### The Approach Taken to Establish the Access To Medicine Index Framework

#### Background Research

The Access To Medicine Index project builds on a large body of work published on this issue in recent years. Innovest has collected and reviewed the latest academic, industry, and other third-party reports on access to medicines (ATMs) and related issues.

#### ATMs Questionnaire

A questionnaire was designed to help identify the key issues to be included in an evaluation of healthcare companies’ ATMs strategies and performance based on the background research. The questionnaire was delivered to over 200 leading ATMs experts around the globe. This key stakeholder group included academics, consultants, investors, government representatives, and non-governmental organizations (NGOs).

#### Stakeholder Roundtables

Stakeholder roundtables were held in London and New York to discuss and debate the questionnaire results and refine ATMs indicators. Each stakeholder roundtable included representatives from the stakeholder groups, who shared their expertise and continued to provide input during the Access To Medicine Index building.

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### Access To Medicine Index Framework

<table>
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<tr>
<th>Percentage</th>
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<tr>
<td>20%</td>
<td>Access to Medicines Management</td>
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<tr>
<td>20%</td>
<td>Research &amp; Development into Neglected Diseases</td>
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<tr>
<td>18%</td>
<td>Equitable Pricing</td>
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<td>15%</td>
<td>Patents &amp; Licensing</td>
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<td>10%</td>
<td>Policy Influence &amp; Lobbying</td>
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<td>7%</td>
<td>Drug Donations</td>
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<td>5%</td>
<td>Philanthropic Activities</td>
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<tr>
<td>5%</td>
<td>Ethical Promotion &amp; Marketing Activities</td>
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This table includes the eight most relevant criteria, ranked in order of importance, as indicated by the percentage weighting. This criteria will be used to evaluate each pharmaceutical company’s performance during the benchmarking phase.

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This report is written by: Innovest Strategic Value Advisors www.innovestgroup.com

On behalf of: access to medicine foundation www.access-to-medicine.org

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THE APPROACH TAKEN TO ESTABLISH THE ACCESS TO MEDICINE INDEX FRAMEWORK (CONTINUED)

phase. During this phase of the project, we focused initially on the opinion of healthcare sector stakeholders, outside of the company sphere. The findings of this report will allow us to provide the healthcare industry with a comprehensive and unique multi-stakeholder view of current expectations from external actors. Detailed interaction and discussion with the industry will allow further insight into the relevance and applicability of the criteria, indicators and metrics refined from external stakeholder input.

**Access To Medicine Index Framework**

Through a comprehensive research and evaluation process a preliminary weighting system was formulated by Innovest based on stakeholder input, which will ultimately determine company benchmarking within the *Access To Medicine Index*.
Foreword

Providing access to medicine to all the world’s citizens is one of the most important challenges of our time. There is a major imbalance in global access to medicine between rich and poor countries. According to the WHO, approximately 30% of the world’s population – between 1.3 and 2.1 billion people\(^1\) particularly in Africa and India – lack regular access to the medicines they need to improve their health and quality of life.

In an era where the march towards globalization may ignore the needs of the more vulnerable members of society, the role of the pharmaceutical industry during this period of rapid change is of critical importance in helping to deliver some of the benefits of globalization to the wider community. Some progress is already being made, and the pharmaceutical industry is beginning to tackle this challenge; but the effectiveness of their input is so far difficult to assess.

That is why the Access To Medicine Foundation believes that the efforts being made in this sector to increase global ATM should be measured, reported on and tracked over time using an agreed set of indicators and benchmarks. A periodic independent Access To Medicine Index would provide insights into the relative performance levels of the companies involved and highlight examples of best practice that in turn may inspire the entire industry to help deliver one of the eight UN Millennium Development Goals.

A key objective of this multi-stakeholder initiative – founded in 2005 - is to stimulate improvements in global ATM by developing an Access To Medicine Index to provide the necessary transparency in relation to performance, initially focusing on the largest pharmaceutical companies. In essence, the Access To Medicine Index aims to provide an annual overview of the extent to which the world’s leading pharmaceutical companies address the risks and opportunities presented by the ATMs issue. The Access To Medicine Index will serve as a robust foundation for accelerating the debate between the pharmaceutical industry and its external stakeholders on ATMs concerns, and it is hoped it will be a catalyst for improving ATMs responses from the industry.

The development of the Access To Medicine Index comprises two separate research phases. This first report sets out the work and findings of Phase I, in which the framework of the Index is defined. The next step, Phase II of the Access To Medicine Index program, is to actually measure the performance of the pharmaceutical industry against these benchmarks and to compile the Index itself.

Therefore, we are delighted that Innovest has agreed to take the lead in creating the framework that will form the basis of the Index going forward. It is by mobilizing their expertise in this area that we can ensure the success of the Access To Medicine Index effort. Their professionalism encourages all of us.
Finally, we are very grateful for the generous contributions of 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)
» HIVOS (Humanist Institute for Cooperation with Developing Countries)
» ICCO (Interchurch Organization for Development Co-operation)
» ICCR (Interfaith Center on Corporate Responsibility)
» Oxfam Novib
» Rabobank
» For the next phase DFID (UK Department for International Development) announced their funding partnership

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. www.access-to-medicine.org

INNOVEST STRATEGIC VALUE ADVISORS

Founded in 1995, Innovest is an internationally recognized investment research and advisory firm. It specializes in analyzing corporate performance on environmental, social and strategic governance issues, with a particular focus on their impact on competitiveness, profitability and share price performance. 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 our Healthcare analysts have evaluated the 45 largest global firms. Innovest was rated the #1 global provider of “non-traditional” investment research in the 2006 Thomson Extel survey of major institutional investors. www.innovestgroup.com
Acknowledgements

The following stakeholders generously gave their time and views to the project. We are indebted to them for their contribution to the Access To Medicine Index framework.

» Anil Soni (Clinton Foundation)
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» Daniel Graymore (UK Department For International Development)
» Daniel Rosan (Interfaith Center on Corporate Responsibility)
» David Gershon (Standard & Poor’s)
» Hannah Kettler (Bill & Melinda Gates Foundation)
» Helena Vines Fiestas (Oxfam Great Britain)
» Helene Rossert (AIDeS & Former Global Fund Vice Chair)
» Jacques de Milliano (Former Médecins Sans Frontières President)
» Jacqui Patterson (Independent Consultant)
» Mary Moran (The George Institute for International Health)
» My-Linh Ngo (Henderson Global Investors)
» Neeraj Mistry (Global Business Coalition on HIV/AIDS)
» Richard Laing (World Health Organization)
» Sophia Tickell (SustainAbility & Pharma Futures)

Disclaimer

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

**ABPI**  Association of the British Pharmaceutical Industry  
**AIDS**  Acquired Immune Deficiency Syndrome  
**ARV**  Antiretroviral  
**ATM**  Access To Medicine  
**AZT**  Azidothymidine  
**CEO**  Chief Executive Officer  
**CSR**  Corporate Social Responsibility  
**EFPIA**  European Federation of Pharmaceutical Industries and Associations  
**DFID**  Department for International Development (UK Government)  
**HDI**  Human Development Index  
**HIC**  High-Income Country  
**HIV**  Human Immunodeficiency Virus  
**ICCR**  Interfaith Center on Corporate Responsibility  
**IFPMA**  International Federation of Pharmaceutical Manufacturers & Associations  
**KPI**  Key Performance Indicator  
**LDC**  Least Developed Country  
**LIC**  Low-Income Country  
**MDGs**  Millennium Development Goals  
**MDR-TB**  Multi-drug Resistant Tuberculosis  
**MIC**  Middle-Income Country  
**MSF**  Médecins Sans Frontières
<table>
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<tr>
<th>Acronym</th>
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<tr>
<td>MTCT</td>
<td>Mother to Child Transmission</td>
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<td>NDRA</td>
<td>National Drug Regulatory Authority</td>
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<td>NGO</td>
<td>Non-Governmental Organization</td>
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<td>PAC</td>
<td>Political Action Committee</td>
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<td>PDP</td>
<td>Product Development Partnership</td>
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<td>PPP</td>
<td>Public-Private Partnership</td>
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<td>US Pharmaceutical Manufacturers and Research Association</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>STI</td>
<td>Sexually Transmitted Infection</td>
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<td>TB</td>
<td>Tuberculosis</td>
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VIII
Executive Summary

BACKGROUND TO THE ACCESS TO MEDICINE INDEX PROJECT

The pharmaceutical industry is specifically recognized in the United Nations (UN) Millennium Development Goals (MDGs) as an actor that contributes to their ultimate realization. As manufacturers of life-saving drugs and innovators in the development of new treatments, pharmaceutical companies can play a significant role in their sphere of influence. What is this role? How far does it extend beyond traditional philanthropy? And how should it evolve to address the lack of access to treatments to disadvantaged people?

On behalf of the Access To Medicine Foundation, Innovest Strategic Value Advisors has completed Phase I of a unique multi-stakeholder study that seeks ultimately to determine how best to evaluate pharmaceutical companies’ strategy and performance on improving the access to medicines (ATMs) for those in need in the least developed, developing and developed countries. The aim of the Access To Medicine Index is to build a rational, yet aspirational framework to analyze pharmaceutical companies’ responses to the access challenge and to encourage continuous improvement. This Interim Report represents progress to date on achieving this goal.

STUDY STRUCTURE

An online questionnaire was created and sent to over 200 experts worldwide on the subject of ATMs. At this stage experts were drawn from external healthcare industry actors in order to channel an accurate perspective from outside the company sphere. Questions were derived from published research on the subject as well as from Innovest’s expertise in evaluating the pharmaceutical industry. Open feedback was gathered from a wide range of stakeholders including NGOs, academia, consultants, investors and government officials on pharmaceutical company practice and potential contribution.

Subsequently, two roundtables were conducted in London and New York, to which non-pharmaceutical company stakeholders were invited to participate and further discuss and refine a framework to assess pharmaceutical companies’ performance. Pharmaceutical company representatives were excluded at this stage in order to collate a broad stakeholder consensus on all possible indicators; however, their involvement and collaboration is critical to the project going forward.
SUMMARY OF RESULTS

The study to date has determined that pharmaceutical companies should be involved in eight specific areas, with stakeholder discussions determining the criteria and criteria weightings that best evaluate company policies and performance. Weightings have been assigned to each of the eight criteria based on the stakeholder discussions. The results reflect the current focus of debate and publicity with regard to the topic of ATMs. As a result, many of the indicators explore issues most prevalent in the least developed and developing countries. Whilst the Index framework does not neglect ATMs issues within developed countries, the scope of the study does reflect the current coverage of this issue. The fluid nature of the Index framework will allow for adjustments in geographical and demographic scope in future years.

