer*** began a partnership with Grameen Health, an affiliate of Grameen Bank, to explore ways to improve the group's existing healthcare delivery systems in rural Bangladesh. The partnership aims to develop new health financing and delivery models which could eventually be replicated in other countries.

Topic	Sustainable Funding for Philanthropic Activities
Company	***GlaxoSmithKline***
Description	In 2009, ***GlaxoSmithKline*** committed to reinvesting 20% of its profits from the sale of medicines in LDCs back into these countries to support and strengthen philanthropic programs in health services infrastructure.

Generic pharmaceutical companies

ACCESS TO MEDICINE LANDSCAPE

While originator companies contribute to the future of access through the development of new innovative products, generics companies play an essential role in assuring the affordability and accessibility of existing products.

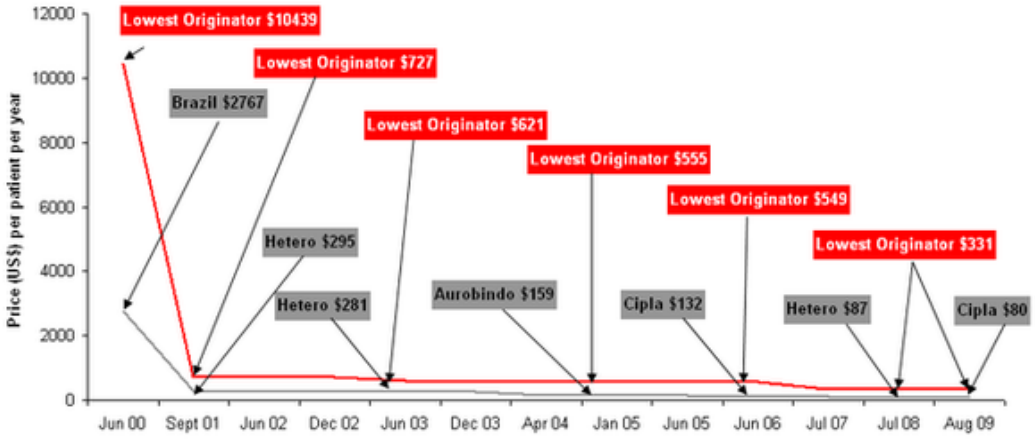
Generics companies are the main suppliers of essential drugs in developing countries, as measured by the breadth of their product lines as well as their sales volume. For example, Médecins Sans Frontières has called India “the pharmacy of the developing world” and highlighted that 67% of the drugs produced in India are exported to developing countries.[70] The US President's Emergency Plan for AIDS Relief (PEPFAR) found that by December 2007, 73% of all anti-retroviral drugs delivered in their focus countries were generic and medicine costs decreased 90% between 2005 and 2008[71].

Competition acts as a catalyst for price reduction in the generic market, especially since generic manufacturing costs do not include the R&D expenditures required for new breakthrough drugs. Médecins Sans Frontières research has confirmed the positive impact of generic products on the market price of antiretrovirals (ARVs) in Index Countries (see Figure 14). According to the study, following increased generic competition, the price of a first-line ARV combination of Stavudine/ Lamivudine/ Nevirapine has decreased 99% compared to prices offered ten years ago.

In the past decade, emerging economies such as India and China have made rapid progress in drug manufacturing. India, in particular, made fast progress in developing its drug manufacturing capacity, partly because of more flexible patent laws prior to compliance with TRIPS in 2005. Indian firms offer products covering a broad therapeutic spectrum, both for communicable and non-communicable diseases. China and India are also important producers of active pharmaceutical ingredients (API), the raw material for medicines. This has resulted in substantial decreases in manufacturing costs of medicines.

[70] MSF (2007) EXAMPLES OF THE IMPORTANCE OF INDIA AS THE “PHARMACY FOR THE DEVELOPING WORLD”
[71] The US President's Emergency Plan for AIDS Relief (2008) - http://www.pepfar.gov/press/fourth_annual_report/

Figure 15. Competition as a Catalyst for Price Reductions



The fall in the price of first-line combination of Stavudline (d4t), Lamivudine (3tc) and Nevirapine (NVP), since the first edition of Untangling the Web of Price Reductions. (Source: MSF: (2009) Untangling the web of antiretroviral reductions)

Generics companies can be divided into two general categories: international generics companies, which have a global footprint and are mostly based in India and Western countries and local generics companies, which primarily target their national markets. The two groups of generics companies play widely differing roles in regard to ATM.

International generics companies, who must comply with various international, regional and country-level quality standards, have generally achieved high-quality manufacturing standards. Besides manufacturing off-patent products, international generics companies also engage in voluntary licensing arrangements with originators for patented products. For more information please refer to the Patents and Licensing section of this chapter. This model has already led to far-reaching improvements in accessibility and affordability of patented products, such as ARVs, in the Index Countries.

The in-licensing component of the generic' business model gives them access to proprietary information across a wide range of products. This puts them in a privileged position to undertake research aimed at adapting existing products to Index Country needs. The geographical proximity of generics companies, especially those in India, to Index Countries also helps achieve a better understanding of Index Country adaptive research needs. For more information

please refer to the Research and Development section of this chapter.

Local generics companies, however, have no need to meet the standards of global or developed-world regulatory authorities. Local firms typically lack the competitive advantages of international generics companies in manufacturing, distribution, access to APIs and human resources[72]. Nonetheless, when local firms succeed in achieving high manufacturing and packaging standards, they can play an important role in supporting ATM. Seven international generics companies are included in Access to Medicine Index 2010. They were chosen because of their large market capitalizations and the relevance of their product portfolios to ATM. Four of the firms are Indian and the others are from Israel, Canada and the USA. For a list of generics companies covered by Access to Medicine Index 2010, please refer to Table 14.

[72] Kaplan, W.A., R. Laing, B. Waning, L. Levison, Foster, S. (2003) "Is Local Production of Pharmaceuticals A Way to Improve Pharmaceutical Access in Developing and Transitional Countries? Setting a Research Agenda", Boston School of Public Health, mimeo.

Table 14. Index 2010 Generics Company List

	Included in Index 2008	Ticker	Company	Country	Revenue ('000) - 2009	Market Cap (billion) as of June 1st, 2010
1	Yes	TEVA-TV	Teva Pharmaceutical	Israel	USD 13,899	USD 50.62
2		BOM:524715	Sun Pharmaceuticals	India	USD 819	USD 7.44
3		MYL-O	Mylan Inc	USA	USD 5,090	USD 5.94
4	Yes	BOM:500087	Cipla Limited	India	USD 1,105	USD 5.53
5	Yes	BOM:500359	Ranbaxy Laboratories Limited	India	USD 1,570	USD 5.02
6		BOM:500124	Dr. Reddy's	India	USD 1,493	USD 3.82
7		Not Publicly Listed	APOTEX	Canada	Approx. USD 1,000	

GENERICS COMPANY METHODOLOGY

WHAT WE MEASURE:

As with the originator companies, the generics companies are evaluated across seven technical areas.

Below is a brief overview of how the Access to Medicine Index 2010 perceives the role of generics companies across each of the technical areas of the Index. For a more in-depth coverage of the general principles underlying each technical area, please refer to the Introduction – Access to Medicine Index 2010 Methodology.

General ATM Management

Good governance and management systems are essential to the success of corporate ATM-related initiatives. For this technical area, we evaluate companies' business rationale for ATM initiatives and note those companies that have established board or executive management representation and oversight, have a dedicated ATM team and have management systems in place for ATM-related operations.

Public Policy and Market Influence

As international generics companies continue to expand their global footprint, their public policy and market influence also expands. For example the largest generics company in the sector (***Teva***) is

now the world's 10th largest pharmaceutical company by market capitalization. Like their originator counterparts, generics companies can play a significant role in maintaining a healthy influence on the public policy debate and also in facilitation of competitive markets. We assess generic firms' influence and market power by studying their lobbying and advocacy activities, their marketing behavior and their competition practices.

We assess the companies' transparency on lobbying, their advocacy positions and their political contributions, which may impact ATM.

Access to Medicine Index 2010 considers the competition policies and practices of the generics companies[73]. Generics companies are expected to commit to pursuing healthy competition and to refrain from practices such as "pay for delay" which can result in delayed introduction of generic version of products with expired patents.

Generics companies may publicly market and promote their products, especially branded generic drugs. While this can help to inform healthcare professionals, it could also have undue influence on prescription and usage practices. Under this technical area, we evaluate the companies' marketing policies and practices and their adherence to codes and commitments to ethical marketing conduct. Also, like their originator counterparts, generics companies are expected to disclose information about their payments to physicians, healthcare providers and other promotional activities in the Index Countries.

R&D for Index Diseases

Generics companies possess competitive advantages in the area of adaptive R&D. Adaptive research seeks to tailor products specifically for certain patient groups such as children and special environmental condition such as heat stable formulations. In addition, adaptive research can focus on developing drug combinations (combi-packs) and FDCs, which can help improve patient compliance and reduce the complexity of dosing regimens. Such formulations can also help lower the spread of resistance through more rational use of drugs. Index 2010 considers the Index Country focused R&D policies and practices of the generics companies.

Equitable Pricing, Manufacturing and Distribution

The generics companies help drive down prices by increasing competition in the market for off-patent drugs. Consequently, pricing mechanisms such as "tiered pricing" are not considered for the

[73] Introduction of the Hatch-Waxman Act in the US in 1984 has further delineated the market access terms for the generics companies vis-à-vis the originators

generics companies. However, for certain drugs in certain markets, generics companies may hold significant market power. Index 2010 considers such cases, which typically involve:

- An exclusive voluntary licensing agreement with an originator company for a patented product
- An agreement with an originator firm for launch of an 'Authorized Generic'[74] product

In such cases, through using equitable pricing the companies can ensure the affordability of their products for the individuals with financial barriers to access.

In addition, the generics companies can lend their manufacturing and/or distribution capacity to international ATM programs such as the Clinton Foundation, UNITAID and PEPFAR.

For registration (obtaining marketing approval) generics companies are expected to take into consideration Index Country needs as part of their decision making process. As for their originator counterparts, broad registration of products for high priority diseases is considered a best practice for generics companies.

The generics companies play an important role in delivering medicines to many Index Countries where local regulatory enforcement is weak. Consequently, maintaining high standards of manufacturing quality is a high priority area for these companies.

International generics companies have achieved substantial quality improvements during the past few years. These improvements have been driven by both the demands of developed markets and the emergence and fast expansion of international quality standards such as the WHO Good Manufacturing Practices (GMP) and new quality audit processes such as the WHO prequalification process.

Under this area, companies are rewarded for working towards higher quality standards for products for Index Countries. Index 2010's consideration of product quality also includes analysis of efforts to develop product packaging suitable for Index Countries.

Each company's capacity to maintain high standards of drug recalls in the Index Countries is also analyzed under this technical area.

[74] An authorized generic is a pharmaceutical product that was originally marketed and sold by an originator company, but following patent expiry, is relabeled and marketed under a generic product name by the same company or in arrangement with a generics manufacturer.

Patents and Licensing

While patents and licensing are a larger concern for originator companies, the fast growth of research by generics companies (especially adaptive research), makes it increasingly relevant for this sector as well. As with the originators, the policies and practices of the generics companies are analyzed in order to reward companies whose intellectual property policies and practices do not act as barriers to access. In addition the level of involvement of generics companies in non-exclusive voluntary licensing of patented products from originator companies is analyzed under this technical area.

Capability Advancement in Product Development and Distribution: Generic firms have the potential to significantly improve Index Country focused product development and distribution. International generics companies can partner with smaller local companies to improve their manufacturing and quality management capacities. Generics companies are also well-positioned to work with Index Country organizations on adaptive research. Such initiatives will benefit the target countries and also help manufacturers broaden their global capacity and footprint. Index 2010 rewards generics companies who have been innovative in working in partnership with Index Country organizations.

Donations and Philanthropic Activities:

Donations and philanthropic activities are not considered to be long-term solutions for access to medicine. However, for certain scenarios, such as disease eradication and humanitarian crises, donations are considered effective models of pharmaceutical product delivery. Generics companies are expected to abide by international codes such as the WHO Inter-agency Guidelines for Drug Donations.

In considering philanthropy, we focused on efforts aimed at long-term healthcare infrastructure improvements in the Index Countries.

HOW WE MEASURE

Despite the growing convergence of business models between originators and generics companies, significant differences remain between the drivers for undertaking ATM initiatives. These differences are acknowledged by the decision of Access to Medicine Index 2010 to assess these sectors separately. Index 2010 uses the same indicators for both company sets. Indicator weighting is adjusted based on the percentage of the company revenues sourced from generic products. In addition, scoring guidelines for some indicators have been adjusted to reflect the range of practices of generics companies. For more details about

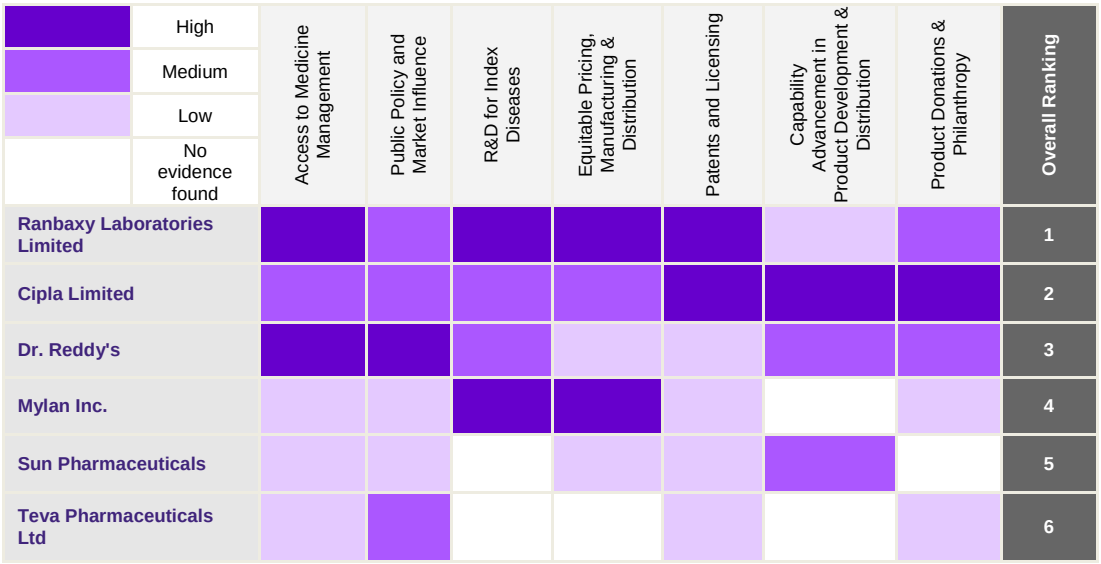
weighting approach to Index 2010 and an example of the weight adjustment, please refer to the Introduction to Access to Medicine Index section of this report. For indicator level weights for 100% originator and 100% generics companies please refer to Indicators and Scoring Guidelines in Appendix D.

Apotex, an unlisted Canadian company was covered in our analysis and in this report. However, its low level of disclosure and its irresponsiveness to our information requests made us unable to accurately assess its ATM performance. It was thus covered in the report but not in the ranking process.

Sources: Three out of the seven generics companies covered by the Access to Medicine Index 2010 responded to our data requests (***Cipla***, ***Ranbaxy*** and ***Mylan***). For the other companies the level of public disclosure was low and our analysis primarily relied on public disclosure of the companies, WHO public databases, several independent research articles, reports and interviews.

OVERALL RANKING

Figure 16. Overall Ranking of Generics Companies



* Apotex, which is not a publicly listed company, is not included in the ranking due to lack of sufficient and reliable information about the company policies and operations.

Please note that Access to Medicine Index is a relative index. This Index does not evaluate the companies against aspirational best practices; it only provides only a comparison of the companies to each other.

Note that the ranking of generics companies was hampered by the low level of disclosure by several of these companies. This issue combined with the small sample size of the large generics companies covered by Index 2010 made presentation of generics rankings in a format similar to originators statistically unreliable.

The three generics companies that provided us with partial to complete data make us optimistic about higher levels of disclosure in future iterations of the Index.

For the future iterations of the Index, we plan to use the same quantitative rankings graphs both for originator and generics companies.

All the generics companies under coverage have broad product portfolios covering a significant number of Index Diseases.

Ranbaxy, ***Cipla and Dr. Reddy's*** emerged as the top generic companies in the Access to Medicine Index 2010. All

these companies have significant market presence in the Index Countries and broad focus on adaptive research for Index Diseases. For more information on company policies and practices you can refer to their respective report cards in the following section and the full company profiles on the www.accesstomedicineindex.org website.

ATM management systems and **reporting** remain weak across the sector. ***Dr. Reddy's*** is the only company with annual reporting on access related initiatives. ***Ranbaxy*** has improved reporting of its ATM policies, objectives and initiatives on its website. For more information, please refer to the General ATM Management section of this chapter.

Disclosure on **lobbying & advocacy** positions & activities and **marketing activities** remains weak across the sector. Patent-related litigations with the originator companies are pervasive and examples of competition related controversies continue to be found across the sector. For more information, please refer to the Public Policy and Market Influence section of this chapter.

As for **R&D**, generics companies are rapidly expanding their adaptive research pipelines for Index Diseases. ***Ranbaxy*** is the highest performer with a mix of innovative and adaptive research initiatives for the Index Diseases and three research collaborations. ***Cipla and Mylan*** are also undertaking adaptive research for Index Country needs. For more information, please refer to the Research & Development section of this chapter.

For off-patent products, considering that prices are driven by competition, **tiered pricing** models are not needed in most cases. ***Ranbaxy, Mylan and Cipla*** are the only generics companies under coverage which have been found to collaborate with international organizations delivering affordable pharmaceutical products in the Index Countries.

As for **quality management**, ***Mylan*** and ***Ranbaxy*** are the only companies that commit to uniform application of international quality standards to all their products destined for the Index Countries. Most of the companies in the sector have been facing drug recalls, but information available in this area was insufficient for a thorough comparative analysis. The generics companies under coverage currently have minimum involvement in adapting product packaging to Index Country needs. ***Ranbaxy and Mylan*** are the only companies covered that commit to wide registration of some of their products in the Index Countries in need. For more information, please refer to the Equitable Pricing, Manufacturing and Distribution section of this chapter.

Non-exclusive licensing is a very promising area for building a more constructive relationship between the originator and generics companies with potentials for contributing to ATM. ***Cipla and Ranbaxy*** are the only two generics companies covered by Index 2010 which appear to have current non-exclusive licensing activities. Most of the generics companies covered by Index 2010 are involved in multiple patent related lawsuits with their originator peers. For more information, please refer to the Patents and Licensing section of this chapter.

In the area of **Capability Advancement**, ***Cipla*** has been the leading company with success stories of collaborative manufacturing with Index Country organizations and governments. None of the other companies under coverage has significant initiatives in this area. For more information, please refer to the Capacity Advancement in Product Development and Distribution section of this chapter.

As for **Product Donations and Philanthropic Activities**, all the generics companies covered by Access to Medicine Index 2010 have carried out multi-drug donations in some instances. But none of them commits to the WHO Inter-agency Guidelines for Drug Donations and none have been involved in strategic, need based “single-drug donations” programs. ***Cipla***, ***Dr. Reddy’s, Ranbaxy and Teva*** all have philanthropic activities in the Index Countries. However, none have a strategic long term goal for their philanthropic programs. For more information, please refer to the Donations and Philanthropic Activities section of this chapter.

REPORT CARDS

IN THIS SECTION

APOTEX, INC

Full Company Profile Available at: www.accesstomedicineindex.org/apotex

HQ	Toronto, Canada	**Index Disease Focus**	**Existing Index Disease Commercial Products:** HIV/AIDS (further information not available)
Employees	6,800 (As of December 31, 2009)		**Index Disease R&D Pipeline:** Not Available (N/A)
Revenues	**2009**: Approx. USD 1,000 million		

Leading Practices

- To date, ***Apotex*** has been the only company to have received a license under Coalition for the Advancement of Medical Research **(**CAMR) to produce patented medicines for export; Apo-TriAvir is a fixed dose combination which includes two of ***GlaxoSmithKline***'s patented drugs (Zidovudine and Lamivudine) and Nevirapine of ***Boehringer-Ingelheim***. CAMR is an initiative of the Canadian Government to enable domestic pharmaceutical firms to produce lower cost generic versions of patented drugs for export to developing countries at not-for-profit prices under compulsory licenses.

Changes Compared to Index 2008

- ***Apotex*** was not included in the Access to Medicine Index 2008.

