access to medicine index

Access to Medicine Index 2008

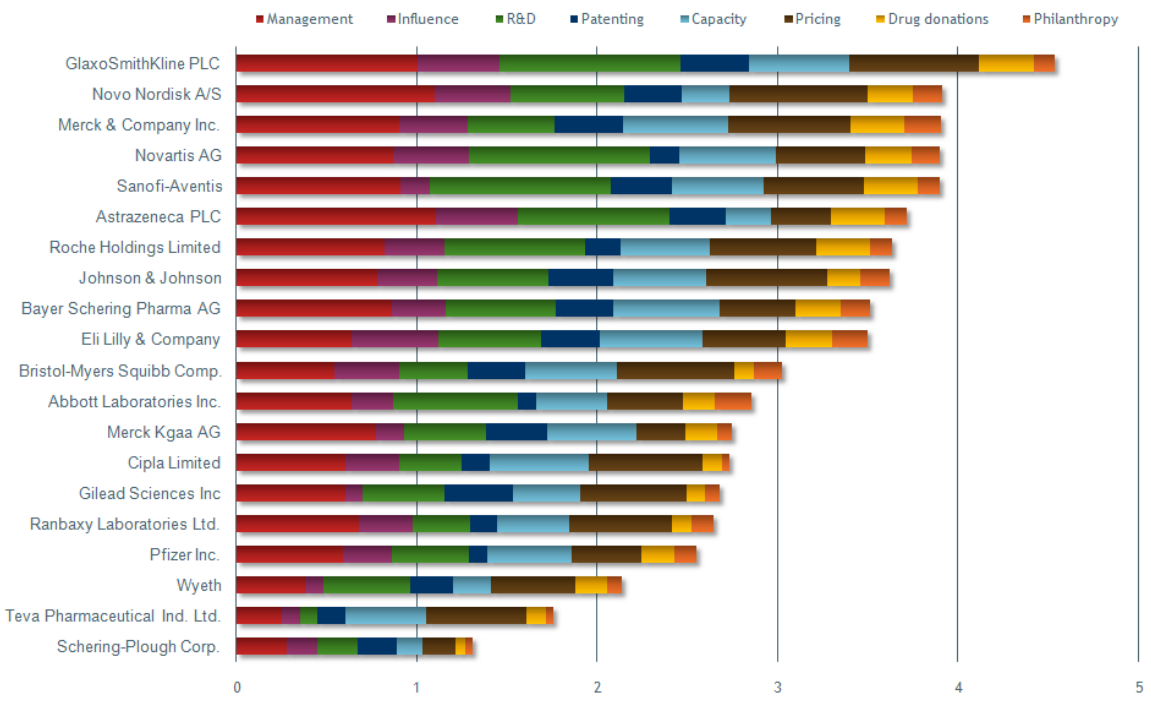
June 2008

Access to Medicine Index

Ranking Access to Medicine Practices

June 2008

Report prepared by the Innovest Healthcare Team:
Veronique Menou, Allison Hornstein and Elizabeth Lipton-McCombie



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

Mr. Peter Wilkes, Managing Director USA, +1 212 421 2000 ext. 216,
pwilkes@innovestgroup.com

On behalf of and in cooperation with:
Access to Medicine Foundation
www.atmindex.org
Mr. Wim Leereveld, Chair, Access to Medicine Foundation, +31 23 5339187
wleereveld@atmindex.org

The Access to Medicine Foundation

The Access to Medicine Index is created and maintained by the Access to Medicine Foundation, which is based in Haarlem, The Netherlands. Founded in 2005, the Foundation aims to advance access to healthcare (in the widest sense of the word) in developing countries and, in particular, to encourage the pharmaceutical industry to accept a bigger role in that respect. The Access to Medicine Foundation has charity status under Dutch Tax law. Website: www.atmindex.org.

Innovest Strategic Value Advisors

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

Acknowledgements

The Access to Medicine Foundation and Innovest are grateful to representatives from all stakeholders, including the pharmaceutical industry, for the time and energy they have invested. The Index could not have been successfully completed without their insights, efforts and frank comments. A draft of this report was sent to many stakeholders for review. We would especially like to thank the following experts for their generous input:

» Charles Clift, UK Department for International Development (DFID)
» Elias Mossialos, London School of Economics
» Helena Viñes-Fiestas, Oxfam
» My-Linh Ngo, Henderson Global Investors.

The Foundation thanks the following partners for their financial and in-kind support.

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

Preface

ENGAGING INDUSTRY THROUGH TRANSPARENCY

Three years ago, the Access to Medicine Foundation set itself a daunting task. Enlisting the help of stakeholders from all sides of the issue, we set about to create an Index that will help give millions of people on the planet better access to medicines that they urgently need.

Reducing child mortality, improving maternal health and combating HIV/AIDS, malaria and other poverty-related diseases comprise three of the United Nations' eight Millennium Development Goals. Getting universal access to existing treatments, and finding new, affordable treatments for diseases that have been largely neglected in the past, are crucial for the development of low-income countries.

The Access to Medicine Foundation believes that improving global access to medicine is a responsibility of us all. That includes governments, medical researchers and non-governmental organizations. It also includes investors and pharmaceutical companies, which, as the owners of vital knowledge, technology and infrastructure, have particular roles to play. Indeed, the last Millennium Goal includes the aim to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies.

An innovative, fully independent and collaborative tool, the Access to Medicine Index was set up to do just that. It was designed to measure and compare the efforts of drug companies to help close the gap. By bringing such transparency, it aims to further engage private investors and the pharmaceutical industry and, in doing so, to encourage collaboration with other stakeholders as well.

Examples

Over the past three years, we have built a comprehensive database of major companies' efforts to help improve access. Our research drew on numerous sources and rated the data against dozens of carefully chosen criteria. Companies themselves were invited to verify data accuracy, and independent world experts reviewed a draft research report.

This first edition of the Index demonstrates clearly that there are large differences within the industry as a whole. For the very first time, the Index identifies successful practices and holds them up as examples to others. Companies that are now at the lower end of the scale will have an added incentive to reach for the top. At the same time, companies now ranked near the top will have every incentive to reinforce that position.

We firmly believe that all stakeholders, including millions of patients, will benefit greatly from having this information available in the public domain. For example, it will provide valuable information to a growing number of investors who want to take companies' commitment to social responsibility more strongly into account, as witnessed by the number of institutional investors who already signed on to our Investor Statement.

Information taken from the Index also will enable governments, researchers and NGOs to find suitable industry partners, and develop new practices together with them.

Along with this report, a web-based tool is available at our website, www.atmindex.org. Visitors of the site will be able to click through the data and sort companies according to the criteria they find important. They will also have instant access to detailed profiles, which highlight companies' actions and policies or the relative lack thereof.

Feedback

On behalf of the Board, I would like to express the Foundation's sincere appreciation for the great support we have received from many partners. We hope all those stakeholders will remain as closely committed to our work as we expand on the Index in the coming years.

A special thanks goes to Veronique Menou and her colleagues of the Innovest healthcare team for their dedicated research, which is reflected in this report.