Indicators Breakdown
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: The company has a public global policy in place, in which it explains its rationale for ATMs and its contents, and details its specific objectives. (20%)

» A3. Systems: The company has clear management systems, including quantitative targets, to implement and monitor its ATMs strategy. (20%)

» A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management. (25%)

» A5. Reporting: The company produces a public annual report on ATMs management which addresses all key issues, has qualitative and quantitative reporting on all key issues, and enables an assessment of strategy. (15%)

B. Policy Influence & Lobbying (10%)

» B1. The company and subsidiaries provide disclosure of lobbying positions and activities at regional, national and international levels that impact ATMs. (35%)

» B2. The company annually discloses financial support in terms of amounts, beneficiaries and channels; these should include key opinion leaders, patient associations, political parties, trade associations and academic departments, through which it seeks to influence public policy and regional, national and international practices. (45%)

» B3. The company can demonstrate a process of board approval of the above reporting that is appropriate to the nature and scale of the activity. (20%)

C. R&D into Neglected Diseases (20%)

» C1. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases. This may be reflected in the number of dedicated scientists and projects and the existence of a dedicated neglected disease division. (30%)

» C2. The company invests in R&D into neglected diseases in partnership with groups with developing country health expertise, such as product development public-private partnerships (PPPs), academic institutions and/or the World Health Organization (WHO). (35%)

» C3. The company shows temporal evidence that their research program is focused on formulations suitable for developing country use and for all key affected patient groups. (20%)

» C4. The company undertakes other activities (not covered by other C indicators) to support R&D into neglected diseases including research into new
treatments and improvement of formulations of existing medicines for developing countries. (15%)

D. Patents & Licensing (15%):
» D1. The company does not enforce patents in least developed countries. (30%)
» D2. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing countries. (30%)
» D3. The company can demonstrate evidence of consent given to National Drug Regulatory Authorities (NDRAs) to use test data/override test data exclusivity for registration purposes in least developed countries. (20%)
» D4. The company does not extend patent duration or file patents for new indications for existing medicines in developing countries. (20%)

E. Equitable Pricing (18%):
» E1. The company can demonstrate efforts to register relevant drugs in developing countries. (25%)
» E2. The company has a policy to facilitate ATMs in developing countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews. (40%)
» E3. The company has mechanisms in place to prevent product diversion. (10%)
» E4. The company has a policy for the very poorest in all markets. (25%)

F. Drug Donations (7%):
» F1. The company has a signed policy that fully conforms to the WHO’s Guidelines for Drug Donations. (60%)
» F2. The company discloses the absolute volume of its drug donations and number of patients treated per year. (40%)

G. Philanthropic Activities (5%):
» G1. The company has philanthropic programs related to ATMs not covered by any of the other criteria. (100%)

H. Ethical Promotion & Marketing Activities (5%):
» H1. The company has a marketing policy that explores gender-related issues and labeling possibilities in developing countries. (50%)
» H2. The company has a signed policy that fully conforms to the WHO’s Ethical Criteria for Medicinal Drug Promotion. (50%)
Project Objective

TO IMPROVE ACCESS TO MEDICINE

Access to Medicines Issue
The UN MDGs signed in 2000 by all 191 UN member states recognize that pharmaceutical companies are among those who share the responsibility of providing access to essential drugs in developing countries. Several of these goals refer to the relationship between health and poverty and include targets relating to child mortality, maternal health and infectious diseases such as HIV/AIDS, malaria and tuberculosis (TB). In addition, the last goal calls for a “global partnership for development” and highlights the cooperation between governments and pharmaceutical companies to provide access to affordable drugs in developing countries.2

The responsibility for improving ATMs does not rest solely with the pharmaceutical industry but rather with the international community as a whole. Input from external actors such as NGOs, grassroots communities, national governments, international organizations, the private sector and investors, amongst others, is essential; however, the pharmaceutical industry certainly plays a critical role in complementing and leveraging government efforts to develop effective access policies.3

In addition, the pharmaceutical industry faces risks associated with the ATMs issue. At stake is a lot more than just good public relations. Failure to properly address the current health crises around the world may not only tarnish a company’s reputation but also call into question its license to operate. Business risks include endangering the credibility of the intellectual property system and reducing business opportunities in emerging markets.4

Access To Medicine Index
The main purpose of the Index is to facilitate the propagation of advanced policy solutions, improve cooperation between stakeholders, increase awareness across the board, as well as contribute to superior equity and debt investment decision making for the investment community.

The rational, yet aspirational Access To Medicine Index framework will be used to evaluate pharmaceutical companies’ efforts to improve ATMs and to benchmark these against those of their competitors. The Index framework will continue to be evaluated as further research is completed in the field, evolving over a number of years. The strength of any innovative Index is its ability to be non-prescriptive and flexible in the early years without compromising the ability to use backdated data.5

The dynamic nature of the Access To Medicine Index will fully incorporate safeguards
to allow developing issues to be re-weighted, included or excluded dependent on changes in the current thinking and opinion from all stakeholders, not least the pharmaceutical industry. The project aims to encourage and highlight best practice and evaluate which companies’ efforts are actually increasing ATMs on the ground, especially in developing countries. The Index will provide objective and comparative information on the status of some of the largest pharmaceutical companies worldwide.

The findings will also contribute to the evaluation of what constitutes best practice in the programs and initiatives of the pharmaceutical industry, and which activities actively militate against global inequality in ATMs.

The Index also aims to determine and delineate the responsibility of pharmaceutical companies within the scope of the ATMs issue. Discussion and debate with external stakeholders who play significant roles in improving access on a global scale in their own right also allows for delineation of company accountability. The intended audience for this initial report and for the Index itself includes:

» The Pharmaceutical Industry (Companies and Industry Associations)
» Foundations and Donor Agencies
» Responsible Investors
» Pharmaceutical Sector Analysts
» Other Industry Stakeholders

Feedback
The Access To Medicine Foundation welcomes all comments and suggestions on the findings of this report, as well as any thoughts that would benefit the development of the Access To Medicine Index.
Methodology

BACKGROUND RESEARCH

The Access To Medicine Index framework is building on a large body of work published on this issue in recent years. Innovest has collected and reviewed the latest academic, NGO, industry and other third-party reports on ATMs and related issues. Previous reports that have drawn on stakeholder opinion to formulate benchmarks on the issue of ATMs, such as those by the Pharmaceutical Shareowners Group, the UK Department for International Development, and the World Health Organization, all represent one stakeholder group only. Whilst these reports and others have been central to the research process and direction of the Index framework, they primarily represent the view of their authors. The Access To Medicine Index is unique in its approach, bringing together the views of these and other external actors involved in healthcare, with the unrivaled aim of achieving a multi-stakeholder consensus on the vital approaches expected by those stakeholders pressing for progress on the issue of ATMs.

TIMELINE – KEY ACCESS TO MEDICINES REPORTS

2002 – Beyond Philanthropy: The pharmaceutical industry, corporate social responsibility and the developing world (Oxfam, VSO, Save the Children).


2005 – Increasing People’s Access to Essential Medicines in Developing Countries: A framework for good practice in the pharmaceutical industry (DFID).


The issues highlighted in these and other key studies on the subject of ATMs are supplemented with the latest research and developed throughout this report.
ACCESS TO MEDICINES QUESTIONNAIRE

The initial research phase allowed a comprehensive list of assessment criteria to be defined, which subsequently served as a basis for the questionnaire. An online questionnaire [See Appendix 1] was created and sent to over 200 leading experts in the area of ATMs and healthcare issues. The stakeholder groups that were represented in the survey included academia, consultants, investors, government, and NGOs. The stakeholders were selected based on their expertise on the issue and work in the field of ATMs. The prominence of their organization or department was also taken into account when selecting stakeholders. Contacts from the Access To Medicine Foundation and Innovest's experience in the healthcare sector and surrounding issues were also approached.

Of the more than 200 experts contacted 63 replied to the questionnaire, a response rate of almost 30%. Stakeholders were asked to express their judgment on company practice relating to ATMs and were also offered the opportunity to make additional comments and remarks on this matter, which were then used to prompt discussions at the roundtables. The response rate allows for significant analysis of data submitted, including cross-stakeholder group analysis. It is expected that in future years the questionnaire phase will provide increasing response rates as awareness of and interest in the Index increases.

STAKEHOLDER ROUNDTABLES

From the larger stakeholder group 15 stakeholders were selected for their diverse and respected expertise on the impact of companies on ATMs. Stakeholder roundtables were conducted in London and New York to discuss the questionnaire results and refine ATMs indicators drawn from the questionnaire analysis. Each stakeholder roundtable included representatives from the key stakeholder groups who shared their expertise and continued to provide input during the Access To Medicine Index criteria-building phase. The roundtables were facilitated by an expert independent consultant from Peoplematters Ltd., a professional organization specializing in designing and garnering the best responses for these types of meetings. Stakeholders attending the London roundtable were asked to work in sub-groups to discuss a criterion and refine a set of indicators provided, based on questionnaire analysis. Sub-groups were created based on the participants’ expertise and responses to the questionnaire. Cross-fertilization of ideas allowed the roundtables to draw majority consensus on the issues discussed, with all stakeholders having the opportunity to comment on all findings.

Stakeholders in New York were presented with the initial set of criteria and indicators derived from the questionnaire as well as those refined at the London roundtable.
Innovest compiled the results from both roundtables and distributed the findings to all roundtable participants for further input and comment. The results of this process are documented in the main body of this report.

At this stage, purposely no input from the pharmaceutical industry or its representation was sought in order to derive a broad consensus on all indicators from an external stakeholder perspective. The Industry Engagement Phase that follows the release of this report will, in a unique and innovative attempt to align stakeholder and industry opinion on the issue of ATMs, provide a perspective on the findings and allow any omissions to be incorporated. The inclusion and support of the healthcare industry is essential to the success of this project.

ACCESS TO MEDICINE INDEX FRAMEWORK FORMULATION

Through a comprehensive research process that involved assessing debate and opinion regarding the various approaches discussed in this report, Innovest formulated a preliminary weighting system that will ultimately determine which companies will be included and their rankings within the Access To Medicine Index itself. Weightings were assigned to each criterion based on the apparent importance and effectiveness of the strategy in improving ATMs based on stakeholder discussion. This method was also employed for each of the indicators within the set of criteria. The indicator weighting demonstrates the importance and effectiveness in improving the performance of the criterion. The weighting is essential in order for strategic performance to be ascertained.

Suggested metrics are provided alongside each of the indicators. These allow an initial insight into the performance evaluation phase. Metrics at this stage are intentionally non-prescriptive in anticipation of the significant input expected from the Industry Engagement Phase into this area of the framework. Internal, company specific, key performance indicators may present innovative methods of performance analysis that can be translated to other companies in the final Access To Medicine Index.