Suggested Areas for Improvement

- As an unlisted firm, ***Apotex***'s level of disclosure across the seven technical areas evaluated by the Access to Medicine Index 2010 is significantly below that of its industry peers. While unlisted companies are not subject to the same regulatory requirements as listed firms, further disclosure of the company's ATM initiatives, long- and short-term objectives and R&D pipeline can help with better evaluation of company's practices.
- Various incidents of manufacturing and quality control violations throughout 2008 and 2009[75] raise concerns over the company's quality standards; the company is not transparent regarding its quality manufacturing standards and how it ensures manufacturing of products destined for Index Countries comply with standards such as WHO's Good Manufacturing Practices (GMP).
- Unlike many of its peers, the company has not been found to engage in adaptive research for the Index Diseases targeting specific Index Country needs.

[75] Phrma Manufacturing (2010) - Apotex Faces Ban on U.S. Drug Imports - http://www.pharmamanufacturing.com/industrynews/2009/150.html

CIPLA

Full Company Profile Available at: www.accesstomedicineindex.org/cipla

HQ	Mumbai, India	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Wide coverage of Index Diseases – both communicable and non-communicable **Index Disease R&D Pipeline:** HIV/AIDS (coverage might be incomplete due to lack of public disclosure)
Employees	20,000 (as of December 31, 2009)		
Revenues	**2009**: USD 1,193 million (INR 55,504 million) **2008**: USD 1,105 million (INR 49,606 million)		

Leading Practices

- ***Cipla*** has an active Index Country expansion strategy for the range of its Index Disease products.
- ***Cipla*** shows strong performance in building local manufacturing capabilities highlighted by its partnership with the government of Uganda for production of ARVs and malaria (since December 2008).
- The company is one of the partners of DNDi for production and distribution of fixed-dose, artesunate-based Combination Therapies for malaria for endemic countries.

Changes Compared to Index 2008

- A manufacturing partnership with the government of Uganda for ARVs was established in 2008 (Please refer to the related leading practice).
- ***Cipla*** is one of the generics companies involved in the HIV/AIDS equitable pricing scheme of the Clinton Health Access Initiative.

Suggested Areas for Improvement

- ***Cipla*** does not have formal ATM representation at a senior management level.
- The company is not transparent in areas such as public policy positions, lobbying activities, marketing in the Index Countries, research pipeline and research investments
- The company does not carry out public annual reporting on ATM-related policies, performance and objectives.

DR. REDDY'S

Full Company Profile Available at: www.accesstomedicineindex.org/drreddys

HQ	Hyderabad, India	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Unipolar Depressive Disorder, Diabetes Mellitus, Arthritis, Ischemic Heart Disease, Respiratory Diseases **Index Disease R&D Pipeline:** Ischemic Heart Disease (coverage might be incomplete due to low level of public disclosure)
Employees	11,228 (as of March 31, 2009)		
Revenues	**2010 (March 2009-March 2010)**: USD 1,511 million (INR 70,300 million) **2009 (March 2008-March 2009)** USD 1,493 million (INR 69,441 million)		

Leading Practices

- ***Dr. Reddy's*** has begun reporting on ATM-related activities and issues in an annual sustainability report, including some performance data and long- term future goals.
- The company publicly states its commitments on specific ATM issues, such as stakeholder engagement, ethical marketing and promotional practices, quality standards and philanthropic activities in Index Countries.
- The company has developed a FDC for cardiovascular disease named the 'Red Heart Pill' and is currently awaiting regulatory approval in India; ***Dr. Reddy's*** is the only company in the generic sector that is conducting adaptive research into non-communicable Index Diseases, based on an explicit Index Country need.

Changes Compared to Index 2008

- ***Dr. Reddy's*** was not evaluated in Access to Medicine Index 2008.
- In June 2009, ***Dr. Reddy's*** and ***GlaxoSmithKline*** entered into a strategic alliance targeting emerging markets. As per the agreement, ***Dr. Reddy's*** will manufacture over 100 branded pharmaceuticals in its product portfolio and ***GlaxoSmithKline*** will market and distribute them to various countries in Africa, the Middle East, Asia Pacific and Latin America.
- In 2009, ***Dr. Reddy's*** initiated a pilot survey project in various rural areas in India, as a means to help them develop and market an exclusive portfolio for local needs, with a pricing policy that promotes both ATM and financial sustainability. While no further information is provided on this initiative, it appears that ***Dr. Reddy's*** is attempting to establish a more tailored ATM strategy to reach patients in varying social settings and circumstances within India.

Suggested Areas for Improvement

- Despite annual reporting which covered some ATM initiatives, ***Dr. Reddy's*** level of transparency is low across all technical areas. Based on the limited disclosure on the company's actual ATM activities, its ATM strategy and performance are hard to evaluate and benchmark compared to peers.
- Unlike sector peers such as ***Cipla*** and ***Ranbaxy***; and with the exception of the polypill, ***Dr. Reddy's*** does not appear to conduct much adaptive R&D for Index Diseases (e.g. formulations for specific social segments, such as pediatrics, pregnant women, heat stable formulations, fixed-dose combinations – FDCs).

MYLAN

Full Company Profile Available at: www.accesstomedicineindex.org/mylan

HQ	Canonsburg, Pennsylvania, USA	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Wide coverage of Index Diseases – both communicable and non-communicable **Index Disease R&D Pipeline:** HIV/AIDS (coverage might be incomplete due to low level of public disclosure)
Employees	12,000 (as of September 2009)		
Revenues	**2009**: USD 5,090 million **2008**: USD 5,138 million		

Leading Practices

- ***Mylan*** is the one of the largest suppliers of generic HIV drugs, with over 30 products on the WHO prequalification list.
- ***Mylan*** has a needs-based marketing approval approach for HIV/AIDS drugs and has committed to wide and fast registration of its HIV medications and to reliable and sustainable delivery of products that meet international quality standards.
- The company has successfully developed adaptive formulations of HIV drugs including both pediatric formulations and FDCs. The company has made commitments to further investments in this area. Most of these products will be distributed through UNITAID and the Clinton HIV/AIDS Initiative.
- The company has used the FDA tentative approval process for its new adaptive HIV/AIDS products.

Changes Compared to Index 2008

- ***Mylan*** was not included in Index 2008.
- During the period of analysis the company has received new marketing approvals for HIV/AIDS adaptive products and has worked closely with international organizations for their distributions.

Suggested Areas for Improvement

- ***Mylan*** has a low disclosure of its pricing strategies for new HIV products and also on ATM-related public policy positions, lobbying activities and marketing practices in the Index Countries.
- The company's ATM strategy only covers its ARVs, not to all its Index Disease products.
- ***Mylan*** does not have an annual reporting on ATM-related policies, targets and practices.

RANBAXY LABORATORIES LTD

Full Company Profile Available at: www.accesstomedicineindex.org/ranbaxy

HQ	Guragon, India	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Wide coverage of Index Diseases – both communicable and non-communicable **Index Disease R&D Pipeline:** Malaria, Dengue, Tuberculosis
Employees	12,995 (as of December 31, 2009)		
Revenues	**2009**: USD 1,570 million (INR 73,021 million) **2008**: USD 1,549 million (INR 72,038 million)		

Leading Practices

- Through collaborations, ***Ranbaxy*** is the only generics company covered by Index 2010 that conducts innovative R&D for dengue and tuberculosis.
- The company commits to making its best efforts to control the pricing practices of local sales agents and prevent 'profiteering'.

Changes Compared to Index 2008

- Since the publication of Access to Medicine Index 2008, Ranbaxy has commenced Phase III clinical studies for its anti-malarial FDC in India, Bangladesh and Thailand.
- In 2008, ***Ranbaxy*** began collaboration with the Department of Biotechnology of the Indian Ministry of Science and Technology, to explore its compound library with the aim of identifying new chemical entities (NCEs) for tuberculosis.
- Ranbaxy is one of the generics suppliers involved in the HIV/AIDS equitable pricing scheme of the Clinton Health Access Initiative.

Suggested Areas for Improvement

- ***Ranbaxy***'s ATM management system lacks quantitative and qualitative target setting and comprehensive and systematic reporting of ATM activities.
- Unlike some of its sector peers such as ***Cipla,*** the company has not been found to engage in capacity building initiatives with local Index Country institutions and/or manufacturers in the areas of research, quality management and distribution.
- ***Ranbaxy*** lacks public disclosure across all technical areas, particularly its public policy positions on important ATM issues, marketing activities in the Index Countries and specific resources (human, financial and technical) dedicated to ATM activities.

SUN PHARMACEUTICALS

Full Company Profile Available at: www.accesstomedicineindex.org/sunpharmaceuticals

HQ	India	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Cerebrovascular Disease, Diabetes Mellitus, Asthma, Epilepsy
Employees	8,000 (as of December 31, 2009)		**Index Disease R&D Pipeline:** N/A
Revenues	**2009 (March 2008-March 2009):** USD 819,024 (INR 42,732 million)		
	2008 (March 2007-March 2008): USD 867,293 (INR 34, 605 million)		

Leading Access to Medicine Practices

No leading practice identified for this company.

Changes Compared to Index 2008

- ***Sun Pharmaceuticals*** was not included in Access to Medicine Index 2008.
- ***Sun Pharmaceuticals*** is seeking to enter into exclusive licensing agreements and to extend its market presence further in Index Countries such as China and regions of South-East Asia and Africa.
- There is evidence that ***Sun Pharmaceuticals*** is increasing local research capabilities in India by permitting students to use the Sun Pharmaceuticals Advanced Research Centre (SPARC), one of its primary research facilities.

Suggested Areas for Improvement

- ***Sun Pharmaceuticals*** has not adopted a strategic and tailored approach to Index Country markets.
- ***Sun Pharmaceuticals'*** sales of its existing Index Disease-relevant products are limited to few Index Countries.
- ***Sun Pharmaceuticals*** does not participate in adaptive research for the Index Diseases targeting specific Index Country needs, in areas such as, fixed-dose combinations (FDCs) and heat-sensitive formulations. Due to the company's expertise in dosage form development and innovative drug delivery approaches, ***Sun Pharma*** should be well-positioned to carry out adaptive research for Index Disease-related products.

TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Full Company Profile Available at: www.accesstomedicineindex.org/teva

HQ	Petach Tikva, Israel	**Index Disease Focus**	**Existing Index Disease Commercial Products:** Portfolio of 405 products, dominated by Non-Communicable Diseases: Unipolar Depressive Disorders and Epilepsy, Respiratory Diseases, Osteoarthritis, Ischemic Heart Disease, plus some Communicable Disease products inc; HIV/AIDs, Tuberculosis, Anti-Helminths. **Index Disease R&D Pipeline:** N/A
Employees	35,089 (as of December 31, 2009)		
Revenues	**2009**: USD 13,899 millions **2008**: USD 11,085 millions		

Leading Access to Medicine Practices

No leading practice identified for this company.

Changes Compared to Index 2008

- ***Teva*** made a record-sized multi-drug donation valued at GBP 12.1 million (or 2 million treatments) to the Index Countries through International Health Partners (IHP), during the survey period.
- Currently ***Teva*** has no ATM policies, objectives or governance representation. There are no changes in the company's overall approach compared to Index 2008.
- The company's only emerging markets strategy in Eastern Europe and Latin America is focused on "Authorized Generics", which is not conducive to generic competition and increased affordability.

Suggested Areas for Improvement

- Unlike most of its peers, ***Teva*** does not have a strategic focus on ATM and it lacks senior governance representation and reporting around ATM issues.
- While it is the largest generics company in the sector, the company does not harness its significant market influence to the benefit of ATM in areas such as competition practices, lobbying and advocacy.
- The company has one of the lowest levels of disclosure among the generics companies covered by the Index 2010 .

RANKINGS BY TECHNICAL AREA

IN THIS SECTION

GENERAL ACCESS TO MEDICINE MANAGEMENT

This technical area covers the ATM governance, ATM management systems and stakeholder engagement platforms of the generics companies.

GOVERNANCE

Two of the seven companies, ***Ranbaxy and Dr. Reddy's*** have formally acknowledged that ATM practices can increase the sustainability of their businesses.

Dr. Reddy's considers sustainability, ATM and affordable drugs as the main pillars of the company's strategy, though proof of formal ATM representation at board or executive level was not found.

Cipla makes a commitment to "affordable, high-quality drugs" as part of its business rationale. In the absence of broader commitments to ATM, we note disease area-specific commitments such as those of ***Ranbaxy*** (HIV/AIDS and malaria) and ***Mylan***, who, through its subsidiary ***Matrix***, makes a specific commitment to make ARV therapies accessible in developing countries.

ATM MANAGEMENT SYSTEMS

ATM management systems remain sporadic and reporting of policies, objectives and performance is mostly non-existent.

One exception is ***Dr. Reddy's,*** which uses its annual report to disclose not just information on its ATM policies and initiatives but also broad future ATM targets. Also, ***Ranbaxy*** is expanding the information disclosed about its ATM objectives on its website.

Generics companies still do not disclose financial or human resources used to support their ATM efforts.

STAKEHOLDER ENGAGEMENT

Three companies, ***Cipla***, ***Ranbaxy*** and ***Dr. Reddy's***, have demonstrated evidence of engagement with stakeholders over ATM issues during the survey period. ***Dr. Reddy's*** has implemented a business strategy which includes identification of and engagement with, multiple stakeholders (see "Recent Innovations"). Both ***Cipla*** and ***Ranbaxy*** have participated in global conferences dedicated to ATM.

Examples of Leading Practices

- **Ranbaxy:** Introduction of Access to Medicine policy and objectives for malaria and HIV access programs
- **Dr. Reddy's:** The only company undertaking annual reporting on ATM related initiatives
- **Cipla, Ranbaxy and Dr. Reddy's:** Engagement with multiple stakeholders over ATM issues

Suggested Areas for Improvement

- **Strategic Focus on ATM:** Given their business model, the generics companies are well positioned to target the "bottom of the pyramid" in the Index Countries, which could result in significant long-term financial growth for the companies, as well as improving ATM. To achieve this, generics companies could make ATM a strategic priority at the board, executive and operational levels.

PUBLIC POLICY AND MARKET INFLUENCE

This technical area provides an analysis of current policies and practices related to lobbying and advocacy and marketing and competition practices of the generics companies in the Index Countries.

ADVOCACY AND LOBBYING

Like their originator peers, generics companies also can pursue their public policy objectives through advocacy and lobbying activities. Despite this, none of the generics companies in the sector currently publicly discloses the positions it pursues, either directly or through industry associations. The only publicly available information is found through third parties, such as the companies' filings to the US Securities and Exchange Commission (SEC), the European Register of Interest Representatives and the opensecrets.org website[76].

These sources reveal that ***Ranbaxy***, ***Teva*** and ***Mylan*** have made political contributions in the US. However, these disclosures do not directly pertain to activities which may impact ATM in Index Countries. ***Dr. Reddy's***, ***Mylan***, ***Ranbaxy*** and ***Teva*** disclose their board seats at and affiliations to industry associations, some publicly and the others through engagement.

COMPETITION

Most of the companies in the sector commit to fair competition. ***Mylan*** specifically commits to refraining from anti-trust violations or price-fixing behavior. However, no generics company under coverage mentions specific competition practices that could have negative impacts on ATM. Most legal cases and controversies in which generics companies were involved (or implicated) occurred in developed markets.

One important category of cases is "pay-for-delay" cases. Pay-for-delay involves a generics company accepting an economic compensation from an originator company, in exchange for delaying its entry into the market (for example as part of a settlement of a patent infringement lawsuit with an originator company). One example occurred in February 2008, when the US Federal Trade Commission (FTC) filed a

[76] The website of the Center for Responsive Politics which is a US based not for profit organization.

lawsuit against Cephalon, Inc., the maker of Provigil (used for sleep disorders) alleging that Cephalon entered into anti-competitive agreements with four generics companies, Barr Laboratories (now ***Teva***), ***Ranbaxy***, ***Teva*** and ***Mylan*** for delayed entry to the market.

So far, no such cases have surfaced in the Index Countries. None of the companies under coverage currently has disclosed a public policy stance in this area.

Interestingly, due to their growing research activities, generics companies increasingly engage in both sides of the competition debate. For example, during the survey period, ***Teva*** filed a citizen petition and a number of complaints with the US FDA against other (potential) competitors in an attempt to prolong its monopoly protection of Copaxone (glatiramer acetate injection), its multiple sclerosis treatment.

No major competition-related litigations or controversies were found in the Index Countries. The scarcity of litigations and controversies in the Index Countries might be due to weaker regulatory platforms in many Index Countries.

MARKETING AND PROMOTIONAL PRACTICES

Currently, none of the generics companies covered by the Index adhere to the only applicable global marketing guidelines for the generics companies – the WHO Code for Ethical Marketing. However, some companies, including ***Ranbaxy***, commit to the codes of local industry associations. In ***Ranbaxy's*** case, this is the Organization of Pharmaceutical Producers Code of Conduct for Marketing Practices in India.

Dr. Reddy's sets ethical marketing guidelines for its suppliers, bulk manufacturers and other third-party organizations. ***Teva*** has an internal code of conduct that covers ethical marketing and promotion; however, its guidelines are vague and training or compliance procedures are unknown. ***Teva*** has stated that it is adapting its internal code of conduct to match the international marketing standards set by IFPMA.

None of the generics companies under coverage disclose information about their marketing practices in the Index Countries. No major marketing-related litigations or controversies in the Index Countries were discovered.

Examples of Leading Practices

- ***Dr Reddy's*** has marketing guidelines applicable to its third parties.
- ***Mylan*** explicitly commits to refraining from anti-trust or price-fixing behavior.
- ***Ranbaxy*** commits to a national level marketing code to ensure ethical marketing and promotion of its products.

Suggested Areas for Improvement

- **Transparency in Lobbying:** Generics companies' reporting on lobbying and advocacy activities is on average, low. More disclosure in this area could help increase accountability regarding public policy influence.
- **Clear Stance on Competition Issues:** While efficient competition normally serves the business interests of the generics companies they may engage in practices such as 'pay for delay', which can result in delayed introduction of generic products. Such practices can hamper access. More disclosure of official stance on such competition practices would be welcome.

RESEARCH & DEVELOPMENT FOR THE INDEX DISEASES

This section provides an analysis of the Index Disease-related research pipelines and collaborations of the generics companies. Note that the same exclusions regarding coverage of research activities are applied to originator and generics companies. For more information, please refer to the 2010 Methodology and Stakeholder Review.

ADAPTIVE RESEARCH & DEVELOPMENT

Four out of the seven generic companies are found to be active in this area. These companies include ***Cipla***, ***Dr. Reddy's***, ***Mylan*** and ***Ranbaxy***.

Adaptive research activity is currently concentrated on malaria, HIV/AIDS and tuberculosis. These diseases present great need for new formulations (as highlighted by both WHO[77] and various NGOs[78]), both for special target groups such as children and pregnant women and for easier dosing regimens Low level of disclosure across the sector has hampered our analysis of the generics companies' current pipeline and research activities.

Mylan and ***Ranbaxy*** make commitments to undertake adaptive R&D to meet Index Country product needs. Through its acquisition of ***Matrix***, ***Mylan*** has significantly improved its commitment and capacity in this area primarily for HIV/AIDS. (for more information, please refer to ***Mylan***'s profile).

Ranbaxy has several FDCs and pediatric formulations under development for HIV/AIDS, plus an adult and pediatric FDC for malaria. ***Ranbaxy*** is notable for being the only company in the sector conducting innovative R&D for Index Diseases. The development of its adult and child anti-malarial treatment is covered under "Recent Innovations" at the end of this chapter.

Cipla is also active in this area through work in reproductive health (outside Index

[77] The World Heatlh Organization (WHO)'s Pediatric Antiretroviral Working Group (2008).Report
[78] Médecins Sans Frontières (2008). Untangling the Web of ARV Price Reductions

2010 scope) and HIV/AIDs. ***Sandoz*** (see originator R&D under Novartis) has historically contributed to FDCs for tuberculosis, with its latest launch occurring in 2005 (RIMSTAR 4- FDC).

Dr. Reddy's 'Red Heart Pill' is a unique effort in the development of an FDC for non-communicable diseases. This polypill consists of four drugs (aspirin, a statin, an ACE inhibitor and a thiazide diuretic), a common combination for patients suffering from cardiovascular disease.

Overall, the adaptive research activities of the sector are currently too narrowly focused on the 'The Big Three' (tuberculosis, malaria and HIV/AIDS). Diversification of research activities into other priority areas such as NTDs would be welcome.

