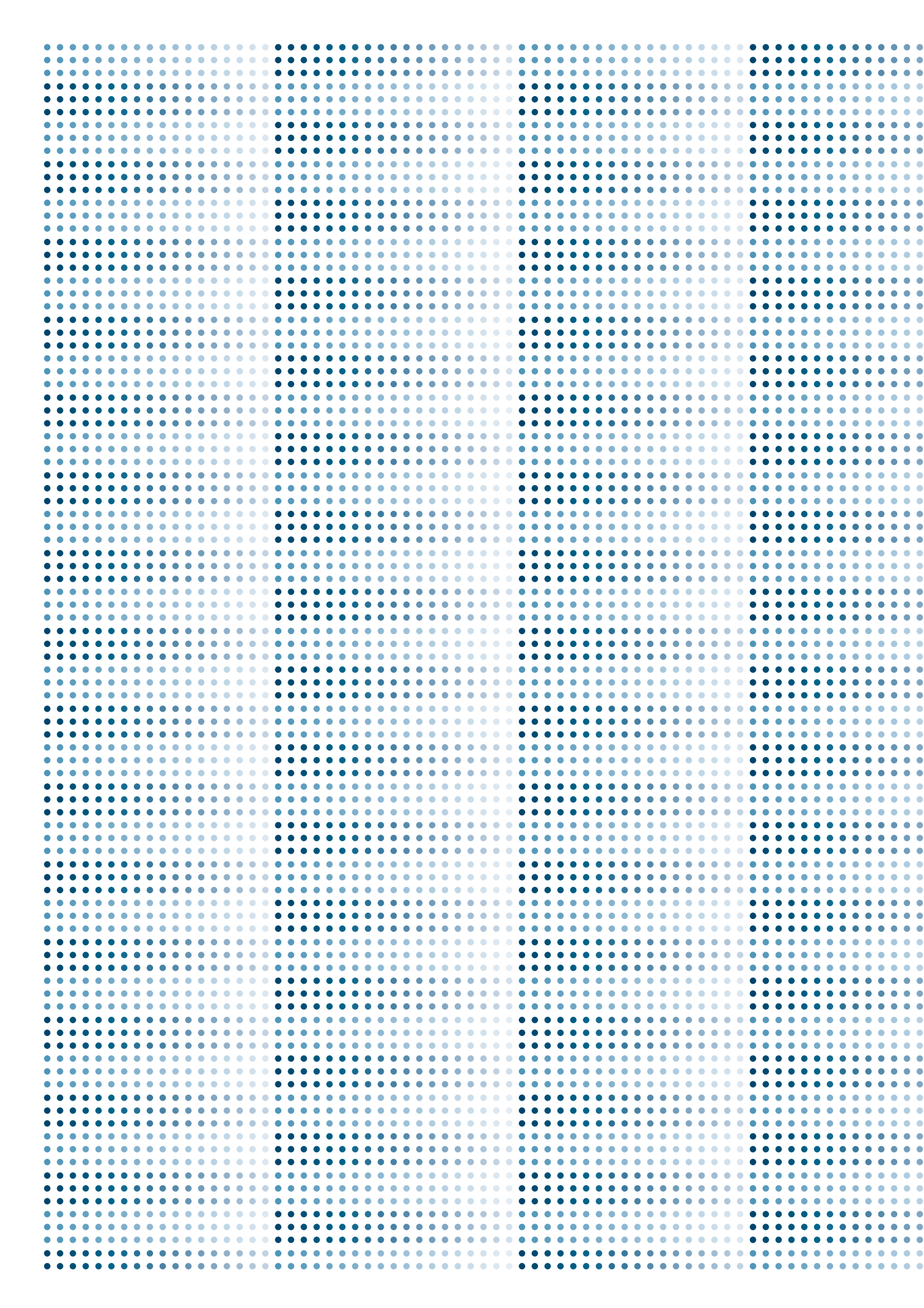


A black and white photograph of three young children, likely of African descent, smiling and looking towards the camera. The child in the foreground is slightly out of focus, while the two children behind them are more prominent. The image has a blue tint.

# Industry & Stakeholder Review

Final  
Report





# Industry & Stakeholder Review

Final  
Report



This report is written by:

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# Access to Medicine Index

## Industry & Stakeholder Review

Final Report  
November 2007

Report prepared by the Innovest Healthcare Team:  
Veronique Menou, Adam Savitz and Katharine Preston

### FINAL ACCESS TO MEDICINE INDEX FRAMEWORK

20%	Access to Medicines Management
20%	Research & Development that Reflects both the Global Disease Burden and Neglected Diseases
15%	Equitable Pricing
15%	Drug Manufacturing, Distribution and Capability Advancement
10%	Patents & Licensing
10%	Public Policy Influence & Advocacy
6%	Drug Donations
4%	Philanthropic Activities

This table includes the eight most relevant criteria, ranked in order of importance, as indicated by the percentage weighting.

### FINAL REVIEW OF THE ATM INDEX FRAMEWORK

#### Partners in a Global Venture

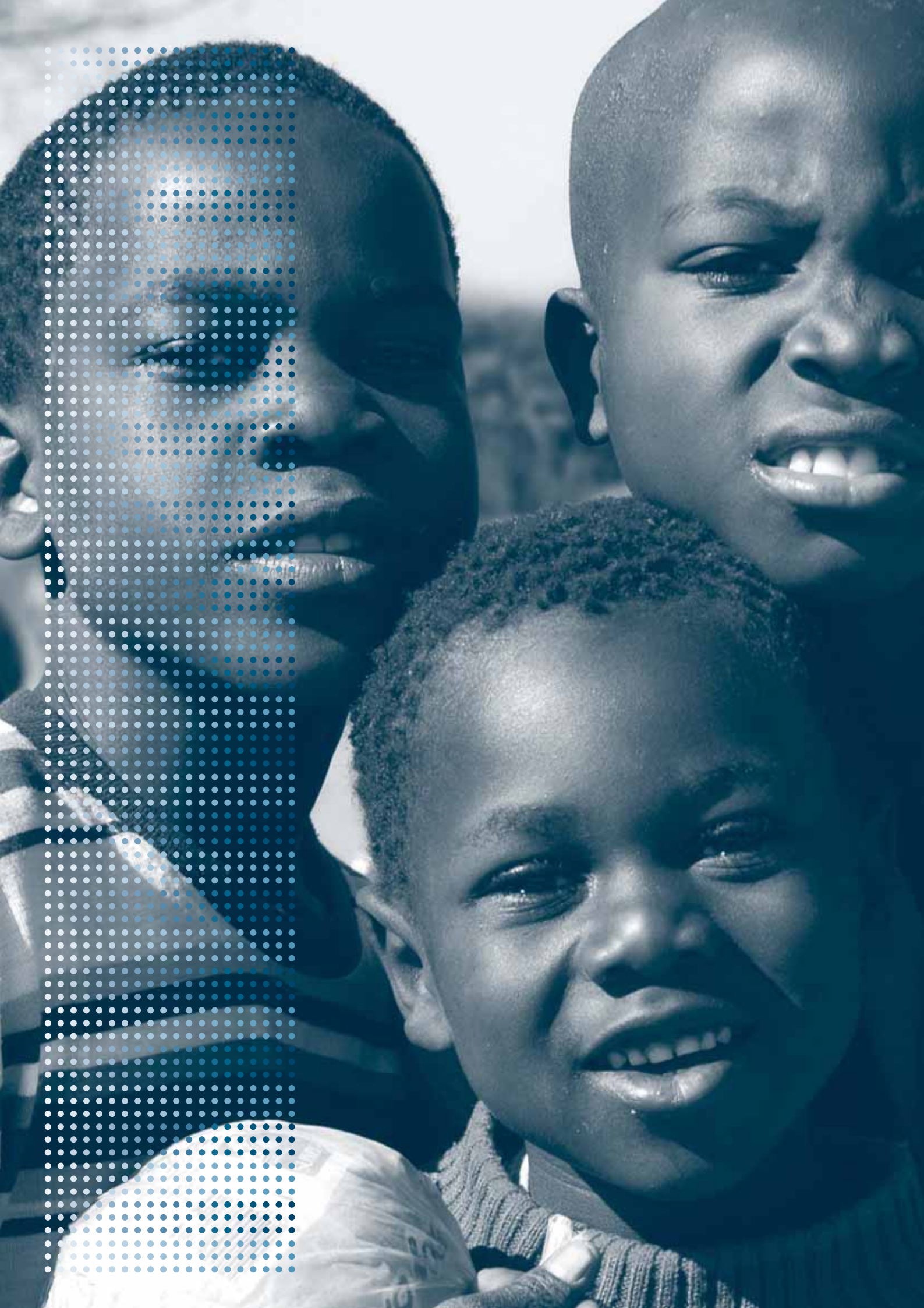
The Access to Medicine Index (AtM Index) framework is part of a global initiative to improve access to medicines (ATMs) world-wide. The project aims to highlight that ATMs is the joint responsibility of all stakeholders involved in improving global health, with pharmaceutical companies an essential actor in providing access to drugs to those in need.

#### A Multi-Stakeholder and Collaborative Project

Feedback from ATMs stakeholders was received through three consultation phases. The first phase gathered the views of a wide range of experts from NGOs, investors, governments, consultants and academics. The second phase was focused on getting the pharmaceutical industry perspective on the initial findings. The third period allowed further input on the framework from both the industry and its stakeholders.

#### Index Evolution

The report incorporates as many suggestions as possible from the experts contacted during the three consultation periods. It also presents the final list of Criteria, Indicators, Metrics and Weightings that will be used to benchmark company performance with regard to ATMs. The AtM Index will be the result after an evaluation and ranking of 20 companies, to be published in spring 2008.





## FOREWORD

# A continuing dialogue

In the development of an innovative project like this there are many challenges to be faced. Each one has to be resolved through a process of discussion, allowing all stakeholders to express their views. Looking back at this exciting year I am pleased to report that we have been successful in clearing the many hurdles along the way and that the AtM Index project has now evolved into a truly multi-stakeholder project.

We see the concerted effort of creating this Index, as contributing to the eighth Millennium Development Goal. This goal calls for a global partnership, with special reference to access to medicine and the pharmaceutical industry. Finding out what the position of the pharmaceutical industry should be within a global partnership requires constructive input from all stakeholders, including the industry itself.

Several questions arise. What are the stakeholder expectations, how can the knowledge best be communicated, which approaches represent best practice? I believe we have been able to set up a process that will be valuable in helping to address these questions. This *Industry and Stakeholder Review - Final Report* presents the result of what I would describe as an unprecedented global dialogue, that has included both the pharmaceutical industry itself as well as its key stakeholder constituents. Two reports have preceded this final report, meticulously documenting the different stages of the process. This dialogue will continue over the coming years, incorporating improvements and updates to the metrics; to account for developments in the access to medicine environment and allowing for an annual measurement of company positions using the benchmarking model we have now formulated.

Over the past year, we have received increasing levels of support and interest from investors, who see access to medicine as one of the key ethical and business issues for the pharmaceutical industry. We also received support from companies that welcome a constructive dialogue and from the global health sector whose belief it is that our work can help to improve the effectiveness of partnerships to deliver access to medicine on the ground. Furthermore our model has been a key reference point for the United Nations Special Rapporteur - for the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.

The coming months will be devoted to the producing the first performance analysis using the benchmark model, with an expected publication of the Index Spring 2008. Again we have gained from the expertise of Innovent, who have a long standing experience of this type of highly specialized company analysis.

I would like to thank all the people that have co-operated to make this part of the project a success and would like to encourage all stakeholders and the industry itself to remain with us in our efforts to make the next phase of the Index just as successful.

Wim Beersveld





## THE ATM INDEX DEVELOPMENT PROCESS

This report is the third and final in a series of three reports that chart the development of the AtM Index. The report documents the results of the final consultation phase and presents an analytical framework that forms the foundation for the first AtM Index benchmark assessment, due in spring 2008.

The AtM Index will be the first attempt to turn research from academic, business and NGO communities into an evaluation of company performance. The list of Criteria, Indicators, Metrics, and Weightings will be used as a means of assessing companies' management of ATMs and will result in an explanatory ranking of 20 companies. The list of companies will most likely include both generic and originator companies in the healthcare sector (for details on how we will assess different business models, please see the chapter 'Next Steps in AtM Index Development' p. 38-39).

## Feedback

*The Access to Medicine Foundation welcomes all comments and suggestions on the findings of this report, as well as thoughts that would benefit the development of the AtM Index.*

## INVESTOR STATEMENT ON THE ACCESS TO MEDICINE FOUNDATION INDEX PROJECT

Investors with current total combined assets under management of EUR 913.6 billion (as at 31 December 2006) have signed the AtM Index Investor Statement in support of the Index. These companies include:

Bank Sarasin  
CIS (Cooperative Insurance Society)  
Ethos  
F&C  
Henderson Global Investors  
ICCR Access to Healthcare Working Group  
Morley  
Schroders  
SNS Asset Management  
USS

The financial institutions listed above agree on the following:

- Believe the issue of ATMs may have material impact on long-term shareholder value.
- Acknowledge the existence of the Access to Medicine Index Project.
- Welcome the project's efforts to develop a tool which could improve transparency and may be useful to assess the long term value of pharmaceutical companies.
- Look forward to learning the outcomes of the project.
- Consider that pharmaceutical companies have a role to play in addressing the access to medicine issue.

The statement is provided in full in Appendix 6. The Access to Medicine Foundation welcomes the support of these organizations and we anticipate that this initial list of signatories will be expanded as awareness of the Index grows.



## PARTNERS AND FUNDING PARTNERS OF THE ACCESS TO MEDICINE FOUNDATION

We are very grateful for the generous contributions of the many people and organizations that have supported us to date and who share our view that the Access to Medicine Index will represent an important new initiative in tackling the disease burden of many of the world's poorer countries.

Partners and Funding partners of the Access to Medicine Foundation are:

- Aedes (European Agency for the Development and Health)
- DGIS (Dutch Ministry of Foreign Affairs)
- DFID (UK Department for International Development)
- HIVOS (Humanist Institute for Cooperation with Developing Countries)
- ICCO (Interchurch Organization for Development Co-operation)
- ICCR (Interfaith Center on Corporate Responsibility)
- Oxfam Novib
- Rabobank
- SNS Reaal

## ACCESS TO MEDICINE FOUNDATION

Launched in 2005, the Access to Medicine Foundation was established with the goal of developing an Access to Medicine Index that will offer objective and comparative information regarding the approaches of pharmaceutical companies to ATMs issues. The foundation is based in Haarlem, The Netherlands. Website: [www.atmindex.org](http://www.atmindex.org)

## INNOVEST STRATEGIC VALUE ADVISORS

Founded in 1995, Innovest Strategic Value Advisors is an international investment research and advisory firm specializing in analyzing “non-traditional” drivers of risk and shareholder value, including companies’ performance on environmental, social and strategic governance issues. Analyzing these hidden links and value drivers and translating that analysis into actionable investment insights has been Innovest’s core business for over a decade. The firm currently has over USD1.1 billion under direct sub-advisory mandates and has clients in 20 countries. Innovest’s coverage includes more than 80 industry sectors, including Pharmaceuticals, where the company’s Healthcare analysts have evaluated the 45 largest global firms. Innovest was rated the #1 global provider of “extra-financial” investment research for the second year in a row by Thomson Extel’s 2007 survey of major institutional investors.

Website: [www.innovestgroup.com](http://www.innovestgroup.com)

## ACKNOWLEDGEMENTS

The Access to Medicine Foundation together with Innovest would like to thank those industry representatives and stakeholders who gave their time and input into this project. Without their insight, effort and frank discussion this project would not have proceeded in the manner it has.