The following eight sections of the report will discuss each of the criteria in detail, with indictors and weightings, and clearly outline stakeholder expectations for healthcare companies. Potential metrics provide the reader with an insight into the avenues for benchmarking performance in these areas.
Access to Medicines Management

KEY ISSUES FOR STRATEGIC MANAGEMENT

Background Research

A management system is the framework of processes and procedures used to ensure that an organization can fulfill all tasks required to achieve its objectives. How does this definition relate to the ATMs context? In 2004, the Pharmaceutical Shareowner Group (PSG), comprising 14 institutional investors, engaged with pharmaceutical companies to ensure that they were addressing the key risks associated with the issue. The group identified the following components as best practice in strategic management:

» Articulate the business case
» Promote leadership at board level
» Take a forward-looking approach
» Assess alternative options
» Show flexibility and breadth
» Collaborate and share best practice
» Demonstrate responsible use of influence in public policy
» Track performance and be transparent

An essential part of a management system is a set of policies that companies develop in order to address various issues. In 2005, the UK’s Department for International Development (DFID) provided guidance to pharmaceutical companies by encouraging them to adopt numerous practices including: implementation of differential pricing mechanisms in developing countries, especially the world’s poorest, to support the development of viable markets. Particular attention should be paid to medicines produced by one manufacturer, where competition is often limited. Increasing R&D investments in diseases affecting developing countries, including engagement in PPP. Working to support broader health and development goals in developing countries, including consideration of voluntary licenses. Reporting on activities designed to increase access to essential medicines.

Box 1

“DFID encourages pharmaceutical companies to go further by:

- Engaging in widespread differential pricing of essential medicines in developing countries, especially the world’s poorest, to support the development of viable markets. Particular attention should be paid to medicines produced by one manufacturer, where competition is often limited.
- Increasing R&D investments in diseases affecting developing countries, including engagement in PPP.
- Working to support broader health and development goals in developing countries, including consideration of voluntary licenses.
- Reporting on activities designed to increase access to essential medicines.”

Increasing People’s Access to Essential Medicines in Developing Countries. DFID, 2005.

Combining the results from the online questionnaire and the stakeholder roundtables, Innovest derived a total combined weighting of 20% for all the criteria falling within the ‘key issues for strategic management’ category.

Our research indicates that the following indicators are considered to be essential components of a comprehensive ATMs management framework:

A1. Governance: The company has a governance system, which includes direct board-level responsibility and accountability for its ATMs strategy.
The results of the questionnaire indicated that a large majority of stakeholders consider it essential for healthcare companies to have oversight of their ATMs strategy at the board level.

Discussions at the roundtables concluded that responsibility should be institutionalized and not specifically driven by the CEO, especially given the current high turnover of CEOs in the sector. The strategy should be critically overseen and signed off on by the company’s board of directors. Accountability was viewed as the key word in this indicator.

Potential metrics that companies will be measured on will include information on the skill set of employees involved, time spent on the issue at the board level, committees, links to incentivization, and specific departmental responsibility.

This indicator accounts for 20% of the overall ‘key issues for strategic management’ criterion weighting.

A2. Policy: The company has a public global policy in place, in which it explains its rationale for ATMs, its contents and its specific objectives.

Discussions with stakeholders concluded that an ATMs policy should be a central part of a healthcare company’s culture and business strategy. The rationale for specific projects should be clearly communicated, as well as concerns about risks and opportunities. During the questionnaire, 83% of all respondents agreed and/or strongly agreed that when making ATMs investment decisions outside pure philanthropy, the business rationale should be presented (including the risk management element and the projected value of any tangible returns). Some stakeholders questioned spending resources on assessing the rationale at this stage and favored the 'learning by doing' strategy, but they agreed that quantitative modeling would encourage a 'snap into action' by companies.

Discussions concluded that pharmaceutical companies should not only disclose their global ATMs policy but should provide detail on its content and scope. The inclusion of the word ‘global’ was significant to stakeholders who strongly believe it is crucial for pharmaceutical companies to address the ATMs issues not only in developing countries, but in all markets.

Potential metrics may include target and objective attainment, level of integration within the company, and the global extent of the policy.

This indicator accounts for 20% of the overall criterion weighting.

A3. Systems: The company has clear management systems, including quantitative targets, to implement and monitor its ATMs strategy.

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Box 2

Approximately 82% of all respondents agreed and/or strongly agreed that it is essential for pharmaceutical companies to formulate and oversee ATMs issues at the board level to ensure long-term continuity.

Box 3

Approximately 83% of all respondents agreed and/or strongly agreed that when making ATMs investment decisions outside pure philanthropy, the business rationale should be presented (including the risk management element and the projected value of any tangible returns).
Stakeholders agreed that it is essential to assess how a company delivers a strategy, fulfills all tasks required to meet its objectives and targets, and how effective the implemented programs are at improving access to treatments to people in need. Questionnaire results stated that 74.6% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should disclose the monetary value and nature of long-term dedicated resources (including specific research facility, staff and budget versus public relations costs) for ATMs strategies.

Potential metrics used to evaluate this indicator will ascertain normalized levels of resources including budgets, employees and training, as well as explore the management and funding models used, together with the methods implemented to audit such systems. The effectiveness of the company’s strategy would be assessed in terms of the degree to which it has engaged in the ATMs debate, how it has performed against its own key performance indicators, and the feedback it receives from a wide range of stakeholders, especially local NGOs.

This indicator accounts for 20% of the overall criterion weighting.

A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management.

Results from the questionnaire indicated that 91.5% of all respondents agreed and/or strongly agreed that large pharmaceutical companies should collaborate with stakeholders in designing the type of ATMs programs that would be the most effective and appropriate within the context of each country.

At the two roundtables, there was general agreement that stakeholder engagement was the most critical part of this criterion. Stakeholders are seen as the key to allowing greater ATMs primarily as a result of their 'on-the-ground' knowledge. However, some stakeholders highlighted that a distinction should be made between stakeholders, such as patient groups or organizations that receive funding from pharmaceutical companies, and grassroots community and/or NGOs on the ground, who are independent and may have a better understanding of local realities.

Potential metrics will aim to detail specific stakeholder relationships, their importance, levels of engagement and critically positive outcomes.

This indicator accounts for 25% of the overall criterion weighting.

A5. Reporting: The company produces a public annual report on ATMs management, with qualitative and quantitative reporting on all key issues enabling an assessment of strategy.

Previous reports, such as Benchmarking AIDS by the Interfaith Center on Corporate Responsibility (ICCR), suggest that reporting should include “an articulation of the business case for action, an assessment of the options for action, systematic
reporting of the company’s goals and activities, and evidence of leadership at the board level. The report also has pricing schemes and timetables for its access to medicines goals.\textsuperscript{13} There was consensus amongst most stakeholders regarding the importance of company transparency and a need to push for regular reporting. The idea was not to be prescriptive or to require a specific framework for reporting on the issue, but rather to give leeway to encourage companies to report on a regular basis.

Potential metrics will assess competency and quality of reporting with a specific focus on accuracy and external verification.

This indicator accounts for 15\% of the overall criterion weighting.
Public Policy Influence & Lobbying

KEY ISSUES FOR PUBLIC POLICY & LOBBYING

Background Research

Lobbying practices are crucial to the holistic ATMs approach of a company. In order to demonstrate consistency in ATMs strategies, as well as give credence to such strategies, companies should not demonstrate contradictory political approaches.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) legislation and the lobbying for stricter applicability is allegedly having, and will continue to have, a negative effect on public health by increasing prices and decreasing availability of newer drugs.\textsuperscript{10} The latest recommendations from Oxfam\textsuperscript{11} call for companies to stop lobbying developed country governments to promote stricter intellectual property rules worldwide and stop pressuring developing countries to accept stronger intellectual property rules. The report also claims that lobbying the US government to impose TRIPS-plus rules has reaped major strategic and monetary benefits for pharmaceutical companies. The response from The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to the report refutes intellectual property as a major obstacle to access, highlighting the WHO’s List of Essential Medicines and the fact that 95% of all drugs are not patented anywhere in the world, and 99% are not patented in sub-Saharan Africa.\textsuperscript{12} The core list presents the minimum medicine needs for a basic healthcare system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance and potential for safe and cost-effective treatment.\textsuperscript{13} It must be noted that this WHO list will be updated this year, but by the very nature of the list, it cannot take into account diseases for which medicines are currently not readily available.

Many believe it is in the interest of business to open up the ‘black box’ of lobbying, allowing the interface between private business and governments to be more transparent and better understood.\textsuperscript{14} There are, however, practical concerns in determining the level of consistency, e.g. how is it possible to measure issues such as political lobbying?\textsuperscript{15} It is our aim to explore possible answers to this question.

The indirect lobbying activities of pharmaceutical companies through patient and advocacy groups has been a major issue of contention in recent years. The UK House of Commons Health Committee Enquiry into ‘The Influence of the Pharmaceutical Industry’\textsuperscript{16} noted that the level of support which patient organizations receive from pharmaceutical companies is not known and that such groups need to openly declare “all significant funding and gifts in kind.” In April 2006, the Association

Box 6

“Corporations should disclose their lobbying positions on public policy issues, as well as membership and funding of trade associations, think-tanks and campaigns to influence public policy.”


Box 7

Some 77% of respondents agreed and/or strongly agreed that disclosure of companies’ political contributions and lobbying stances across jurisdictions positively impacts the transparency of ATMs strategies.
of the British Pharmaceutical Industry’s (ABPI) revised code of practice came into force, now requiring of all members that "core funding, unrestricted grants, sponsorship and partnership activities, including non-financial support, should be transparent." Despite this strong stance, patient organization websites do not provide enough information for visitors to assess whether a conflict of interest with companies exists. An ethical code to guide patient organizations and their staff members on how to operate and interact with companies is also needed, if patient organizations are to remain independent and truly represent the interests and views of patients.

Research indicates that pharmaceutical companies would benefit from greater transparency, but given the current lack of disclosure on this issue and reservations from stakeholders over difficulties in collecting such information, Public Policy Influence & Lobbying has been given a relative low weighting of 10%.

Our research indicates that the following indicators are considered to be essential components to assessing Public Policy Influence & Lobbying.

B1. The company and subsidiaries provide disclosure of lobbying positions and activities that impact ATMs at regional, national and international levels.

Stakeholders believe that a formal ‘political contributions report’ would allow for consistency analysis with specific ATMs policies. In order to complete this analysis, Innovest will focus specifically on the approach of companies towards lobbying and public policy, as it relates to patents and licenses. All stakeholders conceded that this would be difficult to achieve in the first instance but would add great value to a company’s holistic ATMs approach.

Potential metrics may explore the levels of spending through various lobbyists and disclosure at varying scales of impact, including direct and indirect lobbying activities. The information derived from the Index formulation will allow us to pursue further detailed analysis of the data.

This indicator accounts for 35% of the overall criterion weighting.

B2. The company annually discloses financial support in terms of amounts, beneficiaries and channels; these should include key opinion leaders, patient associations, political parties, trade associations and academic departments, through which it seeks to influence public policy and regional, national and international practice.

A number of stakeholders expressed caution and concern over the high weighting given to this criterion due to the expected limited availability of data from companies.

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Box 8

Of all investor respondents, 63% agreed and/or strongly agreed that lobbying by large pharmaceutical companies in developing countries can positively improve healthcare infrastructures and the drug registration process, while 45% of all NGOs and 33% of all government respondents agreed or strongly agreed.

The breakdown illustrates the difference of opinions between the financial community and the other stakeholders on the extent to which pharmaceutical companies should or should not be involved in the governmental sphere of activity.

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See Glossary for definition.
It was noted, however, that the aspirational nature of the Access To Medicine Index framework did need indicators that were forward-looking.