The Access to Medicine Foundation welcomes all comments and suggestions on the findings of this report, as well as any thoughts that may benefit further development of the Access to Medicine Index. Stakeholder support and feedback will remain crucial, we know, if only to ensure the long-term validity of the Index' content and to further improve on the analysis.

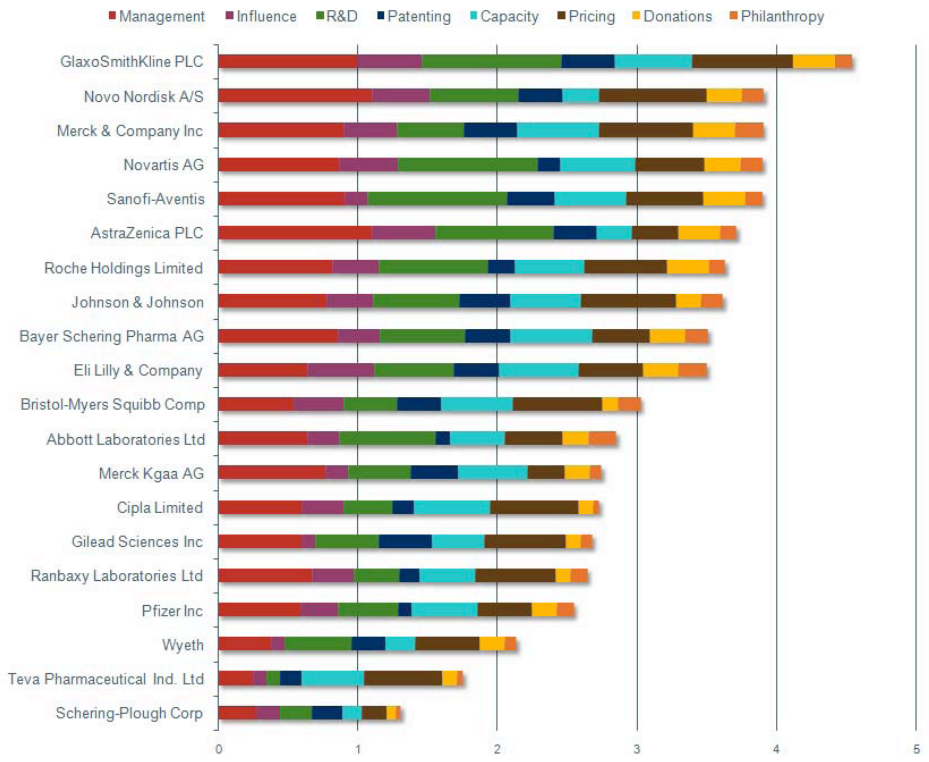
Wim Leereveld, Chair, Access to Medicine Foundation

Haarlem, The Netherlands, June 2008,
wleereveld@atmindex.org

Executive Summary

2008 ACCESS TO MEDICINE INDEX RESULTS

» **The first Acess to Medicine Index:** the chart below presents the results of the first Access to Medicine Index with ranking and scoring for each company using a best in class approach (1= lowest overall score and 5 = highest overall score). The colour legend shows the relative contribution of each of the eight AtM assessment criteria to the overall score of each company. For a detailed explanations of the Index methodology, please see Appendices 1 and 4



» ***GlaxoSmithKline* ranked highest in the Access to Medicine Index:** *GlaxoSmithKline* is the leader overall and in a number of separate categories, for "Access to Medicine Management", "R&D that Reflects both the Global Disease Burden and Neglected Diseases", "Equitable Pricing" and "Patents & Licensing." The company is amongst the top five for the other criteria except for "Philanthropic Activities." *GSK* has developed solid Access to Medicine practices including strong

investments into R&D, flexibility with regards to patents, and willingness to be more transparent on pricing issues not only for communicable diseases but also for chronic diseases. Other companies ranked in the top quartile are *Novo Nordisk, Merck & Co., Novartis* and *Sanofi-Aventis.*

Leaders, middle and lower ranked companies

- **Industry leaders perform well on most Access to Medicine Index criteria**: Industry leaders outperform on most criteria included in the Access to Medicine Index Framework and appear to have developed a significant Access to Medicine strategy addressing key issues in the access to medicine debate. They have built strong access to medicine management systems, they are relatively transparent in public policy and advocacy, and they use pathways such as equitable pricing and licensing agreements to increase greater access to affordable and good-quality drugs in the developing world. Leaders are also investing in R&D programs that reflect both the global disease burden and neglected diseases, both internally and in partnerships with R&D institutes.
- **Middle ranked companies have less sophisticated access to medicine strategies:** Generally speaking, medium performers have specific access to medicine programs in place but often fail to consistently address all key issues in the access to medicine debate.
- **Lower ranked companies do not consider access to medicine as a key issue:** Lower performers usually do not have a formal access to medicine policy that is backed at the board level, and/or they disclose little information on their efforts to improve access to medicine. They have very few programs in place to address the access to medicine issue and most of them do not have a clear commitment to respond to access to medicine challenges in the future.

Key findings

- **Investment into R&D for neglected diseases:** The number of R&D programs focused on neglected diseases is growing. Companies with or without expertise relevant to R&D for neglected diseases indicate that they recognize the need for new treatments. Several companies appear to proactively use their expertise to respond to the lack of medicines for neglected diseases. European companies have traditionally been more active in this field but involvement of US-based companies is increasing. Examples include the recently inaugurated Lilly Not-For-Profit Partnership for TB Early Phase Drug Discovery, *Merck & Co.*'s support and sharing of library compounds within the Lilly TB Drug Discovery project, and the sharing of *Pfizer's* library compounds to help search for treatments for neglected diseases (refer to the Glossary for the full list of neglected diseases).

- **Collaborative R&D programs:** Companies increasingly rely on partnerships to implement R&D programs into neglected diseases. While leaders in R&D such as *Novartis*, *GlaxoSmithKline*, *Sanofi-Aventis* and *AstraZeneca* have been involved in public/private product development partnerships for several years, new collaborations have recently emerged such as the collaboration between *Wyeth* and the WHO on river blindness, between *Tibotec* (Johnson & Johnson's subsidiary) and the TB Alliance on TB, and between *Merck KGaA* and the WHO on malaria and sleeping sickness. Partnerships have developed between companies and research institutes with strong developing country expertise, which will most likely help address the current lack of formulations suitable for developing countries and children.
- **Access to medicine management:** Most companies recognize the relevance of the access to medicine issue and have developed access to medicine policies at the board level. They have made efforts to integrate the access to medicine issue into their long-term strategy and have developed policies and processes to plan, implement, measure, monitor and report on their programs in collaboration with stakeholders. Leaders such as *Novo Nordisk* and *GlaxoSmithKline* have set up goals and quantitative targets; they report on progress over the years and rely on independent agencies to certify the validity of the data. Strong access to medicine management will most likely help companies implement effective access to medicine programs.
- **Licensing and technology transfer agreements**: Companies increasingly rely on licensing agreements and/or technology transfer agreements with generics manufacturers in the developing world to increase manufacturing capacity and ensure long-term supply of affordable and good-quality drugs. Voluntary licenses keep ownership in the hands of patent-holders and protect companies from negative publicity associated with the pricing of branded products. However, companies have yet to develop performance indicators (KPI) to show their effectiveness. Most licences involve infectious diseases, not other disease areas.
  Licensees can be manufacturers of treatments for diseases such as hepatitis or flu, but most of them produce first-line HIV/AIDS drugs in LDCs and MICs. Examples of licensing agreements include: *Merck & Co.* has granted royalty-free licenses for its HIV drug Efavirenz to five South-African generics manufacturers since 2004; *Gilead* has granted more than ten licenses in South Africa and India since 2005; *Bristol-Myers Squibb* granted two royalty-free voluntary licenses and full technology transfer to generics companies in South Africa and India in 2006. *Tibotec* entered into a licensing agreement with Aspen in South Africa in 2007.
  Examples of technology transfer agreements include: *Eli Lilly* signed agreements with four generics companies in South Africa, China, Russia and India; In 2007, *Roche* launched a "Technology Transfer Initiative" to provide local manufacturers in LDCs and SSA with technical expertise to produce the second-line treatment saquinavir.