## DISCLAIMER

As a multi-stakeholder and collaborative project, the findings, interpretations, and conclusions expressed herein may not necessarily reflect the views of all companies, 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.



## ACRONYMS

Association of the British Pharmaceutical Industry	ABPI
Acquired Immune Deficiency Syndrome	AIDS
Access to Medicines	ATMs
Access to Medicine Index	AtM Index
Department for International Development (UK Government)	DFID
European Federation of Pharmaceutical Industries and Associations	EFPIA
European Agency for the Evaluation of Medicinal Products	EMA
Food and Drug Administration	FDA
United Nations Human Development Index	HDI
High-Income Country	HIC
Human Immunodeficiency Virus	HIV
Industry Classification Benchmark	ICB
Interfaith Center on Corporate Responsibility	ICCR
International Federation of Pharmaceutical Manufacturers & Associations	IFPMA
Intellectual Property	IP
Least Developed Country	LDC
Low-Income Country	LIC
Middle-Income Country	MIC
National Drug Regulatory Authority	NDRA
Non-Governmental Organization	NGO
Patient Assistance Program	PAP
Public-Private Partnership	PPP
Product Development Partnership	PDP
US Pharmaceutical Manufacturers and Research Association	PhMRA
Research and Development	R&D
Tuberculosis	TB
Trade-Related Aspects of Intellectual Property Rights	TRIPS
World Health Organization	WHO
World Trade Organization	WTO



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# Executive Summary

## ENGAGEMENT PHASE

The first phase of the AtM Index project was focused on gathering the views of pharmaceutical company stakeholders with expertise on ATMs issues. The Scoping Report and Stakeholder Review February 2007 is available at [www.atmindex.org](http://www.atmindex.org).

The second phase of the project allowed pharmaceutical companies to provide their perspectives on the initial findings and to refine the list of indicators and metrics, to meet both the expectations of the industry and its stakeholders. The Industry Engagement Report September 2007 is available at [www.atmindex.org](http://www.atmindex.org).

The third consultation phase allowed both the industry and its stakeholders to comment on the set of benchmarks developed during the two previous phases. There was general agreement amongst the industry and its stakeholders on the set of Criteria and their Weightings. The feedback we received mostly focused on the list of Indicators, their Weightings and Metrics.

This third and final report presents the list of Criteria, Indicators, Metrics and Weightings that make up the framework that will be used to assess pharmaceutical companies' performance with regard to ATMs. The report also documents the main discussion points and the amendments to the benchmarks and weights presented since the second report.

## SUMMARY OF RESULTS

The three consultation phases resulted in the proposition that companies should be involved in eight specific areas, with discussions determining the criteria and criteria weightings that best evaluate company policies, performance, and impacts. Weightings have been assigned to each of the criteria based on the discussions with company representatives and their stakeholders. The engagement process highlighted the benefits of cross-stakeholder participation in attempting to improve access. Critically, cooperative strategies were discussed for both the complete lifecycle of a product and an ATMs program. The AtM Index framework intentionally does not include a distinct criterion on partnerships, but rather looks at the partnership approach within the ATMs criteria and in particular in "R&D that Reflects both the Global Disease Burden and Neglected Diseases", "Equitable Pricing", "Drug Manufacturing, Distribution and Capability Advancement", "Drug Donations" and "Philanthropic Activities". The framework also aims to highlight that the responsibility for ATMs lies with all stakeholders involved in improving global health, with pharmaceutical companies being an essential contributor to the achievement of ATMs delivery. The AtM Index will attempt to stress this multi-stakeholder responsibility by drawing attention to bottlenecks in the actual access process. Many stakeholders recognized that a lack of resources within states can in some cases account for the delay or ineffective delivery of drugs. Lack of enforcement mechanisms for international codes of conduct may also limit their net impact.

Many of the indicators explore issues most prevalent in least developed and developing countries, reflecting the current coverage of the issue. While the indicators in the criteria "R&D that Reflects both the Global Disease Burden and Neglected Diseases" indicate the urgent need for new treatments into neglected diseases and for new formulations for the global disease burden, the seven other criteria will look predominantly at the global disease burden. The Index framework does not intend to neglect ATMs issues within developed countries but it emphasizes the current urgency of the matter. The fluid nature of the Index framework will allow for adjustments in geographical and demographic scope in future years. With changing perceptions and strategies with regard to ATMs the Index will be adapted through continued stakeholder and industry input.





## ATM INDEX FRAMEWORK EVOLUTION

Below is an illustration of the proposed minor criteria refinements made from the initial Scoping Report and Stakeholder Review. Further detailed discussions on these changes are included in the report.

Weight Criteria

20%	Access to Medicines Management
20%	Research & Development into Neglected Diseases
18%	Equitable Pricing
15%	Patents & Licensing
10%	Public Policy Influence & Lobbying
7%	Drug Donations
5%	Philanthropic Activities
5%	Ethical Promotion & Marketing Activities

February 2007

Scoping Report & Stakeholder Review

20%	Access to Medicines Management
20%	Research & Development that Reflects the Global Disease Burden and Neglected Diseases
15%	Equitable Pricing
15%	Drug Manufacturing, Distribution and Capability Advancement
10%	Patents & Licensing
10%	Public Policy Influence & Advocacy
6%	Drug Donations
4%	Philanthropic Activities

September 2007

Industry Engagement

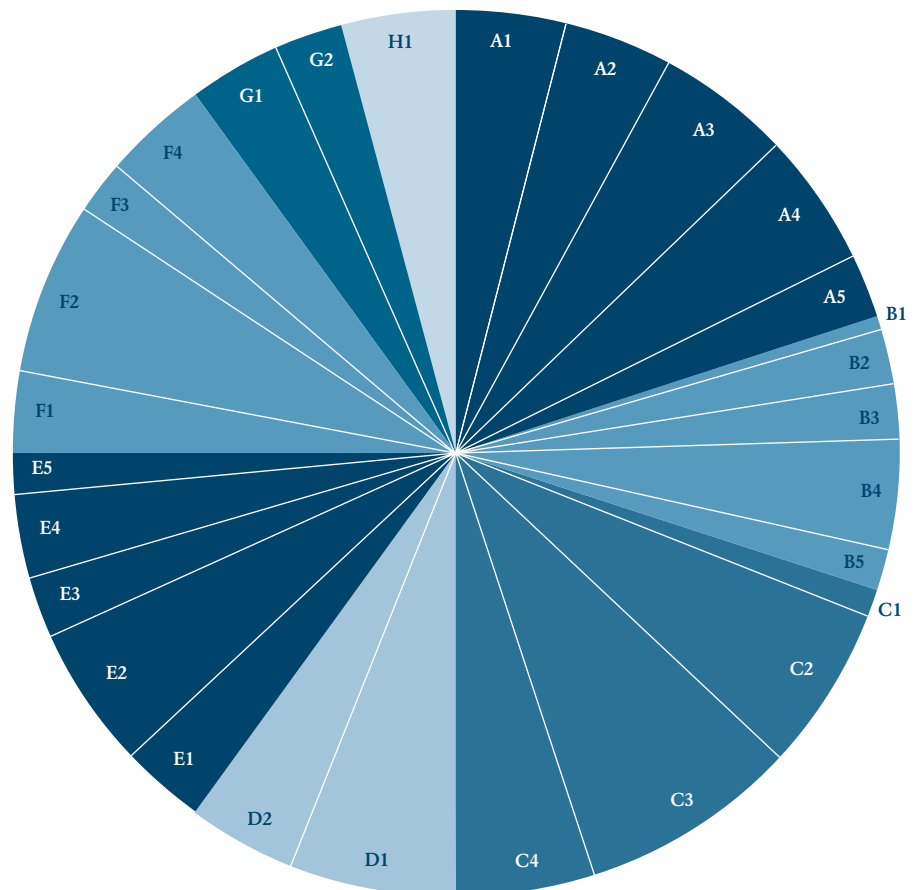
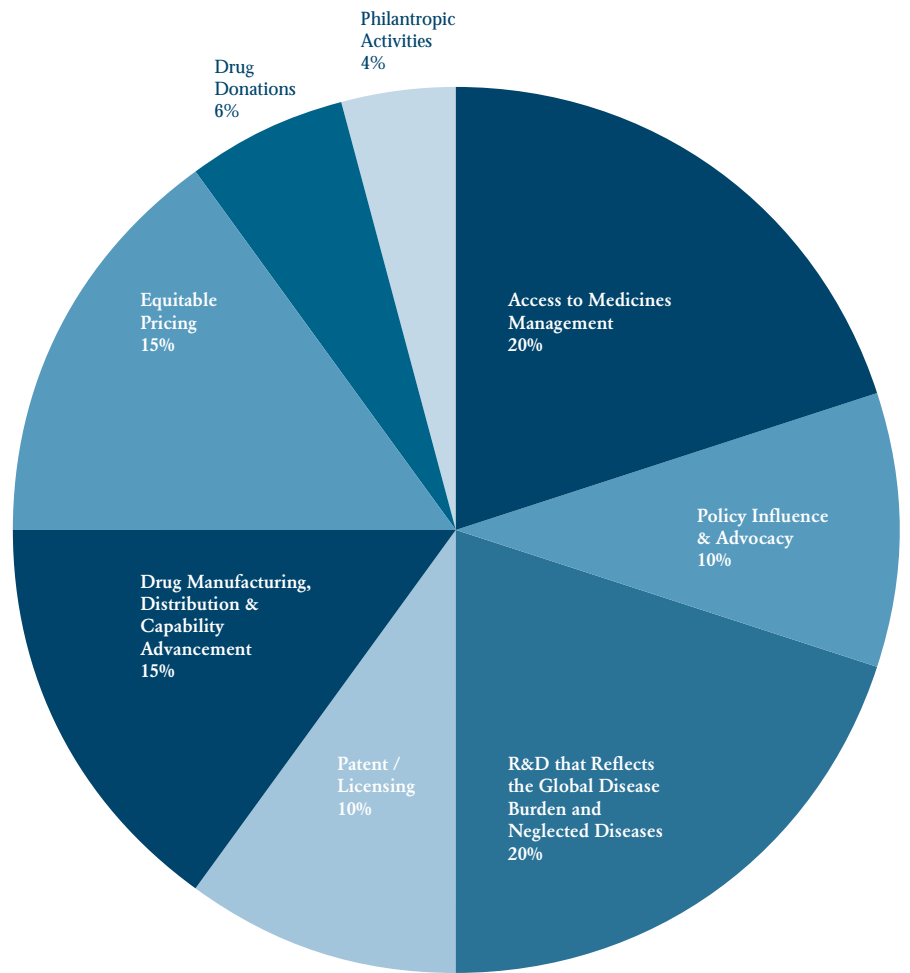
Second Interim Report

20%	Access to Medicines Management
20%	Research & Development that Reflects the Global Disease Burden and Neglected Diseases
15%	Equitable Pricing
15%	Drug Manufacturing, Distribution and Capability Advancement
10%	Patents & Licensing
10%	Public Policy Influence & Advocacy
6%	Drug Donations
4%	Philanthropic Activities

November 2007

Industry and Stakeholder Review

Third Report (no changes have occurred in the criteria since the second report)





## CRITERIA & INDICATOR BREAKDOWN

The following breakdown of Criteria and Indicators, and their respective Weightings, now includes the results of the final industry and stakeholder review process. *Italic font indicates that the Criteria, Indicators and Weightings have changed since the second report. Please see Appendix 5 for the AtM Index framework presented in the Industry Engagement Report.*

8 Access to Medicine Criteria  
28 Access to Medicine Indicators  
88 Access to Medicine Metrics

### A ACCESS TO MEDICINES MANAGEMENT (20%)

- A1 Governance: The company has a governance system that includes direct board level responsibility and accountability for its ATMs strategy. (20%)
- A2 Policy and Disclosure: The company has a public global policy in place, in which it explains its rationale for ATMs, its contents and details its specific objectives. (20%)
- A3 Systems and Reporting: The company has a management system, including quantitative targets to implement and monitor its ATMs strategy. (25%)
- A4 Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management. (25%)
- A5 The company has globally applicable ethical business practices and marketing policies that conform to appropriate standards. (10%)

### B PUBLIC POLICY INFLUENCE & LOBBYING (10%)

- B1 The company has a position on public policy advocacy and transparency. (5%)
- B2 *The company and subsidiaries disclose major public policy positions at regional, national and international levels related to the ATMs debate. (20%)*
- B3 The company and subsidiaries actively advocate health reforms that foster ATMs and for policies that would result in improvements in public health. (20%)
- B4 The company annually discloses which individuals, patient associations, political parties, trade associations and academic departments it supports with which it might advocate on public policy positions and practices; at a regional, national and international level. (40%)
- B5 The company demonstrates a process of board approval of the approach to public policy advocacy, its transparency and reporting. (15%)

### C RESEARCH & DEVELOPMENT THAT REFLECTS BOTH THE GLOBAL DISEASE BURDEN AND NEGLECTED DISEASES (20%)

- C1 The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases. (5%)
- C2 *The company provides evidence of in-house investment in R&D into new treatments for neglected diseases. (30%)*
- C3 The company **with in-house investment in R&D** into new treatments for neglected diseases provides evidence of partnership with groups with developing country health expertise, such as product development public-private partnerships, academic institutions and/or the World Health Organization. / The company **with no in-house neglected diseases R&D investment** provides evidence of investment into such R&D conducted by others. (40%)
- C4 *The company shows temporal evidence that its research program into both the global disease burden and neglected diseases considers research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups. (25%)*

### D PATENTS & LICENSING (10%):

- D1 The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing and least developed countries. (60%)
- D2 *The company publicly commits itself to respecting the right of developing and least developed countries to use the provisions in the TRIPS agreement. (40%)*



**E DRUG MANUFACTURING, DISTRIBUTION AND CAPABILITY ADVANCEMENT (15%):**

- E1 The company demonstrates efforts to manufacture drugs to the highest quality standards. (20%)
- E2 The company enters into technology transfer agreements with local companies in developing and least developed countries. (35%)
- E3 *The company undertakes external activities to support the monitoring of drugs that reflect both the global disease burden and neglected diseases including participation in public private partnerships. (15%)*
- E4 The company has mechanisms in place to help prevent product diversion and to address counterfeiting, in collaboration with states. (20%)
- E5 The company demonstrates efforts to provide ATMs to its employees and their relatives in developing and least developed countries. (10%)

**F EQUITABLE PRICING (15%):**

- F1 The company can demonstrate efforts to register treatments that reflect both the global disease burden and neglected diseases in developing and least developed countries. (20%)
- F2 The company has a policy to facilitate ATMs in developing and least developed countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews. (50%)
- F3 The company demonstrates that its discount schemes place the minimum administrative burden on the beneficiary health system. (10%)
- F4 The company has a policy for the very poorest in countries with no public healthcare provision. (20%)

**G DRUG DONATIONS (6%):**

- G1 The company has a policy that fully conforms to the WHO's Guidelines for Drug Donations. (60%)
- G2 The company discloses the absolute volume of its drug donations and, to the extent possible, the number of treatments approved for patient use per year. (40%)

**H PHILANTHROPIC ACTIVITIES (4%):**

- H1 The company has philanthropic programs related to ATMs not covered by any of the other criteria. (100%)



## INDEX METHODOLOGY & TIMELINE





		COMPANIES	NGO	ACADEMICS	CONSULTANTS	INVESTORS	GOVERNMENTS
Spotlight on ATMs	The project fosters debate on ATMs among various stakeholders.	●	●	●	●	●	●
Stakeholder Opinion	The views of each stakeholder group are documented.	●	●	●	●	●	●
Greater Transparency	The project calls for more disclosure and transparency around ATMs.	●	●	●	●	●	●
Best Practices	The project offers an evaluation of companies' performance and presents leading practices on eight criteria.	●	●	●	●	●	●
Independent Data Collection & Analysis	Research and assessment of companies are conducted by an independent body and disclosed in one central place.	●	●	●	●	●	●
Net Impact	The AtM Index aims to evaluate the impact of companies' actions on the ground.	●	●	●	●	●	●
Promotion of Activities & Articulation of the Business Case	Companies have the opportunity to communicate on their commitment towards ATMs and to present the rationale for their ATMs programs.	●					
Development of New Advocacy Policies	The AtM Index will allow for identification of key failures and development of advocacy activities.		●				
Identification of New Research Areas	The AtM Index will allow for identification of research gaps.			●			
Selling of New Line of Services	The AtM Index publication may lead to an increasing need for advisory services among companies.				●		
Better Understanding of Management of ATMs	An assessment of companies practices will lead to a better understanding of the management of risks and opportunities relating to ATMs.					●	
Development of New Regulations	The AtM Index will reinforce the need for regulations in various areas.						●



# Project Objective

## TO CONTRIBUTE TO A GLOBAL APPROACH

The UN Millennium Development goals recognize the need for a “global partnership for development” to provide access to affordable drugs to people in developing countries. Addressing access to medicines requires action and cooperation from all stakeholders including governments, companies, investors, academics, NGOs and other civil society partners, using their own capabilities, resources and cultures. By looking at companies’ individual performance in increasing access, the AtM Index project is one among numerous initiatives relating to ATMs. The AtM Index participates in a global trend to enhance access to medicines.