COLLABORATIVE MODELS OF RESEARCH & DEVELOPMENT

Ranbaxy has been the top performer in this area with three current collaborations for Index Disease product development. Two of these involve innovative R&D for tuberculosis and dengue and are funded by the Indian government (see "Recent Innovations" at the end of this chapter).

Ranbaxy's third collaboration was with MMV for developing a new anti-malarial medicine (arterolane maleate) ended in 2007. The company continues the development of this with funding from the Department of Science & Technology in India. The drug's development is close to completion. This is the first innovative product for an Index Disease from an Indian generics company.

Examples of Leading Practices

- ***Ranbaxy*** discloses part of its Index Country motivated R&D pipeline and involved in three current, Index Disease-relevant R&D collaborations.
- ***Dr. Reddy's*** is the first among the covered generics companies to launch an FDC developed for a non-communicable disease for specific Index Country needs.
- ***Mylan*** and ***Ranbaxy*** have explicit commitments to undertake R&D for Index Country needs.

Suggested Areas for Improvement

- **Broader Adaptive R&D Focus:** Generics companies are currently playing an important role in adaptive R&D for tuberculosis, malaria and HIV/AIDS. Despite their competitive advantage for carrying out adaptive research, generics companies have not increased the scope of their adaptive R&D activities to other Index Diseases and the number of research collaborations in the sector is low. ***Teva*** which is one of the largest pharmaceutical companies in the world has no involvement in R&D for Index Country needs.
- **More Transparency Regarding R&D for Index Diseases:** Unlike originator companies, generics companies are not bound to disclose their development pipelines. As a result, there is poor disclosure with respect to adaptive R&D plans and investments in this sector. Additionally, only one company, Ranbaxy, voluntarily provided this information to our research team. Access to Medicine Index 2010 would welcome further disclosure across all strategic pillars (commitments, performance and innovation) particularly on development activities, relevant product launches, the resources used to support these efforts and the terms

of any collaborative agreements in place. More disclosure in this area can help both public and private actors better coordinate their R&D activities and priorities.

EQUITABLE PRICING, MANUFACTURING & DISTRIBUTION

This area considers the generics companies' equitable pricing, registration, manufacturing, quality management and distribution policies and practices in the Index Countries.

EQUITABLE PRICING

In the period covered by Index 2010, ***Cipla, Mylan*** (through ***Matrix***) ***and Ranbaxy*** are the only companies covered by the Index which have collaborated with equitable pricing programs for Index Countries. In a program subsidized by UNITAID, these companies have partnered with the Clinton Health Access Initiative to deliver affordable HIV/AIDS medicines to a large number of Index Countries.

Cipla is one of the partners of DNDi for production and distribution of fixed-Dose, artesunate-based combination therapies for malaria in endemic countries.

There is also evidence of a pilot project in equitable pricing being undertaken by ***Dr. Reddy's*** in India's rural areas, but the outcome of this project and the decision regarding a large-scale implementation have yet to be announced.

One challenge in pricing schemes in the Index Countries is the addition of significant mark-ups by distributors and retailers of pharmaceutical products.

Ranbaxy is the only company under coverage that commits to limit local sales "profiteering," especially for ARVs.

MARKETING APPROVAL

Ranbaxy and ***Mylan*** are the only companies under coverage that have made a needs-based commitment to market registrations in Index Countries during the survey period. ***Mylan***, through its subsidiary ***Matrix***, has committed to registering its ARV products wherever disease burden indicates the need. ***Ranbaxy*** explains the rationale for the registration of its ARV and anti-malaria products as being need-driven. Three companies (***Cipla***, ***Ranbaxy*** and ***Mylan / Matrix***) have been responsive to the WHO Expression of Interests (EOIs) for prequalification of their eligible products. ***Cipla*** has 40 products for HIV and malaria

treatment, ***Ranbaxy*** has 20 such products and ***Mylan / Matrix*** has 31 HIV drugs on the WHO's prequalification list. ***Mylan*** has obtained FDA tentative approval for some of its new adaptive HIV/AIDS products.

With the exception of ***Ranbaxy***, this information has been provided by third-party research, since the companies' disclosure of registration and prequalification practices is weak. ***Ranbaxy*** has been exceptional in this area by disclosing country-by-country registration data for all its Index Disease products to the Index 2010 team, although this information is not available in the public domain.

MANUFACTURING & PACKAGING

The generics companies covered by Index 2010 constitute a significant portion of the global generic pharmaceutical market and all seven are global players, supplying both developed and developing countries. As such, these companies comply with different international manufacturing standards as required in different markets. However, there is a low level of disclosure about whether and how such standards are applied to products destined for countries with weak quality standards and regulatory enforcement. ***Mylan*** and ***Ranbaxy*** are the two companies which commit to maintaining international quality standards for their products regardless of the destination. Product quality issues reported during the period of analysis further demonstrate the need for more focus and disclosure in this area. ***Ranbaxy*** has received FDA warning letters raising quality issues at ***Ranbaxy***'s manufacturing plants in the US and India in 2008. ***Apotex*** has also received several warnings from the FDA over quality issues during the period of analysis. As an indicator of the scale of recalls and their financial impacts, the cost of drug recalls at ***Sandoz*** (Sandoz is covered under its parent company ***Novartis*** under the originator listing) which reports its recalls more extensively than all its sector peers reached USD 28 million in 2009.

Ranbaxy has made efforts in some Index Countries to ensure stringent quality controls and fast recalls, if necessary, through its regional hubs in South Africa, Brazil and Malaysia. However, no specific process or performance information was provided by the company. No other company under coverage has disclosed its approach to carry out effective drug recalls in the Index Countries.

Index 2010 found no indication of efforts by generics companies to adapt the packaging of their products to Index Country needs, except for adaptations required by local regulatory authorities.

The companies could go beyond regulatory requirements in many index

countries, by including brochures in local languages and pictograms for the illiterate, more environmentally resistant packaging and special packaging to prevent counterfeiting. The only practice in this area found by the Index team is ***Dr. Reddy's***' and ***Ranbaxy***'s special packaging to prevent counterfeiting for some products destined for Index Countries.

Examples of Leading Practices

- ***Mylan*** and ***Ranbaxy*** commit to needs-based ARV-product registrations.
- ***Cipla***, ***Mylan / Matrix*** and ***Ranbaxy*** each have 20 or more products/formulations currently included on the WHO's prequalification list.
- ***Cipla, Mylan (through Matrix) and Ranbaxy*** supply ARVs to UNITAID and Clinton HIV/AIDS Initiative (CHAI) for several Index Countries.
- ***Ranbaxy*** is the only company to commit to efforts to limit local sales 'profiteering' for ARVs sold in Index Countries.

Suggested Areas for Improvement

- **Commitment to International Quality Standards for Products Destines for the Index Countries and More Disclosure on Recalls:** Substandard products remain as a key challenge in the Index Countries. With some exceptions, the generics companies under coverage have not explicitly committed to international standards such as EMA, FDA or WHO Good Manufacturing Practices for their products destined for the Index Countries. In addition disclosure on quality issues and recalls in the Index Countries is very low across the sector. More information in this area can help with better assessment of the role the generics companies are playing in addressing the product quality challenged in the Index Countries.
- **Adapting Packaging to Index Country Environments:** None of the generics companies under the coverage has been found to undertake adaptive packaging aimed at increasing shelf life and ease of distribution in the Index Countries. In addition none of these companies has made extra efforts in making product documentation understandable to target communities by providing it in multiple local languages and by including pictograms for the illiterate. Considering the important role the generics companies play in distributing medicines in the Index Countries, this is a very important area that can contribute to more rational drug use and decreased supply chain burden in the Index Countries.

PATENTS AND LICENSING

This technical area focuses on policies and practices of the generics companies regarding patents & intellectual property protection and their engagement in non-exclusive voluntary licensing activities with the originator companies.

PATENTS

As the generics companies undertake further in-house research and collaboration with originator companies or product development partnerships, patent-related issues become more relevant to these companies.

Three companies out of seven have a public stance regarding TRIPS and Doha flexibilities. ***Cipla*** and ***Dr. Reddy's*** make specific commitments to respect patent protection. For the products for which ***Ranbaxy*** is the patent holder, it has made specific commitments not to enforce patents in such as way that "it would affect access to medicine".

Originators and generics companies continue to be involved in a large number of litigations around intellectual property. A more constructive approach to intellectual property protection from both the originators and the generics companies through arrangements such as non-exclusive voluntary licensing could help improve affordability and accessibility of patented products in the Index Countries. Low disclosure hampered further analysis of performance under this technical area.

NON-EXCLUSIVE VOLUNTARY LICENSING

Generics companies are mostly on the in-licensing side of the voluntary licensing agreements.

Ranbaxy and ***Cipla*** have been involved in non-exclusive voluntary licensing mostly for ARVs. None of the generics companies under coverage has expressed strategic commitment to expand non-exclusive voluntary activities to other Index Disease areas.

None of the companies discloses the terms and conditions for its non-exclusive licensing practices including license territories, pricing controls, technology transfer, etc.

Unfortunately, generics companies disclose little information about their engagement in “exclusive” voluntary licensing agreements and how they make such products affordable to different socioeconomic segments of the target markets.

Examples of Leading Practices

- ***Apotex*** has been the only company to have received a license under Coalition for the Advancement of Medical Research (CAMR) to produce patented medicines for export to Index Countries at no-for profit prices under compulsory license
- ***Ranbaxy and Cipla*** are involved in the ‘in-licensing’ side of non-exclusive voluntary licenses issued by originator companies for Index Diseases.

Suggested Areas for Improvement

- **More Disclosure about Voluntary Licensing Practices:** Most of the disclosure about existing voluntary licensing activities across the sector is provided by originator companies. Non-exclusive voluntary licensing has been proven to have significant positive impact on affordability and accessibility of pharmaceutical products in the Index Countries. Currently the disclosure level about the terms of such licensing agreements from the generics companies is low.
- **Expansion of Non-Exclusive Voluntary Licensing to Other Disease Areas:** Most of the current non-exclusive voluntary licensing focus on HIV/AIDS. These type of arrangements have significant potential for expanding supply, decrease prices for needed patented medicines. Under the increasingly

CAPABILITY ADVANCEMENT IN PRODUCT DEVELOPMENT AND DISTRIBUTION

Due to their geographical proximity and experience in product development and manufacturing in Index Countries, generics companies are well placed to help improve the capabilities of Index Countries. This technical area looks at these efforts with respect to R&D and also the production and distribution process.

Three companies ***Cipla***, ***Dr. Reddy's*** and ***Ranbaxy*** have made commitments to assist local Index Country manufacturers, with ***Cipla*** and ***Dr. Reddy's*** providing evidence of performance.

Cipla is the leader in the area, providing assistance in technology and knowledge transfer in Brazil, South Africa and most recently in Uganda. ***Cipla's*** collaboration with the government of Uganda for producing ARVs and achieving international quality standards is an example of successful technology transfer. For more information, please refer to "Recent Innovations" at the end of this chapter.

Dr. Reddy's states that it provides training and helps local manufacturers adhere to the good manufacturing practice (GMP) approval process.

Generics companies have a comparative advantage in the area of adaptive research. Such research can be carried out in collaboration with local organizations which are aware of local environmental and social needs. No evidence of 'Capability Advancement for R&D in Index Countries' was found at the time of analysis.

Examples of Leading Practices

- ***Dr. Reddy's*** provides training and helps local partners adhere to the good manufacturing practice (GMP) standards.
- ***Cipla*** invested in an ARV manufacturing plant in Uganda in partnership with the local government. For more information, please refer to "Recent Innovations" at the end of this chapter.

Suggested Areas for Improvement

More Collaboration with Index Country Organizations: Currently there are very few examples of generics companies engaging in collaborations with Index Country manufacturing or research organizations. Given the strong presence of several of the generics companies under coverage in the Index Countries, such companies have far-reaching potentials for collaborating for adaptive research. In addition, projects such as ***Cipla***'s collaboration with the government of Uganda demonstrate how Generics Companies can effectively help build local capacity in manufacturing and quality management through devising an innovative and financially sustainable business model (for details please refer to the related "Recent Innovation" at the end of this chapter).

PRODUCT DONATIONS AND PHILANTHROPIC ACTIVITIES

This technical area considers the policies and practices of the generics companies in engaging in single and multi-drug donations and also philanthropic activities.

PRODUCT DONATIONS

While there has been an increase in generics companies' involvement in drug donations compared to Index 2008, their activity in this area remains limited. Three companies (***Dr. Reddy's***, ***Ranbaxy*** and ***Teva***) have been found to undertake multi-drug donations, responding to natural or human-made disasters. None of the companies in the sector have strategic, long term single-drug donations activities. During the survey period, ***Teva*** released USD 14.4 million (GBP 12.1 million) worth of medications to a third-party agency for donation to the developing world. This was one of the largest multi-drug donations by a generic manufacture in history. It has been attributed to duplicate stocks arising from an acquisition.

None of the companies has made an explicit commitment to the WHO Inter-agency Guidelines for Drug Donations. Nonetheless, no company has been involved in litigations or controversies related to drug donations.

Furthermore, all three companies have collaborated with International Health Partners, which requires that all products comply with WHO guidelines. The value, volume or products included in such donations are not reported on a case-by-case basis.

PHILANTHROPIC ACTIVITIES

Generics companies' philanthropic efforts have mainly been educational programs to increase the health awareness of the population and/or contribute to the development of local health infrastructure. Three companies have commitments in this direction: ***Cipla***, ***Dr. Reddy's*** and ***Ranbaxy*** (***Sandoz***'s significant philanthropic activities have been captured under originator company Novartis). ***Dr. Reddy's*** has made a general commitment to philanthropic activities in the communities around manufacturing sites and to support of NGO operations. The company has a foundation which promotes post-graduate certification in healthcare management. As for ***Ranbaxy***,

one project involves mobile healthcare units operating in 90 villages. Another initiative seeks to establish local healthcare groups to promote rural community involvement and self-sustainability in India.[79]

The disclosure of resources dedicated to such initiatives, human or financial, is poor at this time and thus no conclusion can be made regarding the generics companies' scale of involvement in this area.

Example of Leading Practices

- ***Cipla***, ***Dr. Reddy's*** and ***Ranbaxy*** have made commitments to undertake philanthropic activities.
- ***Dr. Reddy's*** philanthropic activities are conducted through its own foundation.
- ***Dr. Reddy's***, ***Ranbaxy*** and ***Teva*** made multi-drug donations during the survey period.

Suggested Areas for Improvement

- **Targeted Product Donations and Philanthropy:** Overall, with few exceptions, company activities in this area have been limited. Philanthropy targeted at local healthcare infrastructure projects could help the generics companies expand and improve ATM and also expand their footprint in the Index Countries in the long run.
- **Commitment to WHO Inter-Agency Guideline for Drug Donations:** Most of the generics companies under coverage carry out multi-drug donations, but none explicitly commits to the WHO Inter-Agency Guidelines for Drug Donations. Drug donations when carried out without attention to international norms and standards and when not aligned with target country needs can be a burden to the target communities.

[79] IFPMA 2008 - **Ranbaxy Community Health Care Society**
http://www.ifpma.org/index.php?id=2172

RECENT INNOVATIONS- GENERIC MANUFACTURERS

Topic	Capacity Advancement Project in Collaboration with Local Governments
Company	***Cipla***
Description	***Cipla*** has invested USD 38 million in an ARV manufacturing plant in Uganda. The company says that the finished products will be sold "for as little as 5% of the costs of equivalent imports," due to lower production costs and exemption from TRIPS requirements in Uganda. The public private partnership between ***Cipla*** and the government of Uganda for production of ARVs and other drugs provides a good example of collaboration between companies and Index Country organizations that can lead to improved local production and quality management capacity.

Topic	Engaging in Innovative R&D for Index Diseases
Company	***Ranbaxy***
Description	***Ranbaxy*** is unique amongst its peers for undertaking innovative R&D for Index Diseases. Currently, these activities include the in-house development of a Phase III anti-malarial (Arterolane & Piperaquine) and "discovery" stage activities for both tuberculosis and dengue. These projects are occurring in partnerships; the tuberculosis partner is the New Delhi Department of Biotechnology (DBT); the dengue partner is the International Centre for Genetic Engineering and Biotechnology (ICGEB). Considering the limited scale of overall innovative R&D within the sector (compared to its originator peers), this is best practice, as no other generics company has demonstrated innovative R&D for Index Diseases.

Topic	Canadian Access to Medicines Regime (CAMR) as a way to improve ATM in the ICs
Company	***Apotex***
Description	In 2008, Apotex was the first company to make use of Canada's Access to Medicines Regime to improve ATM in Rwanda. Under the CAMR, which reflects the World Trade Organization's article 31(f) of the TRIPS agreement, Apotex was able to produce and export the generic triple-combination ARV therapy "Apo-TriAvir" to improve access to HIV medicines throughout Rwanda. This was based on a compulsory license demanded by Rwanda. CAMR is a major breakthrough for countries wishing to use compulsory licensing provisions of TRIPS which do not have local production capacity. Apotex's first shipment of "Apo-TriAvir" (containing molecules from ***GlaxoSmithKline***, ***Boehringer-Ingelheim*** and ***Shire)*** was delivered in September 2008, followed by a second shipment in September of the following year. The two shipments combined provide HIV treatment to approximately 21,000 HIV patients for one full year.

Review of achievements outside the scope of the Index

In order to develop a robust Index and to focus on high priority areas, the Index Methodology must have a clear geographical, company and disease scope. However, this means there are some ATM initiatives that fall outside the scope of the Index. These include:

- Activities of companies that are too small for Index inclusion
- Company initiatives for diseases that are not causing the highest health burdens in the Index Countries
- Initiatives carried out in countries not covered by the Index

In this chapter, we describe some of the promising ATM initiatives that fall outside the scope of Index 2010.

OUTSIDE COMPANY SCOPE

Company: Sigma-Tau (Italy)

Initiative: Eurartesim International Development Program for malaria

Sigma-Tau, in partnership with the Medicines for Malaria Venture (MMV), has completed development of Euratesim – a fixed–dose Artemisinin-based Combination Therapy (ACT). This combines a potent but short-lived Artemisinin-based active ingredient (dihydroartemisnin) with a second antimalarial (piperaquine) which remains longer in the body. A registration dossier was submitted to EMA in mid-2009, to the US FDA at the end of the year and subsequently, in the countries where malaria is endemic. The treatment schedule is very simple: one daily administration for a total of 3 days. In clinical trials, the new medicine was found to be well-tolerated with no significant side effects[80]. Pfizer will be Sigma-Tau's commercial partner in Africa, where the drug is to be commercialized for the public and private sectors.

LESSON LEARNED: This project of Sigma-Tau demonstrates a strong case of collaborative research for an important need area, an effective approach to registration and commercial partnerships to maximize outreach to the communities in need. By using collaborative models, the company has succeeded in maximizing health burden impact while also achieving economic gains.

Company: Piramal Healthcare

Initiative: Helpyourbody™ Chronic Disease Campaign

By 2025, India will have 70 million diabetics, 213 million people with hypertension and 60 million with arthritis. Helpyourbody™ is an Indian nationwide campaign launched by the Piramal Group to help reduce the projected increases in the incidence of chronic diseases, notably type 2 diabetes, hypertension, cardiac problems and arthritis. This is achieved through education about disease prevention and management, healthy lifestyle training, regular check-ups and

[80] IFPMA (2010) Eurartesim™ International Development Program http://www.ifpma.org/index.php?id=3668

facilitating activism in communities. So far, some 4,000 Helpyourbody™ activists and 20,000 health care practitioners have enrolled. They are running detection camps across India to disseminate knowledge and encourage action by the public. Ninety diagnostic centers across 47 Indian cities are providing specialized tests for chronic illnesses and limited free testing.

LESSON LEARNED: This project is special because it targets non-communicable disease areas and is based on mobilizing communities and practitioners. Such creative models can help the companies engage their knowledge and organization capabilities while mostly using locally available resources.

Company: Aspen Pharmacare

Initiative: 'Paving the way': Aspen's leadership in non-exclusive voluntary licensing among generics companies.