- **Public policy influence & advocacy**: Drug companies have been criticized for extensive lobbying activities that may not be in the general interest. Over the last two years, companies have generally moved towards more disclosure of their positions on issues related to the access to medicine debate and on their funding of patient groups, medical associations, trade groups, and political parties. Details have been published on lobbying activities in the US and Europe. Leaders also disclose positions they seek to pursue within industry associations. *Eli Lilly*'s grant registry report provides a list of all grants made in 2007 and includes a brief description of all beneficiaries. *GlaxoSmithKline* and *Novartis* disclose some positions they promote within industry groups, such as greater transparency on patient group funding, more R&D funding for neglected diseases, and better supply-chain management. Greater transparency into lobbying and advocacy, in particular when applied indirectly through governments and patient groups, would increase companies' accountability to shareholders and society as a whole.
- **Drug donation programs:** All companies run drug donation programs in compliance with WHO's guidelines on drug donations. Most companies indicate that they realize that drug donations do not represent a key component of a long-term access to medicine strategy, as they are unsustainable and create distortion of local markets. Most companies support drug donations if they are part of a clear strategy, such as in emergency situations, or of a disease eradication program, and if they are run in partnership with local NGOs or international organizations. Examples include *Abbott Lab's* disaster response, *Merck & Co.*'s Mectizan program, and *Bayer*'s donations as part of the Global Polio Eradication Initiative.
- **Transparency**: Many companies provided clear access to medicine policies at the global level but did not disclose how programs are implemented at local levels, for instance by local subsidiaries.
- **Sustainable business models:** Industry leaders have mechanisms in place to manage access to medicine risks but most companies faill to recognize business risks associated with access to medicine. Long-term commercial benefits are often not well-presented. There is a need for a more progressive and entrepreneurial approaches that seek to create sustainable business models. While companies expand their activities in the developing world, it becomes increasingly relevant for them to identify strategic opportunities and focus on sustainable value creation.
- **Pricing strategies**: Some companies rely on potentially counterproductive drug donation programs rather than more sustainable equitable pricing mechanisms. Equitable pricing policies applied by others have focused on treatments for infectious diseases, not yet for non-communicable diseases and chronic diseases. Although pharmaceutical companies often do not have full control over pricing, sustainable pricing schemes that address the purchasing powers of populations in middle and high-income countries are becoming increasingly important.

Table of Contents

CHAPTERS

Introduction

ABOUT THE ACCESS TO MEDICINE INDEX

Preventable and treatable diseases such as HIV/Aids, malaria, tuberculosis and many others continue to claim millions of lives every year in developing countries. About two billion people cannot afford the drugs or vaccines that have been developed against diseases that are threatening them, or suffer from devastating diseases for which no affordable remedies are being developed.

While all of us share a common responsibility to improve global access to drugs, diagnostics, vaccines, and other healthcare technologies, it is also clear that pharmaceutical companies, as the owners of unique knowledge, technology and infrastructure, have to be an integral part of such efforts.

Companies can assist in all sorts of ways. For example, they can invest in research and development geared towards treatments for poverty-related and neglected diseases; they can increase efforts to out-license patented products to generics producers in developing countries; they can apply equitable pricing mechanisms for brand products; they can help to build sustainable research, manufacturing and distributing capacity in low-income countries; or they can limit their drug donation programs to situations where better options are not available.

To their great credit, many pharmaceutical companies have already stepped up to the plate. To the outside world, however, it is often difficult to gauge the extent to which individual companies are engaging the problem. Companies that are actively involved may not get the credits they really deserve, while companies less committed may avoid some tough questions.

In 2007, the UN Special Rapporteur on the right to the highest attainable standard of health has proposed draft guidelines for pharmaceutical companies in relation to access to medicine. In those guidelines, transparency plays a crucial role. The Access to Medicine Index is an important tool to that end.

A role for investors

Investors have recently joined a general trend towards taking more social responsibility. A growing number of investors and asset managers, including very large ones, recognize the need to take environmental, social and corporate governance (ESG) issues into account -- if only because companies with superior ESG performance and positioning often prove to be better long-term investments.

Several projects exist today that help investors take ESG issues into consideration when making investment decisions. These include the Dow Jones Sustainability Indexes, FTSE4Good, the U.N. Principles for Responsible Investment, and the Carbon Disclosure Project..

The Access to Medicine Index follows in the footsteps of such successful initiatives. The Index will enable pharmaceutical companies to visibly increase their ESG performance and become more attractive to ESG-conscious investors. It could also enable them to improve their reputation with the general public, enhance their relationship with governments, and reduce the risk of substantial changes to intellectual property systems.

For its part, the investment community has shown strong interest in the Index. Twelve large investors, together managing more than USD 1.2 trillion (as per 31 Dec 2006), have signed a statement in support of the Index (see www.atmindex.org).

The Index

The Access to Medicine Index assesses and ranks 20 of the world's largest pharmaceutical companies based on criteria such as their active access to medicines management, their public policy influence and advocacy, their research & development into neglected diseases, their patent and licensing policies, their efforts to build local capacity, their drug donations, and their other philanthropic activities.

The Index' framework of benchmarks was developed through extensive consultation with representatives of all stakeholders to the issue, including governments, researchers, non-governmental organizations, investors and pharmaceutical companies. Its procedures incorporate continuous feedback and discussion and ensure that the Index will be evaluated and adjusted each year.

The Index will serve three major goals:

- Supply all stakeholders, including investors, with independent, impartial and reliable information on company efforts to provide global access to medicine;
- Provide pharmaceutical companies with a transparent means by which to assess, monitor and improve their own performance and their public and investment profiles.
- Provide a platform on which all stakeholders can continuously discuss best practices and lessons learned.

Research

This report is the fourth written by Innovest on behalf of the Access to Medicine Foundation. It presents the findings of the research and benchmarking phase of the Access to Medicine Index development process, as well as rankings of twenty selected

pharmaceutical companies with regard to their efforts to increase global access to medicine.