Below are a few examples of initiatives looking at key players’ role with regard to ATMs:

- **The Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines**<sup>1</sup>: In September 2007, Paul Hunt, the UN Special Rapporteur on the ‘right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, launched a draft Human Rights Guidelines for Pharmaceutical Companies in relation to ATMs, for public consultation. “The draft Guidelines are designed to help pharmaceutical companies, as well as those monitoring their activities. I look forward to finalizing the Guidelines in 2008”, said Professor Hunt.
- **Medicines Transparency Alliance (MeTA)**<sup>2</sup>: The principal objective, according to the group, is to support national efforts to enhance transparency and build capacity in medicines policy, procurement and supply chain management. MeTA is a multi-stakeholder approach that is centered on governmental efforts and focuses on drug quality, availability and pricing all along the supply chain.
- **The Access Metric Initiative (AMI)**<sup>3</sup>: The AMI is an initiative created by the Universities Allied for Essential Medicines (UAEM), a coalition of students with chapters at more than forty major research universities in the United States, Canada, and the United Kingdom. The AMI’s objective is to develop metrics for universities licensing offices that account for the non-profit mission of university research. The final outcome of the Access Metrics Initiative’s work will be a comprehensive index evaluating and ranking universities with respect to the degree that their policies and practices encourage access to university-developed biomedical technologies in developing countries.

<sup>1</sup> [http://www2.essex.ac.uk/human\\_right\\_centre/rth/](http://www2.essex.ac.uk/human_right_centre/rth/).  
Last accessed on October 22, 2007.

<sup>2</sup> Medicines Transparency Alliance  
<http://www.dfidhealthrc.org/MeTA/index.html>  
Last accessed on October 22, 2007.

<sup>3</sup> The Access Metric Initiative  
<http://www.essentialmedicine.org/>.  
Last accessed on October 22, 2007.

## TO IMPROVE ACCESS TO MEDICINES

The AtM Index’s main purpose is to raise awareness on access to drugs across the board, and improve collaboration between stakeholders. It will be used by stakeholders as an objective, rational, yet aspirational framework for benchmarking companies in the management of ATMs. It will provide a platform for ongoing dialogue, highlighting best practices and sharing lessons learned. The strength of the Index is that it will continue to be evaluated and further refined as research continues in this field. The dynamic nature of the Index will allow for issues to be re-weighted and included or excluded based on the current opinion from all stakeholders at the local, national and international level.

## TO PROMOTE ACTION ACROSS THE BOARD

The AtM Index will be a useful tool for all stakeholders.  
The main benefits are summarized in the table on p. 8.





# The AtM Index

## Development Process

### FIRST STEP

#### CONSULTATION OF PHARMACEUTICAL COMPANY STAKEHOLDERS

On behalf of the Access to Medicine Foundation, Innovest collected the views of a wide range of worldwide experts on the role pharmaceutical companies should play with regard to ATMs. Pharmaceutical companies were excluded during the first phase of the project in order to reach a large consensus on a set of benchmarks and create a basis for discussion with the industry. Retrospectively we feel that it was the right move to successfully develop a detailed list of benchmarks.

The first phase was divided into three sub-phases:

- **Background Research:** we undertook an in-depth analysis of reports on ATMs and related issues published by third parties in recent years, such as those by the Pharmaceutical Share-owners Group, the UK Department for International Development, ICCR, Oxfam, and the WHO (for additional information on the sources, please see the Scoping Report & Stakeholder Review ).
- **ATMs Questionnaire:** we designed a questionnaire which was circulated to more than 200 experts worldwide to collect their views on pharmaceutical company practices and potential role in improving ATMs. A wide range of pharmaceutical company stakeholders were consulted including academia, consultants, investors, government officials and NGOs both from the developed and the developing world.
- **Stakeholder Roundtables:** two roundtables were organized with representatives from each stakeholder group in London and New York to further discuss ATMs and develop a framework for benchmarking companies in the management of the issue (for the list of key stakeholders, please see Appendix 4).

*For additional information on the first phase, please see the Scoping Report & Stakeholder Review published in February 2007.*

### SECOND STEP

#### INDUSTRY ENGAGEMENT

The objective of the second phase was to refine the AtM Index framework to meet both the expectations of the industry and its stakeholders. Innovest contacted 21 healthcare companies and five pharmaceutical associations to discuss the results of the first phase and advance the list of Criteria, Indicators, Metrics and Weightings. The industry consultation allowed Innovest to gain expertise in planning, monitoring and measuring ATMs programs, to identify the type of data pharmaceutical companies can realistically disclose, and to formulate measurable benchmarks.

We had discussions with 13 companies and 36 company representatives (for the list of companies, please see Appendix 2).

*For additional information on the second phase, please see the Industry Engagement Report published in September 2007.*



## THIRD STEP

### FINAL CONSULTATION OF STAKEHOLDERS AND THE INDUSTRY

The release of the second report in September 2007 opened a final consultation period for all stakeholders. Investors, NGOs, academia, consultants, government officials, industry bodies and pharmaceutical companies were invited to comment on the set of benchmarks developed after consultation with the industry and its stakeholders. We are extremely grateful to the following experts who gave their input:

#### THE INDUSTRY

EFPIA / Brian Ager

IFPMA / Dr. Harvey Bale

*Several companies' views were presented in the letter sent to Innovest by the IFPMA.*

ASTRAZENECA PLC / Matti Ojanen

BAYER SCHERING PHARMA AG / Denise Rennmann

BRISTOL MYERS SQUIBB / Sunil Patel

JOHNSON & JOHNSON / Patricia Molino, Karen Manson, Angela Culver

MERCK & CO / Jeffrey L. Sturchio, Maggie Kohn

NOVARTIS / Lee Wells

NOVO NORDISK / Susan Stormer

ROCHE HOLDING LTD / Ian Metcalfe

SANOFI-AVENTIS / Robert Sebbag

#### NGOs

OXFAM / Helena Vines Fiestas, Rohit Malpani

#### ACADEMICS

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CORPORATE SRI / Daniel E. Rosan

INDEPENDENT CONSULTANT / Robyn Scott

#### GOVERNMENTS

DUTCH MINISTRY OF HEALTH / Bart Wijnberg

The following pages present the set of Criteria, Indicators and Weightings, and document the main discussion points.



# A. Access to Medicines Management

Access to Medicines Management		
A1. Governance: The company has a governance system that includes direct board level responsibility and accountability for its ATMs strategy	20%	20%
A2. Policy and Disclosure: The company has a public global policy in place, in which it explains its rationale for ATMs, its contents and details its specific objectives	20%	
A3. Systems and Reporting: The company has a management system, including quantitative targets to implement and monitor its ATMs strategy	25%	
A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management	25%	
A5. The company has globally applicable ethical business practices and marketing policies that conform to appropriate standards	10%	

Pharmaceutical companies and their stakeholders were in large agreement with this criterion and stressed the relevance of a strong ATMs management system. The third consultation phase resulted in minor changes in the set of metrics.

Access to Medicines Management will account for 20% of the overall Index framework.

## KEY ISSUES FOR ACCESS TO MEDICINES MANAGEMENT

### A1. GOVERNANCE

**The company has a governance system that includes direct board level responsibility and accountability for its ATMs strategy.** Healthcare experts stressed that board level commitment and accountability were essential to implement effective solutions to improve ATMs. Metrics will include:

- Existence and disclosure of a committee or a member of the board or the executive board that has ATMs issues included in its mandate: this metric reflects the different board structures in Europe and in the US and will look at governance systems.
- External board positions that include ATMs initiatives: it was acknowledged that executives and directors may have other board positions relating to ATMs that may influence a company's ATMs strategy. This metric will explore the link between external activities and directorship. *This indicator will account for 20% of the overall criterion weighting.*

### A2. POLICY AND DISCLOSURE

**The company has a public global policy in place, in which it explains its rationale for ATMs, its contents and details its specific objectives.** There was a large agreement among company representatives and their stakeholders on the need to articulate the business case for ATMs. Disclosure of the rationale for ATMs along with a description of a company's unique business model and corporate culture are essential to illustrate commitment towards ATMs. For the discussion about evaluating different business models, please see p. 38-39. Metrics will include:

- Existence and disclosure of a global policy to ensure the long-term availability of a sustainable supply of drugs, including disclosure of geographical and organizational scope: the implementation of the ATMs strategy throughout a company's operations worldwide will be analyzed.



- Adherence to the Human Rights Guidelines for Pharmaceutical Companies in relation to ATMs: when the Guidelines are finalized, this metric will assess whether or not a company adheres to those principles.
- Evidence of policy endorsement at the board level: this metric will look at the evidence of board level oversight for ATMs policies. This could be done via a CEO statement posted on a company's website or in annual or sustainability reports.
- Disclosure of the rationale via case studies: this metric will focus on examples of programs that demonstrate the business case for ATMs.

*This indicator will account for 20% of the overall criterion weighting.*

### A3. SYSTEMS AND REPORTING

**The company has a management system, including quantitative targets, to implement, monitor and report on its ATMs strategy.** There was a large agreement among the industry and its stakeholders about the need to adopt sound management practices including goal setting, monitoring, auditing and reporting. Metrics will include:

- Existence and disclosure of quantitative targets and target attainment when a program is implemented solely by the company: this metric will look at the existence of targets for corporate policies and the progress towards those targets.
- Requirement that ATMs Public Private Partnerships have stated targets: there was a large agreement among company representatives and their stakeholders about the benefits of PPPs. Even though pharmaceutical companies should not be held accountable for the PPPs' target attainment, they can push for goal setting, which is viewed by the large majority of experts as a sound component of a management system.
- Disclosure of how the effectiveness of the system is measured: it is not the intention of this project to be prescriptive but rather to look at the mechanisms and controls in place to measure the effectiveness of ATMs programs.
- Existence of a public annual report on ATMs: company stakeholders stressed the need for regular reporting on ATMs issues.
- Existence of an external verification system: third-party verification is considered by company stakeholders as an effective means to enhance confidence in corporate statements and help build trust between companies and stakeholders.

*This indicator will account for 25% of the overall criterion weighting.*

### A4. STAKEHOLDER INPUT

**The company has a mechanism for stakeholder engagement which inputs into ATMs management.** Regular engagement with a wide group of stakeholders from developed and developing countries was viewed by the large majority of experts as crucial to formulating appropriate and effective ATMs programs. Metrics will mostly include qualitative data:

- Existence and disclosure of programs/channels which raise the awareness of employees on ATMs and allow feedback to be received: the way a company communicates with its employees will be analyzed.
- Disclosure of evidence that stakeholder feedback has been used to improve, develop and refine a company's ATMs strategy: this metric will look at how a company sets priorities among its stakeholders and how their input impacts the development of ATMs policies and programs.
- Range of major initiatives and policy debates to which the company contributed in the previous year: this metric intends to look at a company's participation in major conferences and debates on ATMs. Examples of major topics and interventions will be reviewed.

*This indicator will account for 25% of the overall criterion weighting.*



#### A5.

**The company has globally applicable ethical business practices and marketing policies that conform to appropriate standards.** Company representatives and their stakeholders stressed the relevance of business ethics and in particular ethical drug promotion and advertising. Metrics will include:

- Adherence to international codes on responsible business conduct (UN Global Compact and/or OECD Guidelines for Multinational Enterprises)
- Compliance and breaches of the IFPMA Code of Pharmaceutical Marketing Practices.
- Adherence to the WHO's Ethical Criteria for Medicinal Drug Promotion:  
this metric will look at the existence of a statement of compliance.
- Number and content of EMEA, US FDA Warning Letters for Advertising and Promotional violations.

We acknowledge that comprehensive data on possible violations may be difficult to collect in the first year of the Index. A complaint procedure exists for the IFPMA code, but a monitoring framework has not yet been developed for the WHO's Code. While there was a large agreement among the industry and its stakeholders that companies should adhere to the WHO's code, there is still a need for an enforcement mechanism. The indicator A5 is a good example of an objective the AtM Index project is willing to pursue, which consists of highlighting the bottlenecks in ATMs. Drawing attention to the lack of enforcement and reporting mechanisms may encourage action among stakeholders.

*This indicator will account for 10% of the overall criterion weighting.*



## B. Public Policy Influence & Advocacy

Public Policy Influence & Advocacy		
B1. The company has a position on public policy advocacy and transparency	5%	10%
B2. The company and subsidiaries disclose major public policy positions at regional, national and international levels related to the ATMs debate	20%	
B3. The company and subsidiaries actively advocate health reforms that foster ATMs and for policies that would result in improvements in public health	20%	
B4. The company annually discloses which individuals, patient associations, political parties, trade associations and academic departments it supports with which it might advocate on public policy positions and practices; at a regional, national and international level	40%	
B5. The company demonstrates a process of board approval of the approach to public policy advocacy, its transparency and reporting	15%	

Public Policy Influence & Advocacy is considered as the most aspirational criterion in the AtM Index framework. It intends to highlight two main aspects: the need for greater disclosure on public policy and advocacy and the consistency between a company's positions and its actual practices. The industry and its stakeholders conceded that data may be difficult to collect in the first instance, but more transparency would add great value to a company's ATMs approach. Greater transparency with respect to financial commitments can help countries and health advocates to prevent activities that may have a negative impact on public health. It also ensures that companies are accountable to their shareholders. The third consultation phase resulted in slight changes in the wording of B2 and in the set of metrics.

Public Policy Influence & Advocacy will account for 10% of the overall Index framework.

### KEY ISSUES FOR PUBLIC POLICY INFLUENCE & ADVOCACY

#### **B1. The company has a position on public policy advocacy and transparency.**

This indicator will look at the existence and disclosure of a commitment towards transparency in public policy influence and advocacy.