Potential metrics may include: a full analysis of the various beneficiary groups, the amount of money they receive from a company and from its Political Action Committee (PAC), the funds beneficiaries receive from a company as a percentage of total receipts, and their respective lobbying positions. These will allow for the determination of the company’s relative strength of support and control of policy positioning. Additional metrics will look at the rationale behind spending shareholders’ funds on lobbying activities.

This indicator accounts for 45% of the overall criterion weighting.

B3. The company can demonstrate a process of board approval of the above reporting that is appropriate to the nature and scale of the activity.

According to the Center for Political Accountability\(^9\), disclosing political contributions can alert directors to potential problems in management performance and the company’s businesses that would otherwise be missed. In addition, reviewing the company’s contributions can raise questions about whether these contributions are in line with the company’s interests or whether they are being made for unrelated purposes that could have negative outcomes for the company.

It was acknowledged in the roundtable discussions that it would be impossible to expect all policy-driven expenditures to be passed by the board of directors for approval, but some accountability was needed, especially when large amounts of resources were being expended.

Potential metrics may explore the level of board involvement in overall policy position strategies and ascertain where accountability lies.

This indicator accounts for 20% of the overall criterion weighting.

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Box 9

There were 67.9% of respondents who agreed and/or strongly agreed that the policy stance taken by the Pharmaceutical Research and Manufacturers of America (PhRMA) relating to the TRIPS Agreement reflects negatively on large pharmaceutical companies.
R&D Into Neglected Diseases

KEY ISSUES FOR RESEARCH AND DEVELOPMENT INTO NEGLECTED DISEASES

Background Research

Globally, an estimated 2.3 million children are living with HIV, the vast majority in sub-Saharan Africa. Only 5% of children receive treatments, and there are no appropriate tests for diagnosing infants and very few adapted tools to treat children.

Tuberculosis (TB) is curable but kills 2 million people every year. TB is the leading cause of death among HIV-infected people; the WHO estimates that TB accounts for up to a third of AIDS deaths worldwide. Existing TB drugs and diagnostics are not adequate to combat the disease. People with Multi-Drug Resistant Tuberculosis (MDR-TB) are resistant to two or more of the primary drugs used for the treatment of TB, while some patients are now resistant even to second-line drugs, making treatment with existing drugs impossible.

Malaria infects between 300 and 500 million people every year and causes between one and three million deaths annually. The virulent strain of the malaria parasite has grown resistant to chloroquine, the most common drug used to combat the disease. Since 2001, the World Health Organization (WHO) has recommended using an artemisinin-based combination therapy (ACT) as first-line treatment for uncomplicated malaria in areas experiencing resistance to older medications. However, the supply of artemisinin is not meeting demand.

The WHO estimates that over 1 billion people suffer from one or more neglected tropical diseases.

Box 10

“Achieving all the MDGs will require addressing health and its determinants in a comprehensive way and will necessitate further health research, of high quality, focused on the needs of developing countries and vulnerable populations.”

Statement by the Global Forum for Health Research at the conclusion of Forum 8, Mexico City, November 2004

Drugs for some of these diseases exist, but most are old, toxic and becoming less effective because of resistance. According to the Global Forum for Health Research, an independent international foundation promoting research into neglected diseases, only 10% of global funding for health research is devoted to 90% of the world’s health problems. There is an urgent need for investment in new and improved technologies to address diseases affecting the poor in developing countries.

R&D is one of the areas where pharmaceutical companies can make a major contribution to enhance ATMs to fight neglected diseases in developing countries. “The vision for the pharmaceutical industry’s role in global healthcare is to create and develop medicines that save and improve the lives of millions of people and, in partnership with governments and other organizations, to help improve access to them.”
Research indicates that pharmaceutical companies would be most effective in improving ATMs for poor people by focusing on their core business and by investing in R&D for neglected diseases. Therefore R&D was given the highest possible weight in the Index framework: 20%. At this stage, discussions did not include distinction between R&D for vaccines or for medications, a topic that may be addressed going forward.

Our research indicates that the following indicators are considered to be essential components to assessing a company’s R&D policy.

**C1. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases.** This may be reflected in the number of dedicated scientists and projects and the existence of a dedicated neglected disease division.

The large majority of stakeholders agreed and/or strongly agreed that large pharmaceutical companies with relevant capabilities in their current portfolio should dedicate a specific amount of their overall R&D budget each year for research into vaccines (75.5% of respondents) and medications (77.4% of respondents) for neglected diseases.

Potential metrics for this indicator may include the number of dedicated full-time equivalent staff and resources assigned to R&D into neglected diseases, as well as the number of in-house projects currently being undertaken in the area of neglected diseases, including the level of development of those projects.

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

**C2. The company invests in R&D into neglected diseases in partnership with groups with developing country health expertise, such as product development public-private partnerships (PPPs), academic institutions and/or the World Health Organization (WHO).**

Some stakeholders voiced concerns about the definition of PPPs. Discussions concluded that a distinction should be made between PPPs that are an activity or function (e.g. private-sector drug donations or information campaigns on public health issues) and PPPs that are actual structures or organizations (e.g. vaccine and drug development organizations, with headquarters, staff, product portfolios, etc.).

There was a consensus amongst the stakeholder roundtables as to the merits of expanding resources on partnerships as opposed to in-house R&D. The questionnaire responses, however, did not show as clear a consensus with only 56% of all respondents (85% of all academics, 63% of all investors, 55% of all governments, 46% of all NGOs and 43% of all consultants) agreeing and/or strongly

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**Box 11**

The central presence of PPPs in neglected disease drug development reflects their crucial role in facilitating multinational company involvement and their catalytic role in much small company activity. It is this ability to catalyze and bring together private-sector drug development activity and public-sector health and neglected disease skills that is central to the superior performance metrics of the PPPs model.

The New Landscape of Neglected Disease Drug Development, Pharmaceutical R&D Policy Project, Dr Mary Moran.
agreeing that PPPs are the most successful model for large companies to emulate in designing an ATMs program that spans from research to distribution. “The central presence of PPPs in neglected disease drug development reflects their crucial role in facilitating multinational company involvement and their catalytic role in much small company activity. It is this ability to catalyze and bring together private-sector drug development activity and public-sector health and neglected disease skills that is central to the superior performance metrics of the PPP model. Appropriate public policies to support PPPs need to be based on a clear understanding of their functions and of the specific advantages of this model. In particular, PPPs do not conduct drug development themselves. Their main functions are to:

» Integrate and co-ordinate multiple industry and academic/public partners and contractors along the drug development pipeline.

» Allocate philanthropic and public funds to the right kinds of R&D projects from a public health perspective.

» Manage neglected disease drug portfolios by various means including selection and termination of projects based on their relative merits.”

Potential metrics may include exploring the various partnership strategies employed by companies and analyzing positive outcomes to lend support to this debate.

This indicator accounts for 35% of the overall criterion weighting.

C3. The company shows temporal evidence that their research program is focused on formulations suitable for developing country use and for all key affected patient groups.

The quality of drugs imported into developing countries with a tropical climate may be adversely affected if their formulations have not been optimized for stability under these conditions. In addition, without adequate nutrition AIDS sufferers cannot absorb the drug needed to slow the virus. Taking AIDS drugs on an empty stomach also causes severe stomach aches, dizziness and nausea. Discussions concluded that R&D into heat-stable and more appropriate formulations for those with little food or water was needed to improve ATMs.

At both roundtables, pregnant women, children and HIV patients were highlighted as key examples of patient groups neglected by R&D activities. For example, there are concerns about mother-to-child transmission (MTCT). In most cases women who want to prevent MTCT are taking single dose nevirapine. “A major concern about the use of single dose nevirapine is drug resistance. Studies suggest that single dose nevirapine can make future treatment with nevirapine or efavirenz (a related drug) less effective. This could have serious consequences for mothers who wish to prevent MTCT during subsequent pregnancies, or who later use nevirapine or efavirenz as part of combination therapy to improve their own health. There is also
some evidence to suggest that if a mother develops nevirapine resistant HIV, this may be passed through breast milk to her baby.\textsuperscript{28}

In addition, extensive research points to the lack of adequate treatments for newborn babies and children.\textsuperscript{29} Finally, even though single-dose treatments and fixed-dose combination exist, these are not available everywhere and as some patients have to take several drugs per day this may hamper follow-up treatment and increase the risk of drug resistance.

Possible metrics may include the number of trials and their phases, bioequivalence tests and filings with regulators.

\textit{This indicator accounts for 20\% of the overall criterion weighting.}

\textbf{C4. The company undertakes other activities (not covered by other C indicators) to support R&D into neglected diseases including research into new treatments and improvement of formulations of existing medicines for developing countries.}

There was a disagreement amongst questionnaire respondents as to the relevance for a pharmaceutical company to invest in R&D for neglected diseases outside its area of expertise. Of investors, 63\% disagreed or strongly disagreed that large pharmaceutical companies should invest in R&D into vaccines and/or medications for neglected diseases outside of their proven areas of expertise, while only 11\% of all governments, 33\% of all NGOs, 28\% of all consultants and academics disagreed or strongly disagreed. The breakdown indicates that while the financial community is willing to pursue a cost-effective strategy, other stakeholders favor an approach more likely to benefit patients first to the detriment of profit.

At the roundtables, it was noted that there are valuable R&D philanthropy efforts, such as the sharing of library compounds and the training of scientists, that can form a part of an effective R&D strategy outside of traditional measures.

Potential metrics will consider industry provision of expertise to R&D groups who need it, for example in the form of data management and analysis assistance, clinical trial support, medicinal chemistry advice, members for expert scientific advisory committees, employee sabbaticals and the sharing of compound libraries. However, there is a view that these activities are easier to enact and therefore should not be rewarded as highly as other R&D investments.

\textit{This indicator accounts for 15\% of the overall criterion weighting.}
## Patents & Licensing

### KEY ISSUES FOR PATENTS & LICENSING

#### Background Research

In 1994, at the Uruguay round, WTO members negotiated an agreement on patent rules, The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In 2001, developing countries expressed concern that developed countries were insisting on a narrow interpretation of TRIPS, which had adverse effects on their ATMs. Subsequently, the developing countries initiated another round of talks that resulted in the Doha Declaration - a WTO statement that reaffirms the right of developing countries to use safeguards created under TRIPS to ensure that medicines are available and affordable, and that generic drugs can be produced and imported at a lower cost than brand versions.

Now, five years after the Doha Declaration, trade rules still remain a major barrier to accessing affordable versions of patented medicines. The US government has been accused of imposing the so-called “TRIPS plus” rules, which undermine the flexibilities offered to developing countries to adapt the TRIPS agreement to their country context, and the pharmaceutical industry has allegedly been a supporter of such a policy.

Patents are traditionally considered an effective means to boost R&D for unmet medical needs, as they allow pharmaceutical companies to protect their innovation for 20 or more years, thereby helping to recoup costly R&D costs. In addition, by spurring innovation, patents increase medical discoveries that contribute to a better access to treatments. Nevertheless, there has been recent debate as to the relevance of this argument. In particular, the report released in April 2006 by the World Health Organization Commission on Intellectual Property, Innovation and Public Health concludes that intellectual property protection has not led to increased innovation and access to treatment for people in developing countries.