Aspen Pharmacare has been one of the key generic firms to enter into non-exclusive voluntary licensing agreements (as a licensee) with several Index 2010 pharmaceutical companies for key, on-patent anti-retrovirals - licensors of which include ***GlaxoSmithKline*** (initially in 2001 and extended in 2009 to cover HIV medicine abacavir), ***Merck*** (2008), ***Bristol-Myers Squibb*** (2006), ***Gilead*** (2005) and ***Boehringer-Ingelheim*** (2002). Such voluntary licensing agreements have permitted South-African based Aspen to become a leading provider of generic HIV medicines to countries throughout sub-Saharan Africa and beyond. For example, Aspen's non-exclusive voluntary licensing agreement with ***Gilead*** for Viread and Truvada has permitted Aspen to manufacture and distribute generic HIV medicines to all 53 African countries (including South Africa through both public and private channels) at significantly reduced prices. Aspen continues to remain a leader among generics companies by providing a sustainable and affordable supply of generic ARVs to developing world countries while simultaneously achieving substantial increases in revenue, in part as a direct result of products derived from such licensing agreements.

LESSON LEARNED: Aspen's ability to negotiate and enter into voluntary licensing agreements with multinational pharmaceutical companies for on-patent products has permitted the company to strategically place itself as a leader for the production and distribution of affordable generic HIV medicines throughout Africa. In part as a result of non-exclusive voluntary licensing agreements and the company's continued investment in manufacturing facilities, Aspen has achieved and retained its position as a global provider of generic HIV medicines.

OUTSIDE DISEASE SCOPE

Company: Bayer

Initiative: Comprehensive Family-Planning Program

The Access to Medicine Index is focused on high priority diseases whose remedies are primarily developed by the pharmaceutical sector. As a result, areas such as maternal care, family planning and nutritional supplements are not currently covered by the Index. Nonetheless these areas are vital to long term social improvements in the Index Countries.[81]. Bayer has played an active role in addressing this gap

Bayer collaborates with various non-governmental organizations to offer sexual health education programs and other family-planning and reproductive health initiatives. In partnership with the German Foundation for World Population (DSW), the company launched an educational program for young teenagers under the age of 15 in Uganda ("Youth2Youth"). Since 2002, the company has been organizing a series of annual conferences called International Dialogue on Population and Sustainable Development. This is done in partnership with several other organizations to bring together politicians, governmental and non-governmental organizations, scientists and industry, to discuss population development and progress toward achievement of Millennium Development Goals.

In December 2007, Bayer was the first industrial partner to become a member of the Reproductive Health Supplies Coalition (RHSC). Bayer supports family planning programs in over 130 countries in close co-operation with government organizations, multilateral organizations and private organizations. In 2008 alone, Bayer contributed about 33 million cycles of oral contraceptive and more than 3.5 million injectables worldwide, as well as half a million sets of implants.

LESSON LEARNED: Through focus and extensive stakeholder engagement, Bayer has demonstrated how it is possible to mobilize resource and political will of the different stakeholders to make Index Country initiatives sustainable. This approach can be replicated in other therapeutic areas

Company: Sanofi-Aventis

Initiative: Collaborative Approach to Addressing Mental Health Disorders

Sanofi-Aventis has a broad portfolio of anti-psychotic medicines such as Largactil, Nozinan, Piportil L4 and Solian. The company has run pilot programs in Mauritania, Morocco and Vietnam in liaison with national health ministries and universities. These initiatives combine communication, education and affordable medicines.

[81] UN Population Fund on Family Planning (2010). Available at; http://www.unfpa.org/public/about

LESSONS LEARNED: As with many other non-communicable diseases, mental disorders in the Index Countries, while causing significant health burden are mostly neglected by all the stakeholders. The company's comprehensive and innovative approach in this area can be a model for other companies.

Company: Merck & Co.

Initiative: Providing access to HPV vaccines: Gardasil

Cervical cancer is the second most common cancer in women worldwide and approximately 80% of all cases occur in low and lower middle income countries[82]. This cancer is largely linked to genital infection with human papillomavirus (HPV). Merck & Co. provides its HPV vaccine, Gardasil, at no-profit prices to the public sectors of eligible low-income countries (as defined by the Global Alliance for Vaccines and Immunization (GAVI)). For other countries, the company offers a tiered-pricing policy based on ability to pay. Additionally, Merck & Co. has also established a GARDISIL Access Program in which it has committed to donate at least 3 million doses of Gardasil over a period of five years to support HPV vaccination in lowest-income countries. The program is managed by Axios Healthcare Development (AHD), a US non-profit organization and technical assistance is provided by Axios International, a public health consultancy.

[82] IAVI, PATH (2008) Making Cervical Cancer Vaccines Widely Available in Developing Countries: Cost and Financing Issues

Strategic guidance for this program is provided by an independent GARDASIL Access Program Advisory Board, comprised of international public health experts. The first shipments of donated Gardasil were sent to Bolivia, Cambodia and Lesotho in the first half of 2009. Other countries that have been approved for donations to date include Ghana, Haiti, India, Nepal and Nicaragua.

LESSONS LEARNED: Using a multi-pronged approach (i.e., various equitable pricing mechanisms and a long term and targeted donation program), Merck & Co. is positioned to better reach a larger number of patients in resource-limited countries.

OUTSIDE GEOGRAPHICSCOPE

Company: Roche

Initiative: Phelohepa Healthcare Train

Phelohepa Healthcare Train provides basic health care services to poor patients in remote areas of South Africa. The train is 16 cars long and provides a pharmacy, cancer screening and education, psychology and dental and eye clinics, as well as diabetes and smear tests. It serves more than 45,000 people a year and has reached nearly 13 million in total since its inception in 1994. The train is run by the government-owned Transnet group, but Roche is the lead outside sponsor. At each stop, 16 people are nominated to

complete five-day courses in basic health and hygiene. Examinations and screening are free, but nominal fees are charged for services such as prescriptions and glasses. However, a fund of pooled donations helps to ensure that no one unable to pay is refused treatment.

LESSON LEARNED: This is an example of philanthropic activity which innovatively uses the country's existing infrastructure to address 'accessibility' issues facing poor communities. The project has been sustained over the years and output measures are disclosed; both of which signify a sustainable approach to philanthropy.

Company: GlaxoSmithKline

Initiative: Rotavirus Vaccine Program in Brazil

In partnership with GAVI Alliance, WHO and others, ***GlaxoSmithKline*** developed Rotarix, which is a two-dose oral vaccine targeting a rotavirus strain that often causes severe diarrhea. The company obtained WHO prequalification for Rotarix in early 2007. ***GlaxoSmithKline*** is helping Brazil implement a universal mass vaccination program for rotavirus. It will supply enough Rotarix to protect every baby in Brazil for the next five years and will transfer technology to allow Brazil's Fiocruz to produce Rotarix under license for the domestic market and for export. According to Brazilian Ministry of Health, to date, the vaccination program has already resulted in an 85% reduction in rotavirus-related hospitalizations.

LESSON LEARNED: GlaxoSmithKline has provided a good example of targeting an important high health burden disease area and helping create sustainable local capacity to assure the program makes long-term impact.

Appendix

A. ACCESS TO MEDICINE INDEX 2010 SCOPE

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 companies, of which six are publicly listed and one is private. Selection of the companies is based on market capitalization (and only pharmaceutical operations are covered) as well as the relevance of product portfolios 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 companies, since the market failures and priorities with regard to ATM 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 product portfolios and initiatives relevant to ATM in the Index Countries are covered, namely generics company ***Apotex*** and originator company ***Boehringer-Ingelheim.***
- Biotech companies are not covered by Index 2010. 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 were asked to provide data for the full 2008/2009 fiscal years.

Table 15. Index 2010 Originator Company List

Two Lists: One for Originator companies and One for Generic Companies

	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 16. Index 2010 Generics Company List

	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 LHDCs and MHDCs as defined by the UN Human Development Index 2008 excluding the medium high and high income countries based on World Bank classifications[83] [84]. 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.

[83] UNHDI (2008). Human Development Report HDI rankings. Available at: http://hdr.undp.org/en/statistics

[84] World Bank (2009). Country classifications. Available at: http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20420458~menuPK:64133156~pagePK:64133150~piPK:64133175~theSit

Table 17. 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
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 18. 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
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

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)
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
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

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)
109	Indonesia	East Asia & Pacific	0.726	8.7	3455	Lower middle income
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
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

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)
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
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
152	Tanzania (United Republic of)	Sub-Saharan Africa	0.503	36.2	1126	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)
153	Senegal	Sub-Saharan Africa	0.502	17.1	1592	Low income

DISEASE SCOPE

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[85] (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[86]
- 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 ATM priorities depending on age groups. Future 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 Project Report [87].

In addition, for R&D analysis, certain product categories for some diseases were excluded. The R&D for diseases and product areas covered by Index 2010 were established based on one of the conditions listed below:

[85] WHO (2010) .Neglected diseases http://www.who.int/neglected_diseases/en/
[86] WHO (2008)

[87] The Disease Control Priorities Project (2010) Available at: http://www.dcp2.org/

- The disease should be causing significant health burden in the Index Countries.
- Investment in research should have the potential to significantly decrease the social burden.
- The market incentives for developing the needed product should be deficient.

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[88].

[88] G-finder (2010). Global Funding of Innovation for Neglected Diseases. Available at: http://www.thegeorgeinstitute.org/research/health-policy/current-projects/g-find-global-funding-of-innovation-for-neglected-diseases.cfm

Table 19. Index 2010 Communicable Diseases - WHO Neglected Tropical Diseases

	Disease	Reference List		Disease	Reference List
1	Lymphatic filariasis	GBD, NTD	8	Onchoceriasis	NTD
2	Shistosomiasis	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 (uinea-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

Table 20. Index 2010 Communicable Diseases - The WHO Global Burden of Diseases List

	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 21. Index 2010 Non-Communicable Diseases - The WHO Global Burden of Diseases

	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

B. STAKEHOLDER ENGAGEMENT PROCESS

For Index 2010, the methodology update process was designed and launched in late 2008 and the stakeholder outreach started in January 2009. The update process commenced 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.

The following section 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 ATMs 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 generic 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 methodology update process (the anonymous responses to the online survey can be provided upon request).

As demonstrated in the tables below, government representatives were the only stakeholder group that was comparatively 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 22. Online Stakeholder Survey 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 23. Online Stakeholder Survey 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 ATM Workshop in Nairobi

We aim to organize a local workshop on an annual basis to ensure ongoing engagement and involvement of local actors 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.

Index 2010 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 ATM Index framework. Well-known international ATM representatives and stakeholders were invited to the roundtables for Index 2010. The stakeholder groups included:

academics, NGOs, investors, the pharmaceutical industry associations, trans-national organizations, governments and independent experts.

The two roundtable events for 2009 were:

- US Roundtable: Washington D.C. on 24 June, chaired by Femke Markus, Managing Director, Access to Medicine Index
- Europe Roundtable: London on 30 June, chaired by Sophia Tickell, Co-founder and Director of Pharma Futures

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

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

Table 24. 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
Government	Sally Schlippert, World Bank Tatiana Popa, , International Finance Corporation (IFC)	Charles Clift, Department For International Development (DFID) – Since January 2010, he is an independent consultant.
Independent Experts	Jonathan Mwiindi, Independent Expert, Previously with Ecumenical Pharmaceutical Network Jeanne Shen, GAVI Alliance Jeffrey Sturchio, Global Health Council	Jan Bultman, Independent Consultant Javier Guzman, George Institute for International Health Maggie Brenneke, SustainAbility Wilbert Bannenberg, Medicines Transparency Initiative
Industry	Dilip Shah, Secretary General, Indian Pharmaceutical Alliance – CEO, Vision Consulting Corry Jacobs, The Pharmaceutical Research and Manufacturers of America	Brendan Barnes, EFPIA Guy Willis, International Federation of Pharmaceutical Manufacturers & Associations
Investors	Lauren Compere, Boston Common Asset Management . / Interfaith Center on Corporate Responsibility (ICCR) Nadira Narine, ICCR	My-Linh Ngo, Henderson Global Investors
NGOs	David Ripin Brown, The Clinton Foundation	Robyn Scott, Founder of Mothers for All, Independent Consultant & Writer
Chair	Femke Markus, ATM Index	Sophia Tickell, Con-founder and Director of Pharma Futures Co-chair Femke Markus, ATM Index
ATM Index	Wim Leereveld, ATM Index Jocelyn Musters, ATM Index Matthew Kiernan, RiskMetrics Group Afshin Mehrpouya, RiskMetrics Group April Cody, RiskMetrics Group Naomi English, RiskMetrics Group	Wim Leereveld, ATM Index Jocelyn Musters, ATM Index Afshin Mehrpouya, RiskMetrics Group Naomi English, RiskMetrics Group Celia Moeller, RiskMetrics Group
Observer	Regine Webster, Consultant at the Gates Foundation	Helen Vieth, London School of Economics

Other Feedback Sources

In addition to the above primary routes for obtaining stakeholder feedbacks, during the 2010 methodology review process, the ATM Index team remained 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.

Note 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 (ERC). The ERC was

established in 2009 to provide 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

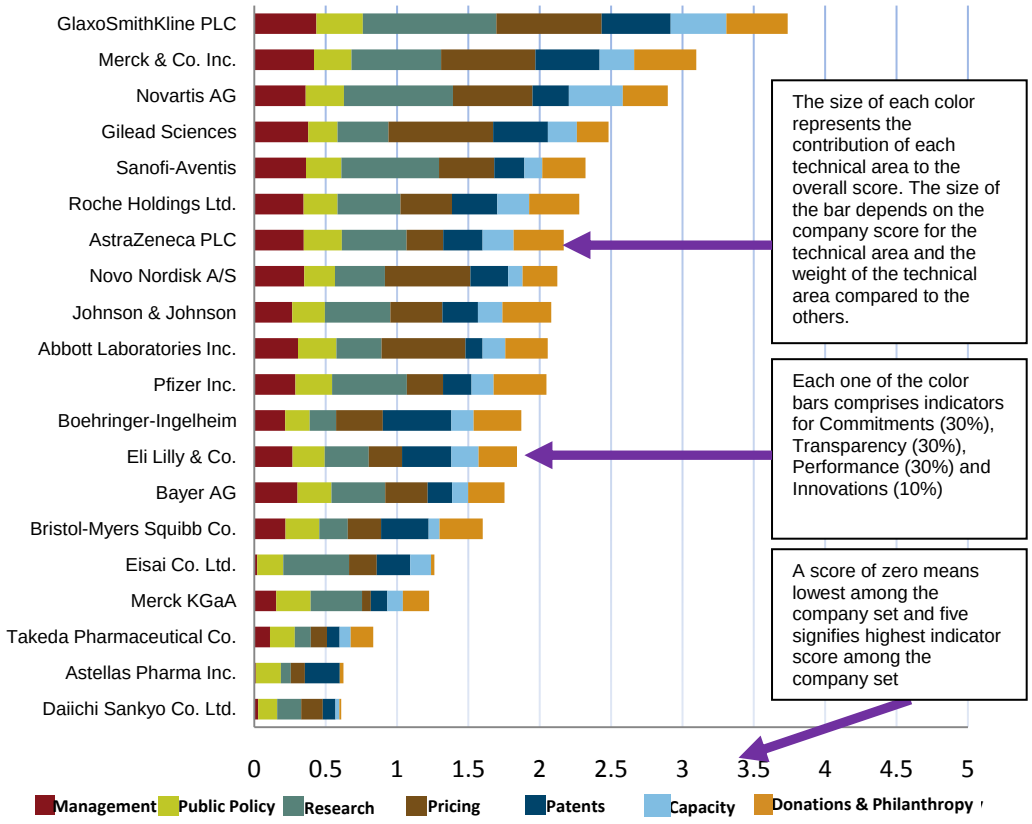
The Expert Review Committee (ERC) is made up of individuals from different stakeholder groups, all active in some capacity on the ATMs agenda. Convened in 2009, the mandate of the ERC is purely advisory in nature, with the objective of providing guidance, recommendations and advice to the ATM Index team on the scope, structure, content and methodology of the second ATM Index assessment. The ERC members' involvement is intended to ensure that different viewpoints and perspectives are taken into consideration in establishing the latest ATM Index methodology and is intended to further build on the preceding consultation exercises that have taken place. The ATM Index team remains ultimately responsible for decisions on the final methodology associated with the reporting material and the findings of the ATM 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 ATM 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 and made available in March 2010. It is downloadable from the Access to Medicine Index website. Note 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 25. The ATM Index 2010 Expert Review Committee

Index 2010 Expert Review Committee	
Academics	Elias Mossialos, London School of Economics
Government	Charles Clift, Department For International Development (DFID) - Since January 2010, he is an independent consultant.
Independent Experts	Sophia Tickell, Con-founder and Director of Pharma Futures Jeff Sturchio, Global Health Council
Industry	Guy Willis, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
Investors	My-Linh Ngo, Henderson Global Investors
NGOs	Eva Ombaka, NGO Consultant
Multi-Lateral Organizations	Richard Laing, World Health Organization Hannah Kettler, Bill and Melinda Gates Foundation

C. RANKING AND SCORING PROCESS



Below is a summary of the scoring process used for the Access to Medicine Index 2010

1- Quantitative indicators such as the number of molecules relevant to the Index Diseases in companies' R&D pipelines are adjusted based on size of pharmaceutical revenues or other figures representing company size. The adjusted numbers are redistributed from zero to five before being used as scores.

2- Some quantitative indicators such as value of philanthropic activities (Indicator G.III.4) or the trends in the sales of the company (Indicator A.III.4) in the Index Countries faced data quality issues. In these cases many companies did not disclose the data or disclosed it in such a way that it was not comparable with the other companies. Such indicators were marked as "experimental" and after refinement of the indicator and hopefully more consistent company disclosure in the next iterations of the Index, they will be used for the ranking process. There are five experimental indicators in Index 2010.

3- To avoid distortion of the weighting system, for the three performance indicators which were changed to experimental after the weights were assigned, a proxy indicator was created based on the average of the companies' score on transparency and commitments under the same technical area.

4- Scoring was carried out based on data from a wide range of information sources including companies themselves, independent reports, databases from WHO, news databases such as Lexis Nexis and Factiva, etc.

5- The final scoring of the companies is the result of scoring by the company analyst following verification by the analyst in charge of each technical area. Finally the scoring has been verified by two senior analysts at RiskMetrics.

6- When an indicator is not applicable to a company, neutral scoring is used. For example, when a company has no non-exclusive voluntary licensing, it gets a lower score for commitments and performance for the indicators related to non-exclusive voluntary licensing. However, for the indicator related to transparency of voluntary licensing activities, a neutral score is used. This is because the company has no data to disclose.

7- For neutral scoring the average of all the indicator scores for the company for the technical area excluding the indicators which receive a neutral score is used. For the licensing example, this would be the average of all the company's indicators scored under Patents and Licensing excluding the indicators which receive neutral score.

8- A statistical analysis has been carried out on the final scores to check for significant correlations between different indicators and the distribution of each indicator. Based on this analysis, adjustments were made to some indicators' scoring guidelines to ensure maximum variability. In addition some indicators with high correlation were marked for possible removal in the next iterations of the Index.

9- The scoring guidelines for all the indicators have been defined in such a way that, relative to all other companies in the peer group, the top performing company receives a score of five and the lowest performing company receives a score of zero. An important exception to this approach was when all the companies scored zero on an indicator, where achieving good distribution is not feasible.