*This indicator will account for 5% of the overall criterion weighting.*

**B2. The company and subsidiaries disclose major public policy positions at regional, national and international levels related to the ATMs debate.** This indicator focuses on transparency and disclosure of public policy positions relating to ATMs. Metrics will include:

- Existence and disclosure of a position on major ATMs issues: this metric will explore the level of disclosure on intellectual property, product diversion, counterfeiting, registration, drug donations, public private partnership, pricing, philanthropy, manufacturing, supply chain, R&D and most importantly on data exclusivity.
- Disclosure of positions companies seek to promote within industry organizations: this metric will explore individual companies' input to industry associations.
- Disclosure of national perspectives by local subsidiaries.

*This indicator will account for 20% of the overall criterion weighting.*



**B3. The company and subsidiaries actively advocate health reforms that foster ATMs and for policies that would result in improvements in public health.** While B2 focuses on disclosure, this indicator will more closely look at the content and results of advocacy activities. While the industry considers advocacy for health reforms as an important social contribution for pharmaceutical companies, its stakeholders stressed the need for collaboration and coordination with the policies and the strategies of the respective Ministries of Health.

Metrics will include:

- Existence and disclosure of a commitment not to advocate for data exclusivity: data exclusivity was raised as an issue by company stakeholders and is often seen as a barrier to introducing generics. Data exclusivity refers to the protection of clinical test data that must be submitted to a regulatory agency to approve the safety and efficacy of a new drug. Even though the patent term (20 years) is often longer than the term of data exclusivity (5 years), the registration of drugs may end up being a very long process resulting in the term of data exclusivity exceeding the term of patent protection particularly in developing and least developed countries. In least developed countries, where companies commonly do not apply for patents, data exclusivity may delay the entry of generics. Finally when a country issues a compulsory license in case of a national emergency, patent protection will be overridden but not data exclusivity, which may again delay the entry of a generic.
- Advocacy of a range of policies and initiatives: this metric will explore the content of major companies' advocacy activities other than data exclusivity and the related influence on health reforms. Examples of advocacy activities will be reviewed.

*This indicator will account for 20% of the overall criterion weighting.*

**B4. The company annually discloses which individuals, patient associations, political parties, trade associations and academic departments it supports and with which it might advocate on public policy positions and practices at a regional, national and international level.** Company representatives judged the data collection too demanding and agreed to provide data on the financial supports to political parties, patient associations, trade associations and academic departments if they were legally required or had agreed to do so via trade association standards. The various positions asked for in B2 will be used in this indicator to assess the inconsistencies and the gaps between positions and practices. Metrics will include:

- Amount spent on federal lobbying activities in the US in current and past years.
- Amount spent on lobbying activities in the EU in current and past years.
- Amount spent on lobbying governments in developing and least developed countries in current and past years.
- Contributions to political organizations in the US, Canada and Australia in current and past years.
- Funding to patient groups, medical associations, and academic centers in the US and Europe: this metric is linked to ABPI requirements and will look at financial support and the percentage of overall funding to patient groups.
- Existence and disclosure of board seats at industry associations and advisory bodies: this metric will analyze the degree of involvement a company has in the formulation of positions taken by industry associations and advisory bodies (e.g. US Trade Representatives).
- Evidence of inconsistency between the company's positions (see B2) and its support to various groups: third-party sources including reports by the media and information from stakeholders will be used. As mentioned below in the "Collection of Company Data" section on page 46, the company will be provided a draft paper for the purpose of factual accuracy.

*This indicator will account for 40% of the overall criterion weighting.*

**B5. The company demonstrates a process of board approval of the approach to public policy advocacy, its transparency and reporting.** According to the Center for Political Accountability<sup>4</sup>, disclosing political contributions can alert directors to potential problems in management performance and the company's businesses that would otherwise be missed. Additionally disclosing the company's advocacy activities to the board can raise questions about whether these activities are consistent with the company's views and whether they could have negative consequences for the company. Accountability at the board level for American companies and at the executive board level for European companies was seen as key in this indicator. Metrics will include the evidence of a board or executive board approval process for advocacy activities and public policy positions.

*This indicator will account for 15% of the overall criterion weighting.*

<sup>4</sup> <http://www.politicalaccountability.net/>.



## C. Research & Development that Reflects both the Global Disease Burden and Neglected Diseases

R&D that reflects both the Global Disease Burden and Neglected Diseases		
C1. The company has a policy on R&D investment that reflects both the global disease burden and the neglected diseases	5%	20%
C2. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases	30%	
C3. The company with in-house investment in R&D into new treatments for neglected diseases provides evidence of partnership with groups with developing country health expertise, such as product development public-private partnerships, academic institutions and/or the World Health Organization	40%	
C3. The company with no in-house neglected diseases R&D investment, provides evidence of investment into such R&D conducted by others		
C4. The company shows temporal evidence that its research programs into both the global disease burden and neglected diseases consider research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups	25%	

Research & Development is seen by company representatives and their stakeholders as a major component of any ATMs strategy. Clarification on the disease focus has been added throughout the three consultation periods and changes in the Indicators, Metrics and Weightings are documented below (for a complete list of diseases, see Glossary). This criterion reflects the urgent need for R&D into new treatments for neglected diseases and into suitable formulations for existing treatments that reflect the global disease burden. While it is recognized that research programs into new treatments for the global disease burden will enable progress into unmet medical needs, a market also exists in the developed world that offers incentive for companies to invest in this field. The AtM Index aims to highlight the gaps and reflect the urgency of the situation. As stated previously, the very nature of the Index will allow for adjustments to be made should the situation evolve.

Research & Development that Reflects both the Global Disease Burden and Neglected Diseases will account for 20% of the overall Index framework.

### KEY ISSUES FOR RESEARCH & DEVELOPMENT THAT REFLECTS BOTH THE GLOBAL DISEASE BURDEN & NEGLECTED DISEASES

**C1. The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases.** Metrics will include:

- Existence and disclosure of a policy that considers investment into treatments for neglected diseases and into suitability for the global disease burden: this metric will explore a company's commitment and plans to invest in R&D to discover new treatments for neglected diseases and to find formulations of existing treatments that are appropriate to the developing world and that reflect the global disease burden.
- Compliance with the WHO Ethical Guidelines on clinical trials:



this metric will assess a company's compliance with international standards on clinical trials. *This indicator will account for 5% of the overall criterion weighting.*

**C2. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases.** Metrics will include:

- Existence of a dedicated neglected diseases division: having a department focused on R&D for neglected diseases is a sign of a company's commitment to investing in this field.
- Number of scientists dedicated to neglected diseases: even though we acknowledge that scientists may be involved in programs for neglected diseases as well as for other diseases, the number will give an indication of a company's desire to invest in neglected diseases.
- Number of compounds in the neglected diseases portfolio.
- Number of papers contributing to scientific debates on neglected diseases: this metric will analyze a company's willingness to share its knowledge and expertise on neglected diseases.

*This indicator will account for 30% of the overall criterion weighting. The weight will be reduced for companies without expertise in R&D for neglected diseases (for details on the methodology, please see p. 38).*

**C3. The company with in-house investment in R&D into new treatments for neglected diseases provides evidence of partnership with groups with developing country health expertise, such as product development public-private partnerships, academic institutions and/or the World Health Organization.** This indicator reflects the need for a partnership approach. The trend towards a new R&D model confirms the collaborative approach with companies moving from a vertical model, where all functions necessary to perform drug development exist within the business entity, to a horizontal model where the company has a core business model supported by external resources in partnership or on a contract basis. In addition, company stakeholders highlighted the benefits of Product Development Partnerships (PDPs) as opposed to in-house R&D. Companies without in-house investment will not score on this indicator but will score on the indicator below. Metrics will include:

- Evidence of R&D programmatic collaboration with groups with developing country health expertise (e.g. development of product profiles).
- Number of clinical trials involving collaboration with groups with developing country health expertise.

*This indicator will account for 40% of the overall criterion weighting.*

**C3. The company with no in-house neglected diseases R&D investment, provides evidence of investment into such R&D conducted by others.** Companies with in-house investment will not score on this indicator. Metrics will include:

- Evidence of consultation with organizations with a view to contributing to R&D: this metric will analyze a company's commitment to collaborating with external research institutes or other relevant organizations to enhance R&D into neglected diseases.
- Evidence of sharing of library compounds: this metric will explore the various instances when a company gave free access to its library compounds.
- Evidence of intellectual property rights given to research institutes: this practice is a sign of a company's commitment to enhancing R&D into neglected diseases.
- Evidence of participation on scientific advisory or management boards of external organizations conducting R&D into neglected diseases: this metric will look at how a company can use its scientific expertise to provide independent advice to research programs on neglected diseases.
- Evidence of provision of expertise to such organizations (e.g. chemistry and regulatory expertise, and staff sabbaticals): examples of knowledge transfer in the form of staff sabbaticals, regulatory knowledge and chemistry expertise will be analyzed.
- Evidence of provision of training to such organizations: examples of training courses will be reviewed.

*This indicator will account for 40% of the overall criterion weighting.*



**C4. The company shows temporal evidence that its research programs into both the global disease burden and neglected diseases consider research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups.** This indicator will explore investments in formulations that are appropriate to developing country health systems and are easy to use for patients. Metrics will include:

- Evidence of research programs on suitability (oral formulations, dosing intervals, length of treatments or requirement for cold chain).
- Evidence of clinical trials to support treatment indications aimed at children and people living in developing and least developed countries: this metric will analyze examples of clinical trials for particular patient groups including children and patients from developing and least developed countries.
- Number of approvals in the last year for compounds and formulations useful in developing world settings and for affected patient groups.

*This indicator will account for 25% of the overall criterion weighting.*



## D. Patents & Licensing

Patents & Licensing		
D1. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing and least developed countries	60%	10%
D2. The company publicly commits itself to respecting the right of developing and least developed countries to use the provisions in the TRIPS agreement	40%	

Intellectual property rights were the source of much debate among company representatives and their stakeholders. It is not the intention of this project to take a stance on this emotional and complex debate but rather to look at pathways that would enable companies to protect their innovation and people to get access to the treatments they need. While this criterion will not neglect patents and licensing for neglected diseases treatments, more weight will be given to the global disease burden to reflect the urgency of this matter. The third consultation phase resulted in slight changes in the wording of D2 and in the set of metrics.

Patents & Licensing will account for 10% of the overall Index framework.

### KEY ISSUES FOR PATENTS & LICENSING

**D1. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing and least developed countries.** Voluntary licensing is one pathway that companies and their stakeholders considered as a sound component of an ATMs approach. Metrics will include:

- Disclosure of terms of agreement (non exclusivity, royalty-free conditions, sourcing, manufacturing limits and exports): this metric will analyze the information on non exclusivity, royalty, supplier selection, manufacturing limits and exports.
- Number and type of collaborations with peers:  
this metric will explore the practices of coformulation or comarketing.
- Number of drugs and treatments produced by licensees:  
this metric will look at actual performance and measure the impact of voluntary licensing.

*This indicator will account for 60% of the overall criterion weighting.*

**D2. The company publicly commits itself to respecting the right of developing and least developed countries to use the provisions in the TRIPS agreement.** Metrics will explore:

- Involvement in country specific TRIPS flexibility use: this metric will explore if and how a company tries to influence country decisions with regard to TRIPS. It will rely on the WTO to decide if a country is abiding by the TRIPS agreement.
- Existence and disclosure of a commitment not to enforce patents in least developed countries: according to TRIPS, least developed countries have until 2016 to abide by the TRIPS agreement. This metric will look at a company patent policy in least developed countries.
- Existence and disclosure of a commitment not to extend patent duration for new indications for existing medicines that are not innovative: while this metric recognizes the need for patent protection for innovation, it attempts to prevent patent extension for tiny modifications of existing treatments. Information on the level of innovation will come from different sources including regulatory authorities and companies.

*This indicator will account for 40% of the overall criterion weighting.*



## E. Drug Manufacturing, Distribution and Capability Advancement

Drug Manufacturing, Distribution and Capability Advancement		
E1. The company demonstrates efforts to manufacture drugs to the highest quality standards	20%	15%
E2. The company enters into technology transfer agreements with local companies in developing and least developed countries	35%	
E3. The company undertakes external activities to support the monitoring of drugs that reflect both of the global disease burden and neglected diseases including participation in public private partnerships	15%	
E4. The company has mechanisms in place to help prevent product diversion and to address counterfeiting, in collaboration with states	20%	
E5. The company demonstrates efforts to provide ATMs to its employees and their relatives in developing and least developed countries	10%	

This criterion was added during the industry engagement phase to reflect how expertise in drug development, manufacturing, quality control, delivery and human resources management can foster ATMs capacity in developing and least developed countries. This section is distinct from philanthropy, as it focuses only on a company's core business activities. The third consultation phase resulted in slight changes in the wording of E3 and in the weightings.

Drug Manufacturing, Distribution and Capability Advancement will account for 15% of the overall Index framework.

### KEY ISSUES FOR DRUG MANUFACTURING, DISTRIBUTION AND CAPABILITY ADVANCEMENT

**E1. The company demonstrates efforts to manufacture drugs to the highest quality standards.** Drug quality was raised as an issue by all experts. There are concerns that quality standards may be lower in resource-poor countries and therefore pharmaceutical companies should not only abide by local regulations but make sure that their quality standards are consistent throughout their operations worldwide. Good manufacturing practices will help to prevent access delays related to manufacturing failures. Metrics will include:

- Existence and disclosure of a policy that considers inadequate infrastructure in developing and least developed countries: the content of a policy addressing the lack of appropriate infrastructures, resources and less stringent regulations in developing and least developed countries will be analyzed.
- Existence and disclosure of a policy on drug manufacture that is in line with the quality requirement of the FDA, the EMEA, the WHO or better, for use in developing and least developed countries.
- Evidence and type of violations and disclosure of fines: the degree of compliance with the standards defined by the FDA, the EMEA or the WHO will be assessed.

*This indicator will account for 20% of the overall criterion weighting.*



**E2. The company enters into technology transfer agreements with local companies in developing and least developed countries.** This indicator was included following the industry consultation phase. Even though key stakeholders involved in the first phase of the report indicated that there was limited evidence that technology transfer agreements would actually have a positive impact on ATMs, companies suggested that they were relevant practices to improve manufacturing capability in the developing world. The final consultation period did confirm the inclusion of this indicator. It was decided to include technology transfer agreements to Drug Manufacturing, Distribution and Capability Advancement and not to Patents & Licensing, as these programs also exist for drugs that are off-patents. In addition, voluntary licensing agreements are not necessarily combined with transfer of technology, equipment and expertise. Metrics will include:

- Existence and disclosure of mechanisms for sharing of manufacturing skills in developing and least developed countries: the way companies deal with the transfer of skills, expertise, equipment and technology to manufacture drugs will be analyzed.
- Existence and disclosure of quality control mechanisms in developing and least developed countries: as raised in E1, drug quality is a concern, and this metric will focus on the processes in place (training, monitoring and audits) to ensure local manufacturers produce drugs to the highest quality standards.
- Existence and disclosure of support provided for registration in developing and least developed countries: registration requires expertise in data collection and experience in dealing with national drug regulatory authorities. If and how companies share their experience in filing for registration will be measured.
- Number of drugs and treatments produced: this metric will focus on the outcomes of a technology transfer agreement and will help determine the net impact of such initiative.

*This indicator will account for 35% of the overall criterion weighting.*

**E3. The company undertakes external activities to support the monitoring of drugs that reflect both the global disease burden and neglected diseases including participation in public private partnerships.** This indicator will look at the existence and disclosure of support to implement a pharmacovigilance system in developing and least developed countries. By providing advice on how to best collect, monitor and evaluate information from healthcare providers and patients based on their experience in the developed world, a company can contribute to the improvement of healthcare infrastructures in least developed and developing countries.