Each company's business model was analyzed before its access to medicine practices were researched through public sources as well as interviews with stakeholders and company representatives. Companies' performances were rated relative to each other using a so-called "best in class approach", awarding 5 points to the best practices that are found and rating others accordingly.

Eight main criteria were identified, and each of them was awarded an individual weighting. Within most criteria, more detailed indicators were measured, each with their own weightings as well.
For some companies, weightings were adjusted to compensate for specific circumstances within their respective markets. For example, generics companies do not have R&D capacities; for them, the weighting of this particular criterion was downgraded.

It is important to note that the Index often relies on companies making information available. In rare instances, low scores and rankings may reflect low transparency rather than low performance. It is hoped that this inherent bias can be further reduced in subsequent editions of the Access to Medicine Index.
More detailed explanations of weighting adjustments are available in Appendix 1.

Performance scores and rankings are also published on the Access to Medicine Index website (www.atmindex.org).

Multi-stakeholder feedback

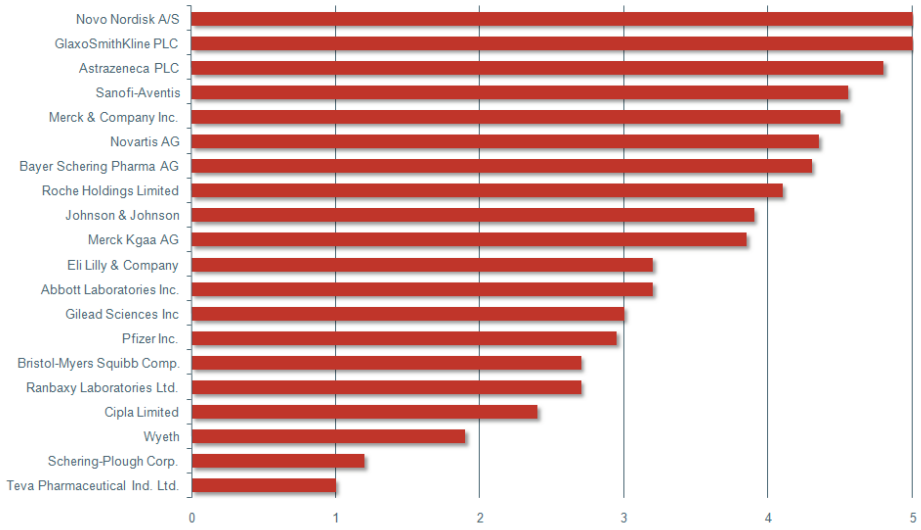
Each year, criteria, indicators and weightings will be evaluated and adjusted after taking into account multi-stakeholder feedback. Following that, companies' scores and rankings will be updated.

As stated before, the Access to Medicine Index will have a broad audience. Companies are offered the opportunity to communicate on their commitment towards access to medicine; investors can get a better understanding of the management of risks and opportunities relating to access to medicine; governments and NGOs will be able to pinpoint the need for regulations and for development of advocacy activities; researchers can identify knowledge gaps and collaboration partners. Last but not least, the Index provides a platform for ongoing dialogue among stakeholders and for the development of robust partnerships.

On the following pages, best practices, examples of relevant programs and suggested improvements will be highlighted for each of the eight criteria included in the Access to Medicine Index Framework.

A. Access to Medicine Management

Drug companies generally demonstrate a commitment towards Access to Medicine and have developed solid access to medicine practices. This will most likely help them implement effective solutions to improve access to medicine.



BEST PRACTICES FOR ACCESS TO MEDICINE MANAGEMENT

- **Board-level oversight of access to medicine issues:** Industry leaders demonstrate evidence that a board member or a board committee is responsible and accountable for access to medicine issues.
- **Existence of a global policy backed at the board level:** Industry leaders have developed a worldwide and long-term policy for access to medicine and present the rationale behind their access to medicine strategy via case studies. The business drivers include enhancing employee motivation, maintaining the intellectual property right system, securing future markets in the developing world, and acting as a good corporate citizen. Leaders consider that the access to medicine issue is key to outperforming over the long term.
- **Implementation of sound management systems**: Industry leaders have developed targets for access to medicine programs and quarterly and/or annually report on progress towards targets. Most companies rely on their partners to assess

the effectiveness of access to medicine programs and pay regular visits on site. Leaders also rely on external agencies to certify the validity of the data.

- **Commitment to regular dialog with a wide range of stakeholders:** Leading practices include the existence of numerous channels to communicate on access to medicine issues internally and externally, programs to get feedback from employees on the company's Access to Medicine practices, examples of how stakeholders' views have influenced the company's approach, and active company participation in policy debates regionally, nationally, and internationally.
- **Commitment to ethical marketing:** Common practices include the existence of a company statement to adhere to the IFPMA Code of Pharmaceutical Marketing Practices. Leaders disclose a clear commitment towards the WHO's Ethical Criteria for Medicinal Drug Promotion.

Examples of leading edge practices:

- ***Sanofi-Aventis'* separate Access to Medicine organization**: the French group has created an Access to Medicine division within the Corporate Affairs department that is separate from the philanthropic activities and drug donation programs, which are part of Public Affairs and Communication. The Vice-President of Access to Medicine reports to the Senior Vice-President of Corporate Affairs who directly reports to the CEO. Such an approach indicates that the company considers Access to Medicine as a strategic issue.
- **Pfizer's Global Health Fellows Program**: employees at *Pfizer* have the opportunity to volunteer for four to six months at non-profit health organizations and share their expertise to improve access to health in the developing world. Such practice seems to be a relevant tool to raise awareness among employees and to get feedback from employees themselves and local partners.
- ***Ranbaxy's* access to medicine policy:** even though *Ranbaxy*'s reporting is less sophisticated than leading originator companies, the Indian generic company has developed an approach backed at the board level in which it discloses the business rationale for Access to Medicine. It mentions the need to uphold company reputation and maintain the license to operate in developing countries. It also recognizes the need for new treatments for neglected diseases and the opportunities India has to offer in terms of low cost and high scientific skills for R&D investments.

AREAS SUGGESTED FOR IMPROVEMENT

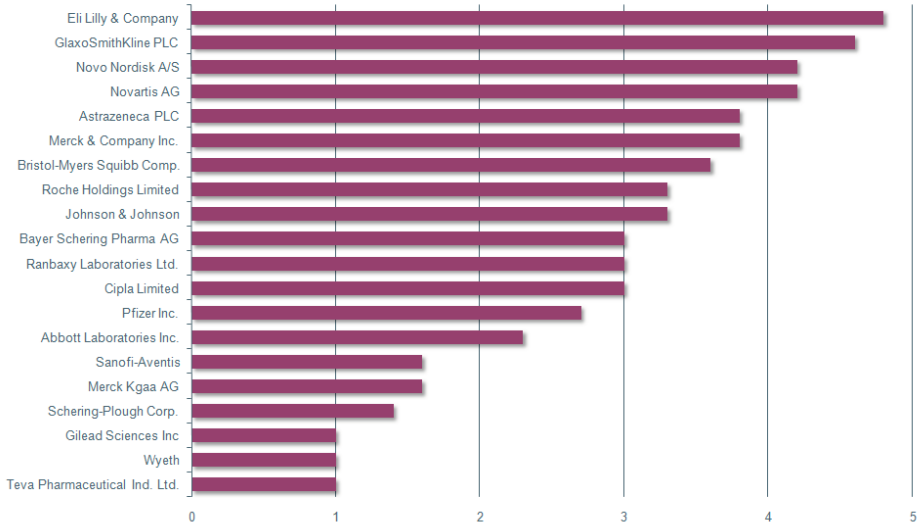
- **Stronger monitoring protocols:** There is room for improvement among drug companies in terms of developing clearer mechanisms, at both the global and the

local levels, to measure the effectiveness of programs, report on impacts, and implement corrective actions. access to medicine programs are increasingly conducted in partnerships with stakeholders, and therefore we hope to see more information about the monitoring role of partners going forward.