D. INDICATORS AND SCORING GUIDELINES

General Access to Medicine Management

I. Commitments- 30%			
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.	Originators	35%	5 - Board level representation + executive committee dedicated to access to medicine related issues or an executive role (such as VP) dedicated to access to medicine issues. 3.5 - The company has a board level process and representation for ATM related issues + a director for access related issues. 1.5- Board level representation but no director or executive dedicated to ATM. 0- No representation of ATM related issues in the company's senior governance bodies <u>Adapted guidelines for generics companies:</u> 5- Dedicated senior director in charge of access programs + regular reporting to the board 3.5 - A CSR director that is also in charge of ATM 1.5- Statement of ATM commitment by a senior executive 0- No management position dedicated to ATM related issues.
	Generics	35%	
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.	Originators	35%	5- The company has a general ATM policy including business rationale and strategic firm objectives in this area - pure philanthropy is not considered a sustainable business rationale in the scoring process 2.5 The company discloses ATM policy without explaining the business rationale and objectives 0 No disclosure on ATM policy <u>Adapted guidelines for generics companies:</u> 5- An ATM policy based on a sustainable financial approach with specific focus areas 2.5 - A public policy and ATM policy disclosure based on humanitarian reasons 0- No public policy disclosure in this area
	Generics	35%	
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.	Originators	30%	5- The company has a strategy and platform for outreach most of the stakeholder groups with the goal of having dialog and knowledge sharing aimed at improved access to medicines in the Index Countries 2.5- The company mentions examples of stakeholder outreach but does not have a comprehensive strategy and platform in this area. 0- The company does not have a stakeholder outreach policy or platform related to access to medicine. <u>Adapted guidelines for generics companies:</u> 5- A platform for stakeholder outreach and active engagement and dialog with all the stakeholders 2.5 Committed to engagement with some stakeholder but does not have a strategy/platform for outreach 0- No commitments in this area.
	Generics	30%	

II. Transparency- 30%			
A.II.1 The company publishes a publicly available annual report on its access to medicine policies and practices	Originators	35%	5- The company publishes an annual report on its ATM related policies/activities and short/long term objectives and output (as part of annual report or separate) which is issued not later than one year from the end of the fiscal year under coverage. 3.5- The company publishes an annual report on its ATM related policies/activities and long term objectives but no information on short term targets or performance. 1.5- The company's annual reporting is issued more than 1 year from the end of the fiscal year under coverage. 0- No annual reporting on access to medicine activities
	Generics	35%	Adapted guidelines for generics companies: 5- Annual report or regularly updated website mentioning ATM achievements, objectives and policies. 3.5- Annual report or regularly updated website mentioning achievements and policies 1.5 - pages in annual report or not updated page on website mentioning policies and/or achievements 0- Nothing
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.	Originators	30%	5- The company publicly discloses the HR and/or financial resources dedicated to all its different ATM related activities regularly. 3.5 - The company publicly regularly discloses resource related information (HR and/or financial) for a subset of its ATM initiatives. 2.5 - The company discloses all HR and/or financial resources on an engagement basis. 1- The company discloses examples of its HR and/or financial resources on an engagement basis. 0- The company has no disclosure in this area
	Generics	30%	Adapted guidelines for generics companies: 5- detailed financial and human resources invested in ATM related projects 4- Aggregate numbers about resources dedicated 2.5- Mention of resources for some projects 1- Mention of resources for at least one project 0- No disclosure
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.	Originators	35%	5- The company discloses the quantitative and qualitative performance measures and targets related to its different ATM initiatives for the coming business cycle examples are products to achieve marketing approvals; number of collaborations, price targets for the Index Countries. 3.5- The company discloses qualitative and quantitative performance measures and objectives for some of its ATM initiatives 1.5 Long term objectives but no quantitative targets. 0- The company has no disclosure in this area.
	Generics	35%	Adapted guidelines for generics companies: 5- The company sets future objectives for all its ATM activities 2.5 - The company provides examples of objectives for some of its ATM activities. 0- no disclosure in this area.

III. Performance- 30%			
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)	Originators	10%	Total number of employees including scientists, administrative workers etc. employed full time (FTE) by the company who are dedicated to the company's access to medicine related activities relevant to the Index adjusted for the company's total employees. Due to the absence of reliable data for this indicator, we used the companies' average scores for ATM Management. For more information please refer to Appendix D: Ranking and Scoring Process.
	Generics	10%	
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.	Originators	40%	5- The company has a management and measures system for ATM that monitors quantitative / qualitative measurement which is centralized and collects data for all the company's global operations in this area. 2.5 - The company has a management systems for some of its access to medicine programs that monitors quantitative/ qualitative measurements 0- None
	Generics	40%	
A.III.3 The company participates in public debate and engages with the different stakeholder groups with the goal of dialog 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.).	Originators	30%	5- above 15 conferences sponsored/hosted 4 -5-15 conferences sponsored/hosted 2.5 - under 5 conferences sponsored/hosted 1- If company has not provided any numbers of conferences, they get this score if we are able to find (online search) evidence of participation in more than one conference during the period of analysis. 0 - no sponsorship/hosting <u>Adapted guidelines for generics companies</u>: 5-The company has participated in several multi-stakeholder conferences or has at least sponsored one conference related to ATM. 2.5 - The company has participated in at least one conference during the period of analysis with focus on ATM 0 - no activities in this area.
	Generics	30%	
A.III.4 Trends in the company's revenue from sales in the emerging markets compared to revenues from sales in the rest of the world during the past five years.	Originators	20%	The growth of the companies' emerging markets revenues divided by the overall company growth in terms of revenues during the past 5 years. Due to the absence of reliable data for this indicator, we used the companies' average scores for ATM Management. For more information please refer to Appendix D: Ranking and Scoring Process.
	Generics	20%	
IV. Innovation- 10%			
A.IV.1 The company has adopted innovative (unique in the sector) approaches to General Access to Medicine Management including ATM governance, ATM Management System and stakeholder engagement.	Originators	100%	5- The company has adopted innovative (unique in the sector) approaches to general access to medicine management, including ATM governance, ATM management systems and stakeholder engagement and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) approaches to general access to medicine management, including ATM governance, ATM management systems and stakeholder engagement but does NOT disclose progress or resources inputs. 0- No innovative initiatives discovered in this area.
	Generics	100%	

Public Policy and Market Influence

I. Commitments- 30%			
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.	Originators	30%	5- The company commits to transparency with regard to its public policy positions and activities including political contributions in the Index Countries (or emerging markets) 3.5- Commitment to transparency in lobbying activities, at least relevant or related to ICs/ATM. 1.5 The company commits to transparency with regard to its public policy positions or activities in general (lobbying, contributions etc.) 0 The company makes no commitments with regard to transparency in its lobbying activities. <u>Adapted guidelines for generics companies</u>: 5- General commitment to transparency both in lobbying stances and activities (expenditures) 3.5 - Commitment to one of the above two items 1.5 - General commitment to transparency in lobbying. 0- No disclosure in this area.
	Generics	35%	
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.	Originators	30%	5- The company has a detailed policy statement related to competition with its peers (both originator and generic) which endorses competition and commits not to adopt practices that hamper competition (arrangements with competitors for delayed entry to the market, etc.) 2.5- The company makes a general statement about endorsement of competition with its peers. 0 The company does not make any policy statements in this area.
	Generics	30%	
B.I.3 The company refrains from pursuing data exclusivity for products related to the Index Diseases in the Index Countries.	Originators	20%	5- The company systematically commits not to pursue data exclusivity for all its products related to Index Diseases in the Index Countries 3.5 – The company commits not to pursue data exclusivity for most (more than 50%) of the Index Countries specific conditions and or diseases. 1.5- Commits to refrain from data exclusivity for a sub-set of products in a few Index Countries 0- No policy statement on data exclusivity/ negative stance on data exclusivity. <u>Adapted guidelines for generics companies</u>: 5- The company systematically commits not to pursue data exclusivity for all its products related to Index Diseases in the Index Countries 2.5 – The company commits not to pursue data exclusivity for specific conditions and or diseases. 0- No policy statement on data exclusivity/ negative stance on data exclusivity.
	Generics	0%	
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	Originators	10%	5- The company commits to either of the mentioned two codes (for generics company the only viable option is the WHO Ethical Criteria for Medicinal Drug Promotion which is an 1988 code) or an equivalent industry code 2.5- The company has an internal code of ethical marketing practices which cover the core principles of the mentioned external codes.

Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Marketing Practices).	Generics	20%	0- No code for ethical marketing The 2.5 score guideline is for innovator companies - if a Generic Manufacturer has an internal code of ethical marketing, given no viable up to date and auditable external code is available, it will get a 5 Adapted guidelines for generics companies: 5- Commitment to an international (e.g. WHO code for ethical marketing) or national code such as OPPI 2.5 - Commitment to an internal code of marketing 0- No ethical marketing commitments.
B.I.5 The company commits to demand ethical marketing practices from its local third party distributors consistent with its own internal standards.	Originators	10%	5- The company has specific ethical marketing demands from all its sales agents (third party distributors) in the Index Countries which include auditing of the agent's practices. 3.5- The company has specific ethical marketing demands from all its sales agents (third party distributors) in the Index Countries, but no auditing mechanisms. 1.5 The company sets general ethical marketing guidelines for its sales agents. 0- No provisions with regards to the marketing behavior of the local sales agents.
	Generics	15%	
II. Transparency- 30%			
B.II.1 The company publicly discloses the positions it seeks through its advocacy activities related to access to medicines in the Index Countries (direct advocacy).	Originators	15%	5- Comprehensive public policy disclosure on all major access related issues, such as counterfeiting, clinical trial conduct, pharmacovigilance, pricing and product donations 2.5- The company discloses some of the positions that it seeks in some of the Index Countries in the ATM related areas 0- No disclosure regarding the public policy positions
	Generics	15%	
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.	Originators	15%	5- The company discloses its support for all the institutions of all the mentioned categories for the Index Countries 3.5- Detailed transaction level disclosure on lobbying payments to different stakeholders - but no specific Index Country reporting 1.5- The company has partial disclosure in this area, aggregate figures only 0- The company has no disclosure in this area
	Generics	15%	
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.	Originators	10%	5- The company publicly discloses all the board seats and memberships that it holds in different third party institutions related to access to medicine in the Index Countries including organizations operating in the Index Countries 4- The company only discloses all memberships that it holds in different third party institutions related to ATM in Index Countries, including organizations operating in Index Countries 3- Partial public disclosure of memberships

	Generics	10%	2- Discloses its memberships and board seats through engagement 1- Partial disclosure of board seats and memberships through engagement 0- No disclosure in this area
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.	Originators	30%	5- The company clearly articulates its stance in the following area: patent extension in Index Countries (ever greening), arrangements with generics companies which might delay their market entry, data exclusivity, TRIPS+ (and any major components) and compulsory licensing 1-4 - Disclosure of public policy position on any of the above 5 areas - each one has one score. 0- No disclosure in this area.
	Generics	30%	
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.	Originators	20%	5- The company discloses detailed information related to drug promotion in areas such as payments to physicians and methods for incentivizing healthcare providers, pharmacies etc. in the Index Countries 2.5- The company discloses its approach without regularly disclosing exact contribution figures and performance information in this area (including aggregate data but no details). 0- No disclosure in this area.
	Generics	20%	<u>Adapted guidelines for generics companies</u>: 5- The company discloses detailed information related to drug promotion in areas such methods used for incentivizing healthcare providers, pharmacies etc. in the Index Countries 2.5- The company discloses anecdotal information in this area and not the general approach 0- No disclosure in this area
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.	Originators	10%	5- The company discloses detailed updated information in this area in its annual report including cases having taken place in the Index Countries. 2.5- The company discloses minimal information on breaches and/or litigations (i.e. location, time, year), or aggregate numbers as part of its annual report. 0- No disclosure in this area
	Generics	10%	
III. Performance- 30%			
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.	Originators	30%	5 – The company has not been the subject of any cases or controversies in Index Countries. 3- [For companies with operations in <5 Index Countries]. The company has not been the subject of any cases. 2– The company has been the subject of at least one controversy in an Index Country (backed by evidence/material support from civil society actors) 1 – The company has been the subject of more than one controversy (backed by evidence/material support from civil

	Generics	30%	society actors) or one or more unconcluded litigation in the Index Countries. 0 – The company has been the subject of one or more litigation with a negative ruling/settlement with payment or a regulatory proceeding with a fine in the Index Countries. <u>Adapted guidelines for generics companies</u>: 5- no cases found 2.5 - cases found out of the scope of the index 0 - Cases (including litigations with a ruling, fines or major controversies) found in the scope of the Index
B.III.2 Is there material proof of the company's anti-competitive behavior in the Index Countries based on fines or litigation records during the past five years?	Originators	30%	5 – The company has not been the subject of any cases or controversies in Index Countries. 3- [For companies with operations in <5 Index Countries]. The company has not been the subject of any cases. 2– The company has been the subject of at least one controversy in an Index Country (backed by evidence/material support from civil society actors) 1 – The company has been the subject of more than one controversy (backed by evidence/material support from civil society actors) or one or more unconcluded litigation in the Index Countries. 0 – The company has been the subject of one or more litigation with a negative ruling/settlement with payment or a regulatory proceeding with a fine in the Index Countries. <u>Adapted guidelines for generics companies</u>: 5- no cases found 2.5 - cases found out of the scope of the index 0 - Cases (including litigations with a ruling, fines or major controversies) found in the scope of the Index
	Generics	30%	
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?	Originators	20%	5 – The company has not been the subject of any cases or controversies in Index Countries. 3- [For companies with operations in <5 Index Countries]. The company has not been the subject of any cases. 2– The company has been the subject of at least one controversy in an Index Country (backed by evidence/material support from civil society actors) 1 – The company has been the subject of more than one controversy (backed by evidence/material support from civil society actors) or one or more unconcluded litigation in the Index Countries. 0 – The company has been the subject of one or more litigation with a negative ruling/settlement with payment or a regulatory

	Generics	20%	proceeding with a fine in the Index Countries. Adapted guidelines for generics companies: 5- no cases found 2.5 - cases found out of the scope of the index 0 - Cases (including litigations with a ruling, fines or major controversies) found in the scope of the Index
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 distributors?	Originators	10%	5- In all the sales agreements - binding requirements 2.5 In some cases - or recommendations that are not binding and the company's reaction to breaches is not defined. 0- No mention.
	Generics	10%	
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?	Originators	10%	5- All company's senior officers and all the employees in the Index Countries have to sign a code of conduct, in which there is a process for implementation and monitoring and reporting breaches (i.e. a whistle blower process) for all Index Country locations. 2.5 Has a code without a reporting/monitoring/implementing mechanism 0 No code in this area.
	Generics	10%	
IV. Innovation- 10%			
B.IV.1 The company has adopted an innovative (unique in the sector), sustainable approach to improving the level of competition for Index Disease Products in the Index Countries.	Originators	100%	5- The company has adopted innovative (unique in the sector) approach to improving the level of competition for Index Disease Products in Index Countries and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) approach to improving the level of competition for Index Disease Products in Index Countries but does NOT disclose progress or resources inputs. 0- No innovative initiatives discovered in this area.
	Generics	100%	

Research and Development

I. Commitments- 30%			
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)	Originators	30%	5- The company makes a specific strategic commitment in multiple Index Disease areas, to invest in innovative research and development for Index Diseases with specific implementation objectives in this area. 4- The company makes a specific strategic commitment in multiple Index Disease areas, to invest in innovative research and development for Index Diseases without specific implementation objectives in this area. 2.5 -The company commits to innovative R&D for Index Diseases in general - or specific mention in relation to only one disease area 1 - The company makes a general commitment in this area without including objectives OR specific reference to innovative research. 0 -No commitments in this area. *For companies not expected to have communicable disease R&D activity companies receive a neutral score*
	Generics	0%	
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)	Originators	30%	5- The company makes a specific strategic commitment in multiple Index Disease areas, to invest in adaptive research and development for Index Diseases with specific implementation objectives in this area. 4- The company makes a specific strategic commitment in a number of Index Disease areas, to invest in adaptive research and development for Index Diseases without specific implementation objectives in this area. 2.5 The company commits to adaptive R&D for Index Diseases in general - or specific mention in relation to only one disease area. 1 - The company makes a general commitment in this area without including implementation objectives or specific mention of type (adaptive) research. 0- No commitments in this area.
	Generics	50%	
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.	Originators	5%	5- Company has a specific, detailed approach to post-trial access - for trials conducted in Index Countries - which assures access to patient benefits in a large variety of different circumstances. 3.5- Company has a specific approach to post-trial access - for trials conducted in Index Countries - which does not assure access to patient benefits in all likely circumstances. 1.5 - Company does not specifically refer to post-trial access other than through its stated compliance with the Declaration of Helsinki OR no evidence of any clinical trial conduct in Index Countries (Neutral) 0- no commitments
	Generics	10%	
C.I.4 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.	Originators	25%	5- The company makes a general commitment to be open to sharing its molecules library with institutions involved in research on the Index Diseases, plus realized commitments in a number of instances. 2.5- The company has made a specific commitment to share its molecules library on either a 'case-by-case' basis or in relation to one partner/disease area. 0- No commitments in this area.
	Generics	30%	

C.I.5 The company commits to waive its rights in the Index Countries to the intellectual capital generated in public private partnerships for the Index Diseases.	Originators	10%	5- The company systematically waives its rights in the Index Countries over the Intellectual Capital generated in public private partnerships and PDPs for Index Diseases 4 - The company has committed to consider waiving rights to IP to a third party (for ATM gain) OR makes an advance commitment to do so for specific initiatives. 3- The company commits to manage 'shared IP' for ID's with favorable 'access' terms in a majority of relevant situations. 2- The company has realized (at least) 1 commitment to waive its IP rights/ or provide favorable access terms with respect to the IP generated in public private partnerships for a subset of Index Diseases in a subset of the Index Countries (explicit conditions for waiving disclosed) 1 - There is evidence of a 'flexible' approach to IP management for relevant R&D 0- The company makes no commitments in this area. *Where does not apply, companies receive a neutral score*
	Generics	10%	
II. Transparency- 30%			
C.II.1 The company discloses the resources dedicated to its research and development activities related to the Index Diseases suitable the Index Countries (exclusions apply - for details please refer to the Access to Medicine Index 2010 Methodology Document).	Originators	30%	5- The company discloses (a minimum of) 2 of the following 3: the amount of capital investments, financial resources or human resources it dedicates to all the Index Diseases for which it carries out R&D on a periodic basis (in-house only) 4- The company discloses (a minimum of) 1 of the following 3: the amount of capital investments, financial resources or human resources dedicated to research to a majority of the disease areas in which the company is active. 2.5- The company discloses 1 of the following 3; the amount of capital investments, financial resources or human resources dedicated to 1 or more specific research initiatives OR does not undertake in-house R&D for Index Diseases. 1 - The company discloses examples of resource disclosure with respect to its in-house R&D for Index Diseases OR is unable to separate Index Disease investments due to overlap with commercial incentives. 0 No disclosure in this area *Where does not apply, companies receive a neutral score*
	Generics	30%	
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.).	Originators	30%	5- The company publicly discloses the existence and mandate of all Index Disease related collaborations plus terms and conditions with regards to duration of engagements, company's obligations and IP rights (such as supply channels, country applicability). 4- The company carries out a full public disclosure of the existence and mandate of the majority of its Index Disease related collaborations plus partial terms and condition information for some of its collaborations (disclosure of one of the above-mentioned examples suffices for getting this score) 3- The company publicly discloses the existence and mandate of most its Index Disease related collaborations or provides examples of its terms and conditions. 2- The company discloses information at 4 or 5 level on an engagement basis 1- The company discloses information at the level of 3 only on engagement basis. 0- No disclosure in this area. *Where does not apply, companies receive a neutral score* <u>Adapted guidelines for generics companies</u>*:* 5- Full disclosure of resources for all research collaborations
	Generics	30%	

			3.5- Partial disclosure of research collaboration resources 1.5 - No research collaborations. 0 - No disclosure of collaboration resources *Where does not apply, companies receive a neutral score*
C.II.3 The company discloses the resources dedicated to its research collaborations related to the Index Diseases (both human resources and financial).	Originators	20%	5- The company discloses (a minimum of) 2 of the following 3: the amount of capital investments, financial or human resources it dedicates to a majority of its Index Disease relevant research collaborations, on a periodic basis. 2.5 The company discloses aggregates in this area for all its collaborations - or detailed info only on (at least) one of the collaborations 0- No disclosure in this area. *Where does not apply, companies receive a neutral score* <u>Adapted guidelines for generics companies</u>: 5- Full disclosure of terms and conditions for all research collaborations 3.5- Partial disclosure of research collaboration terms 1.5 - No research collaborations. 0 - No disclosure of collaboration terms *Where does not apply, companies receive a neutral score.*
	Generics	20%	
C.II.4 The company publicly discloses its research pipeline related to both in-house research and collaborations targeting Index Diseases (where disclosure is not legally required).	Originators	10%	5- The company publicly discloses its a) research and development pipeline (phase I, 2 and 3), for all products, with diseases/indications specified) + b) areas of basic/pre-clinical activity for all Index Diseases and products related to its in-house and c) collaborative research 4- Two of the above three [as defined above] are publicly disclosed (complete Index Disease pipeline, or basic research/pre-clinical activity or in-house/collaborative) 3- One of the above three [as defined above] are publicly disclosed (complete Index Disease pipeline, or basic research/pre-clinical activity or in-house/collaborative) 2.5- The company discloses one of the above three [as defined above] levels of detail re: its research pipeline for Index Diseases, at the disease category level 2- Complete disclosure (as defined for score 5) is provided on an engagement basis 1- Partial disclosure (1 or 2 of the defined areas) is provided on an engagement basis 0- No disclosure For unlisted companies public disclosure is not required. *If no info to disclose the company will receive a neutral score* <u>Adapted guidelines for generics companies</u>: 5- pipeline discloses on engagement or publicly 2.5 - examples of Index Disease molecules in the pipeline and the drug development phase disclosed. 0- No disclosure in this area. *Where does not apply, companies receive a neutral score.*
	Generics	10%	