*This indicator will account for 15% of the overall criterion weighting.*

**E4. The company has mechanisms in place to help prevent product diversion and to address counterfeiting, in collaboration with states.** Product diversion refers to products sold by a manufacturer that are distributed into markets other than originally intended in violation of a contract or a regulation. Such product diversion means that medicines will not reach the target population and that the company will suffer reduced sales in high-income countries. In addition, parallel trade increases the risk of counterfeiting, which endangers patient safety. There was a large agreement among company representatives and their stakeholders about the necessary collaboration between a company, its peers, its suppliers and the local authorities to improve the distribution network and tackle both product diversion and counterfeiting. Metrics will include:

- Existence and disclosure of a corporate policy on diversion and counterfeiting: a company's commitment to work with all stakeholders to minimize the risks of diversion and counterfeiting in the form of incident reporting and investigation will be assessed.
- Existence and disclosure of processes in place to prevent diversion and counterfeiting: a company can develop different mechanisms to address diversion and counterfeiting such as supply chain management, oversight on the ground and monitoring of sales organizations. This metric will analyze examples of processes in place.
- Evidence of cooperation with states and peers on anti-counterfeiting initiatives: examples of collaboration programs (e.g. training of officials) will be analyzed.
- Existence and disclosure of a policy on primary, authorized distributors: this metric will analyze the distributor selection process and any audit system.
- Existence and disclosure of examples of legal strategies to deter counterfeiting: examples of initiatives undertaken by companies to push for more stringent regulations and their enforcement will be analyzed.



It is not the intention of this project to request companies to disclose all initiatives and programs but rather to demonstrate via examples the collaborative projects in place to address product diversion and counterfeiting.

*This indicator will account for 20% of the overall criterion weighting.*

**E5. The company demonstrates efforts to provide ATMs to its employees and their relatives in developing and least developed countries.** Companies that have operations in developing and least developed countries contribute to some extent to ATMs through the benefits they offer to their employees and their relatives. This indicator will focus on treatments, medical exams, prevention programs and other health services offered by companies in developing and least developed countries. Metrics will include the percentage of employees in developing and least developed countries covered by healthcare benefits and the type of benefits offered.

*This indicator will account for 10% of the overall criterion weighting.*



## F. Equitable Pricing

Equitable Pricing		
F1. The company can demonstrate efforts to register treatments that reflect both the global disease burden and neglected diseases in developing and least developed countries	20%	15%
F2. The company has a policy to facilitate ATMs in developing and least developed countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews	50%	
F3. The company demonstrates that its discount schemes place the minimum administrative burden on the beneficiary health system	10%	
F4. The company has a policy for the very poorest in countries with no public healthcare provision	20%	

There was general agreement among company representatives and their stakeholders on the relevance of equitable pricing policies. While pricing issues for neglected diseases will be reviewed, more weight will be given to the global disease burden to reflect the urgency of this matter. In the previous section on Patents & Licensing we raised the idea of pathways. Equitable pricing is another pathway to maintain patent protection while ensuring access to treatments to those in need. The third consultation phase resulted in minor changes in the set of metrics.

Equitable pricing will account for 15% of the overall Index framework.

### KEY ISSUES FOR EQUITABLE PRICING

**F1. The company can demonstrate efforts to register treatments that reflect both the global disease burden and neglected diseases in developing and least developed countries.**

Metrics will include:

- Disclosure of the list of countries where marketing applications filed, not heard from and approved for major products: this metric will analyze the registration status of a number of drugs produced by each of the companies in the Index that reflect both the global disease burden and neglected diseases. Disclosure of registered drugs and the current status of applications in developing and least developed countries can be used to illustrate a company's efforts to improve access and also highlight any bottlenecks in state registration systems. We plan to use the WHO's data on registration and complement it by knowledge from NGOs and companies.
- Evidence and disclosure of rebranding: a company may use registration as an opportunity to rebrand drugs. Such a move will most likely help to prevent product diversion and can also reduce the risks of reference pricing, especially where there is a growing concern in developed nations about perceived unfair discounts in the developing world.

*This indicator will account for 20% of the overall criterion weighting.*



**F2. The company has a policy to facilitate ATMs in developing and least developed countries through pricing mechanisms which include reporting on scope, pricing levels and pricing reviews.** It was acknowledged that more research needed to be done in this area to provide guidance for companies on the most effective methods of pricing. Certainly, pharmaceutical companies do not have full control over pricing issues, as local governments may charge important markups on drugs, but greater transparency by pharmaceutical companies regarding their pricing mechanisms worldwide would be appreciated by stakeholders. Metrics will look at the impact of without-profit, not-for-profit and discounted pricing programs over a number of years.

- Evidence and disclosure of pricing mechanisms, their implementation and impact.
- Evidence and disclosure of the rationale behind pricing policies.
- Number of countries where a company does sell drugs at cost, as a percentage of all countries where a drug is received.
- Number of countries where a company does provide a discount, as a percentage of all countries where a drug is received.
- Decrease in drug prices over the year, as a percentage of the total original cost.
- Number of drugs sold or shipped at cost in current and past years: this metric will be used to measure progress. If data is only available for a one-year period the company would not score or score neutrally on this metric.
- Number of drugs sold or shipped at a discounted price in current and past years.

*This indicator will account for 50% of the overall criterion weighting.*

**F3. The company demonstrates that its discount schemes place the minimum administrative burden on the beneficiary health system.** The terms of equitable pricing programs such as the existence of intermediaries or the adoption of a particular currency for trade may hinder access programs. This indicator will look at the safeguards in place to limit administrative barriers. Metrics will look at the existence and the content of measures to facilitate transactions between a drug maker and the beneficiaries of equitable pricing programs.

*This indicator will account for 10% of the overall criterion weighting.*

**F4. The company has a policy for the very poorest in countries with no public healthcare provision.** At this stage, the AtM Index focuses mostly on access issues relevant in developing and least developed countries. It is the intention of the AtM Index project to broaden the scope of the Index going forward and include the numerous efforts done by pharmaceutical companies to address ATMs in the developed world. This indicator is the first move towards this goal as it reflects the need for assistance for patients in developed countries with no public healthcare system. Poor people in developed countries would not necessarily have greater capacity to afford expensive treatments than poor people in developing and least developed countries. This indicator reflects the relevance for pharmaceutical companies to implement equitable pricing programs for poor people in developed nations. Metric will include:

- Existence and disclosure of a public policy.
- Number of treatments and patients benefiting from patient assistance programs (PAPs) in the US and other relevant countries in current and past years: a company's efforts to increase the number of patients reached by its programs over the year will be measured.
- Disclosure of eligibility rules: full transparency around eligibility was seen by the majority of experts as essential to measure the net impact of PAPs.
- Additional programs to help the poorest: companies may adopt various approaches to improve ATMs in developed countries, such as support of government-subsidized insurance or microinsurance programs.

*This indicator will account for 20% of the overall criterion weighting.*



## G. Drug Donations

Drug Donations		
G1. The company has a policy that fully conforms to the WHO's Guidelines for Drug Donations	60%	6%
G2. The company discloses the absolute volume of its drug donations and, to the extent possible, the number of treatments approved for patient use per year	40%	

Drug donations were the source of much debate among company representatives and their stakeholders with concerns about the relevance of such a practice in any ATMs strategy. Drug donations can certainly make a major contribution in emergency situations and assist in finite disease eradication programs; but concerns were raised that they may not be ultimately sustainable and may create distortion on the market. The criterion on Drug Donations is not included in Philanthropic Activities, as a distinction was made between companies' core business (i.e. drug manufacturing and distribution) and philanthropic activities (i.e. improvement of healthcare infrastructures, educational programs) that are run in collaboration with governments. It was also acknowledged that donation programs would have a greater impact if they were conducted in close collaboration with local authorities and NGOs. The third consultation phase resulted in slight changes in the set of metrics.

Drug Donations will account for 6% of the overall Index weighting.

### KEY ISSUES FOR DRUG DONATIONS

**G1. The company has a policy that fully conforms to the WHO's Guidelines for Drug Donations.** The WHO's Guidelines for Drug Donations require that donated drugs are of good quality and that they have a shelf life of more than a year. Additionally, the guidelines are intended to ensure the relevance of drug donations to the country context and require that donations are announced and needed by the recipient country. There was a large agreement between companies and their stakeholders on the comprehensive nature of the WHO's Guidelines. Metrics will include:

- Existence and disclosure of a policy that considers the sustainability of each donation program: this metric will look at the relevance and the sustainability of drug donation programs and in particular the rationale for donating drugs in emergency situation or for making an open-ended commitment to donate drugs where there are no other alternatives.
- Number and type of breaches per year: evidence of violations of the WHO's Guidelines will be analyzed.

*This indicator will account for 30% of the overall criterion weighting.*

**G2. The company discloses the absolute volume of its drug donations and, to the extent possible, the number of treatments approved for patient use per year.** Data collection was raised as an issue in this indicator. While stakeholders claimed that the monetary value of drug donations may not be relevant, company representatives voiced concerns that the exact number of patients treated would be both very difficult to measure and resource-intensive on a consolidated basis. It was acknowledged that more transparency was needed on the value of drug donations and on estimations of the number of patients treated in some programs.

Metrics will include quantitative data that will be analyzed over a number of years:

- Number of drug doses donated in current and past years.
- Total value of drug donations as a percentage of pre-tax profit.
- Total value of drug donations as a percentage of special tax allowances: company stakeholders suggested this metric be added to compare drug donations with special tax advantages in developing and least developed countries.

*This indicator will account for 20% of the overall criterion weighting.*



# H. Philanthropic Activities

Philanthropic Activities		
H1. The company has philanthropic programs related to ATMs not covered by any of the other criteria	100%	4%

Lack of healthcare infrastructures and resources were raised as barriers to access in poor countries with discussions focusing on where to draw the line between states' and companies' responsibility. It was acknowledged that governments have the primary responsibility for developing their healthcare systems, and that pharmaceutical companies would be in a good position to collaborate with them to reduce health disparities. Once again the industry and its stakeholders stressed the relevance of a partnership approach for philanthropic activities. Following the third consultation phase, this criterion remains unchanged.

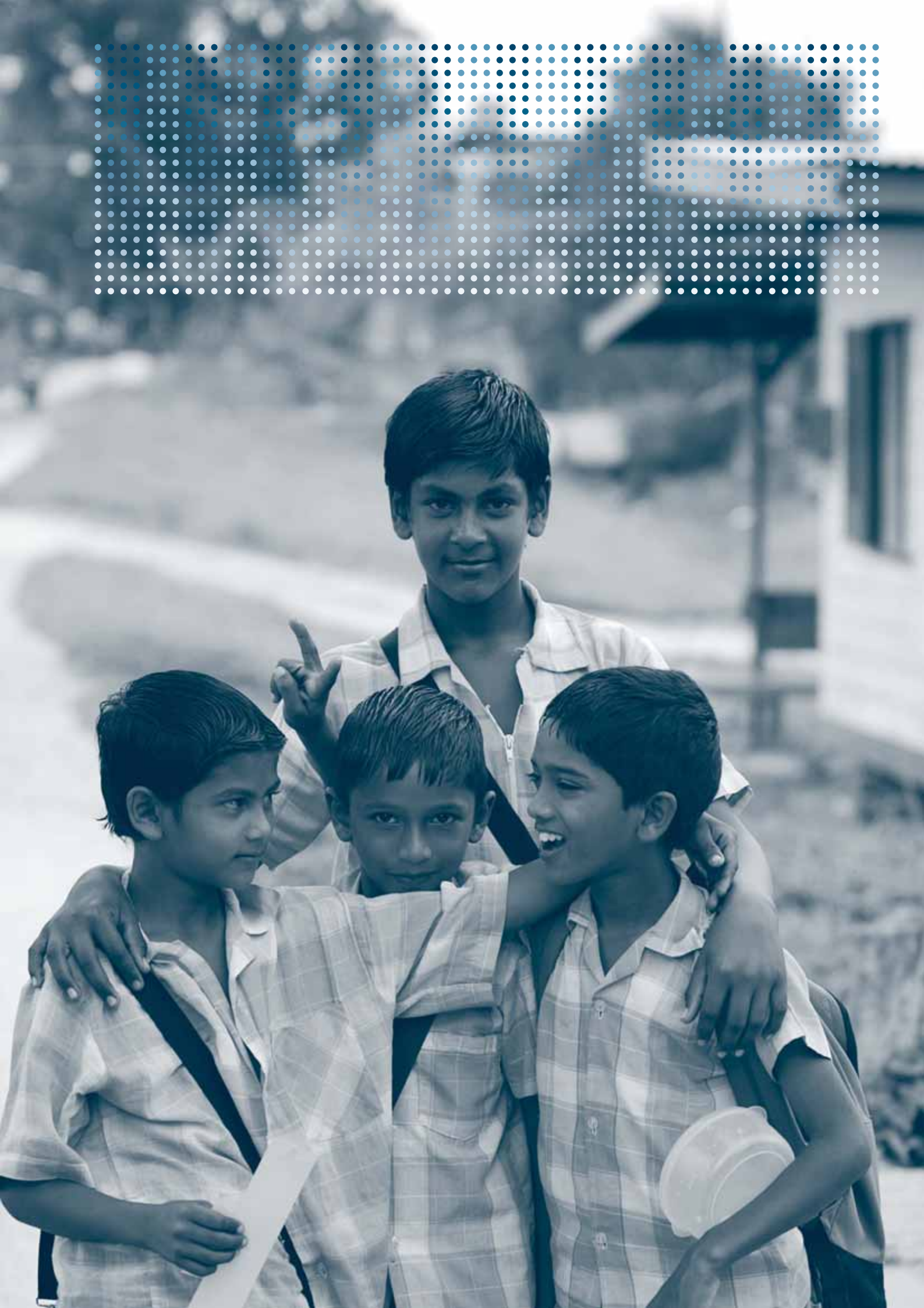
Philanthropic activities will account for 4% of the overall Index weighting.

## KEY ISSUES FOR PHILANTHROPIC ACTIVITIES

**H1. The company has philanthropic programs related to ATMs not covered by any of the other criteria.** It was acknowledged by the large majority of experts that current company programs do have a positive impact on ATMs. Metrics will include quantitative data that will be analyzed over a number of years:

- Community donation as a percentage of pre-tax profit excluding donations in current and past years.
- Breakdown of cash donations as a percentage of pre-tax profit in current and past years.
- Existence and disclosure of support given to local NGOs in current and past years: collaboration with local NGOs was seen as an important aspect of philanthropic activities.
- Number of health professionals trained in current and past years.
- Number of hospitals or healthcare facilities built or supported in current and past years.

*This indicator will account for 100% of the overall criterion weighting.*





# The Access to Medicine Index Framework

The following chart summarizes each of the Criteria, Indicators, Metrics and Weightings that have been proposed to constitute the Access to Medicine Index framework.

Criteria	Weight	Indicator
A. Access to Medicine Management	20%	A1. Governance: The company has a governance system that includes direct board level responsibility and accountability for its ATMs strategy.
		A2. Policy and Disclosure: The company has a public global policy in place, in which it explains its rationale for ATMs, its contents and details its specific objectives.
		A3. Systems and Reporting: The company has a management system, including quantitative targets, to implement, monitor and report on its ATMs strategy.
		A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management.
		A5. The company has globally applicable ethical business practices and marketing policies that conform to appropriate standards.