- **Stakeholder feedback:** Companies recognize the need for stakeholder engagement but more information is needed on their relationships with stakeholders, in particular how stakeholders' views influence company strategies.
- **Better demonstration of the benefits of access to medicine programs:** there is a need for more quantitative data on the benefits derived from access to medicine programs. In addition, examples of innovative approaches that seek to identify sustainable opportunities related to Access to Medicine would be appreciated.

B. Public Policy Influence & Advocacy

While the goal was to assess consistency between a company's public and private positions and its practices, the research had to focus on disclosure practices due to a lack of consistent data across the board. Greater transparency in this area would enable a more content-based analysis in subsequent editions of the Index and would ensure stronger accountability towards shareholders.



BEST PRACTICES FOR PUBLIC POLICY INFLUENCE & ADVOCACY

- **Existence of a commitment towards transparency:** Industry leaders publish a statement presenting their commitment towards transparency in public policy influence and advocacy.
- **Disclosure of a wide range of company positions relating to the access to medicine debate**: Industry leaders make public their position on the main access to medicine issues including intellectual property, TRIPS and compulsory licenses, public-private partnerships, product diversion and counterfeiting, registration, pricing, drug donations, philanthropy, R&D for neglected diseases, clinical trials, and ethical marketing practices.

- **Examples of advocacy policy**: Industry leaders offer several examples of advocacy activities on the international scene calling for better healthcare infrastructures in the developing world, sustained funding for the global disease burden and neglected diseases, political commitment to address the shortage of healthcare professionals in the developing world and better treatments for chronic diseases. In the US, activities focus on healthcare reform and enhancing basic healthcare coverage for the uninsured. In the EU, examples include faster regulatory registration, diabetes prevention and control, development of pediatric medicines, and drug quality.
- **Contributions to political organizations, patient groups, medical associations and academic centers:** Industry leaders disclose a full list of organizations receiving funding from the company in the US and the EU including patient groups, medical associations and academic centers. The company's funding does not exceed 25% of the organizations' total funding, and the details of the funding and the scope of the partnerships are publicly available. Addtionnally, leaders disclose the list of state candidates they support in the US and their political views. They also publish their lobbying expenditures in the US and/or the number of lobbyists employed by the company in Brussels and in Washington D.C.
- **Board approval process :** Leading practices in public policy influence and advocacy include evidence that the board or the excecutive board approves the company's public policy practices.

Examples of leading edge practices:

- ***Eli Lilly's* disclosure of cash grant requests**: since May 2007, *Eli Lilly* has publicly disclosed its grants to US organizations including medical societies, academic centers, patient groups and non-profit institutions. *Eli Lilly* was the first company to open its records in the US and to demonstrate greater commitment towards transparency in educational funding.
- ***Bristol-Myers Squibb*'s (BMS) reporting on payments to trade associations**: *BMS* has recently taken a step towards greater transparency by publishing dues paid to trade associations. In 2008, BMS decided that for each trade association that receives USD100,000 in dues or other payments from the company during a given year, the company will disclose, on a semi-annual basis, the portion of such payments that is identified by the trade association as being used for non-deductible political expenditures.
- ***GlaxoSmithKline's* (GSK) presentation of a national perspective**: while drug companies express their general support of IP rules, *GSK* has taken a step forward by applying its views regionally and in particular to the Indian patent system and the issuance of compulsory licenses by the Thaï government.

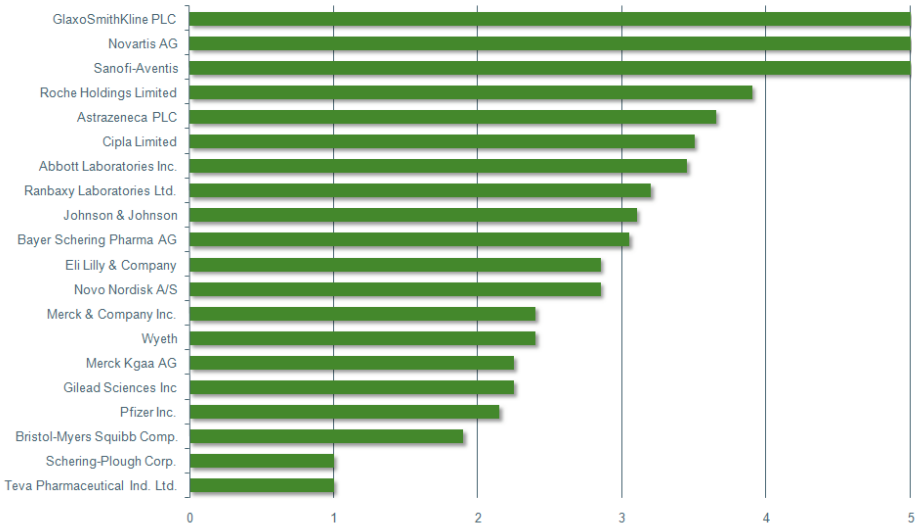
- ***Novartis* and *Merck & Co.'s* push towards greater transparency in Europe and in the US respectively**: *Merck & Co.* has been working closely with the Center for Political Accountability on a model code of conduct for political spending and hopes to encourage a number of major companies to come out in public support of this code in 2008. Similarly, *Novartis* clearly expresses its desire to foster a debate on greater transparency in lobbying expenditures in Europe.

AREAS SUGGESTED FOR IMPROVEMENT

- **Companies' public positions and advocacy activities:** not all companies disclose their positions on issues related to Access to Medicine regionally, nationally and internationally. Going forward, more examples of advocacy activities aiming to foster Access to Medicine would be appreciated by stakeholders. This will allow for deeper analysis of consistencies between a company's positions and its practices.
- **Data exclusivity:** none of the companies disclose a commitment not to advocate for data exclusivity. Drug companies strongly believe that the intellectual property right system is essential to boost innovation and does not prevent Access to Medicine to those in need.
- **Indirect lobbying:** following the ABPI guidelines, some, but not all, companies have started publishing the list of patient groups they support in Europe and in the US. There is a need, however, for more information on funding, project objectives, and the link between an organization's members and the pharmaceutical companies.