Since patents are only as valuable as the profits they can generate, it is clear that patents alone cannot stimulate innovation in drug development for diseases prevalent in developing countries, where profit opportunities are limited.

On the other hand the absence of intellectual property rights is often associated with a drop in prices of medicines due to generic drug competition, which turns out to be an effective way of improving ATMs. In 2001, before India implemented the TRIPS agreement, Indian generic producers were able to market ARV’s for much less than large pharmaceutical companies - USD360 per patient per year compared to USD10,000 per patient per year. Due to such dramatic global decrease in ARV...
prices, the number of people receiving treatment has substantially increased reaching 1.6 million in developing countries in 2006. India, like other developing countries, was allowed to delay implementation of the TRIPS agreement until 2005 but had to establish a “mailbox” system to receive and file patent applications from the beginning of 1995. The large majority of generic drugs on the market are not being affected by the compliance with TRIPS, as it is impossible to file a patent retrospectively. However, new applications and pending applications in the “mailbox” are likely to be patented, which may reduce the access to affordable medicines to people.

The issue of technology transfers was heavily debated by roundtable participants. There was however, a consensus among most stakeholders that more research was needed in order to prove both the negative and positive impacts of this practice on ATMs. On one hand, there is a support for the negative impacts of technology transfers with a report written by Warren Kaplan and Richard Laing stating that, “In many parts of the world, producing medicines domestically makes little economic sense. If many countries begin local production, the result may be less ATMs, since economies of scale may be lost if there are production facilities in many countries.” Conversely, there is some anecdotal evidence of the positive impacts of technology transfer agreement programs for specific neglected disease drugs, however detailed studies into the topic are lacking. Should further research studies surface regarding the impact of technology transfers on ATMs, an extra indicator will be added in the Index framework.

Our research suggests that the following indicators are considered to be essential components to assessing pharmaceutical companies’ Patents & Licensing practices. This criterion is weighted at 15%. All indicators pursue a similar goal, which is to encourage the entry of generics on the market in order to reduce the price of medicines.

**D1. The company does not enforce patents in least developed countries.**

There was a general consensus among stakeholders that pharmaceutical companies should not enforce their patent right in least developed countries (LDCs).

According to TRIPS, LDCs have until 2016 to abide by the TRIPS agreement. Nevertheless, some LDCs are already compliant with TRIPS, but their populations are not in a position to afford expensive branded medicines. The rationale behind this indicator is that by developing a patent relaxation policy, a company will leave the market open to generic entry and the importation of cheaper drugs, which will improve the ATMs by poor people.

Some stakeholders had few reservations with patents being enforced on the proviso that voluntary licenses and technology transfers were implemented. In some cases,
local companies face administrative barriers (e.g. delay in drug registration) often too cumbersome for them to deal with without outside support. Therefore, local companies enter into voluntary license agreements with originator companies that assist them in the regulatory process and help them to overcome difficulties relating to registration. Voluntary licenses will be discussed below.

Possible metrics include third-party reports of violation and the exploration of the number and reasons why companies have enforced patents in LDCs.

This indicator accounts for 30% of the overall criterion weighting.

D2. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing countries.

As noted previously, pharmaceutical companies can enter into licensing agreements with governments or local drug manufacturers and provide them with the right to produce a patent-protected drug and sell it on the local market for a lower price. The questionnaire indicated that 75% of all respondents agreed and/or strongly agreed that voluntary drug license agreements by the patent-holding large pharmaceutical companies with local governments or local pharmaceutical companies are an effective strategy to improve ATMs.

There was general agreement that current voluntary license agreement disclosures were insufficient and left stakeholders with many questions on the exact benefits of such strategies. License terms vary greatly and may impose significant restriction on the amount of production, the right to export and the quantities allowed, and also the targeted customers (NGOs, government, pharmacies).

Potential metrics will include the number of voluntary licensees and will aim to improve disclosure on the various terms and conditions of agreements including restrictions on production, sourcing, co-formulation, imports and exports, as well as full provision of crucial technological patents to allow equally high production yields. The time taken to make the first product from first issue of license will also be assessed.

This indicator accounts for 30% of the overall criterion weighting.

D3. The company can demonstrate evidence of consent given to National Drug Regulatory Authorities (NDRAs) to use test data/override test data exclusivity for registration purposes in least developed countries.

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. It allows pharmaceutical companies to prevent generic drug manufacturers from using the safety and efficacy evidence that they produced to file the originator drug. As a
consequence, generic companies are forced to repeat time-consuming, expensive studies in order to receive regulatory approval. Therefore, even when a drug is not under patent, data exclusivity creates a patent-like monopoly, which has dramatic consequence for ATMs.34

This indicator will investigate originator companies and their policies on data exclusivity and sharing test data with generic companies allowing for efficient registration.

Potential metrics will look at issues of contention and the impacts on delivering access.

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

**D4. The company does not extend patent duration or file patents for new indications for existing medicines in developing countries.**

There are several ways for a pharmaceutical company to extend patent life. The company could complain that NDRAs take an unreasonably long time to examine an application, or a patent office is delaying approval of a patent. The company could in principle also file a patent for each new use of a drug, which in turn can prolong the patent life for 20 or more years.35

A consensus emerged at the roundtables that pharmaceutical companies should not adopt such practices, which compromise ATMs.

Potential metrics will detail evidence that shows the number of times companies have extended patents or ‘refiled’ patents.

*This indicator accounts for 20% of the overall criterion weighting.*
Equitable Pricing

KEY ISSUES FOR EQUITABLE PRICING

Background Research

Many factors restrict ATMs: poverty (i.e. lack of money to buy medicines), lack of political will of governments, poor health infrastructures, and inappropriate drug selection. The price of medicines is also a key barrier in poor countries. The cost of medicine represents the greatest share of healthcare expenditures for people in poor countries. Expenditure on pharmaceuticals ranges from 10-20% of expenditure on health in the richest countries and 20-60% in poorer countries.

Equitable pricing is the adaptation of prices charged by the manufacturer or seller to countries with different purchasing power. Equitable pricing is especially important for newer essential medicines that are still protected by patents or other instruments that provide market exclusivity. Widespread equitable pricing is economically feasible provided that low-priced medicines do not leak back to high-income countries.

Médecins Sans Frontières (MSF) finds that there are still common problems affecting the availability of the most needed essential medicines, namely that most originator companies establish a country premium, thereby excluding patients in some developing countries, and that even if companies announce discounted prices for their products in some eligible developing countries, the products are in fact not always available or affordable.

DFID indicates that “In 2002 the working group on increasing access to essential medicines in developing countries found that differential pricing was economically and commercially viable.”

Our research confirms the relevance of equitable pricing as an effective practice to address ATMs and therefore weighted this criterion at 18%. The following indicators are considered to be essential components to assessing the practice of Equitable Pricing by companies.

E1. The company can demonstrate efforts to register relevant drugs in developing countries.

In order to reach the market a drug needs to be approved by a country’s NDRA, which means that the drug has been proven to meet certain quality, safety, and effectiveness criteria. There was general agreement among stakeholders of the need for additional drug registration in developing countries.
A consensus emerged at the roundtables that drug registration could be an indicator under “Patents & Licensing” and under “Equitable Pricing”. Innovest decided that the drug registration issue belongs under “Equitable Pricing” as the US has been targeted by a negative media campaign about its attempt to turn NDRAs into patent offices when entering into Free Trade Agreements with developing countries (e.g. Chile). If the NDRA becomes the enforcer of patents, it will not be able to register generic versions of patented drugs. In the TRIPS agreement there is no reference to such role.

Stakeholders commented that it was important to expose the shortfalls in civil society, highlighting systematic failures and countries with especially poor records on registration. Through the benchmarking of companies on this issue, data may draw attention to NDRAs with recurring failures in registration efficacy. Stakeholders did acknowledge the political implications of such transparency.

Potential metrics will look at the time lapse of registration in rich and poor countries, the transparency around reporting on registration status, and the work with WHO to get on the pre-qualified and essential drugs lists.

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

**E2. The company has a policy to facilitate ATMs in developing countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews.**

Differential pricing strategies were the source of much debate among stakeholders at the roundtables with a call for much greater research in this area, including economic modeling to provide guidance for companies on the most effective methods of pricing. It was noted this could only materialize with greater transparency by pharmaceutical companies regarding their worldwide pricing strategies. Third-party research, such as the ICCR’s Benchmarking AIDS report, calls for predictable and affordable prices for both developing and least developed countries.

Potential metrics will look for transparency in pricing policies, explore various methods linked to disease prevalence and human development, along with tiered pricing and other such scales (Global Fund Price) identified and analyzed for performance. Following the industry consultation phase, Innovest expects to come up with a tool to measure performance on pricing issues.

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

**E3. The company has mechanisms in place to prevent product diversion.**

Drug diversion is defined here as the diversion of licit drugs for illicit purposes. There was a consensus among stakeholders around a need to address diversion practices as a means of preventing reverse import of drugs destined for developing country
markets. This is of particular concern for single-source products that are sold at high prices in developed countries. However, some stakeholders voiced concerns that this issue is highly overstated and marginally important to ATMs.

Potential metrics will look into anti-diversion policies (including use of different color drugs and packaging schemes) and progress made over the years to reduce the amount of drugs diverted and their monetary value.

This indicator accounts for 10% of the overall criterion weighting.

**E4. The company has a policy for the very poorest** in all markets.

It was acknowledged that companies should implement strategies for markets where consumers are unable to even pay the cost price of drugs. The rationale behind this indicator relates to poor people in developed or developing countries who have no greater capacity to pay for expensive drugs than poor people in the least developed countries, where pharmaceutical companies may have a differential pricing policy in place and may offer drugs at cost. In addition, a recent paper written by Trillium Asset Management (a client of Innovest) and the Interfaith Center on Corporate Responsibility indicates that a 5-10% price cut in drugs would not affect the budget pharmaceutical companies can allocate to R&D. The paper suggests that a drop in company profit resulting from price cuts would be offset by a combination of health plan cost-savings and increases in consumer spending power.43

This indicator highlights the critical need for pharmaceutical companies to develop a pricing policy not only in developing countries and least developed countries, but also in developed countries. This indicator will investigate the flexibilities offered by pharmaceutical companies to poor people at a country level.

Potential metrics will look into policies and scope, discounts and beneficiaries.

This indicator accounts for 25% of the overall criterion weighting.

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* See Glossary for definition.
Drug Donations

KEY ISSUES FOR DRUG DONATIONS

Background Research

Donation programs can make major contributions to improved global public health, particularly when directed at time-limited needs such as disease eradication. Studies have shown that tropical disease drug donation PPPs have provided considerable benefits, facilitating greater drug availability with negligible negative side effects. The donation programs have been embraced by countries (specifically Botswana, Sri Lanka, Uganda and Zambia) with rudimentary health infrastructure. There are concerns, however, that donation programs may overwhelm the limited absorptive capacity of national health systems by diverting staff, duplicating financial, monitoring and evaluation systems, and incur ancillary costs for governments. It is therefore vital to continue operational support as well as to assure drug supplies during the maintenance phase of these programs, if disease resurgence is to be avoided.