Criteria	Weight	Indicator
B. Public Policy Influence & Advocacy	10%	B1. The company has a position on public policy advocacy and transparency.
		B2. The company and subsidiaries disclose major public policy positions at regional, national and international levels related to the ATMs debate.



Weight	Metrics
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a committee or a member of the board or the executive board that has ATMs issues included in its mandate.</li> <li>• External board positions that include ATMs initiatives.</li> </ul>
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a global policy to ensure the long-term availability of a sustainable supply of drugs, including disclosure of geographical and organizational scope.</li> <li>• Adherence to the Human Rights Guidelines for Pharmaceutical Companies in relation to ATMs.</li> <li>• Evidence of policy endorsement at the board level.</li> <li>• Disclosure of the rationale via case studies.</li> </ul>
25%	<ul style="list-style-type: none"> <li>• Existence and disclosure of quantitative targets and target attainment when a program is implemented solely by the company.</li> <li>• Requirement that ATMs Public-Private Partnerships have stated targets.</li> <li>• Disclosure of how the effectiveness of the system is measured.</li> <li>• Existence of a public annual report on ATMs.</li> <li>• Existence of an external verification system.</li> </ul>
25%	<ul style="list-style-type: none"> <li>• Existence and disclosure of programs/channels which raise the awareness of employees on ATMs and allow feedback to be received.</li> <li>• Disclosure of evidence that stakeholder feedback has been used to improve, develop and refine a company's ATMs strategy.</li> <li>• Range of major initiatives and policy debates to which the company contributed in the previous year.</li> </ul>
10%	<ul style="list-style-type: none"> <li>• Adherence to international codes on responsible business conduct (UN Global Compact and/or OECD Guidelines for Multinational Enterprises).</li> <li>• Compliance and breaches of the IFPMA Code of Pharmaceutical Marketing Practices.</li> <li>• Adherence to the WHO's Ethical Criteria for Medicinal Drug Promotion.</li> <li>• Number and content of EMEA, US FDA Warning Letters for Advertising and Promotional Violations.</li> </ul>

The Access to Medicine Index framework  
A. Access to Medicine Management

Weight	Metrics
5%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a commitment towards transparency in public policy advocacy.</li> </ul>
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a position on major ATMs issues.</li> <li>• Disclosure of positions companies seek to promote within industry organizations.</li> <li>• Disclosure of national perspectives by local subsidiaries.</li> </ul>

The Access to Medicine Index framework  
B. Public Policy Influence & Advocacy



	B3. The company and subsidiaries actively advocate health reforms that foster ATMs and policies that would result in improvements in public health.
	B4. The company annually discloses which individuals, patient associations, political parties, trade associations and academic departments it supports with which it might advocate on public policy positions and practices; at a regional, national and international level.
	B5. The company demonstrates a process of board approval of the approach to public policy advocacy, its transparency and reporting.

Criteria	Weight	Indicator
C. Research & Development that Reflects both the Global Disease Burden and Neglected Diseases	20%	C1. The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases.
		C2. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases.
		C3. The company with in-house investment in R&D into new treatments for neglected diseases provides evidence of partnership with groups with developing-country health expertise, such as product development public-private partnerships, academic institutions and/or the World Health Organization.
		C3. The company with no in-house neglected diseases R&D investment provides evidence of investment into such R&D conducted by others.
		C4. The company shows temporal evidence that its research programs into both the global disease burden and neglected diseases consider research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups.



20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a commitment not to advocate for data exclusivity.</li> <li>• Advocacy of a range of policies and initiatives.</li> </ul>
40%	<ul style="list-style-type: none"> <li>• Amount spent on federal lobbying activities in the US in current and past years.</li> <li>• Amount spent on lobbying activities in the EU in current and past years.</li> <li>• Amount spent on lobbying governments in developing and least developed countries in current and past years.</li> <li>• Contributions to political organizations in the US, Canada and Australia in current and past years.</li> <li>• Funding to patient groups, medical associations, and academic centers in the US and Europe.</li> <li>• Existence and disclosure of board seats at industry associations and advisory bodies.</li> <li>• Evidence of inconsistency between the company's positions (see B2) and its support to various groups.</li> </ul>
15%	<ul style="list-style-type: none"> <li>• Evidence of a board or executive board approval process for advocacy activities and public policy positions.</li> </ul>

Weight	Metrics
5%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a policy that considers investment into treatments for neglected diseases and into suitability for the global disease burden.</li> <li>• Compliance with the WHO Ethical Guidelines on clinical trials.</li> </ul>
30%	<ul style="list-style-type: none"> <li>• Existence of a dedicated neglected diseases division.</li> <li>• Number of scientists dedicated to neglected diseases.</li> <li>• Number of compounds in the neglected diseases portfolio.</li> <li>• Number of papers contributing to scientific debates on neglected diseases.</li> </ul>
40%	<ul style="list-style-type: none"> <li>• Evidence of R&amp;D programmatic collaboration with groups with developing-country health expertise (e.g. development of product profiles).</li> <li>• Number of clinical trials involving collaboration with groups with developing-country health expertise.</li> </ul>
40%	<ul style="list-style-type: none"> <li>• Evidence of consultation with organizations with a view to contributing to R&amp;D.</li> <li>• Evidence of sharing of library compounds.</li> <li>• Evidence of IP rights given to research institutes.</li> <li>• Evidence of participation on scientific advisory or management boards of external organizations conducting neglected disease R&amp;D.</li> <li>• Evidence of provision of expertise to such organizations (e.g. chemistry and regulatory expertise, and staff sabbaticals).</li> <li>• Evidence of provision of training to such organizations.</li> </ul>
25%	<ul style="list-style-type: none"> <li>• Evidence of research programs on suitability (oral formulations, dosing intervals, length of treatments, and requirement for cold chain).</li> <li>• Evidence of clinical trials to support treatment indications aimed at children and people living in developing and least developed countries.</li> <li>• Number of approvals in the last year for compounds and formulations useful in developing world settings and for affected patient groups.</li> </ul>

The Access to Medicine Index framework  
**C. Research & Development that Reflects both the Global Disease Burden and Neglected Diseases**



Criteria	Weight	Indicator
D. Patents & Licensing	10%	D1. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing countries.
		D2. The company publicly commits itself to respecting the right of developing countries to use the provisions in the TRIPS agreement.

Criteria	Weight	Indicator
E. Drug Manufacturing, Distribution and Capability Advancement	15%	E1. The company demonstrates efforts to manufacture drugs to the highest quality standards.
		E2. The company enters into technology transfer agreements with local companies in developing and least developed countries.
		E3. The company undertakes external activities to support the monitoring of drugs that reflect both the global disease burden and neglected diseases including participation in public private partnerships.
		E4. The company has mechanisms in place to help prevent product diversion and to address counterfeiting, in collaboration with states.
		E5. The company demonstrates efforts to provide ATMs to its employees and their relatives in developing and least developed countries.



Weight	Metrics
60%	<ul style="list-style-type: none"> <li>• Disclosure of terms of agreement (non exclusivity, royalty-free conditions, sourcing, manufacturing limits and exports).</li> <li>• Number and type of collaborations with peers.</li> <li>• Number of drugs and treatments produced by licensees.</li> </ul>
40%	<ul style="list-style-type: none"> <li>• Involvement in country-specific TRIPS flexibility use.</li> <li>• Existence and disclosure of a commitment not to enforce patents in least developed countries.</li> <li>• Existence and disclosure of a commitment not to extend patent duration for new indications for existing medicines that are not innovative.</li> </ul>

The Access to Medicine Index framework  
D. Patents & Licensing

Weight	Metrics
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a policy that considers the inadequate infrastructure in developing and least developed countries.</li> <li>• Existence and disclosure of a policy on drug manufacture that is in line with the quality requirement of the FDA, the EMEA, the WHO or better, for use in developing and least developed countries.</li> <li>• Evidence and type of violations and disclosure of fines.</li> </ul>
35%	<ul style="list-style-type: none"> <li>• Existence and disclosure of mechanisms for sharing of manufacturing skills in developing and least developed countries.</li> <li>• Existence and disclosure of quality control mechanisms in developing and least developed countries.</li> <li>• Existence and disclosure of support provided for registration in developing and least developed countries.</li> <li>• Number of drugs and treatments produced.</li> </ul>
15%	<ul style="list-style-type: none"> <li>• Existence and disclosure of support to implement a pharmacovigilance system in developing and least developed countries.</li> </ul>
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a corporate policy on diversion and counterfeiting.</li> <li>• Existence and disclosure of processes in place to prevent diversion and counterfeiting.</li> <li>• Evidence of cooperation with states and peers on anti-counterfeiting initiatives.</li> <li>• Existence and disclosure of a policy on primary, authorized distributors.</li> <li>• Existence and disclosure of examples of legal strategies to deter counterfeiting.</li> </ul>
10%	<ul style="list-style-type: none"> <li>• Percentage of employees in developing and least developed countries covered by healthcare benefits.</li> <li>• Type of benefits offered.</li> </ul>

The Access to Medicine Index framework  
E. Drug Manufacturing, Distribution and Capability Advancement



Criteria	Weight	Indicator
F. Equitable Pricing	15%	F1. The company can demonstrate efforts to register treatments that reflect both the global disease burden and neglected diseases in developing and least developed countries.
		F2. The company has a policy to facilitate ATMs in developing and least developed countries through pricing mechanisms which include reporting on scope, pricing levels and pricing reviews.
		F3. The company demonstrates that its discount schemes place the minimum administrative burden on the beneficiary health system.
		F4. The company has a policy for the very poorest in countries with no public healthcare provision.

Criteria	Weight	Indicator
G. Drug Donations	6%	G1. The company has a policy that fully conforms to the WHO's Guidelines for Drug Donations.
		G2. The company discloses the absolute volume of its drug donations and, to the extent possible, the number of treatments approved for patient use per year.

Criteria	Weight	Indicator
H. Philanthropic Activities	4%	H1. The company has philanthropic programs related to ATMs not covered by any of the other criteria.



Weight	Metrics
20%	<ul style="list-style-type: none"> <li>• Disclosure of the list of countries where marketing applications filed, not heard from and approved for major products.</li> <li>• Evidence and disclosure of rebranding.</li> </ul>
50%	<ul style="list-style-type: none"> <li>• Evidence and disclosure of pricing mechanisms, their implementation and impact.</li> <li>• Evidence and disclosure of the rationale behind pricing policies.</li> <li>• Number of countries where a company does sell drugs at cost, as a percentage of all countries where a drug is received.</li> <li>• Number of countries where a company does provide a discount, as a percentage of all countries where a drug is received.</li> <li>• Decrease in drug prices over the year, as a percentage of the total original cost.</li> <li>• Number of drugs sold or shipped at cost in current and past years.</li> <li>• Number of drugs sold or shipped at a discounted price in current and past years.</li> </ul>
10%	<ul style="list-style-type: none"> <li>• Existence and disclosure of programs to facilitate transactions between the company and the beneficiaries of equitable pricing programs.</li> </ul>
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a public policy.</li> <li>• Number of treatments and patients benefiting from patient assistance programs (PAPs) in the US and other relevant countries in current and past years.</li> <li>• Disclosure of eligibility rules.</li> <li>• Additional programs to help the poorest.</li> </ul>

The Access to Medicine Index framework  
F. Equitable Pricing

Weight	Metrics
60%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a policy that considers the sustainability of each donation program.</li> <li>• Number and type of breaches per year.</li> </ul>
40%	<ul style="list-style-type: none"> <li>• Number of drug doses donated in current and past years.</li> <li>• Total value of drug donations as a percentage of pre-tax profit.</li> <li>• Total value of drug donations as a percentage of special tax allowances.</li> </ul>

The Access to Medicine Index framework  
G. Drug Donations

Weight	Metrics
100%	<ul style="list-style-type: none"> <li>• Community donation as a percentage of pre-tax profit excluding donations in current and past years.</li> <li>• Breakdown of cash donations as a percentage of pre-tax profit in current and past years.</li> <li>• Existence and disclosure of support given to local NGOs in current and past years.</li> <li>• Number of health professionals trained (in current and past years).</li> <li>• Number of hospitals or healthcare facilities built or supported (in current and past years).</li> </ul>

The Access to Medicine Index framework  
H. Philanthropic Activities



# Next Steps in AtM Index Development

## DIFFERING BUSINESS MODELS

During all three consultation periods the variety of business models within the healthcare industry was regarded as a key challenge to objectively assess company performance with regard to ATMs.

Innovest will draw on its experience as a globally recognized investment research firm with specialized expertise in analyzing all healthcare sectors, to develop an objective evaluation system. A detailed analysis of a company's business model (disease focus and product pipeline) will be conducted at the outset, which will help to identify what can realistically be expected from a company with regards to the eight criteria developed by the industry and its stakeholders.

Below are a few examples to illustrate the methodology:

- **Generic versus originator companies:** it is not the intention of the AtM Index project to penalize generic companies with no or limited R&D capability. The criterion "R&D that Reflects both the Global Disease Burden and Neglected Diseases" would therefore be zero weighted for generic companies. The weighting from the R&D section would then be distributed across the seven other criteria.
- **Lack of expertise in R&D for neglected diseases:** the indicator C2 "The company provides evidence of in-house investment in R&D into new treatments for neglected diseases" would be weighted 15% for companies without expertise in R&D for neglected diseases instead of 30% for companies with expertise in R&D for neglected diseases. It is not the intention to penalize companies without expertise in R&D for neglected diseases but to give credit to companies that have in-house investment in R&D into new treatments for neglected diseases. In the case of companies without expertise, the remaining 15% weight of the indicator C2 would be distributed across the three other indicators.

Essentially, although companies would be scored relative to one another, due to the diverse set of business practices within the sector, each company's business practices would be assessed on an absolute basis.

## COLLECTION OF COMPANY DATA

To begin the benchmarking process Innovest will obtain data from the following sources:

- **Corporate documents:** annual reports, environmental and social reports, securities filings, 10k and other, websites, etc.
- **Government data:** publications, databases and interviews with governmental officials, e.g. the Center for Responsive Politics (Public Policy Influence & Advocacy), the US National Institutes of Health (R&D and Clinical Trials), FDA (drug quality and promotion), EMEA, WHO (Registration), WTO (Compliance with TRIPS), DFID (Meta).
- **On-line news databases:** Factiva.
- **Industry sources:** pharmaceutical industry publications and reports, eg. IFPMA, ABPI, PhRMA, EFPIA, NEFARMA, LEEM. Trade journals, e.g. BioExecutive, PharmaFocus, Pharmaceutical Executive, Pharmatimes.



- **NGOs and non-profit organizations:** reports and interviews with organizations familiar with the companies' operations and any controversy they may have caused, or could potentially cause (e.g. Oxfam, MSF, SOMO, Healthy Skepticism, Tax Payers Against Fraud Educational Fund)
- **Other third-party sources:** reports and interviews with the stakeholders we consulted during the development of the Index framework including investors, consultants and academics.
- **Company executives:** It is not the intention to request that companies collect the data for all metrics, as this may be too burdensome. Only specific information will be sought from company representatives where there are gaps in data or inconsistencies among the above mentioned sources. Companies will be provided with a draft analysis prior to publication of the Index for the purpose of factual accuracy.