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

Research & Development is a key component of a sound Access to Medicine approach, as it will most likely result in the discovery of new and more effective medicines and help the company consolidate market share and open new markets. The majority of companies have invested in R&D programs aiming at discovering new treatments and new formulations for neglected diseases (ND) and the global disease burden (GDB).



BEST PRACTICES FOR RESEARCH & DEVELOPMENT THAT REFLECTS BOTH THE GLOBAL DISEASE BURDEN & NEGLECTED DISEASES

» **Existence of a policy on investment for new treatments for neglected diseases and new formulations for the global disease burden and neglected diseases:** Industry leaders recognize the need for more investments into R&D for neglected diseases. They also recognize that existing treatments are not always suitable in a developing country context and for patient groups such as children, and they implement programs addressing both issues.

- **Strong in-house investment in R&D into new treatments for neglected diseases**: Industry leaders invest in several in-house research programs into more than two neglected diseases. They have a group of scientists (around 100 scientists) dedicated to neglected diseases, in a department dedicated to the issue. They also provide evidence of discovery programs and clinical trials in various phases focusing on new treatments, new formulations, and pediatric use.
- **Evidence of robust partnerships with research institutes**: most companies realize the benefits of a partnership approach when it comes to R&D. Leaders have developed robust collaborations with several research institutes specializing in neglected diseases and with expertise in working in developing countries such as the TB Alliance, the Drugs for Neglected Diseases iInitiative (DNDi), or the Medicines for Malaria Venture (MMV). They have researchers working hand in hand with scientists employed by research institutes, they share library compounds, and jointly conduct discovery phases and clinical trials.
- **R&D contribution amongst companies without R&D expertise relevant to neglected diseases**: companies without expertise relevant to neglected diseases are still in a position to contribute to R&D activities conducted by others. Leading practices include sharing library compounds, giving IP rights to research institutes, participating in scientific advisory boards, donating expertise, and offering training.
- **Existence of several research programs on suitability in the developing world and for children**: best practices include consulting R&D institutes with expertise in the developing world, developing fixed-dose combination (e.g. HIV drugs and/or anti-malaria treatments) to make it easier for patients to follow up their treatments, developing formulations that do not require taking food with the treatment, and working on heat-stable formulations and mechanisms for preventing drugs from getting spoiled before reaching their destination. Some companies are also working on reducing the length of treatments (e.g. TB) and improving the dosing intervals. Lastly, leaders are conducting research into pediatric formulations of new and existing treatments for neglected diseases and the global disease burden.

Examples of leading edge practices:

- **Dedicated neglected diseases divisions at *GlaxoSmithKline*, *AstraZeneca*, *Novartis* and *Eli Lilly*:** all four companies have created dedicated divisions specializing in R&D for neglected diseases. Divisions are run in partnership with research institutes and focus on one or more therapeutic areas. Leaders such as *GlaxoSmithKline*, *Novartis* and *Sanofi-Aventis* also have vaccine departments focusing on tropical diseases.
- ***Wyeth*'s collaboration with the WHO:** for eight years, *Wyeth* has been partnering with the WHO on a program which aims to determine the efficacy of moxidectin to

treat river blindness. *Wyeth* provides the drug as well as clinical expertise and helps facilitate clinical trials. The company expects Phase III trials to take place by October 2008 and is committed to working with the WHO to obtain regulatory approval and distribution in the next five to six years.

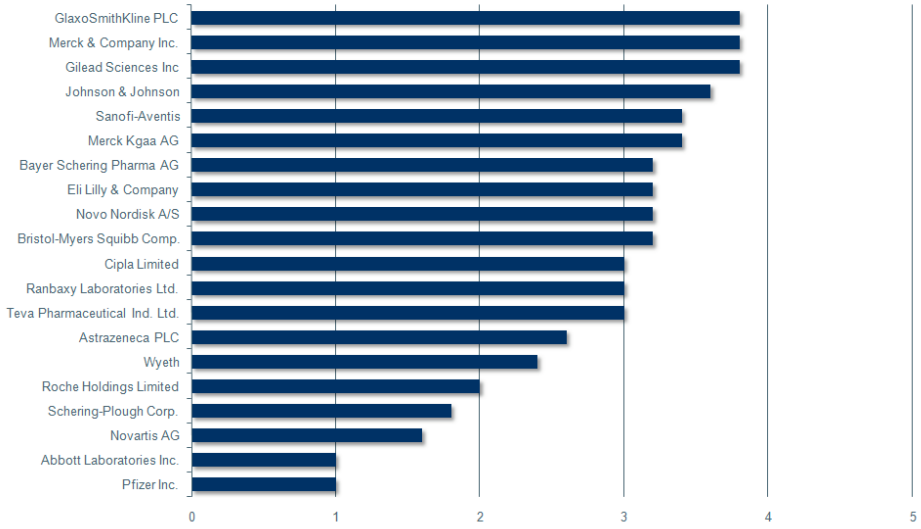
- ***Cipla*'s involvement in coformulations:** *Cipla* demonstrates sound practices with regard to heat-stable and pediatric formulations of HIV and malaria drugs. In August 2007, the US FDA approved Triomune, the first fixed-dose, triple combination HIV/AIDS tablet approved for children under the age of 12 years. *Cipla* is also working with DNDi on a fixed-dose combination for treatment of malaria.
- ***Roche's* support to R&D activities conducted by others**: *Roche* clearly recognizes that even though its R&D expertise is not relevant to neglected diseases, it can still play a role in this field by donating its rights and technology to help research on neglected diseases (e.g. donations to the Brazilian government relating to Chagas disease) and by supporting training in good clinical practices and quality assessment.

AREAS SUGGESTED FOR IMPROVEMENT

- **R&D activities into neglected diseases**: as mentioned previously, companies are increasingly getting involved in R&D programs in-house and in partnership with peers and research institutes. This trend will most likey continue going forward, as debates are currently taking place among stakeholders to get sustained funding for R&D into neglected diseases. Additionally, the growing importance of emerging markets in the pharmaceutical sector result in companies entering into R&D collaborations with companies in the developing world to benefit from their expertise on the local needs.
- **Pediatric R&D**: similar to neglected diseases, there is a significant need for pediatric formulations of new and existing treatments for the global disease burden. We hope to see companies getting more involved in such R&D programs in collaboration with peers or research institutes in the near future.
- **Better disclosure**: there is a need for more quantitative data on R&D activities such as the number of scientists dedicated to neglected diseases and/or the number of compounds in the portfolio. In addition, information about the performance, the status of R&D efforts and the returns on R&D investments would be welcomed by stakeholders.

D. Patents & Licensing

Most drug companies see IP rights as crucial to fostering R&D. They do not consider patents a barrier to access to medicine. Many use pathways such as licensing agreements with generics companies in developing countries. Most of the licensing agreements concern HIV drugs in MICs. Some companies have entered into licensing agreements with generics companies in the developed world, for instance in the areas of flu and hepatitis.