Concerns that activities such as donations are ultimately unsustainable - supported by questionnaire analysis - are based on past experience, where post-emergency drug donations have been inefficient and ineffective, and this is the main reason for the lower weighting in this section. Innovest research indicates that the majority of pharmaceutical companies have extensive, well-publicized donations programs that do currently improve ATMs. Drug Donations was given a low weight in the Index framework: 7%

The following indicators are considered to be essential components to assessing the practice of a company’s Drug Donations policy.

F1. The company has a signed policy that fully conforms to the WHO’s Guidelines for Drug Donations.

Stakeholder agreement on the comprehensive nature of the World Health Organization’s Guidelines led to little discussion on this topic. Analysis will follow performance against the various safeguards within the Guidelines, even in situations where a company has not publicly acknowledged or follows the Guidelines, which are intended to ensure that drug donations are relevant to the country context and are announced and needed by the recipient country. They also ensure that donated drugs are of good quality and that they have a shelf life of more than a year. Other principles include presentation, packing, labeling, information and management.
This indicator accounts for 60% of the overall criterion weighting.

F2. The company discloses the absolute volume of its drug donations and number of patients treated per year.

Whereas this indicator was generally seen as a less effective avenue to pursue for companies, greater transparency on actual action taken was called for. The reporting of the total value of donations was deemed unnecessary, as most stakeholders acknowledge that the monetary value of donations, currently disclosed by a large number of companies, has little relevance, since costs are often based on the most expensive drug prices and generally do not include an evaluation of the number of full treatments provided.

Potential metrics will include the number of treatment courses received by patients and the number of employees dedicated to such programs as a percentage of entire staff.

This indicator accounts for 40% of the overall criterion weighting.
Philanthropic Activities

KEY ISSUES FOR PHILANTHROPIC ACTIVITIES

Background Research

In 2002, Oxfam, Save the Children, and VSO called on the pharmaceutical industry to contemplate various initiatives for improving ATMs, highlighting that many companies were defining ATMs policies largely in terms of philanthropic ventures. In the years since this observation ATMs strategies have evolved quite rapidly with the focus shifting away from philanthropy.

There was general agreement among stakeholders that philanthropy should be rewarded but not seen as a long-term strategy for improving ATMs, and therefore philanthropy was given 5% weight in the Index framework. The following indicators will be considered when assessing a company’s philanthropic activities.

G1. The company has philanthropic programs related to ATMs not covered by any of the other criteria.

Despite conjecture over apportion of monetary and other resources to philanthropy over other avenues, there was almost universal acknowledgement that current company programs do have a positive impact on ATMs. Stakeholder debate centered on the issue of responsibility, in particular the role of capacity building as an auxiliary obligation for pharmaceutical companies. Questionnaire respondents strongly favored both infrastructure and training initiatives across all regions, many arguing strongly for capacity building activities to lessen infrastructure barriers currently preventing access. Respondents argued that with companies needing structured healthcare infrastructures to facilitate access programs, it would be justified to expect they should play a role in any public healthcare improvements.

Potential metrics will consider normalized spending, capacity advancement, employee matched donations and the disclosure of sustainability and/or exit strategies for such programs.

This indicator accounts for 100% of the overall criterion weighting.
Ethical Promotion and Marketing Activities

KEY ISSUES FOR ETHICAL PROMOTION AND MARKETING ACTIVITIES

Background Research
Pharmaceutical companies have been criticized for allegedly overstating a drug's benefits and understating the risks of taking a particular medicine. This unethical promotion can lead to irrational drug prescribing and drug use, and to needless injury or even death. The issue of responsible marketing is particularly important in developing countries where regulatory controls and independent information are lacking or if they do exist are less stringent than in highly developed countries.

Studies have found that doctors in developing countries rely heavily on industry-based sources of information.

In 1988, the WHO published a set of Ethical Criteria for Medicinal Drug Promotion. These criteria are intended to provide a strong ethical framework for drug promotion and ensure that the customer gets the proper information and not advertising in disguise.

There was general agreement among stakeholders at the roundtables that an extra criterion should be added to allow for the analysis of corporate marketing strategies, specifically for campaigns in developing countries. It was suggested that ethical performance should make up a small section of the Index framework and therefore responsible marketing was weighted at 5%. The following indicators will assist in the evaluation of marketing and promotional activities in relation to keeping a consistent ATMs message.

H1. The company has a marketing policy that explores gender-related issues and labeling possibilities in developing countries.

Concern was voiced that companies are inaccurately targeting patients in developing countries and hampering overall access to effective treatments. Some stakeholders mentioned that there was a need to address gender issues when marketing drugs and especially in relation to microbicides, which are substances intended to reduce or prevent transmission of HIV and/or other sexually transmitted infections (STIs) when applied topically to genital mucosal surfaces. Even though microbicides are not yet publicly available marketing of these products will need to be addressed going forward.
Potential metrics will include the adoption of a specific marketing code for the least developed and developing countries, including references to marketing to women. Third-party reports of violations or breaches of such codes or standards will contribute to assessment of this indicator.

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

**H2. The company has a signed policy that fully conforms to the WHO’s Ethical Criteria for Medicinal Drug Promotion.**

Analysis will follow performance measured against the various safeguards within the guidelines.

Potential metrics will include the number of warning letters received from regulatory authorities and the number of ethical breaches per year compared to number of employees.

*This indicator accounts for 50% of the overall criterion weighting.*
The Access To Medicine Index Framework

The following chart summarizes each of the criteria and indicators that make up the Access To Medicine Index framework. Weightings summing to 100% have been assigned to each of the eight criteria based on stakeholder discussions and Innovest expertise. The same process has been used to determine the weighting of each indicator listed under each criterion.

<table>
<thead>
<tr>
<th>20%</th>
<th>A. Access to Medicines Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>A1. Governance: The company has a governance system that includes direct board-level responsibility and accountability for its ATMs strategy.</td>
</tr>
<tr>
<td>20%</td>
<td>A2. Policy: The company has a public global policy in place, in which it explains its rationale for ATMs and its contents, and details its specific objectives.</td>
</tr>
<tr>
<td>20%</td>
<td>A3. Systems: The company has clear management systems, including quantitative targets, to implement and monitor its ATMs strategy.</td>
</tr>
<tr>
<td>25%</td>
<td>A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into ATMs management.</td>
</tr>
<tr>
<td>15%</td>
<td>A5. Reporting: The company produces a public annual report on ATMs management which addresses all key issues, has qualitative and quantitative reporting on all key issues, and enables an assessment of strategy.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>10%</th>
<th>B. Public Policy Influence &amp; Lobbying</th>
</tr>
</thead>
<tbody>
<tr>
<td>35%</td>
<td>B1. The company and subsidiaries provide disclosure of lobbying positions and activities at regional, national and international levels that impact ATMs.</td>
</tr>
<tr>
<td>45%</td>
<td>B2. The company annually discloses financial support in terms of amounts, beneficiaries and channels; these should include opinion leaders, patient associations, political parties, trade associations and academic departments, through which it seeks to influence public policy and regional, national and international practices.</td>
</tr>
<tr>
<td>20%</td>
<td>B3. The company can demonstrate a process of board approval of the above reporting that is appropriate to the nature and scale of the activity.</td>
</tr>
</tbody>
</table>
## C. R&D into Neglected Diseases

<table>
<thead>
<tr>
<th>20%</th>
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<tbody>
<tr>
<td><strong>C1.</strong> The company provides evidence of in-house investment in R&amp;D into new treatments for neglected diseases. This may be reflected in the number of dedicated scientists and projects, and the existence of a dedicated neglected disease division.</td>
</tr>
<tr>
<td>30%</td>
</tr>
<tr>
<td><strong>C2.</strong> The company invests in R&amp;D into neglected diseases in partnership with groups with developing country health expertise, such as product development public-private partnerships (PPPs), academic institutions and/or the World Health Organization (WHO).</td>
</tr>
<tr>
<td>35%</td>
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<tr>
<td><strong>C3.</strong> The company shows temporal evidence that their research program is focused on formulations suitable for developing country use and for all key affected patient groups.</td>
</tr>
<tr>
<td>15%</td>
</tr>
<tr>
<td><strong>C4.</strong> The company undertakes other activities (not covered by other C indicators) to support R&amp;D into neglected diseases including research into new treatments and improvement of formulations of existing medicines for developing countries.</td>
</tr>
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</table>

## D. Patents & Licensing

<table>
<thead>
<tr>
<th>15%</th>
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<tbody>
<tr>
<td><strong>D1.</strong> The company does not enforce patents in least developed countries.</td>
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<tr>
<td>30%</td>
</tr>
<tr>
<td><strong>D2.</strong> The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase ATMs in developing countries.</td>
</tr>
<tr>
<td>30%</td>
</tr>
<tr>
<td><strong>D3.</strong> The company can demonstrate evidence of consent given to National Drug Regulatory Authorities (NDRAs) to use test data/override test data exclusivity for registration purposes in least developed countries.</td>
</tr>
<tr>
<td>20%</td>
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<tr>
<td><strong>D4.</strong> The company does not extend patent duration or file patents for new indications for existing medicines in developing countries.</td>
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## E. Equitable Pricing

<table>
<thead>
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<th>18%</th>
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<tr>
<td><strong>E1.</strong> The company can demonstrate efforts to register relevant drugs in developing countries.</td>
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<td>25%</td>
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<tr>
<td><strong>E2.</strong> The company has a policy to facilitate ATMs in developing countries through pricing mechanisms, which include reporting on scope, pricing levels and pricing reviews.</td>
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<tr>
<td>40%</td>
</tr>
<tr>
<td><strong>E3.</strong> The company has mechanisms in place to prevent product diversion.</td>
</tr>
<tr>
<td>25%</td>
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<tr>
<td><strong>E4.</strong> The company has a policy for the very poorest in all markets.</td>
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## F. Drug Donations

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<th>7%</th>
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<tbody>
<tr>
<td><strong>F.</strong> Drug Donations</td>
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<tr>
<td>60%</td>
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<td>40%</td>
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<td>5%</td>
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<td>100%</td>
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<td>5%</td>
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<tr>
<td>50%</td>
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<td>50%</td>
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</tbody>
</table>
INDUSTRY ENGAGEMENT

The next stage in building the Access To Medicine Index will involve consultation with the healthcare industry and its input into the work done to date. It will explore the various research possibilities and viewpoints while maintaining the core framework developed through the original stakeholder group. It is essential to engage with the industry to provide a perspective on the findings and allow any omissions to be incorporated. The findings of Phase I of the Index will be presented through face-to-face meetings with the 20 companies identified in Appendix 4. The companies selected for this consultation phase have been chosen with the objective to amass contributions from companies of various size and geographic distribution, including those that implement best practice ATMs strategies; the largest companies in the industry will be consulted as well. The companies were selected from a number of traditional sectors within the broad healthcare industry. The significant role of Medical Equipment and Biotechnology companies in improving ATMs in all markets justifies their inclusion at this stage.