## ANNUAL REVIEW

It is the intention that the AtM Index will continue to evolve over a number of years, cementing standards in the early years as debate and research evolves. The Access to Medicine Foundation and Innovest will continue to work in partnership to review the Index on a yearly basis; amending and editing criteria, indicators, metrics and weightings based on new research studies conducted on the subject, as well as through monitoring of expert discussions at regional, national and international levels. An annual questionnaire will be sent to a wide group of experts to provide further insight into developing issues associated with improving ATMs. A Technical Advisory Committee made of industry representatives and key stakeholders with a wide range of expertise will then be asked for recommendations on how to best amend the AtM Index framework to reflect the current debate around ATMs and to meet the expectations of both the industry and its stakeholders. Company performance will be reassessed considering the latest best practices and progress made to enhance ATMs annually.

## CHALLENGES GOING FORWARD

The Access to Medicine Foundation, together with Innovest continues to explore a number of challenges prior to the final disclosure of the AtM Index. These challenges include:

- Discussions about the size and makeup of the final AtM Index. The formal criteria for company inclusion will likely follow turnover or market capitalization, with constituents taken from a number of formal sectors under the umbrella term of the Healthcare Sector including pharmaceutical (generic and originator), biotechnology and medical equipment and supplies. We recognize the impact and potential impact generic companies can have in improving ATMs, and has therefore attempted to formulate indicators that are relevant to all companies. It is important that an assessment can be made of the industry as a whole, incorporating a plethora of differing business models. The first year will see a ranking of 20 companies, but the list of companies may increase going forward.
- Refining and disclosing a rigid scoring system that is likely to include both absolute and relative performance assessment. This will occur as the preliminary research is conducted on companies.



# Appendix 1

The following IFPMA member review and comments on the “AtM Index Industry Engagement Second Interim Report” dated 10 October, 2007 was received by Innovest (p. 41).

# Appendix 2

During the industry engagement phase we received responses from a total of 13 companies from the potential list of 21 listed below.

## ABBOTT LABORATORIES INC

*14 June, 2007, Innovest Office, New York.*

## ASTRAZENECA PLC

*Contributed to the IFPMA response.*

## BAXTER INTERNATIONAL

*16 and 26 July, 2007, written response and conference call.*

## BAYER AG

*20 June, 2007, conference call.*

## BRISTOL MYERS SQUIBB COMPANY

*The company was unable to provide feedback within the allotted time frame.*

## CIPLA

*The company did not reply to numerous communications.*

## ELI LILLY & COMPANY

*16 July, 2007, conference call.*

## GENZYME

*The company was unable to provide feedback within the allotted time frame.*

## GILEAD SCIENCES

*The company was unable to provide feedback within the allotted time frame.*

## GLAXOSMITHKLINE PLC

*Contributed to the IFPMA response.*

## JOHNSON & JOHNSON

*18 June, 2007, J&J Head Office, New Brunswick, New Jersey.*

## MERCK & CO INC

*21 June, 2007, Merck Head Office, Whitehouse Station, New Jersey, USA.*

## MERCK KGAA

*16 August, 2007, conference call.*

## NOVARTIS AG

*31 July, 2007, Novartis Head Office, Basel, Switzerland.*

## NOVO NORDISK

*26 June, 2007, Innovest Office, Paris. France.*

## PFIZER INC

*Contributed to the IFPMA response.*

## RANBAXY LABORATORIES LTD

*The company did not reply to numerous communications.*

## ROCHE HOLDING LTD

*25 June, 2007, Roche Head Office, Basel, Switzerland.*

## SANOFI-AVENTIS

*The company is unable to give feedback at this stage.*

## SCHERING PLOUGH CORPORATION

*The company is unable to give feedback at this stage.*

## WYETH

*The company did not reply to numerous communications.*



International Federation of Pharmaceutical Manufacturers & Associations  
Fédération Internationale de l'Industrie du Médicament  
Federación Internacional de la Industria del Medicamento

Dr Harvey E. Bale, Jr.  
Director General

Ms Veronique Menou  
Innovest Strategic Value Advisors  
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225 East Beaver Creek Rd. Ste 290  
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Canada

11 October 2007

Dear Ms Menou,

Thank you for your e-mail and opportunity to review the second version of the Access to Medicines Index document. We have reviewed the latest version with interest and have consulted with our member companies and particularly those who had taken the time to engage with Innovest in a detailed response to the first report.

Although we accept that this is not the final format of the proposed ATM index, that many of the comments we made in our review and letter on April 30<sup>th</sup> 2007 have not been addressed. Although we appreciate that there have been some changes to the framework, much of the feedback and views expressed by IFPMA and its member companies have not been taken into account.

Many of the points (e.g., including methodology, the proposed metrics, and the focus solely on innovator companies) that we raised in our detailed summary remain valid, and have not been addressed in the revised version. e.g.:


- The duplicative nature of this ATM index given the various other rankings and benchmarking activities that already exist.
- The impression given by this index that the solution to the problem of access to medicines lies primarily in the hands of the research-based pharmaceutical industry

Our industry has been and is committed to doing its part in improving access to health and medicines in the developing world, and we agree with the overall goals and objectives of continuing to do so, however we do not see how the proposed approach will help to meet these objectives.

Some of the companies that took the time for lengthy meetings with Innovest will be communicating their specific concerns to you and we sincerely hope that the index will then reflect the points raised by them

The pharmaceutical industry remains committed to the research and development of medicines for improving health world wide – and that includes the diseases that disproportionately affect people in developing countries, and is also committed to supporting policies that sustainably expand access to our medicines.

Yours sincerely,



Dr Harvey E. Bale, Jr.  
Director General, IFPMA



## Appendix 3

Five leading pharmaceutical associations were contacted for feedback on the Access to Medicine Index *Scoping Report and Stakeholder Review*, February 2007. Below is the response from each organization.

IFPMA / International Federation of Pharmaceutical Manufacturers & Associations.  
*The association sent us feedback on the AtM Index framework on 30 April, 2007.  
Please refer to the Second Interim Report for the IFPMA review and the AtM response.*

NEFARMA / Dutch Association of the Innovative Pharmaceutical Industry.  
*Please refer to the Second Interim Report for the NEFARMA letter.*

ABPI / The Association of the British Pharmaceutical Industry.  
*The association did not reply to our requests for a response.*

EFPIA / European Federation of Pharmaceutical Industries Associations.  
*The association did not reply to our requests for a response.*

PhRMA / Pharmaceutical Research and Manufacturers of America.  
*The association did not reply to our requests for a response.*



## Appendix 4

The following key stakeholders participated in the roundtables we organized in London and New York in 2006 to discuss the questionnaire results and refine ATMs indicators drawn from the questionnaire analysis.

AIDES & GLOBAL FUND / Helene Rossert  
BILL & MELINDA GATES FOUNDATION / Hannah Kettler  
CLINTON FOUNDATION / Anil Soni  
DFID / Daniel Graymore  
THE GEORGE INSTITUTE FOR INTERNATIONAL HEALTH / Mary Moran  
GLOBAL BUSINESS COALITION ON HIV/AIDS / Neeraj Mistry  
HENDERSON GLOBAL INVESTORS / My-Linh Ngo  
ICCR / Daniel Rosan  
INDEPENDENT CONSULTANT / Jacqui Patterson  
MEDECINS SANS FRONTIERES / Jacques de Milliano  
OXFAM GREAT BRITAIN / Helena Vines Fiestas  
QUEEN MARY, UNIVERSITY OF LONDON / Brigitte Granville  
STANDARD & POOR'S / David Gershon  
SUSTAINABILITY & PHARMA FUTURES / Sophia Tickell  
WHO / Richard Laing

## Appendix 5

The following table presents the results of the industry engagement phase.  
This framework was used by Innovest when discussing the Index with all stakeholders in the final consultation phase.



Criteria	Weight	Indicator
A. Access to Medicine Management	20%	A1.Governance: The company has a governance system that includes direct board level responsibility and accountability for its ATMs strategy.
		A2. Policy and Disclosure: The company has a public global policy in place, in which it explains its rationale for ATMs, its contents and details its specific objectives.
		A3. Systems and Reporting: The company has a management system, including quantitative targets to implement and monitor its ATMs strategy.
		A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management.
		A5.The company has globally applicable ethical business practices and marketing policies that conform to appropriate standards.

Criteria	Weight	Indicator
B. Public Policy Influence & Advocacy	10%	B1. The company has a position on public policy advocacy and transparency.
		B2.The company and subsidiaries disclose major public policy positions and advocacy activities at regional, national, and international levels that impact access related to the ATMs debate.
		B3. The company and subsidiaries actively advocate health reforms that foster ATMs and for policies that would result in improvements in public health.
		B4. The company annually discloses which individuals, patient associations, political parties,trade associations and academic departments it supports with which it might advocate onpublic policy positions and practices; at a regional, national and international level.
		B5. The company demonstrates a process of board approval of the approach to public policy advocacy, its transparency and reporting.



Weight	Metrics
20%	<ul style="list-style-type: none"> <li>Existence and disclosure of a committee or a member of the board or the executive board that has ATMs issues included in its mandate.</li> <li>External board positions that include ATMs initiatives.</li> </ul>
20%	<ul style="list-style-type: none"> <li>Existence and disclosure of a global policy to ensure the long-term availability of a sustainable supply of drugs, including disclosure of geographical and organizational scope.</li> <li>Disclosure of policy creation date.</li> <li>Evidence of policy endorsement at the board level.</li> <li>Disclosure of the rationale via case studies.</li> </ul>
25%	<ul style="list-style-type: none"> <li>Existence and disclosure of quantitative targets and target attainment when a program is implemented solely by the company.</li> <li>Requirement that ATMs PPP have stated targets.</li> <li>Disclosure of how the effectiveness of the system is measured.</li> </ul>
25%	<ul style="list-style-type: none"> <li>Existence and disclosure of programs/channels which raise the awareness of employees on ATMs and allow feedback to be received.</li> <li>Disclosure of evidence that stakeholder feedback has been used to improve, develop and refine a company's ATMs strategy.</li> <li>Range of major initiatives and policy debates a company contributed to in the last year.</li> </ul>
10%	<ul style="list-style-type: none"> <li>Compliance and breaches of the IFPMA Code of Pharmaceutical Marketing Practices.</li> <li>Compliance and breaches with the WHO's Ethical Criteria for Medicinal Drug Promotion.</li> <li>Number of US FDA Warning Letters for Advertising and Promotional violations.</li> </ul>

The Access to Medicine Index framework  
A. Access to Medicine Management

Weight	Metrics
10%	<ul style="list-style-type: none"> <li>Existence and disclosure of a position on public policy advocacy and transparency.</li> </ul>
30%	<ul style="list-style-type: none"> <li>Existence and disclosure of a position on Intellectual Property, Product Diversion, Registration, Drug Donations, PPP, Pricing, Philanthropy, Manufacturing, Supply Chain, Corruption and R&amp;D.</li> <li>Existence and disclosure of board seats at industry associations.</li> <li>Disclosure of national perspectives by local subsidiaries.</li> </ul>
30%	<ul style="list-style-type: none"> <li>Advocacy of a range of policies and initiatives.</li> <li>Evidence of inconsistency between advocacy position and practice.</li> </ul>
20%	<ul style="list-style-type: none"> <li>Amount spent on federal lobbying activities in the US (2006, 2005 and 2004).</li> <li>Amount spent on lobbying governments in developing and least developed countries (2006, 2005 and 2004).</li> <li>Contributions to political organizations in the US, Canada and Australia (2006, 2005 and 2004).</li> <li>Funding to patient groups, to medical associations, to academic centers in the US, Europe and the UK.</li> </ul>
10%	<ul style="list-style-type: none"> <li>Evidence of a board approval process for advocacy activities.</li> </ul>

The Access to Medicine Index framework  
B. Public Policy Influence & Advocacy



Criteria	Weight	Indicator
C. Research & Development that Reflects both the Global Disease Burden and Neglected Diseases	20%	C1. The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases.
		C2. The company provides evidence of investment in R&D into new treatments that reflects both the global disease burden and neglected diseases.
		C3. The company shows temporal evidence that their research program overall considers research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups.
		C4. The company supports external research initiatives that contribute to R&D into new treatments that reflect both the global disease burden and neglected diseases.
		C5. The company shows appropriate management of past R&D programs that reflects both the global disease burden and neglected diseases.

Criteria	Weight	Indicator
D. Patents & Licensing	10%	D1. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing countries.
		D2. The company demonstrates efforts to respect the right of developing countries to use the provisions in the TRIPS agreement.

Criteria	Weight	Indicator
E. Drug Manufacturing, Distribution and Capability Advancement	15%	E1. The company demonstrates efforts to manufacture drugs to the highest quality standards.



Weight	Metrics
5%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a position statement.</li> <li>• Existence and disclosure of a policy.</li> <li>• Compliance with the Guidelines for Good Clinical Practice of the International Conference in on Harmonization, and the Declaration of Helsinki.</li> </ul>
55%	<ul style="list-style-type: none"> <li>• Evidence of consultation with organizations with a view to contribute to R&amp;D.</li> <li>• Extent of engagement in PDPs. Number of discovery programs and the area of development.</li> <li>• Number of Phase 2/3 compounds being developed for these diseases.</li> <li>• Number of trials for such diseases as a proportion of all company trials.</li> <li>• Number of patients participating in trials for such diseases.</li> <li>• Number of fast-track status designations granted by the FDA.</li> <li>• Number of approvals in the last year.</li> </ul>
25%	<ul style="list-style-type: none"> <li>• Number of phase 2/3 trials specifically focused on developing country use.</li> <li>• Number and type of patients participating in clinical trials.</li> <li>• Number of approvals in the last year for compounds useful in developing world settings and for affected patient groups.</li> </ul>
10%	<ul style="list-style-type: none"> <li>• Amount and focus of spending on scholarships and medical grants.</li> <li>• Number of papers contributing to scientific debates.</li> </ul>
5%	<ul style="list-style-type: none"> <li>• Evidence of sharing of library compounds. Evidence of IP given to research institutes.</li> </ul>

The Access to Medicine Index framework  
**C. Research & Development that Reflects both the Global Disease Burden and Neglected Diseases**

Weight	Metrics
60%	<ul style="list-style-type: none"> <li>• Disclosure of terms of agreement (non exclusivity, royalty- free, sourcing, manufacturing limits and exports).</li> <li>• Number and type of collaborations with peers.</li> <li>• Number of drugs and treatments produced by licensees.</li> </ul>
40%	<ul style="list-style-type: none"> <li>• Involvement in country specific TRIPS flexibility use.</li> </ul>

The Access to Medicine Index framework  
**D. Patents & Licensing**

Weight	Metrics
20%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a policy that considers the inadequate infrastructure in developing and least developed countries.</li> <li>• Existence and disclosure of a policy on drug manufacture that is in line with the quality requirement of the FDA, the WHO or better, for use in developing and least developed countries.</li> <li>• Evidence and type of violations and disclosure of fines.</li> </ul>

The Access to Medicine Index framework  
**E. Drug Manufacturing, Distribution and Capability Advancement**



	E2. The company enters into technology transfer agreements with local companies in developing and least developed countries.
	E3. The company undertakes external activities to support the development and monitoring of drugs that reflect both the global disease burden and neglected diseases as part of a PPP.
	E4. The company has mechanisms in place to help prevent product diversion and to address counterfeiting, in collaboration with states.
	E5. The company demonstrates efforts to provide ATMs to its employees and their relatives in developing and least developed countries.

Criteria	Weight	Indicator
F. Equitable Pricing	15%	F1. The company can demonstrate efforts to register treatments that reflect both the global disease burden and neglected diseases in developing and least developed countries.
		F2. The company has a policy to facilitate ATMs in developing countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews.
		F3. The company demonstrates that its discount schemes place the minimum administrative burden on the beneficiary health system.