BEST PRACTICES FOR PATENTS & LICENSING

- **Several licensing agreements with local generic companies in the developing world:** Industry leaders have entered into several licensing agreements and disclose the terms of these agreements. Licenses are non-exclusive, royalty-free, allow for sale in a wide range of markets, and do not entail any restrictions on sourcing or production. A sound practice is granting the licensee the right to set prices. Additionally, leaders demonstrate the positive impacts of licensing agreements by disclosing the progress in terms of volume of production or registration.
- **Clear policy on TRIPS:** leading practices include a clear statement by the company not to enforce patents in LDCs and not to get involved in the rights of developing countries to use flexibilities such as compulsory licenses in case of emergency.

Examples of leading edge practices:

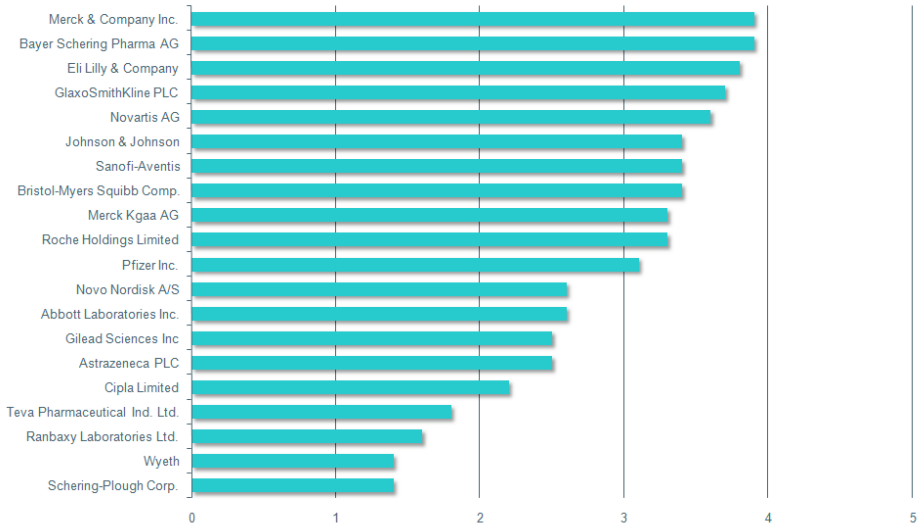
- ***Sanofi-Aventis'* patent approach with the anti-malarial ASAQ:** *Sanofi-Aventis* and DNDi have developed the artesunate + amodiaquine fixed-dose combination, called ASAQ. They have agreed not to take out any patent covering this drug. Like its peers, Sanofi-Aventis is a proponent of IP, but it considers ASAQ to be an exception. The rationale for such practices is that ASAQ is used by very poor populations and was developed in partnership with DNDi whose founding partners are primarily from the public sector.
- ***GSK*'s licensing agreements with a generic company in Canada**: in the summer of 2007, *GSK* gave consent to the Toronto-based drug company Apotex to use two of its patented antiretroviral drugs, lamivudine and zidovudine, to manufacture Apo-triAvir - a fixed-dose combination of the two drugs and the antiretroviral nevirapine, developed by Boehringer Ingelheim. The drug is meant for distribution in Rwanda, and the scheme was developed through Canada's Access to Medicine Regime.
- ***Gilead's* numerous licenses in the developing world:** since 2005, *Gilead* has entered into more than ten licensing agreements with local generic companies in South Africa and India and with the International Partnership for Microbicides. Licenses are non-exclusive and allow for sale in a wide range of countries. However, in India *Gilead* receives a 5% royalty on any sales.

AREAS SUGGESTED FOR IMPROVEMENT

- **Improved licensing agreements:** there is a need for new licensing agreements for all disease areas with greater independence for the licensee to establish the pricing policy, to sell in a wide range of markets, and to coformulate drugs. Voluntary licenses with technical assistance would also contribute to the sustainable development of good-quality drugs.
- **Compulsory licenses**: companies that have disclosed their position on TRIPS state that they recognize the rights for countries to use compulsory licenses but only in case of emergency, whereas TRIPS does not specify they must be used in case of emergency. Going forward, we hope to see more companies publicly state their commitment to TRIPS, refrain from involvement in the politics of compulsory licenses, and pledge to negotiate with local governments. Frictions between companies and governments in the developing world relating to intellectual property rights have a negative impact on companies' license to operate.

E. Drug Manufacturing, Distribution and Capability Advancement

A number of companies demonstrate a desire to use their expertise in drug development, manufacturing, quality control, delivery, and human resources management to foster capacity in the developing world. However in some areas, such as pharmacovigilance, involvement is limited.



BEST PRACTICES FOR DRUG MANUFACTURING, DISTRIBUTION AND CAPABILITY ADVANCEMENT

- **Existence and disclosure of a commitment towards drug quality:** Industry leaders have quality standards in line with FDA, EMEA and WHO and call for stronger quality controls in the developing world.
- **Several technology transfer agreements:** leading practices include technology transfer agreements with local companies in MIC and/or LDCs. When drugs are still patent protected, the technology transfer agreement complements the licensing agreement. Leaders demonstrate robust quality mechanisms including a stringent process to select the local partner to ensure the long-term supply of good-quality drugs. Training sessions are also organized, and regular quality checks are conducted by experts from the originator company. Leading practices include mechanisms to measure the impact of such practices on Access to Medicine, e.g.

the number of drugs produced over the past few years or the number of patients reached.

- **Involvement in several programs to improve pharmacovigilance systems in the developing world:** a handful of companies are addressing the need for strong pharmacovigilance systems in the developing world. Leaders are working in partnership with NGOs and local governments to share lessons learned from the implementation of pharmacovigilance systems in the West and apply them in the developing country context.
- **Robust mechanisms to fight counterfeiting and product diversion**: most companies have sound programs in place to prevent product diversion and deter counterfeiting. Leaders have a wide range of mechanisms in place, work in close collaboration with peers, governments and contractors, list their primary authorized distributors on their website and give examples of legal strategies to prevent fraudulent practices.
- **Sound employee programs in the developing world:** Industry leaders have developed a clear policy for their employees worldwide and offer healthcare benefits equal to or above local standards to more than 90% of their employees. Leading practices also include an HIV/AIDS policy in the workplace which offers HIV drugs to employees and their relatives in addition to educational and counseling programs.

Examples of leading edge practices:

- ***Novartis'* call for strong quality standards:** *Novartis* argues that the same quality standards should be applied worldwide and calls for stringent quality control. In particular, the company considers the WHO's prequalification standard as a minimum and would advocate for stronger standards such as the FDA, EMEA or Swissmedic (the Swiss Agency for Therapeutic Products), especially for products covered by the Global Fund.
- ***Roche's* "Technology Transfer Initiative":** in 2006, *Roche* launched the "Technology Transfer Initiative" (TTI) which aims to provide local generic companies in LDCs and SSA with technical expertise to produce the second-line treatment saquinavir. As of May 2008, *Roche* had entered into eight technology transfer agreements with manufacturers in Kenya, Zimbabwe, Tanzania and Bangladesh. The company has implemented a robust quality assurance system including stringent company selection standards, support for plant setup, and regular quality checks conducted by a team of experts from *Roche.*
- **Johnson & Johnson's (J&J) programs to improve pharmacovigilance systems in the developing world**: J&J is a leader in terms of pharmacovigilance. The group is teaming up with stakeholders in order to improve pharmacovigilance systems, build professional expertise in the area of safety, and help establish a sustainable

culture of drug safety in Asia, South America and the European Union. Activities include training, data sharing, and help in formulation of new legislation.