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 (when it is beyond legal requirements).	Originators	10%	5- The company discloses specific, detailed approach to post-trial access for Index Country trial partcipants which assures access to patient benefits in a large variety of different circumstances. Plus the company publicly discloses ALL Index Country-counducted clinical trials to a standard comparable to that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: initial trial registration and result disclosure. 4- Company discloses specific, detailed approach to post-trial access for Index Country trial partcipants which assures access to patient benefits in some likely circumstances. Plus publicly discloses Index Country-counducted clinical trials to a comparable standard with that detailed in the IFPMA 2008 Guidelines, with respect to: initial trial registration and result disclosure. 2.5- Company makes only a broad commitment to post-trial access (without specific details of how access will be assured) or does so only through its stated compliance with the Declaration of Helsinki OR Company either publicly discloses Index Country-conducted clinical trial information to a lower standard, does not disclose relevant information (as described above) 1- Company discloses relevant clinical trial information (as described above) and stance with respect to post-trial access for Index Country based clinical trial participants on an engagement basis only OR no disclosure with respect to post-trial access (directly or through a code). 0- no disclosure on either issues detailed above *2.5 No relevant clinical trials*
	Generics	10%	
III. Performance- 30%			
C.III.1 Portion of financial R&D investments dedicated to Index Diseases (exclusions apply - for details please refer to the Access to Medicine Index 2010 Methodology Document) out of the company's total R&D expenditures.	Originators	10%	Total amount of in-house investments in R&D for the Index Diseases during the survey period. Based on G-Finder Methodology* and adjusted for the total company R&D investments. For the companies that have disclosed this number will be redistributed from 1.5 to 5. 1.5- If the company has not provided any investment figures across its portfolio but we have discovered examples of investment activity for the Index Diseases R&D areas OR the company provides figures but not fully disaggregated from commercial investments. 0- No R&D investments for the Index Diseases
	Generics	10%	
C.III.2 Share of research pipeline reflecting 'new molecules' for Index Diseases (exclusions apply - for details please refer to the Access to Medicine Index 2010 Methodology Document) including in-house and collaborative research.	Originators	20%	Number of qualified molecules in the pipeline for the Index Diseases divided by the company size. For the companies that have disclosed this number will be redistributed from 2 to 5. 2 - Examples of molecules for Index Diseases in the pipeline discovered by the analyst 0- No molecules/activity with respect to R&D for Index Diseases NB: Exclusions delineated in the methodology document where is there is no market failure should be taken into consideration.
	Generics	0%	

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.)	Originators	20%	Number of 'adapted products' (combinations, FDCs, heat resistant preparations etc.) in clinical development for Index Diseases/ Index Country needs. Figure adjusted for the company size. The company should make a clear justification about the dependence of the business case on the Index Country needs / markets. For the companies that have disclosed this number will be redistributed from 1.5 to 5. 1.5 - Examples of adapted products for Index Diseases in the pipeline discovered by the analyst. 0- No adaptive products with respect to R&D for Index Diseases <u>Adapted guidelines for generics companies</u>: 5- Multiple adaptive research projects with explicit Index Country objective 2.5- At least one adaptive project found. 0- No activities in this area.
	Generics	40%	
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).	Originators	15%	Absolute number of collaborations the company is involved in WITH THE AIM OF DEVELOPING NEW PRODUCTS for Index Diseases only. 5- >10 Index Disease product development collaborations active during the survey period. 4- 7-9 Index Disease product development collaborations active during the survey period. 3- 4-6 Index Disease product development collaborations active during the survey period. 2- 2-3 Index Disease product development collaborations active during the survey period. 1- <2 Index Disease product development collaborations active during the survey period. 0- No active Index Disease product development collaborations during the survey period. <u>Adapted guidelines for generics companies</u>: 5- Multiple research collaborations with explicit Index Country objective 2.5- At least one collaboration found. 0- No activities in this area.
	Generics	15%	
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 (R&D exclusions apply - for details please refer to the Access to Medicine Index 2010 Methodology Document).	Originators	5%	Number of peer reviewed journal articles where the company is an official scientific collaborator in the underlying research - adjusted for the number of molecules in the company's research pipeline. 5- >40 relevant papers published - as a result of an Index Disease collaborations during the survey period. 4- 20–40 relevant papers published - as a result of an Index Disease collaboration during the survey period. 3 - 5–20 relevant papers published - as a result of an Index Disease collaboration during the survey period. 2.5 - 1–5 relevant papers published - as a result of an Index Disease collaborations during the survey period OR unlimited manuscripts but unable to exclude manuscripts developed in partnership in an area of 'commercial incentive'

	Generics	5%	1- No disclosure but evidence of collaborative Index Disease R&D activity 0- No relevant papers published - as a result of an Index Disease collaboration during the survey period. Adapted guidelines for originator companies: 5- Several peer- reviewed papers 2.5 - At least one peer- reviewed paper. 0- None
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 access the Index Countries for the individuals with significant financial barriers to access.	Originators	5%	5- The company discloses the existence and mandate of all of its Index Disease related collaborations plus terms and conditions with regards to duration of engagements, company's obligations and IP rights (pricing terms or supply commitments at the level of supply channels and eligible countries). 4- The company carries out a full public disclosure of the existence and mandate of the majority of its Index Disease related collaborations plus partial terms and condition information for some of its collaborations (disclosure of one of the above-mentioned examples suffices for getting this score) 3- The company publicly discloses the existence and mandate of most its Index Disease related collaborations or provides examples of its terms and conditions. 2- The company discloses information at 4 or 5 level on an engagement basis 1- The company discloses information at the level of 3 only on engagement basis. 0- No disclosure in this area. Have taken 'proof' here to be disclosure-related i.e. public disclosure or provision of actual agreements
	Generics	5%	
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?	Originators	5%	5 – The company has not been the subject of any cases or controversies in Index Countries. 3- [For companies with operations in <5 Index Countries]. The company has not been the subject of any cases. 2– The company has been the subject of at least one controversy in an Index Country (backed by evidence/material support from civil society actors) 1 – The company has been the subject of more than one controversy (backed by evidence/material support from civil society actors) or one or more unconcluded litigation in the Index Countries. 0 – The company has been the subject of one or more litigation with a negative ruling/settlement with payment or a regulatory proceeding with a fine in the Index Countries.
	Generics	5%	

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.	Originators	20%	5- The company has demonstrated ≥ 3 examples of where it has provided third-party - or public - access to its Index Disease-related Intellectual Capital during the survey period. 3.5- The company has demonstrated 1–3 examples of where it has provided third-party access to its Index Disease-related Intellectual capital during the survey period. 1.5- The company has demonstrated 1 example of where it has provided third-party access to its Index Disease-related Intellectual capital during the survey period. 0- The company has not demonstrated ANY examples of where it has provided third-party access to its Index Disease-related Intellectual capital during the survey period. These examples should also be within the scope of the Index Diseases (as defined earlier and by G-FINDER) to ensure they have the objective of improving ATM.
	Generics	20%	
IV. Innovation- 10%			
C.IV.1 The company has adopted innovative (unique in the sector), sustainable business models for research into Index Diseases (excluding new molecules for non-communicable Infectious Diseases).	Originators	50%	5- The company has adopted innovative (unique in the sector) R&D approaches or business models for Index Diseases (excluding new molecules for non-communicable Infectious Diseases) with significant potential to improve ATM and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) R&D approaches or business models for Index Diseases (excluding new molecules for non-communicable Infectious Diseases) but does NOT disclose progress or resources inputs. 0- No innovative initiatives discovered in this area.
	Generics	50%	
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.	Originators	50%	5- The company has adopted innovative (unique in the sector) approaches or models for sharing intellectual property and patent rights for Index Diseases where it has significant potential to improve ATM and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) approaches or models for sharing intellectual property and patent rights for Index Diseases but does NOT disclose progress or resources inputs. 0- No innovative initiatives discovered in this area.
	Generics	50%	

Equitable Pricing, Manufacturing and Distribution

I. Commitments- 30%			
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.	Originators	20%	5- The company commits to inter-country tiered pricing for all its products and all the Index Countries where it operates with clear future objectives. 4- The company commits to inter-country tiered pricing for a large number of Index Countries and for a large proportion of its Index Country portfolio. 3- The company commits to inter-country tiered pricing for a large number of Index Countries for at least one of its Index Country products. 2- The company commits to inter-country tiered pricing for at least one product and a small number of countries. 1- The company expresses a general commitment to implement inter-country tiered pricing without specific objectives or defining product or country coverage 0- No tiered pricing commitments. <u>Adapted guidelines for originator companies:</u> 5- General commitment to inter country tiered pricing for all Index Diseases products and all poor countries (be it worded as LHDC or LDC or emerging markets etc.) 2.5 - A general statement without definition of scope 0- No commitment in this area Commitment to collaboration with international organizations such as CHAI which deliver products at equitable prices is accepted as an alternative – based on the same score levels.
	Generics	20%	
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.	Originators	10%	5- The company commits to intra-country tiered pricing for all its products and all the Index Countries where it operates with clear future objectives. 4- The company commits to intra-country tiered pricing for a large number of Index Countries and for a large proportion of its Index Country portfolio. 3- The company commits to intra-country tiered pricing for a large number of Index Countries for at least one of its Index Country products. 2- The company commits to intra-country tiered pricing for at least one product and a small number of countries. 1- The company expresses a general commitment to implement intra-country tiered pricing without specific objectives or defining product or country coverage 0- No tiered pricing commitments. <u>Adapted guidelines for generics companies</u>: 5- Specific commitment with products and countries defined 2.5 A general commitment to try to adjust pricing to different target groups inside the Index Countries. 0 No commitments in this area.
	Generics	5%	

D.I.3 The company commits to make its best efforts to control the pricing practices of its local sales agents or to choose multiple sales agents/distributors for each market with the aim of improving affordability and accessibility of the products.	Originators	15%	5- The company has a pricing monitoring process including training or audit mechanisms for its sales agents (distributors) - or the company commits to choose multiple distributors for the same market where feasible for all Index Disease products and Index Countries. 3.5- The company has a pricing monitoring process including training or audit mechanisms for its sales agents (third party distributors) for some Index Disease products - or the company commits to choose multiple distributors for the same market where feasible for some Index Disease products and Index Countries. 1.5- The company has general pricing guidelines for its sales agents or about local competition. 0- The company has no policies or practices aimed at controlling the pricing of its local sales agents or to facilitate local competition. Adapted guidelines for generics companies: 5- Commitment to control distributors' prices with specific audit mechanism disclosed or to choose multiple distributors in the Ids 2.5 - A general commitment in this area. 0-No commitment in this area.
	Generics	20%	
D.I.4 The company commits to maintain its drug quality standards in the Index Countries at least equal to FDA, EMA or WHO standards.	Originators	15%	5- The company applies the same quality standards to its products for the Index Countries as its products produced for the Western markets - including products produced by its local subsidiaries. 2.5 The company discloses internal standards equivalent to the mentioned external codes for the quality of its products in the Index Countries. 0- The company makes no quality commitments for its products for the Index Countries. Adapted guidelines for generics companies: 5- Commits to comply with an international standard such as WHO PQ or EMEA, FDA etc for all products destined for Index Countries 2.5 - Commits to apply consistent internal standards to all its products including the ones destined for the Index Countries. 0- No commitments in this area
	Generics	25%	
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.	Originators	5%	5- The company commits to maintain drug recall processes in all the Index Countries where it makes its products available and to make its best efforts to achieve highest possible standards 3.5- The company commits to maintain drug recall processes in some of the Index Countries where it makes its products available and to make its best efforts to achieve highest possible standards 1.5- A general commitment to high standard of drug recalls in the Index Countries 0- No commitments in this area. Adapted guidelines for generics companies: 5- Specific commitment to dedicate facilities for efficient drug recalls in the Index Countries. 2.5 - General commitment to apply same standards to drug recalls regardless of the country. 0- No commitments in this area
	Generics	5%	
D.I.6 The company commits to adapt the brochure and packaging of its products to the local needs of the target communities in the Index Countries.	Originators	10%	5- The company commits to adapt the product brochures for the majority of the Index Diseases and Index Countries where its products are sold to Index Country needs. 2.5 - The company commits to adapt the language of its product brochures for some of its products for the Index Diseases and Index Countries where its products are sold. 0 - No commitments in this area.
	Generics	10%	

D.I.7 The company commits to register (obtain marketing approval for) its products for the Index Diseases in the Index Countries in need.	Originators	15%	5- The company's statement with regard to the decision to register products (obtain marketing approval) for the Index Diseases in the Index Countries is needs based (not market based or a mix of need and market criteria) and/or it commits to register all its products for the Index Diseases in all the Index Countries where there is an unfulfilled need. 3.5- The company commits to register a subcategory of the products for the Index Diseases that it has in its portfolio in Index countries with immediate need. 1.5- The company makes a general commitment to need based registration without specifying for which products or conditions. 0- The company makes no commitment to register its products for the Index Diseases in the Index Countries <u>Adapted guidelines for generics companies</u>: 5- Commitment to register widely the products with urgent need with disclosure about the need based decision making process for registration 2.5 - A general commitment 0- No commitments in this area.
	Generics	15%	
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.	Originators	10%	5- The company commits to have a special packaging or bar-coding for all its products for the Index Diseases to be marketed in the Index Countries to support its tiered pricing schemes 2.5 - The company's commitments relating to drug diversion apply to only a part of the products destined for the Index Countries. 0- No commitments in this area. Where does not apply (i.e. no tiered pricing), companies receive a neutral score
	Generics	0%	
II. Transparency- 30%			
D.II.1 The company publicly discloses details of its equitable pricing approach for the Index Countries for products related to the Index Diseases.	Originators	20%	5- The company publicly discloses its tiered pricing mechanisms in areas such country categories, distribution channels and a price relative to a reference price for the lowest tier 4 - The company publicly discloses a subset of the above information - such as country categories, distribution channels and a price relative to a reference price for the lowest tier 2.5 - Engagement based disclosure of tier definition criteria and price for the lowest price tier 1- Engagement based disclosure for either the tier definition criteria or the price for the lowest tier. 0- No disclosure on pricing mechanisms. *Where does not apply, company receives a neutral score.*
	Generics	10%	
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.)	Originators	30%	5- The company discloses the outcome of its equitable pricing programs for all their products for which they have an equitable pricing (based on indicators such as number of patients having received the product, number of doses delivered based on the equitable price etc.) 2.5 - The company discloses examples of 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.) 0- No disclosure in this area. *Where does not apply, company receives a neutral score.*
	Generics	20%	

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.	Originators	20%	5- The company publicly discloses the criteria used in its decision making process for obtaining marketing approval and the registration status of all its products for the Index Diseases in all the Index Countries 4 - The company publicly discloses the criteria + partial information about the registration status of its products for Index Diseases 3 - The company publicly discloses the criteria or partial information about the registration status of its products for Index Diseases 2 - The company discloses the criteria used in its decision making process for obtaining marketing approval and the registration status of all its products for the Index Diseases in all the Index Countries through engagement. 1- The company discloses partial information through engagement. 0- No disclosure
	Generics	30%	
D.II.4 The company discloses information about its quality management systems for products destined for the Index Countries (standards, processes, resources, etc.).	Originators	10%	5- The company discloses how it maintains quality of its products produced in and destined for Index Countries (this should include quality monitoring process for such facilities such as audits based on GMP etc). 2.5 - The company provides anecdotal information about its quality monitoring approach for such production facilities and processes for its products produced in and destined for Index Countries 0- No disclosure with regards to quality management in the Index Countries.
	Generics	20%	
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.	Originators	10%	5- The company publicly discloses the date, location and the reason for drug recalls it has been involved in an integrated accessible way. 3.5- The company publicly discloses the mentioned data in aggregate format only 2.5 - The company discloses the detailed information on an engagement basis 1- The company discloses aggregated information on an engagement basis 0- No disclosure with regard to product recalls and the underlying product side effects. No recalls gets a score of 2.5
	Generics	10%	
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.	Originators	10%	5- The company discloses country level information in the mentioned area at the product level. 3.5- The company discloses aggregate sales figures at the country level or product level sales figure of LDC, LHDC level (or any other grouping based on social criteria) 1.5- Aggregate information for the least developed countries or Low Human Development Countries (or any other grouping based on social criteria) or partial information at the country 0- No disclosure with regards to the mentioned sales revenues in the Index Countries for the Index Diseases
	Generics	10%	

III. Performance- 30%			
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.	Originators	25%	5- The company has inter-country tiered pricing (with defined affordability criteria for countries with financial barriers to access) for multiple patented Index Disease products for the majority of the Index Countries 4- The company has inter-country tiered pricing (with defined affordability criteria for countries with financial barriers to access) for a small number of its Index Disease products for the majority of the Index Countries. 2.5 - The company carries out tiered pricing for at least one product covering most of LHDCs 1- Evidence found for tiered pricing for at least one Index Disease product in a small number of LHDCs 0 - No example of tiered pricing found for patented Index Disease products that take into consideration affordability criteria for countries with financial barriers to access. *Where does not apply (i.e. no patented products), company receives a neutral score* For the generics companies, collaboration with international organizations such as CHAI which deliver products at equitable prices is accepted as an alternative – based on the same score levels.
	Generics	20%	
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.	Originators	20%	5- The company has intra-country tiered pricing for the majority of its Index Disease products for a large number of Index Countries. 3.5 - The company has intra-country tiered pricing for at least one product across a large number of Index Countries. 1.5 - The company has intra-country tiered pricing for at least one product and a few Index Countries. 0 - No intra-country tiered pricing. *Where does not apply (i.e. no patented products), company receives a neutral score.*
	Generics	5%	
D.III.3 What percentage of the total supply units made available by the company to the Index Countries was delivered for free or at cost during the period of analysis (excluding donations)? (Experimental indicator)	Originators	0%	Number to be reported as a percentage for all the Index Countries This indicator is about the effectiveness of tiered pricing for the social segments with the highest financial barriers. If a company gets a score above 2.5 in the non exclusive voluntary licensing indicators - it should get a 2.5 for this indicator - given it uses an effective alternative approach to tiered pricing with no proven empirical superiority or inferiority.
	Generics	0%	
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)	Originators	0%	Number to be reported as a percentage for all the Index Countries The companies' disclose in this area should be specifically captured with regards to the method for calculation of average Western price as a basis for adjustment of the experimental indicator in the next iterations of the Index.
	Generics	0%	

D.III.5 Has the company attempted to register (obtain marketing approval for) its products for Index Diseases in the Index Countries in need?	Originators	25%	5- The company's majority of the Index Disease products are registered in over 20 out of the 26 LHDCs 4 The company has the majority of the Index Disease products registered in 10-20 LHDCs 2.5- The company has at least one of the Index Disease products registered in over 20 LHDCs 1- The company has at least one of the products registered in 10-20 LHDCs; or no registration disclosure; or no registration related controversies 0- Registration efforts achieved less than the above or there were controversies found related to registration indicating the company's behavior in this area as barrier to access.
	Generics	25%	
D.III.6 Have drug recalls occurred due to product or packaging quality issues in the Index Countries for products produced by the company or its voluntary licensees during the past five years?	Originators	10%	5- No company or licensee product recalls related to quality issues during the past 5 years in the Index Countries 2.5 - No cases of company drug recalls found but cases of licensee drug recall due to quality issues in the Index Countries were discovered - or drug recalls due to packaging issues, not due to quality issues. 1- If there is no disclosure. 0- Drug recall related to quality issues with company produced products in the Index Countries occurred during the past 5 years If little or no operations in the Index Countries, the company should be scored 2.5
	Generics	25%	
D.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.	Originators	10%	5 - The company has applied for either of the two mentioned processes for all its products qualifying for these processes 2.5- The company has applied for either of the two mentioned processes for some of its qualifying products. 0- None *Where does not apply (i.e. no qualifying products), companies receive a neutral score.*
	Generics	20%	
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?	Originators	10%	5- All products subject to tiered pricing tagged or packaged differently. 2.5- Specific tagging or packaging applied to some products for some Index Countries. 0- No activities discovered in this area.
	Generics	5%	
IV. Innovation- 10%			
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.	Originators	50%	5- The company has adopted innovative (unique in the sector) business models related to pricing for drugs for the Index Diseases in the Index Countries which can result in more affordability or accessibility of such medications. Only innovative projects for which either progress or human or financial resources are disclosed should be taken into consideration. 2.5 No progress or inputs disclosed 0- No innovative initiatives discovered in this area.
	Generics	50%	
D.IV.2 The company has introduced innovative approaches (unique in the sector) to manufacturing and distribution of products for the Index Diseases	Originators	50%	5- The company has adopted innovative (unique in the sector) business models related to increasing research capacity for the Index Diseases in the Index Countries. Only innovative projects for which either progress or human or financial resources are disclosed should be taken into consideration. 2.5 The company has adopted innovative (unique in the sector)

which may help with sustainable delivery of such products for the Index Diseases in the Index Countries.	Generics	50%	business models related to increasing research capacity for the Index Diseases in the Index Countries but NO progress or inputs disclosed 0- No innovative initiatives discovered in this area.