It should be noted that the companies selected for the engagement phase will not necessarily constitute those that form the final Index [See CHALLENGES GOING FORWARD].

The Industry Engagement Phase will present the findings of this report through discussions with companies, with feedback expected on concerns and potential improvements to further improve the relevance and applicability of the Index. Ideally these findings will be presented to employees with varying degrees of responsibility and perspectives on access issues, especially those with responsibility for ATMs, Corporate Social Responsibility (CSR), R&D, Logistics, Philanthropy, Political Contributions and Corporate Affairs. We will also continue to engage with industry groups, such as IFPMA, EFPIA, ABPI and PhMRA. This will help ensure the Index also considers the availability of specific data.

INDEX FRAMEWORK REFINEMENT

Innovest will amend the list of criteria, indicators, metrics and weightings based on the industry consultation phase to ensure that the Index fulfills the expectations of the
stakeholder group, whilst incorporating the knowledge gained from our engagement with industry representatives.

PERFORMANCE ASSESSMENT

Following the planned industry engagement phase of this study Innovest will integrate and refine indicators and metrics to further strengthen the Index framework. The relative performance of a number of healthcare companies will then be assessed and benchmarked according to the Access To Medicine Index framework. Research into the companies will be based on publicly available information in addition to interviews with key company representatives in order to ensure full data provision.

Each Indicator will be assessed on a number of both relative and absolute metrics. The scoring system will then take account of the weightings within the framework to provide an accurate tiered system of companies.

ANNUAL REVIEW

We see the Access To Medicine Index continuing 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 indicators, criteria, 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 provide further insight into developing issues associated with improving ATMs, providing further support to the Index. Company performance will be reassessed considering the latest best practices and progress made to improve ATMs.

TAKING THE INDEX LIVE

For the Index to achieve maximum impact “on the ground,” it will need to influence the actual investment choices and behavior of major investors – giving more favorable consideration to companies more heavily weighted in the Index. The ideal scenario in this regard would be to create an investable Access To Medicine Index, which would maximize investment flows to superior ATMs performers while simultaneously incentivizing laggards. One prominent example of this is the Dow
Jones Sustainability Index, which now directly influences over USD2 billion. Innovest itself has previously constructed an analogous Index in the field of community investment and development. That Index, co-developed with a leading global index provider, is currently the basis for the multi-million dollar investment portfolio of a foundation with a strong programmatic commitment to these areas. The Index is currently managed by one of the largest asset managers in the world.

CHALLENGES GOING FORWARD

A number of challenges must be overcome in the coming months, as the Index framework is refined through the industry consultation phase prior to the final disclosure of the Access To Medicine Index. Challenges include:

» Discussions about the size and makeup of the final Access To Medicine Index. The formal criteria for 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. The variable criteria for inclusion will therefore result in some companies dropping in and out of the Index.

» Refining and disclosing a rigid scoring system that is likely to include both absolute and relative performance assessment. This will occur as the metrics become formalized through the next phase of the Access To Medicine Index.

» Gauging the relevance at this stage regarding of the Index framework for companies currently without products, or products in their pipelines for diseases prevalent in the least developed and developing countries. Whilst some may argue this is not an issue, as companies should be involved with such products, it must be noted that at this stage a number of indicators do refer to all markets, including developed countries, and others have no geographical range. This issue and others will continuously be monitored, with the idea of potential adjustment of certain weightings already put forward.

» Verification of data, which has been a very important issue throughout the process of designing the Index framework. Innovest will attempt, where possible, to provide assurances on the information used to analyze company performance, but will provide all data and information provided by companies for others to scrutinize. We will continue to track this issue.
## Appendix 1: The Questionnaire

Respondents were asked for their expert opinion on the following statements. After each section, there was an opportunity to add comments and space at the end for comments and suggestions outside of the defined criteria.

### 1. Access to Medicines Management

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) It is essential for large pharmaceutical companies to formulate and oversee ATMs strategies at the board level to ensure long-term continuity.</td>
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<tr>
<td>b) When making ATMs investment decisions outside pure philanthropy, the business rationale should be presented (including the risk management element and the projected value of any tangible returns).</td>
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<tr>
<td>c) Large pharmaceutical companies should disclose the monetary value and nature of long-term dedicated resources (including specific research facilities, staff and budget for PR costs) for ATMs strategies.</td>
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<tr>
<td>d) Reducing costs in the pharmaceutical industry value chain should be incorporated into all large pharmaceutical company ATMs strategies.</td>
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<tr>
<td>e) Large pharmaceutical companies should collaborate with stakeholders in designing the type of ATMs programs that would be the most effective and appropriate in different country contexts.</td>
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</table>

### 2. Public Policy Influence and Lobbying

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Lobbying by large pharmaceutical companies in developing countries can positively improve healthcare infrastructures and the drug registration process.</td>
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</tbody>
</table>
b) The policy stance taken by the Pharmaceutical Research and Manufacturers of America (PhRMA) relating to the TRIPS Agreement reflects negatively on large pharmaceutical companies.

c) Disclosure of companies’ political contributions and lobbying stances across jurisdictions positively impacts the transparency of ATMs strategies.

d) Financial incentives from foundations or governments for development of particular drugs focus the attention of pharmaceutical companies away from neglected diseases and negatively impact efforts to tackle them. The definition of neglected diseases in this instance includes HIV/AIDS, malaria and tuberculosis, as well as those defined as neglected tropical diseases (NTDs) by the World Health Organization.

3. Research and Development into Vaccines and Medication for Neglected Diseases

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) There is a need for more investment in basic scientific understanding of several of the parasites, bacteria and certain viruses causing neglected diseases before it will be cost-effective for large companies to dedicate resources to the development of vaccines of sufficient efficacy.</td>
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<tr>
<td>b) Large pharmaceutical companies should invest in R&amp;D into vaccines and/or medication for neglected diseases outside their proven areas of expertise.</td>
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<td></td>
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</tr>
<tr>
<td>c) Large pharmaceutical companies with relevant capabilities in their current research portfolio should dedicate a specific amount of their overall R&amp;D budget each year for research into vaccines for neglected diseases.</td>
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<tr>
<td>d) Large pharmaceutical companies with relevant capabilities in their current research portfolio should dedicate a specific amount of their overall R&amp;D budget each year for research into medication for neglected diseases.</td>
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<tr>
<td>e) Public-private partnerships are the most successful model for large companies to emulate in designing an ATMs program running from research to distribution.</td>
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</tbody>
</table>
f) Large pharmaceutical companies with compound libraries no longer in use or old mothballed research programs should make arrangements to provide the data to parties who are in a position to take forward the R&D efforts.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
</table>

g. The pharmaceutical sector is currently investing an acceptable level of resources into R&D for vaccines to prevent:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
</table>

- Adult HIV/AIDS in developing countries
- Adult HIV/AIDS in developed countries
- Pediatric HIV/AIDS in developing countries
- Malaria
- Tuberculosis in developing countries
- Other neglected diseases

h. The pharmaceutical sector is currently investing an acceptable level of resources into R&D for medication to treat:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
</table>

- Adult HIV/AIDS in developing countries
- Adult HIV/AIDS in developed countries
- Pediatric HIV/AIDS in developing countries
- Malaria
- Tuberculosis
- Other neglected diseases

4. Patents/Licensing

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
</table>

a) After 2016, drugs patents should not be enforced in countries listed in the UN Human Development Index as Low Human Development Countries. For information on the Human Development Index go to: [http://hdr.undp.org/reports/global/2005/pdf/HDR05_HDI.pdf](http://hdr.undp.org/reports/global/2005/pdf/HDR05_HDI.pdf)
b) Voluntary drug license agreements by the patent-holding large pharmaceutical companies with local governments or local pharmaceutical companies are an effective strategy to improve ATMs.

c) Large pharmaceutical companies should enter into technology transfer agreements with entities in developing countries involving less up-to-date equipment and techniques than those available in countries high on the Human Development Index.

5. Differential Pricing

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Registration of drugs relevant to healthcare priorities in developing countries is currently sufficient.</td>
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<tr>
<td>b) Companies’ provision of differential pricing options for the private sector in developing countries is currently comparable to that for the public sector.</td>
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<tr>
<td>c) Differential pricing can help support viable markets, and competition can lead to lower prices.</td>
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<tr>
<td>d) Large pharmaceutical companies should have a three-tier pricing policy (for countries ranked High, Middle and Low on the Human Development Index) for all neglected diseases medication.</td>
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<tr>
<td>e) The risk of drug diversion can be addressed by various means, including use of different color drugs and packaging schemes, which include the destination address.</td>
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6. Drug Donations

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<tr>
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<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Direct drug donations should only be part of a disease eradication program.</td>
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<tr>
<td>b) Drug donations in post-emergency situations (e.g. tsunami, hurricane, earthquake, etc.) are often inefficient in their distribution.</td>
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</tbody>
</table>
**c) Drug donations as a part of a public-private partnership are an effective way of ensuring access to medicines in:**

<table>
<thead>
<tr>
<th>Region</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
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<tbody>
<tr>
<td>Sub-Saharan Africa</td>
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<tr>
<td>East Asia and the Pacific Region</td>
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<tr>
<td>Eastern Europe &amp; Central Asia</td>
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<tr>
<td>South Asia, Middle East &amp; North Africa</td>
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<td>Latin America &amp; the Caribbean</td>
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<td>North America &amp; Western Europe</td>
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</tbody>
</table>

**7. Philanthropic Activities**

**a) Contributions by large pharmaceutical companies to healthcare infrastructure, including both structural and human capabilities, is necessary to facilitate drug delivery to patients due to lack of capacity in local and national government in:**

<table>
<thead>
<tr>
<th>Region</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree or Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
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<tbody>
<tr>
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<tr>
<td>East Asia and the Pacific Region</td>
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**b) As part of any drug donation program, large pharmaceutical companies must provide adequate training to healthcare workers for drug distribution in:**

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<tr>
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Appendix 2: Questionnaire Results

1a
- Strongly Agree: 59.3%
- Agree: 32.2%
- Neither Agree or Disagree: 3.4%
- Disagree: 0.0%
- Strongly Disagree: 0.0%
- No Response: 5.1%

1b
- Strongly Agree: 39.0%
- Agree: 44.1%
- Neither Agree or Disagree: 6.8%
- Disagree: 3.4%
- Strongly Disagree: 0.0%
- No Response: 6.8%

1c
- Strongly Agree: 33.9%
- Agree: 40.7%
- Neither Agree or Disagree: 8.5%
- Disagree: 11.9%
- Strongly Disagree: 0.0%
- No Response: 5.1%

1d
- Strongly Agree: 25.4%
- Agree: 40.7%
- Neither Agree or Disagree: 13.6%
- Disagree: 5.1%
- Strongly Disagree: 1.7%
- No Response: 13.6%
1e

- Strongly Agree: 52.5%
- Agree: 39.0%
- Neither Agree or Disagree: 5.1%
- Disagree: 0.0%
- Strongly Disagree: 0.0%
- No Response: 3.4%