30%	<ul style="list-style-type: none"> <li>• Existence and disclosure of sharing of manufacturing skills in developing and least developed countries.</li> <li>• Existence and disclosure of quality control mechanisms in developing and least developed countries.</li> <li>• Existence and disclosure of support provided for registration in developing and least developed countries.</li> </ul>
25%	<ul style="list-style-type: none"> <li>• Existence and disclosure of support for data management in developing and least developed countries.</li> <li>• Existence and disclosure of clinical trials auditing in developing and least developed countries.</li> <li>• Existence and disclosure of participation on scientific advisory boards in developing and least developed countries.</li> <li>• Existence and disclosure of support to implement a pharmacovigilance system in developing and least developed countries.</li> </ul>
15%	<ul style="list-style-type: none"> <li>• Existence and disclosure of a corporate policy on diversion and counterfeiting.</li> <li>• Existence and disclosure of processes in place to prevent diversion and counterfeiting.</li> <li>• Evidence of cooperation with states and peers on anti-counterfeiting initiatives.</li> <li>• Existence and disclosure of a policy on primary, authorized distributors.</li> <li>• Existence and disclosure of examples of legal strategies to deter counterfeiting.</li> </ul>
10%	<ul style="list-style-type: none"> <li>• Percentage of employees in developing and least developed countries covered by healthcare benefits.</li> <li>• Type of benefits offered.</li> </ul>

Weight	Metrics
20%	<ul style="list-style-type: none"> <li>• Disclosure of the list of countries where marketing applications filed, not heard from and approved for major products.</li> </ul>
50%	<ul style="list-style-type: none"> <li>• Number or percentage of patients in LDCs covered by a pricing policy (no profit).</li> <li>• Number or percentage of patients in developing countries covered by a pricing policy (discounted price).</li> <li>• Number of countries where a company does sell drugs at cost, as a percentage of all countries where the drug is received.</li> <li>• Number of countries where a company does provide a discount, as a percentage of all countries where the drug is received.</li> <li>• Decrease in drug prices over the year, as a percentage of the total cost originally.</li> <li>• Number of drugs sold or shipped at cost in 2006, 2005 and 2004.</li> <li>• Number of drugs sold or shipped at a discounted price in 2006, 2005 and 2004.</li> </ul>
10%	<ul style="list-style-type: none"> <li>• Existence and disclosure of programs to facilitate transactions between the company and the beneficiaries of equitable pricing programs.</li> </ul>

## The Access to Medicine Index framework F. Equitable Pricing



	F4. The company has a policy for the very poorest in countries with no public healthcare provision.
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Criteria	Weight	Indicator
G. Drug Donations	6%	G1. The company has a policy that fully conforms to the WHO's Guidelines for Drug Donations.
		G2. The company discloses the absolute volume of its drug donations and, to the extent possible, the number of treatments approved for patient use per year.

Criteria	Weight	Indicator
H. Philanthropic Activities	4%	H1. The company has philanthropic programs related to ATMs not covered by any of the other criteria.



- |     |   |
|-----|---|
| 20% | <ul style="list-style-type: none"><li>• Existence and disclosure of a public policy.</li><li>• Number of treatments and patients benefiting from PAPs in the US and other relevant countries (2006, 2005 and 2004).</li><li>• Disclosure of eligibility rules.</li><li>• Additional programs to help the poorest.</li></ul> |
|-----|---|

Weight	Metrics
--------	---------

- |     |   |
|-----|---|
| 60% | <ul style="list-style-type: none"><li>• Existence and disclosure of a policy that considers the sustainability of each donation program.</li><li>• Number and type of breaches per year.</li><li>• Number of drug donation program audits per year.</li></ul> |
|-----|---|

- |     |  |
|-----|--|
| 40% | <ul style="list-style-type: none"><li>• Number of drug doses donated (2006, 2005 and 2004).</li><li>• Total value of drug donations as a percentage of pre-tax profit.</li></ul> |
|-----|--|

Weight	Metrics
--------	---------

- |      |  |
|------|--|
| 100% | <ul style="list-style-type: none"><li>• Community donation as a percentage of pre-tax profit excluding donations (2006, 2005 and 2004).</li><li>• Breakdown of cash donations as a percentage of pre-tax profit (2006, 2005 and 2004).</li><li>• Geographical breakdown.</li><li>• Existence and disclosure of support given to local NGOs (2006, 2005 and 2004).</li><li>• Number of health professionals trained (2006, 2005 and 2004).</li><li>• Number of health information resources distributed (2006, 2005 and 2004).</li><li>• Number of hospitals or healthcare facilities built or supported (2006, 2005 and 2004).</li></ul> |
|------|--|

The Access to Medicine Index framework  
G. Drug Donations

The Access to Medicine Index framework  
H. Philanthropic Activities



# Appendix 6

Investor Statement on the Access to Medicine Foundation Index Project

## INVESTOR STATEMENT ON THE ACCESS TO MEDICINE FOUNDATION INDEX PROJECT

Access to healthcare provision is a basic human right. Ensuring this is one of the major challenges of our time. There is a growing public health crisis which is particularly apparent in developing countries. HIV/AIDS has become the leading cause of premature death in sub-Saharan Africa, and the fourth largest killer worldwide. Other diseases such as TB and malaria are also significant health burdens in these countries. Addressing the problem requires action from all stakeholders, working together, using their specific knowledge and expertise. The drug industry has an important role to play in the global access to medicine challenge.

In addition, there has been a growing recognition among the investment community of the potential for environmental, social and governance (ESG) factors to impact on the financial performance of the companies in which they invest. For investors, how the pharmaceutical industry responds to the access to medicine issue could impact materially on long-term shareholder value. There is, therefore, a need for tools which help investors and analysts assess the long-term investment value of such companies. Investors want to feel confident that company management have fully considered risks and opportunities in relation to the access to medicine issue, and have effective policies and processes for dealing with the challenges.

It is in the context of all of the above that the Access to Medicine Index project (lead by the Access to Medicine Foundation, assisted by Innovest Strategic Value Advisors) has been launched. The aim of the Index is to provide key stakeholders, such as the investment community, with a robust and objective framework for benchmarking companies on the management of this issue and to serve as a foundation for improving the debate on access to medicine.

By their inclusion in this statement, the financial institutions listed overleaf are agreed on the following, they:

- believe the issue of access to medicine may have material impact on long-term shareholder value;
- acknowledge the existence of the Access to Medicine Index Project;
- welcome the project's efforts to develop a tool which could improve transparency and may be useful to assess the long term value of pharmaceutical companies;
- look forward to learning the outcomes of the project;
- consider that pharmaceutical companies have a role to play in addressing the access to medicine issue.



#### Investor contacts

Bank Sarasin / Andreas Holzer  
CIS Cooperative Insurance / Jo Allen  
Ethos / Daniel von Moltke  
F&C / Robert Barrington  
Henderson Global Investors / My-Linh Ngol  
CCR Access to Health Care Working Group / Lauren Compere  
Morley / Steve Waygood  
Schroders / Karen Shaw  
SNS Asset Management / Hans Molenaar  
USS / Daniel Summerfield

Total asset under management: 913,9 Billion (as per 31 Dec 2006)

For more information please contact

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# Glossary

## DEFINITIONS

### DEVELOPED COUNTRIES

All High Income Countries (HICs) in the UN Human Development Index (HDI)

Antigua & Barbuda	Cyprus	Latvia	Saint Kitts and Nevis
Argentina	Czech Republic	Lithuania	Seychelles
Australia	Denmark	Luxembourg	Singapore
Austria	Estonia	Malaysia	Slovakia
Bahamas	Finland	Malta	Slovenia
Bahrain	France	Mauritius	South Korea
Barbados	Germany	Mexico	Spain
Belgium	Greece	Netherlands	Sweden
Bosnia & Herzegovina	HongKong SAR, China	New Zealand	Switzerland
Brunei	Hungary	Norway	Tonga
Bulgaria	Iceland	Oman	Trinidad and Tobago
Canada	Ireland	Panama	United Arab Emirates
Chile	Israel	Poland	United Kingdom
Costa Rica	Italy	Portugal	United States
Croatia	Japan	Qatar	Uruguay
Cuba	Kuwait	Romania	

### DEVELOPING COUNTRIES

All Middle Income Countries (MICs) and Low Income Countries (LICs) in the UN Human Development Index (HDI).

Albania	Egypt	Malaysia	São Tomé and Príncipe
Algeria	El Salvador	Maldives	Saudi Arabia
Antigua and Barbuda	Equatorial Guinea	Mauritius	Solomon Islands
Armenia	Fiji	Mongolia	South Africa
Azerbaijan	FYR of Macedonia	Morocco	Sri Lanka
Bangladesh	Gabon	Myanmar	Sudan
Belarus	Georgia	Namibia	Suriname
Belize	Ghana	Nepal	Syrian Arab Republic
Bhutan	Grenada	Nicaragua	Tajikistan



Bolivia	Guatemala	Oman	Thailand
Bosnia & Herzegovina	Guyana	Pakistan	Timor-Leste
Botswana	Honduras	Palestinian territories	Togo
Brazil	India	Papua New Guinea	Tunisia
Cambodia	Indonesia	Paraguay	Turkey
Cape Verde	Islamic Republic of Iran	Peru	Turkmenistan
China	Jamaica	Philippines	Uganda
Colombia	Jordan	Republic of Moldova	Ukraine
Comoros	Kazakhstan	Romania	Uzbekistan
Congo	Kyrgyzstan	Russian Federation	Vanuatu
Dominica	Lao People's Democratic Republic	Saint Lucia	Venezuela
Dominican Republic	Lebanon	Saint Vincent and the Grenadines	Viet Nam
Ecuador	Libyan Arab Jamahiriya	Samoa (Western)	Zimbabwe

## GLOBAL

All countries in the UN Human Development Index (HDI).

## LEAST DEVELOPED COUNTRIES

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

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



### NEGLECTED DISEASES

The ten diseases identified by the World Health Organization (WHO) [see below] as well as Buruli ulcer disease and pediatric HIV.

### SUBSIDIARY

A company that is owned or controlled by another firm or company. Subsidiaries include firms in which a company owns more than 50% of the outstanding voting stock, as well as firms in which a company has the power to direct or cause the direction of the management and policies.

### VERY POOREST

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

### ORIGINATOR COMPANY

An innovative company that carries out research and development in order to discover new drugs.

### GLOBAL DISEASE BURDEN

The diseases covered under the global disease burden definition are those that contribute to 1% or more of total deaths in the world according to the Disease Control Priorities Project.

They include<sup>5</sup>:

- Tuberculosis
- HIV/AIDS
- Diarrheal diseases
- Measles
- Malaria
- Lower respiratory infections
- Perinatal conditions
- Stomach cancers
- Colon, rectum and liver cancer
- Trachea, bronchus, and lung cancers
- Diabetes mellitus
- Hypertensive and ischemic heart disease
- Cerebrovascular diseases
- Chronic obstructive pulmonary diseases
- Cirrhosis of the liver
- Nephritis and nephrosis

### WORLD HEALTH ORGANIZATION (WHO) NEGLECTED DISEASES

*These are listed below.*

- Human African Trypanosomiasis (HAT or sleeping sickness)
- Chagas disease (American Trypanosomiasis)
- Dengue
- Leishmaniasis (Kala Azar, black fever, sandfly disease, Dum-Dum Fever or espundia)
- Leprosy (Hansen's disease)
- Lymphatic filariasis (Elephantiasis)
- Malaria
- Onchocerciasis (River Blindness)
- Schistosomiasis (bilharzia or bilharziosis)
- Tuberculosis

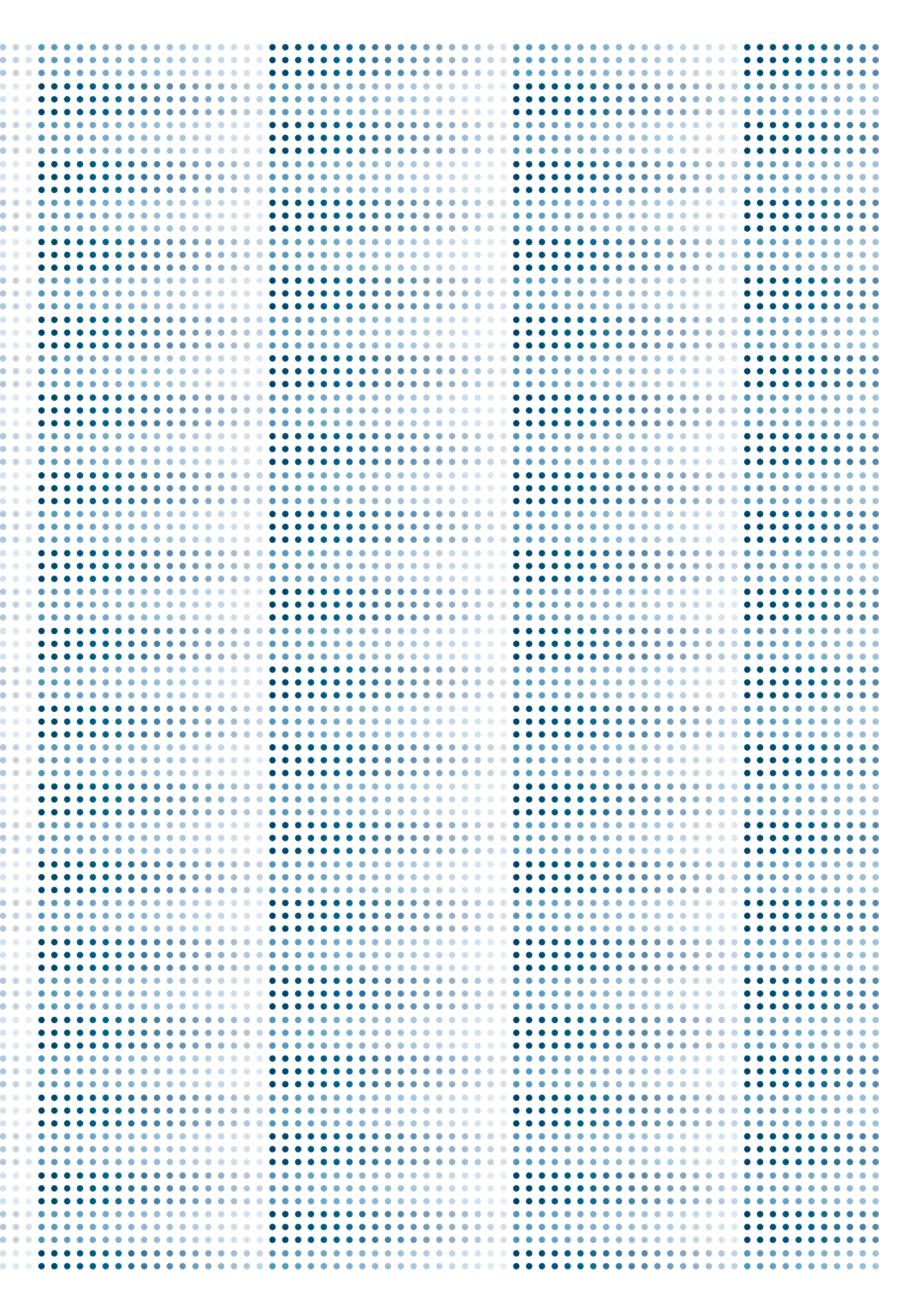
<sup>5</sup> Disease Control Priorities Project, "Measuring the Global Burden of Disease and Risk factors, 1990-2001," <http://www.dcp2.org/pubs/GBD/1/Table/1.1>. Last accessed on August 31, 2007





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