Patents & Licensing

I. Commitments- 30%			
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.)	Originators	25%	5 - The company makes a general commitment not to patent or enforce its patents in any Least Developed Country through direct or indirect means 3.5- The company makes a commitment not to enforce patents in certain regions (such as sub-Saharan Africa) OR for a sub-set of its products 1.5- The company is not involved in sales of patented products (pure generics) 0- The company makes no commitments in this area.
	Generics	25%	
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.	Originators	25%	5- The company states that its respects the countries' right to use the different TRIPS flexibilities (compulsory licenses, parallel importation, not to patent in LDCs etc.) by the qualifying Index Countries either through a public policy statement or engagement 3.5-General commitment to TRIPS with explicit mention to commit to respect at least one of the flexibilities above
	Generics	25%	1.5- General commitment to TRIPS yet no mention TRIPS flexibilities or explicit commitment in this area through either of the above-mentioned channels 1- no statements on TRIPS 0- The company makes a general policy statement against the use of part or all the TRIPS flexibilities by the qualifying Index Countries or no commitment
E.I.3 The company commits to engage in non-exclusive licensing for the Index Disease products to generics companies with the aim of increased accessibility and affordability. *[consider non-exclusive voluntary licenses equivalent to non-assert declarations]*	Originators	35%	5- The company commits to engage in non-exclusive voluntary licensing for relevant Index Disease products across the company's market portfolio with qualified manufacturers where third party production is deemed conducive to increased affordability and accessibility 2.5 - the company commits to consider voluntary licensing where appropriate 0 - No commitments regarding non-exclusive licensing for pharmaceutical products related to the Index Diseases for the Index Countries *Where does not apply, company receives neutral score*.
	Generics	35%	
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	Originators	15%	5- The company commits to have license fees that are conducive to production of affordable products for sales in the Index countries (tiered license fees or moderate license fees (no more than 5% of sales) 2.5- no rationale or commitment toward affordable license fees yet grant voluntary licenses with moderate license fees

Countries.	Generics	15%	0- The company makes no statement related to affordability of the products produced by its voluntary licensees and/or charges license fees greater than 5% of net sales. *Where does not apply, company receives neutral score*.
II. Transparency- 30%			
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, patent extensions, etc. for products related to the Index Diseases in the Index Countries.	Originators	45%	5 - Disclosure of public policy stance on TRIPS, TRIPS+, usage of TRIPS flexibilities, data exclusivity and patent extensions in the Index Countries. 4 - Disclosure of public policy stance on the majority of the above-mentioned items (three to four items) 2.5 - Disclosure on two of the above- mentioned items 1- Disclosure on one out of the above-mentioned items. 0- No disclosure.
	Generics	45%	
E.II.2 The company discloses the patent status of its products for the Index Diseases in the Index Countries.	Originators	25%	5- Public disclosure of the patent status for key patent for *all* the products for all the Index Diseases in all the Index Countries. 4- Public disclosure of the patent status of key patent for *some* Index Disease products in the Index Countries. 2.5 - full disclosure of patent status for all products only on engagement basis or not relevant (for generics) 1- partial disclosure of patent status only on engagement basis 0- No disclosure about patent status.
	Generics	25%	
E.II.3 The company publicly discloses detailed information about the voluntary licensing activities it is engaged in for products related to the Index Diseases for the Index Countries. (Such as license duration, license territory, technology transfer etc.) *[non-assert declarations considered equivalent to voluntary licenses]*	Originators	30%	5- The company publicly discloses the number of voluntary licenses issued per Index Disease drug, the name/location of the licensee, the exclusive/non-exclusive nature of the license, license duration and production information (supply units). 3.5 - The company publicly discloses partial information on the above- mentioned items for a subset of its licensees and products but no production information or license duration 1.5 -the company discloses partial information on an engagement basis. 0- No disclosure in this area. *Where does not apply (i.e. voluntary licensing), company receives a neutral score.*
	Generics	30%	
III. Performance- 30%			
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 Least Developed Countries and acting	Originators	40%	5 – The company has not been the subject of any cases or controversies in Index Countries. 3 - [*For companies with operations in <5 Index Countries*] The company has not been the subject of any cases. 2 – The company has been the subject of at least one controversy in an Index Country (backed by evidence/material support from civil society actors) 1 – The company has been the subject of more than one

against usage of TRIPS flexibilities by the Index Countries based on the Doha Declaration on TRIPS.	Generics	40%	controversy (backed by evidence/material support from civil society actors) or one or more unconcluded litigation in an IC. 0 – The company has been the subject of one or more litigation with a negative ruling/settlement with payment or a regulatory proceeding with a fine in Index Countries. <u>Adapted guidelines for generics companies</u>: 5- no cases found 2.5 - cases found out of the scope of the index 0 - Cases (including litigations with a ruling, fines or major controversies) found in the scope of the Index
E.III.2 Does the company actively engage in non-exclusive voluntary licensing for the Index Countries for its products related to the Index Diseases? [*Multiple 'active' voluntary licenses should be in place for the drug to be counted without global or regional marketing exclusivity for the licensee. An active license is a license under which production is happening or the licensee is actively progressing towards production.*]	Originators	40%	5 - Non-exclusive voluntary licensing for Multiple products – most [more than 90% of Index Countries (including some MDCs)] 4 - Non-exclusive voluntary licensing for Single product - most Index Countries [more than 75% of Index Countries (including some MDCs)] OR Multiple products, at least 10 Index Countries (including some MDCs) 2.5 - Non-exclusive voluntary licensing for Single product- at least 10 ICs 1- Exclusive voluntary licensing with pricing controls on the licensee 0- None *Where does not apply (i.e. no licensable products), company receives a neutral score.* <u>Adapted guidelines for generics companies</u>: 5- Involved in NEVL for several Index Disease products (either for own products or as licensee with innovator company/ies) 2.5- Involved in NEVL for at least one Index Disease relevant product 0- No evidence of engaging in NEVL
	Generics	40%	
E.III.3 Does the company have effective technology transfer regimes in place to improve the quality and production capacity of its voluntary licensees?	Originators	10%	5- The company provides evidence of details of technology transfer (such as descriptions of manufacturing process, stability data, analytical method validation and details on impurities) AND the financial OR technical OR human resources dedicated to technology transfer for production and distribution of products to its local licensees in all the Index Countries. 3.5- The company HAS EFFECTIVE TECHNOLOGY TRANSFER REGIMES but no data on resources 1.5 - The company engages in voluntary licensing but does not have effective technology transfer regimes in place and no data on resources 0 - no proof of effective technology transfer due to lack of engagement in voluntary licensing. *Where does not apply (i.e. no licensable products), company receives a neutral score.*
	Generics	10%	
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.	Originators	10%	5- The company has had several meetings with UNITAID including senior level people (stage III UNITAID ranking) and/OR provides documents proving that it has an active participation/dialog in one or more patent pools which aim at developing FDCs or new preparations of products for the Index Diseases suitable to the Index Countries 3.5 - The company is between UNITAID stage II and III) 1.5 - The company has had initial meetings/discussions with

	Generics	10%	UNITAID excluding senior level people (UNITAID stage II) 0- No evidence of engagement with patent pools such as UNITAID or other patent pools *Where does not apply (i.e. no products relevant to current proposed UNITAID patent pool), company receives neutral score.*
IV. Innovation- 10%			
E.IV.1 The company has adopted innovative (unique in the sector) initiatives aiming at increased effectiveness of its voluntary licensing programs.	Originators	50%	5- The company has adopted innovative (unique in the sector) voluntary licensing approaches or business models for Index Diseases - with significant potential to improve ATM *and* supports this with evidence of progress and/or human or financial resources invested in Index country scope 2.5 The company has adopted innovative (unique in the sector) voluntary licensing approaches or business models for Index Diseases outside Index scope that can have significant access implications - but no disclosure on resources or inputs but does NOT disclose progress or resources inputs 0- No innovative initiatives discovered in this area.
	Generics	50%	
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.	Originators	50%	5- The company has adopted innovative (unique in the sector) sustainable programs with the aim of decreasing the impact of patent enforcement on the affordability and accessibility of medicines - with significant potential to improve ATM *and* supports this with evidence of progress and/or human or financial resources invested in Index country scope 2.5 The company has adopted innovative (unique in the sector) sustainable programs with the aim of decreasing the impact of patent enforcement on the affordability and accessibility of medicines for Index Diseases outside Index scope that can have significant access implications - but no disclosure on resources or inputs but does NOT disclose progress or resources inputs 0- No innovative initiatives discovered in this area.
	Generics	50%	

Capability Advancement in Product Development and Distribution

I. Commitments- 30%			
F.I.1 The company commits to assist its Index Country licensees and contract manufacturers with their quality management systems aimed at achieving international standards such as the FDA, EMA, WHO Good Manufacturing Practices, etc.	Originators	30%	5- The company demands quality standards from its licensees and commits to provide its Index Country licensees with training and tools needed to maintain drug quality consistent with international standards. 2.5 - The company has a program of know-how transfer and commits to provides quality assistance to Index Countries licensees on a case by case basis, but does not commit to systematically assist licensees with their quality management systems. 0 - No such commitments.
	Generics	35%	
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.	Originators	30%	5- Commitment to support local research in Index Country research organizations (such as through PPPs, sponsoring fellowships/grants, supporting clinical research programs) with the aim of transfer of research capacity to Index Country organizations 3.5- The company commits to TWO of the above-mentioned initiatives with the aim of transferring research capacity to Index Country organizations 1.5- The company commits to support academic research OR commits to participate in PPPs OR commits to clinical research programs aimed at transferring research capacity to the Index Countries 0- No commitments in this area.
	Generics	15%	
F.I.3 The company commits to help the Index Country governments and distributors in improving their pharmaceutical supply chain capabilities with the aim of improving affordability, accessibility and quality of the delivered Index Disease Products. Examples include providing help in establishing cold chains and in introducing processes or technologies which can help prevent drug diversion or counterfeiting in the Index Countries.	Originators	30%	5- The company commits to help Index Country governments or distributors through activities such as providing support or training in databases, processes and monitoring & evaluation activities aimed at improving the efficiency and integrity of supply chains that can help prevent drug diversion or counterfeiting in the Index Countries. 2.5- The company makes a general commitment in this area - but provides no specific information about its areas of activity and objectives in this area 0- No commitments in this area
	Generics	40%	
F.I.4 The company commits to support the implementation of pharmacovigilance systems in the Index Countries.	Originators	10%	5- The company commits to work with a large number of Index Country Institutions with the aim of improving the effectiveness of pharmacovigilance systems in a large number of Index Countries where it operates 2.5-The company commit to support the implementation of pharmacovigilance systems for specific disease areas or product(s) or a sub-set of countries 0- No commitment to supporting pharmacovigilance-related systems in the Index Countries
	Generics	10%	
II. Transparency- 30%			

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, EMA and/or WHO Good Manufacturing Practices etc.	Originators	40%	5- The company discloses information about the mechanisms AND financial OR technical OR human resources dedicated to improving quality of production to country licensees and/or contract manufacturers 2.5 - The company discloses information about the mechanisms only - but no mention of resources 0- No disclosure in this area. *Where does not apply, companies recieve neutral score.*
	Generics	50%	
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.	Originators	45%	5- The company discloses information about the mechanisms AND financial OR technical OR human resources dedicated to improving research capacity in the Index Countries for ALL its research partnerships in a systematic manner 3.5 - The company discloses examples of research partnerships and resources- but not in a systematic manner
	Generics	30%	1.5 -The company discloses examples about the mechanisms dedicated to improving research capacity in the Index Countries only for some of its research organizations - but no mention of resources 0- No disclosure in this area. *Where does not apply, companies receive neutral score*.
F.II.3 The company discloses details regarding its activities related to establishing pharmacovigilance systems in the Index Countries.	Originators	15%	5- The company discloses information about its pharmacovigilance approach in the Index Countries AND the financial OR technical OR human resources dedicated to its in-house activities and collaborations aimed at improving pharmacovigilance systems in the Index Countries
	Generics	20%	2.5 - The company discloses its approach in Index Countries but no disclosure related to human or financial resources 0- No disclosure in this area. *Where does not apply, companies receive neutral score.*
III. Performance- 30%			
F.III.1 Is there evidence that the company assists local licensees or contract manufacturers to achieve international drug manufacturing standards (such as FDA, EMA or the WHO Good Manufacturing Practices) in the Index Countries?	Originators	30%	5- The company has provided evidences of carrying out systematic training and/or technology transfer across different Index Countries and geographies with the aim of achieving compliance with WHO GMP or equivalent internal standards 2.5-There is evidence of at least one example of technology transfer or training in at least one Index Country aimed at achieving compliance with WHO GMP or equivalent internal standards- Significant Index Country in-house manufacturing capacity 0- No such activities carried out by the company. *Where does not apply, company receives neutral score*.
	Generics	35%	<u>Adapted guidelines for generics companies</u>: 5- Tech transfer and assistance aimed at helping local manufacturers achieve international standards e.g. WHO PQ 2.5- Information transfer to the local manufacturers only aimed at improving their quality management capacities 0 - No activities in this area.

F.III.2 Is there evidence 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?	Originators	30%	5- Several examples of Index Country PPPs and/or academic collaborations and/or clinical research programs focused on generating local research capacity in multiple Index Countries OR a few examples of significant, repeated exercises aimed at increasing the local research capacity in the Index Countries 3.5 - at least one major, significant, repeated, exercise or a FEW examples of PPPs or academic collaboration or clinical research program aimed at increasing the local research capacity in the ICs 1.5- at least any one, single example of a research collaboration in the Index Countries -yet not repeated 0- No activities in this area.
	Generics	15%	
F.III.3 The company is engaged in programs and partnerships aimed at improving pharmaceutical supply chain capacity in the Index Countries with the aim of improved affordability, accessibility and quality of the delivered Index Disease Products. Examples include providing help in establishing cold chains and in introducing processes or technologies which can help prevent drug diversion or counterfeiting in the Index Countries.	Originators	30%	5- Several examples of helping Index Country governments or distributors with activities aimed at improving the efficiency and integrity of supply chains that can help prevent drug diversion or counterfeiting in the Index Countries OR at least one significant, *long-term (more than 3 years)* exercise in the Index Countries aimed at improving the supply chain in Index Countries. 2.5- At least one short-term (*less than three years*) engagement in programs or partnerships aimed at improving the supply chains in programs and partnerships related to improving the supply chain in Index Countries 0- No engagement in this area
	Generics	40%	
F.III.4 The company actively engages in establishing and supporting pharmacovigilance-related programs in the Index Countries during the analysis period.	Originators	10%	5- Several examples of evidence of engagement with local stakeholders to support and establish pharmacovigilance systems in a large number of Index Countries where the company operates- including disclosure on detailed mechanism OR human or financial inputs 2.5-the company has provided evidence such as detailed approach toward supporting pharmacovigilance programs OR resources in at least one Index Country 0- No engagement in the area of pharmacovigilance in the Index Countries
	Generics	10%	
IV. Innovation- 10%			
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.	Originators	50%	5- The company has adopted innovative (unique in the sector) approaches to local capacity advancements in quality and supply chain management with significant potential to improve ATM and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) approaches to local capacity advancements in quality and supply chain management but does NOT disclose progress or resources inputs 0- No innovative initiatives discovered in this area.
	Generics	50%	
F.IV.2 The company has introduced innovative (unique in the sector) approaches to working with the Index Country organizations which help	Originators	50%	5- The company has adopted innovative (unique in the sector) approaches to local capacity advancements in research with significant potential to improve ATM and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector)

improve the local research capacity for the Index Diseases.	Generics	50%	approaches to local capacity advancements in research but does NOT disclose progress or resources inputs 0- No innovative initiatives discovered in this area.

Product Donations and Philanthropic Activities

I. Commitments - 30%			
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.	Originators	20%	5- The company makes a general commitment to respect the WHO inter-agency Guidelines for Drug Donations in all its donations activities. 2.5 The company's commitment in this area is partial or conditional or based on an internal code equivalent to the WHO Guidelines for Drug Donations 0- The company has not committed to respect the WHO Guidelines for Drug Donations recommendations *Where does not apply (no donations), companies receive a neutral score*
	Generics	20%	
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.	Originators	40%	5- The company has stringent regular monitoring processes or reporting to ensure that the product donations which are donated directly or through intermediaries reach the targeted communities in need based on standards set out in the WHO Interagency Guidelines for Drug Donations. 2.5- The company has a guideline for its donations programs and donation management intermediaries but does not regularly check performance and certify the donations activities carried out on its behalf. 0- The company makes no commitments in this area. *Where does not apply (no donations), companies receive a neutral score*
	Generics	40%	
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.	Originators	40%	5- The company makes specific statement of its focus areas regarding improvement of the health infrastructure/capacity advancement in the Index Countries; aimed at improved drug delivery and use. 2.5 - The company discloses only a general statement in this area without providing details on the areas of its strategic focus for infrastructure building or objectives. 0- The company's philanthropic activities are not focused on bringing about sustainable change in the target Index Countries.
	Generics	40%	
II. Transparency- 30%			
G.II.1 The company publicly discloses the process for deciding the drug types and destinations for its donations programs in the Index Countries.	Originators	30%	5- The company publicly discloses details with regard to how it plans the drug types and volumes for its donations program done directly or through intermediaries in the Index Countries for the Index Diseases. 3.5 - The company publicly discloses the name of the external organizations in charge of managing donations or the internal department in charge of decision making process about donations but provides no details about the basis for decision making. 1- Disclosed through engagement 0- The company discloses no information in this area. *Where does not apply (no donations), companies receive a neutral score*
	Generics	30%	

G.II.2 The company publicly discloses detailed information about the type, volume and destination of the donated products in the Index Countries.	Originators	30%	5- Public disclosure of type, volume and destination (organization or country) 4- Public disclosure of two out of the three mentioned items. 3- Public disclosure of one out of the three mentioned items. 2- Engagement-based disclosure equivalent to 5 1- Engagement-based disclosure equivalent to 3 or 4 0- No disclosure in this area *Where does not apply (no donations), companies receive a neutral score*
	Generics	30%	
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.	Originators	20%	5- The company discloses the rationale behind its philanthropic activities which includes information about sustainability of such initiatives and where applicable their role in long term market development on a project level for all the projects. 3.5- For most of the projects 1.5 - On an aggregate level 0- No disclosure in this area.
	Generics	20%	
G.II.4 The company publicly discloses the output and the amount of resources dedicated to its philanthropic activities in the Index Countries.	Originators	20%	5- The company discloses the financial and/or human resources and/or the output or progress for each of its philanthropic projects 3.5- The company discloses the financial and/or human resources and/or the output for some of its philanthropic projects 1.5- The company discloses the information at the aggregate level 0- No disclosure in this area
	Generics	20%	
III. Performance- 30%			
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?	Originators	20%	5 – The company has not been the subject of any cases or controversies in Index Countries. 3- [For companies with operations in <5 Index Countries]. The company has not been the subject of any cases. 2– The company has been the subject of at least one controversy in an Index Country (backed by evidence/material support from civil society actors) 1 – The company has been the subject of more than one controversy (backed by evidence/material support from civil society actors) or one or more unconcluded litigation in the Index Countries. 0 – The company has been the subject of one or more litigation with a negative ruling/settlement with payment or a regulatory proceeding with a fine in the Index Countries. *Where does not apply (no donations), companies receive a neutral score* <u>Adapted guidelines for generics companies</u>: 5- no cases found 2.5 - cases found out of the scope of the index 0 - Cases (including litigations with a ruling, fines or major controversies) found in the scope of the Index *Where does not apply (no donations), companies receive a neutral score*
	Generics	20%	

G.III.2 Has the company prematurely terminated any of its donations programs in the Index Countries during the last five years?	Originators	10%	5- No such cases found. 2.5- Such issues raised by the regulatory bodies or international multilateral institutions during the last five years 0- Such issues raised by the regulatory bodies or international multilateral institutions during the period of analysis. *Where does not apply (no donations), companies receive a neutral score*
	Generics	10%	
G.III.3 The scale and scope of donated products to the Index Countries during the period of analysis.	Originators	30%	5- More than three strategic long term donations programs or the company produces products based on the needs of the target communities (for example based on the needs established by a donations management organization.) 4- More than one strategic long term donations programs or the company produces products based on the needs of the target communities (for example based on the needs established by a donations management organization.) 3- One strategic long term donations programs or the company produces products based on the needs of the target communities (for example based on the needs established by a donations management organization.) 2 - The company has multi-drug donation programs, targeting known *social* needs or donations to clinical trials programs for facilitation of the development new remedies. 1- The company has multi-drug, without targeting known social needs. 0- No drug donation. Only donations under WHO interagency standards for drug donations should be counted.
	Generics	30%	
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? (Experimental Indicators)	Originators	40%	# of initiatives adjusted for company size for the period of analysis. Due to the absence of reliable data for this indicator, we used the average score of the companies on 'philanthropic' indicators (G.I.3, G.II.3, G.II.4 and G.IV.2). For more information please refer to Appendix D: Ranking and Scoring Process.
	Generics	40%	
IV. Innovation- 10%			
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.	Originators	60%	5- The company has adopted innovative (unique in the sector) approaches to managing drug donations with significant potential to improve ATM and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) approaches to managing drug donations but does NOT disclose progress or resources inputs. 0- No innovative initiatives discovered in this area.
	Generics	60%	
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.	Originators	40%	5- The company has adopted innovative (unique in the sector) approaches to philanthropic programs in Index Countries which may result in sustainable health improvements and supports this with evidence of progress and/or human or financial resources invested. 2.5 The company has adopted innovative (unique in the sector) approaches to philanthropic programs in Index Countries which may result in sustainable health improvements but does NOT disclose progress or resources inputs. 0- No innovative initiatives discovered in this area.
	Generics	40%	

E. ACADEMIC REFERENCES FOR THE INDEX 2010 INDICATORS

The following academic papers and guidelines were used throughout the methodology update process and analysis to achieve a better understanding of the on-going academic studies and policy developments on ATM related issues.