2a

- Strongly Agree: 7.4%
- Agree: 29.6%
- Neither Agree or Disagree: 24.1%
- Disagree: 27.8%
- Strongly Disagree: 9.3%
- No Response: 1.9%

2b

- Strongly Agree: 27.8%
- Agree: 40.7%
- Neither Agree or Disagree: 9.3%
- Disagree: 3.7%
- Strongly Disagree: 0.0%
- No Response: 18.5%

2c

- Strongly Agree: 44.4%
- Agree: 33.3%
- Neither Agree or Disagree: 16.7%
- Disagree: 3.7%
- Strongly Disagree: 0.0%
- No Response: 1.9%
3g (iv) and 3h (iv)

- **Strongly Agree**
  - Vaccine: 1.9%
  - Medication: 0.0%
- **Agree**
  - Vaccine: 3.8%
  - Medication: 7.7%
- **Neither Agree or Disagree**
  - Vaccine: 7.7%
  - Medication: 13.5%
- **Disagree**
  - Vaccine: 50.0%
  - Medication: 44.2%
- **Strongly Disagree**
  - Vaccine: 25.0%
  - Medication: 23.1%
- **No Response**
  - Vaccine: 11.5%
  - Medication: 11.5%

3g (v) and 3h (v)

- **Strongly Agree**
  - Vaccine: 1.9%
  - Medication: 1.9%
- **Agree**
  - Vaccine: 3.8%
  - Medication: 5.8%
- **Neither Agree or Disagree**
  - Vaccine: 3.8%
  - Medication: 7.7%
- **Disagree**
  - Vaccine: 7.7%
  - Medication: 51.9%
- **Strongly Disagree**
  - Vaccine: 46.2%
  - Medication: 30.8%
- **No Response**
  - Vaccine: 7.7%
  - Medication: 9.6%

3g (vi) and 3h (vi)

- **Strongly Agree**
  - Vaccine: 0.0%
  - Medication: 0.0%
- **Agree**
  - Vaccine: 1.9%
  - Medication: 0.0%
- **Neither Agree or Disagree**
  - Vaccine: 7.7%
  - Medication: 7.7%
- **Disagree**
  - Vaccine: 7.7%
  - Medication: 42.3%
- **Strongly Disagree**
  - Vaccine: 46.2%
  - Medication: 32.7%
- **No Response**
  - Vaccine: 15.4%
  - Medication: 11.5%
### 6c (i)

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7a (ii) and 7b (ii)

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7a (iii) and 7b (iii)

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<th>Training</th>
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7a (vi) and 7b (vi)

- Strongly Agree: 2.0% (Infrastructures), 12.2% (Training)
- Agree: 12.2% (Infrastructures), 28.6% (Training)
- Neither Agree or Disagree: 22.4% (Infrastructures), 16.3% (Training)
- Disagree: 24.5% (Infrastructures), 12.2% (Training)
- Strongly Disagree: 12.2% (Infrastructures), 2.0% (Training)
- No Response: 16.3% (Infrastructures), 16.3% (Training)
Appendix 3: List of Questionnaire Respondents

ACADEMIA

Professor Alan Fenwick, Imperial College, Director Schistosomiasis Control Initiative, Department of Infectious Disease Epidemiology.

Professor Alan Whiteside, University of KwaZulu-Natal, Director Health Economics & HIV/AIDS Research Division (HEARD).

Professor Brigitte Granville, Queen Mary, University of London, Professor of International Economics and Economic Policy.

Professor Frederick Abbott, Florida State University, Edward Ball Eminent Scholar Professor of International Law.

Dr. Jessica Ogden*, International Center for Research on Women (ICRW), HIV/AIDS Specialist.

Professor Marleen Boelaert, Institute of Tropical Medicine Antwerp, Public Health Department.

Dr. Mary Moran, The George Institute for International Health, Director Pharmaceutical R&D Policy Project (PRPP).

CONSULTANTS

Mr. Bernard Trude*, Healthlink Worldwide, Executive Director.

Mr. Brendan May*, Weber Shandwick, Head of Corporate Responsibility & Sustainability.

Dr. David Gershon, Standard and Poor's, Healthcare Economics and National Institute for Pharmaco-Economics and Healthcare Policy, Chairman.

Mr. Francis Weyzig, Stichting Onderzoek Multinationale Ondernemingen (SOMO), Senior Researcher.

Mr. Ian Bradley, Arthur D Little, Consultant.
Ms Jacqui Patterson, Independent Consultant.

Mr. Mian Imran Masood, The Network for Consumer Protection Islamabad, Assistant Coordinator Pharmaceuticals, Advocacy and Research Unit.

Ms Ritu Khanna, SustainAbility, Advisor.

Ms Sophia Tickell, SustainAbility Pharma Futures Project, Chair and Director.

Dr. Wilbert Bannenberg, Public health consultant in the field of essential medicines for developing countries.

GOVERNMENT

Professor Carel IJsselmuiden, Council on Health Research for Development (COHRED), Director.

Dr. Carter Diggs, USAID Malaria Vaccine Development Program, Senior Technical Advisor.

Mr. Daniel Graymore, DFID, Private Sector Advisor Business Alliances Team and Global AIDS Policy Team, Policy Division.

Dr. Edvard Beem, ZonMw - National health council appointed by the Ministry of Health (VWS) and the Netherlands Organization for Scientific Research (NWO), Managing Director.

Dr. Diarmuid McClean, Irish Aid, Development Specialist.

Dr. Harry van Schooten, Netherlands Ministry of Foreign Affairs DGIS Department, Senior Health Advisor.

Dr. Judith de Kroon*, The Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty related Diseases (NACCAP), Senior Programme Coordinator.

Ms Miriam Naarendorp*, Ministry of Health (MOH) Suriname, Pharmacy Policy Coordinator.

Dr. Richard Laing, World Health Organization (WHO), Policy, Access and Rational Use, Medicine Policy and Standards.

Dr. S K Sharif, Ministry of Health Kenya, Provincial Medical Officer of Health.

Mr. Sisule Musungu, South Centre and Health Action International Africa, Access to Knowledge and Intellectual Property and Chairman.
INVESTORS

Mr. Aled Jones*, Formerly Jupiter Asset Management SRI Analyst.

Ms Celine Suarez*, Domini Social Investments, Research Analyst.

Mr. Daniel Rosan, Interfaith Center on Corporate Responsibility (ICCR), Program Director Public Health, Access to Capital.

Ms Gemma Taylor-Gee, ABN Amro Asset Management SRI Engagement Specialist.

Ms Karen Shaw, Schroders Asset Management, SRI Analyst.

Mr. Kenny Bell, Baillie Gifford, Corporate Governance and SRI Manager.

Mr. Martin Eijgenhuijzen, ABP Investments, Senior Portfolio Manager.

Ms My-Linh Ngo, Henderson Global Investors, Senior Analyst Sustainable & Responsible Investment.

Mr. Neil Brown, Threadneedle Asset Management, Head of Governance and Responsible Investment.

Dr. Raj Thamotheram, AXA Investment Managers, Responsible Investment Team.

Mr. Steve Lippman, Trillium Asset Management, Vice President of Social Research.

Dr. Stewart Adkins, Formerly Lehman Brothers, Senior Analyst Pharmaceuticals.

Mr. Terence Berkleef, ABN Amro Asset Management, SRI Analyst.

NGOs

Dr. Anne Merriman, Hospice Africa in Uganda, Founder and Director of Policy and International Programs.

Ms Annelies den Boer, Wemos Foundation, Project Manager Medicines.

Dr. Charles Gardner, The Rockefeller Foundation, Associate Director.

Dr. Christopher Elias, Program for Appropriate Technology in Health (PATH), President.

Ms Ellen T’Hoen*, Médecins Sans Frontières (MSF), Access to Essential Medicines Campaign.

Mr. Ed Vreeke, Asrames asbl, Director.
Mr. Frans de Laaf, Oxfam Novib, Responsibility for Special Projects.

Ms Helena Vines Fiestas, Oxfam GB, Policy Advisor Private Sector.

Ms Helene Rossert, AIDeS, General Director.

Dr. J. Carl Craft, Medicines for Malaria Venture (MMV), Portfolio Manager.

Dr. Jean-Marie Kindermans, European Agency for the Development and Health (AEDES), Medical Doctor in Public Health.

Mr. Jerald Sadoff*, Aeras Global TB Vaccine Foundation, President and Chief Executive Officer.

Ms Joelle Tanguy, Global Business Coalition (GBC) on HIV/AIDS, Managing Director.

Dr. Maria Freire, Global Alliance for Tuberculosis Drug Development, President and Chief Executive Officer.

Mr. Mark Harrington, Treatment Action Group (TAG), Executive Director.

Ms Marieke van der Werf, KNCV Tuberculosis Foundation, Senior Director.

Dr. Melinda Moree, Malaria Vaccine Initiative (MVI) Program for Appropriate Technology in Health, Chief Executive Officer.

Dr. Mohga Kamal-Yanni, Oxfam GB, Health Policy Advisor.

Prince Ngongo Bahati, International Aids Vaccines Initiative (IAVI) Africa, Program Officer.

Ms Philippa Saunders, Essential Drugs Project, Director.

Dr. Tim Reed, Health Action International (HAI) Europe, Director.

Dr. Zeda Rosenberg, International Partnership for Microbicides (IPM), Chief Executive Officer.

*Denotes those respondents who completed parts of the questionnaire.
Appendix 4: List of Pharmaceutical Companies

ABBOTT LABORATORIES INC – Illinois, USA.
ASTRAZENECA PLC – London, UK.
BAXTER INT – Illinois, USA.
BAYER – Leverkusen, Germany.
BRISTOL MYERS SQUIBB CO – New York, USA.
ELI LILLY & CO – Indiana, USA.
GENZYME – London, UK.
GILEAD SCIENCES – California, USA.
GLAXOSMITHKLINE PLC – London, UK.
JOHNSON & JOHNSON – New York, USA.
MERCK & CO INC – New York, USA.
MERCK KGAA – Darmstadt, Germany.
NOVARTIS AG – Basel, Switzerland.
NOVO NORDISK – Copenhagen, Denmark.
PFIZER INC – New York, USA.
RANBAXY LABORATORIES LTD – New Delhi, India.
ROCHE HOLDING LTD – Basel, Switzerland.
SANOFI-AVENTIS – Paris, France.
SCHERING PLOUGH CORP – New York, USA.
WYETH – New York, USA.

In the event that any of the above companies fails to disclose adequate information to substantiate inclusion in the Index, the following company will be included:

BOEHRINGER INGELHEIM – Ingelheim, Germany.
## Glossary

### DEFINITIONS

#### Developed Countries

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

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#### Developing Countries

All Middle Income Countries (MICs) and Low Income Countries (LICs) in the Human Development Index (HDI).
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<td>Ecuador</td>
<td>Libyan Arab Jamahiriya</td>
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<td>Zimbabwe</td>
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**Global**

All countries in the Human Development Index (HDI).
Least Developed Countries

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

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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.

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
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