General Access to Medicine Management

- Bebbington, J, Larrinaga, C, Moneva, J M. 2008. Corporate social reporting and reputation risk management. *Accounting, Auditing & Accountability Journal* 21:3, p. 337-361
- Castka P, Bamber, G J, Bamber, D J, Sharp, J M. 2004. Integrating corporate social responsibility (CSR) into ISO management systems- in search of a feasible CSR management system framework. *The TQM Magazine* 16:3, p. 216-224
- Ellerup Nielsen A, Thomsen C. 2007. Reporting CSR- what and how to say it? *Corporate Communications: An International Journal* 12:1, p. 25-40
- Esteban, D. 2008. Strengthening corporate social responsibility in the pharmaceutical industry. *Journal of Medical Marketing* 8:1, p. 77-79
- Mitchell, L E. The Board as a Path toward Corporate Social Responsibility. *GWU Legal Studies Research Paper* No. 354; The New Corporate Accountability: Corporate Social Responsibility And The Law, Doreen McBarnet, Aurora Voiculescu and Tom Campbell, eds., Cambridge University Press, 2007.
- Morsing M and Schultz M. 2006. Corporate social responsibility communication: stakeholder information, response and involvement strategies. *Business Ethics: a European Review* 15:4, p. 323-338

Guidelines and technical documents

- OECD. 2004. Principles of Corporate Governance. Paris: Organization for Economic Co-operation and Development
- UNCTAD. 2006. Guidance on Good Practices in Corporate Governance Disclosure. New York and Geneva: United Nations
- ISO 9000 Principles. 2005. Geneva: International Standard Organization

Public Policy and Market Influence

- Abraham J. 2002. The pharmaceutical industry as a political player. *The Lancet* 360: 9344, p. 1498-1502
- Bala-Miller, P, Macmullan J, Upchurch L. 2007. Drugs, Doctors and Dinners: How drug companies influence health in the developing world. Consumers International.
- Berleant, A. Multinationals, local practice and the problem of ethical consistency. *Journal of business ethics* 1:3, august 1982
- Brezis M. 2008. Big Pharma and health care: unsolvable conflict of interests between private enterprise and public health. *The Israel Journal of Psychiatry and Related Sciences* 45:2, p.83-94
- Hudec, A, Robert E. 2000. WTO Perspective on Private Anti-Competitive Behavior in World Markets. *New England Law Review* 79
- Pugatch, M P. "Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access". ICTSD-UNCTAD Dialogue on ensuring Policy Options for Affordable Access to Essential Medicines. Bellagio, 12-16 October 2004
- Singh, A, Dhumale, R. 1999. The South Centre, Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Working paper #7: Competition policy, development and developing countries (1999)
- Wynia MK. 2007. Public health, public trust and lobbying. *The American Journal of Bioethics* 7:6, p.4-7

Guidelines and technical documents:

- IFPMA. 2007. Code of Pharmaceutical Marketing Practices. Geneva: International Federation of Pharmaceutical Manufacturers and Associations
- Médecins sans Frontières. 2004. Data exclusivity in international trade agreements: What consequences for access to medicines? MSF technical brief. Available: http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_ and_Access_to_Medicines/DataExclusivityInInternationalTradeAgreementsMSF.pdf
- WHO. 1988. Criteria for Medicinal Drug Promotion. Geneva: World Health Organization

Research and Development

- Abergunde DO, Mathers CD, Adam T, Ortegon M, Strong K. 2007. The burden and costs of chronic diseases in low-income and middle-income countries. *The Lancet* 370, p. 1929–38
- Daar, A S., Singer, P A., Persad, D L. et al. 2007. Grand challenges in chronic non-communicable diseases. *Nature* 450, p. 494-496.
- Fisher, W W, Syed, T. 2007. Global justice in healthcare: developing drugs for the developing world. *University of California Davis Law Review* 40, p. 581-678
- Mrazek, M F and Mossialos, E. 2003. Stimulating Pharmaceutical Research and Development for Neglected Diseases. *Health Policy* 64:1, p. 75-88
- Trouiller, P, Olliaro, P, Torreele, E, Orbinski, J, Laing, R, Ford, N. Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet* 359: 9324, p. 2188-2194
- Sheridan M. 2005. The Business of Making Vaccines. *Nature Biotechnology* 23: 11

Guidelines and technical documents:

- Moran M, Guzman J, Ropars AL, McDonald A, Sturm T, Jameson N, Wu L, Ryan S, Omune B 2009. Neglected disease research and development: how much are we really spending? The George Institute for International Health.
- The George Institute. G-FINDER (Global Funding if Innovation for Neglected Diseases). Available at: https://studies.thegeorgeinstitute.org/gfinder_report/index.jsp
- Torreele, E, Usdin M, Chirac, P. 2004. A needs-based pharmaceutical R&D agenda for neglected diseases. Geneva: World Health Organization
- World Medical Association. 2008. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.
- WHO. 2004. Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants: Guidelines on Care, Treatment and Support for Women Living With HIV/AIDS and Their Children in Resource-Constrained Settings. Geneva: the World Health Organization
- WHO. 2007. Model list of essential medicines for children. Geneva: World Health Organization
- WHO. 2001. Macroeconomics and Health: Investing in Health for Economic Development. Report of the Commission on Macroeconomics and Health. Geneva: theWorld Health Organization.
- WHO. 2007. Prioritizing second-line antiretroviral drugs for adults and adolescents: a public health approach. Report of a WHO working group meeting. Geneva: the World Health Organization
- WHO Pediatric Antiretroviral Working Group. 2007. Report: Preferred antiretroviral medicines for treating and preventing HIV infection in younger children. Geneva: WHO Document Production Services
- Wise. J. .2005. Polypill holds promise for people with chronic disease. *Bulletin of the World Health Organization* 83:12

Patents and Licensing

- Abbott, F M. 2009. Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare. *World Intellectual Property Organization Journal* 1, p. 43-50Bird, RC. 2009. Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects. *Journal of Law, Medicine & Ethics* 37:2, p. 209-21
- Bordé, A. "Patent Pool" could ease HIV Drug Prices. Inter-Press Service, October 1st, 2009. Available: http://ipsnews.net/news.asp?idnews=48674
- Flynn, S, Hollis, A, Palmedo, M. 2009. An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries. *The Journal of Law, Medicine & Ethics* 37: 2, p. 184-208
- Merges, R P. 1999. Institutions for Intellectual Property Transactions: the Case of Patent Pools. University of California at Berkeley School of Law
- Moon, S. 2009. Medicines as global public goods: the historical evolution of and contemporary debates on technological Innovations for Global Health. Center for International Development at Harvard University *Working Paper* no. 36
- Mueller, J. 2007. Taking TRIPS to India-Novartis, Patent Law and Access to Medicines. *New England Journal of Medicine* 356:6
- Tahir, A. 2007. Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines? Oxfam GB

Guidelines and technical documents:

- Médecins sans Frontières. 2001. "A Matter of Life and Death: The Role of Patents in Access to Medicines". Available: http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf
- WHO. 2004. Working Paper: "Follow-On Innovation and Intellectual Property". Available: http://www.who.int/intellectualproperty/submissions/Innovation%20&%20Intellectual%20Property%20WIPO.pdf

Capability Advancement in Product Development and Distribution

- Cheri Grace. Developing New Technologies to address Neglected Diseases: Product-Development Partnerships (PDPs) and Advanced Market Commitments (AMCs). DFID Health Resource Centre, September 2006
- Reich, Michael C. 2000. Public-Private Partnerships for Public Health. Nature Medicine 6: 617-620
- Kaplan, W.A., R. Laing, B. Waning, L. Levison, Foster, S. (2003) "Is Local Production of Pharmaceuticals A Way to Improve Pharmaceutical Access in Developing and Transitional Countries? Setting a Research Agenda", Boston School of Public Health, mimeo.
- Creating access to health technologies in poor countries. Frost LJ, Reich MR. Global Health Insights LLC, Montclair, NewJersey, USA.
- Pirmohamed, Munir; Atuah, Kwame N; Dodoo, Alex N O; Winstanley, Peter (2007). “Pharmacovigilance in developing countries”, BMJ 2007;335:462

Guidelines and technical documents:

- Oxfam International Stop Stock-out campaign (2010). Available at: http://www.oxfam.org/campaigns/health-education/stop-stock-outs. Accessed April 29, 2010.
- WHO. 2002. The importance of pharmacovigilance: Safety monitoring of medicinal products. Geneva: the World Health Organisation

Product Donations and Philanthropic Activities

- Michael Reich (ed.). An assessment of US Pharmaceutical Donations: Players, Processes and Products. Boston, The Harvard School of Public Health, 1999
- Snell, Beverly. (2001). "Inappropriate drug donations: the need for reforms." The Lancet 358: 578-580
- Shretta, R, Brugha, R, Robb, A and Snow, RW. 2000. Sustainability, affordability and equity of corporate drug donations: the case of Malarone. The Lancet 355:9216, p. 1718-1720
- Shretta R, Walt G, Brugha R, Snow R. 2001. A political analysis of corporate drug donations: the example of Malarone in Kenya. Health Policy Plan 16(2):161-70.
- Alain Guilloux, Suerie Moon. 2000. Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives. MSF Access to Essential Medicines Campaign and Drugs for Neglected Diseases Working Group
- Reich MR, Wagner AK, McLaughlin TJ, Dumbaugh KA, Derai-Cochin M. Pharmaceutical donations by the USA: an assessment of relevance and time-to-expiry. Bull World Health Organ 1999; 77: 675–80.

Guidelines and technical documents:

- Pinheiro, Cristina P. 2008. Drug Donations: what lies beneath. *Bulletin of the World Health Organization* 86:8
- WHO (ed.). 1999. Guidelines for drug donations. WHO Department of Essential Drugs and Other Medicines

General Documents

- IMS Health. 2010. “Tracking the Effect of the Economic Crisis on Pharmaceutical Consumption”. Report prepared for the World Health Organization.
- IMS Health. 2009. “IMS Forecasts Global Pharmaceutical Market Growth of 4-6% in 2010; Predicts 4-7% Expansion Through 2013.” IMS Health Press Release. Available Online: http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a /?vgnextoid=500e8fabedf24210VgnVCM100000ed152ca2RCRD.
- Médecins sans Frontières. Examples of the importance of India as the “pharmacy for the developing world.” Geneva: Médecins Sans Frontières Access to Essential Medicines Campaign; 2007. Available: www.accessmed-msf.org/prod/publications.asp?scntid=29120071111256&contenttype=PARA&
- Oxfam International .2007. Investing for life: Meeting poor people’s needs for access to medicine through responsible business practices. Oxfam International Briefing paper
- The Disease Control Priorities Project http://www.dcp2.org/
- United Nations. 2008. Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines. Report to the General Assembly of the UN Special Rapporteur on the Right to the Highest Attainable Standard of Health. UN document: A/63/263
- WHO. Global Burden of Disease Project www.globalburden.org
- WHO. Control of Neglected Tropical Diseases http://www.who.int/neglected_diseases/en/
- WHO. 2004. Equitable Access to Essential Medicines: A Framework for Collective Action. *WHO Policy Perspectives on Medicines* 8
- WHO Sixty-First World Health Assembly. 2008. Global strategy and plan of action on public health, innovation and intellectual property. Geneva: World Health Organization

GLOSSARY

Active Licensee

This term indicates 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

This term refers to 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.

Authorized Generics

An authorized generic (AG) is a pharmaceutical product that was originally marketed and sold by an originator company, but following patent expiry, is relabeled and marketed under a generic product name by the same company or in arrangement with a generics manufacturer.

Communicable Index Diseases

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

Company Size

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

DALY (Disability Adjusted Life Years)

WHO definition: One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability.

Generic Manufacturing

In this document, generic manufacturing refers to manufacturing of pharmaceutical products by a company which does not hold the patent for the product or to a product whose patent has expired.

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 'Geographical Scope' section for more details.

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.

Innovative Research

This term is defined as research aimed at developing new 'breakthrough' compounds / remedies (as opposed 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 Upper Middle Income countries, based on the World Bank country income level categories.

Non-Communicable Index Diseases

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

Non-Exclusive Voluntary Licensing

This term refers to 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.

Originator Company

This term indicates a company whose revenues are mostly from sales of patented products and which focuses on research and development aimed at developing new pharmaceutical products.

Period of Analysis

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

Products

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

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.

ACKNOWLEDGEMENTS

The Access to Medicine Index 2010 team would like to thank the following individuals who generously gave their time and valuable feedback throughout the development of the Access to Medicine Index 2010. We are sincerely grateful for their kind contributions and expertise.[89] We would like to extend our appreciation and apologies to any individuals whose names have been inadvertently excluded from the list below.

Stakeholder Engagement Process

A large number of experts from different stakeholder groups have been kind enough to respond to our on-line survey and to provide us with their valuable time through participating in meetings, calls, email exchanges etc. throughout the stakeholder engagement process. We would like to thank them all. Without their participation we would not have been able to achieve an understanding of the viewpoints, concerns and expectations of the different stakeholders. This understanding is essential to what the Access to Medicine Index is trying to achieve.

Our special 'thank you' goes to the organizers (especially Eva Ombaka who at the time directed the Ecumenical Pharmaceutical Network, Frans de Laaf of Oxfam Novib and Kwasi Boahene of HIVOS) and participants of the Access to Medicine workshop in Nairobi. This workshop was a very valuable step in achieving a better understanding of the real impact of the pharmaceutical companies' operations 'on the ground'.

Roundtable Participants

The individuals listed below kindly reviewed the material resulting from the first phase of stakeholder engagement process and participated in one of the two stakeholder roundtables of Index 2010 held in Washington DC and London. While the roundtables yielded valuable results, the ultimate decisions about the needed enhancements in the Access to Medicine Index 2010 were made by the Access to Medicine Foundation.

- Wilbert Bannenberg, Medicines Transparency Initiative
- Brendan Barnes, European Federation of Pharmaceutical Industries and Associations
- Maggie Brenneke, SustainAbility

[89] This acknowledgement is not intended to imply that the individuals and institutions mentioned below endorse the Access to Medicine Index, its final methodology, the analysis or results.

- Jan Bultman, Independent Consultant
- Charles Clift, Department for International Development – Since January 2010, he is an independent consultant.
- Lauren Compere, Boston Common Asset Management - Interfaith Center on Corporate Responsibility (ICCR)
- Joseph Fortunak, Howard University
- Javier Guzman, George Institute for International Health
- Corry Jacobs, The Pharmaceutical Research and Manufacturers of America (PhRMA)
- Elias Mossialos, London School of Economics
- Jonathan Mwiindi, Independent Expert, Previously with Ecumenical Pharmaceutical Network
- Nadira Narine, Interfaith Center on Corporate Responsibility (ICCR)
- My-Linh Ngo, Henderson Global Investors
- Tatiana Popa, International Finance Cooperation (IFC), The World Bank
- David Ripin Brown, The Clinton Foundation
- Sally Schlippert, The World Bank
- Robyn Scott, Founder of Mothers for All, Independent Consultant & Writer
- Dilip Shah, Secretary-General, Indian Pharmaceutical Alliance - CEO, Vision Consulting
- Jeanne Shen, Global Alliance for Vaccines and Immunization (GAVI Alliance)
- Jeff Sturchio, Global Health Council
- Sophia Tickell, Co-founder and Director of Pharma Futures
- Helen Vieth, London School of Economics
- Regine Webster, Consultant at the Gates Foundation
- Alan Whiteside, University of KwaZulu-Natal
- Guy Willis, International Federation of Pharmaceutical Manufacturers & Associations

Expert Review Committee

As members of the Expert Review Committee, the individuals listed below provided us with their valuable time and expertise through participation in meetings and teleconferences and by providing us with their written feedback during the methodology update process. We would like to emphasize that all the decisions about the methodology were ultimately made by the Access to Medicine Foundation.

- Charles Clift, Department For International Development , the UK – Since January 2010, he is an independent consultant
- Hannah Kettler, Bill and Melinda Gates Foundation

- Richard Laing, World Health Organization
- Elias Mossialos, London School of Economics
- My-Linh Ngo, Henderson Global Investors
- Eva Ombaka, NGO Consultant
- Jeff Sturchio, Global Health Council
- Sophia Tickell, Chair, SustainAbility
- Guy Willis, International Federation of Pharmaceutical Manufacturers & Associations

Analysis Phase Exploratory Interviews - Information Sources and Data Providers

The individuals listed below kindly engaged with the Access to Medicine analyst team during the analysis phase to provide them with a better understanding of the context in which the pharmaceutical companies operate. Moreover, some of them kindly reviewed sections of earlier drafts of the report.

- Hugh Chang, PATH
- Javier Guzman, The George Institute for International Health
- Alex Harris, International Health Partners
- Catherine Hennings, PATH
- Robin Hodess, Transparency International
- Suerie Moon, Harvard's Center for International Development
- David Ripin Brown, The Clinton Foundation
- Dominik Schnichels, European Commission Competition
- Alan Staple, The Clinton Foundation
- Ellen t'Hoen, LL.M. Senior Adviser IP & Medicines Patent Pool, UNITAID
- Peter Tinnemann, Institute for Social Medicine, Epidemiology and Health Economics, University Medical Centre Berlin.
- Lindsey Wu, The George Institute for International Health

We would like to thank the George Institute team and especially Javier Guzman for their valuable input on R&D investments and the time & effort they expended to prepare the data requested by the Access to Medicine Foundation.

We would also like to thank Professor Vincenzo Esposito Vinzi of ESSEC business school for kindly providing advice on statistical analysis of the Access to Medicine data and Alan Petrillo

and Shane Bair of RiskMetrics for editorial and graphics consulting and Celia Möller for her contributions to platform design.

Reviewers of the Report

The following individuals kindly reviewed the final report and provided us with their valuable feedback. While all the comments and feedbacks were carefully reviewed, the final decision about whether to reflect them in the final report was made by the Access to Medicine Foundation.

- Charles Clift, Department For International Development
- Richard Laing, World Health Organization
- My-Linh Ngo, Henderson Global Investors
- Eva Ombaka, NGO Consultant
- Marieke Samson, PGGM
- Guy Willis, International Federation of Pharmaceutical Manufacturers & Associations

We would like to give a special thank you to Lauren Compere (Boston Common Asset Management), Marieke Samson (PGGM) and Dilip Shah (Vision Consulting) for their continuous support and advice.

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.

COPYRIGHT

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

info@atmindex.org
www.accesstomedicineindex.org