» ***Merck KGaA's* GPHF Minilab**: the Global Pharma Health Fund, a charitable organization funded by *Merck KGaA* has developed the GPHF-Minilab®, a toolbox which enables health facilities responsible for drug purchase, storage and distribution to protect themselves against fake drugs. So far, more than 270 Minilabs have been supplied to health facilities in 65 countries mostly in Asia and Africa.

AREAS SUGGESTED FOR IMPROVEMENT

» **Better measurement of impact:** while several technology transfers have been developed over the last few years, quantitative data is missing on the actual impact of such practices on Access to Medicine. We expect companies to develop new KPIs and report on the effectiveness of such practices. In addition, more details on mechanisms in place to ensure the manufacturing of good-quality drugs are needed.

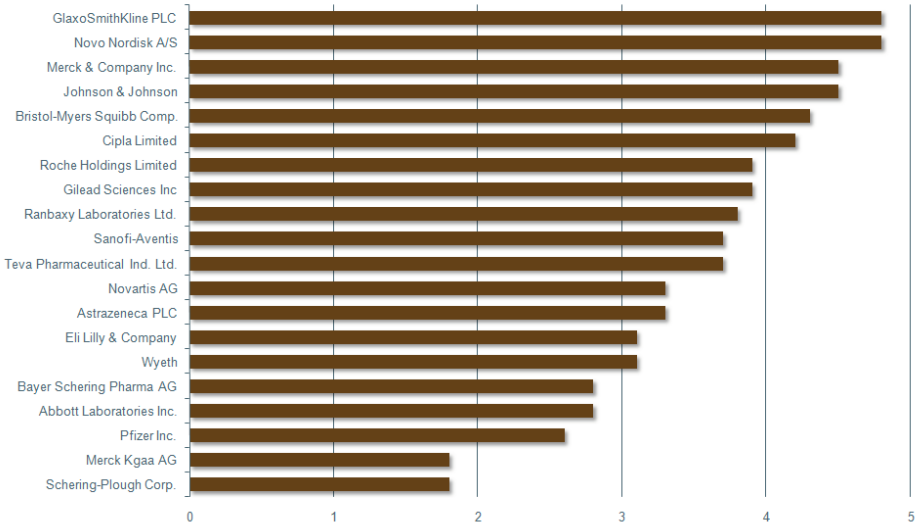
» **Limited involvement in programs to support the development of pharmacovigilance in the developing world**: although many drugs have been extensively used and studied in developed countries, their safety profile cannot necessarily be generalized to developing countries, where the incidence, pattern, and severity of adverse reactions may differ markedly because of local environmental and genetic factors. A handful of companies are currently working on programs aiming to advance the science of pharmacovigilance in the developing world. This trend will most likely continue, as pressure from governments, the WHO, and patient groups is increasing. As companies expand their operations in the developing world, it is also crucial for them to be able to monitor the safety and efficacy of their treatments.

» **More data on employee benefits in the developing world**: companies lack KPIs on healthcare benefits offered to employees in the developing world. The majority claims to offer benefits throughout the group, but only a few report on the actual percentage of employees covered by healthcare benefits and the type of benefits offered.

» **Quality management systems**: quality is a key issue in the sector and especially for generic companies. However, little information is available on processes to ensure quality in manufacturing among generic manufacturers. There is a need for greater transparency from generic companies on the mechanisms in place to demonstrate bioequivalence and ensure good manufacturing protocols.

F. Equitable Pricing

Most companies have developed pricing mechanisms dealing with treatments for the big three infectious diseases (HIV/AIDS, malaria and TB). Similar mechanisms for treatments of chronic diseases are lacking. More third-party research and company reporting are needed with regard to registration and pricing of drugs for chronic diseases.



BEST PRACTICES FOR EQUITABLE PRICING

- **Wide registration of most products**: Industry leaders are committed to widespread registration, and Innovest's research did not uncover any concerns on registration issues involving leading companies. Leaders also demonstrate transparency by disclosing the list of countries where at least one of their main drugs (e.g. an HIV drug or a malaria treatment) has been registered.
- **Sound pricing mechanisms for infectious diseases**: Industry leaders have developed a tiered pricing policy for infectious diseases. They offer affordable and predictable prices and demonstrate evidence of decrease in drug prices over the years. They also disclose the rationale behind pricing mechanisms, detail their implementation, and measure the impact in terms of the number of drugs shipped and/or the countries and the patients reached.
- **Collaboration with international agencies on vaccines**: Industry leaders are working in conjunction with organizations such as GAVI and UNICEF to sell their

vaccines in the developing world. When responding to tenders, companies have to abide by a set of standards to ensure good-quality medicines.

- **Low prices offered by generic manufacturers:** the entry of a generic leads to increased competition and a drop in prices. Sales of a drug can plunge 80% or more the first year after a generic enters the market. Even though generic companies lack disclosure on pricing mechanisms, their prices are often more affordable and predictable than prices established by originator companies.
- **Positive programs in the developed world:** access to medicine is not only an issue of the developing world but is also a key concern in the developed world, particularly in countries with no or limited public healthcare provisions. Most companies realize the need for patient assistance programs through which drugs are provided at a discounted price to poor patients in addition to support and counseling services. Leaders have developed robust strategies and partnerships to improve Access to Medicine to people in need in the US and Eastern Europe.

Examples of leading edge practices:

- ***Gilead*'s transparency in registration**: in response to criticisms from civil society that *Gilead* appears to be delaying the registation of its products, the company has decided to increase transparency by disclosing the list of countries where marketing applications have heen filed, are pending, or have been approved for two of its ARVs; Viread and Truvada.
- ***Merck & Co.* 's tiered pricing policy**: *Merck & Co.* has developed an innovative approach for determining country eligibility for three tiers of pricing discounts for its HIV drugs based on the UN Human Development Index (HDI) and adult HIV/AIDS prevalence rates as reported by UNAIDS. Based on these guidelines, *Merck & Co.* makes no profit on the sale of its current HIV/AIDS medicines in LDCs and countries hardest hit by the pandemic. For medium HDI countries with an adult HIV prevalence of less than 1%, HIV/AIDS medicines are available at significantly reduced prices. For high HDI countries, *Merck & Co.* makes its ARVs available at market-based prices that take into account local purchasing power and competitive products. The offer extends to the governments of developing countries as well as to international donor agencies, NGOs, charitable organizations and private-sector employers.
- ***GSK*'s "Tearing down the barriers" concept**: *GSK* is working on a strategy to expand markets and increase Access to Medicine in low- and middle-income countries. Through a concept called "tearing down the barriers," the company is working on differential pricing schemes within and between India, South Africa and other developing countries. *GSK*'s new strategy not only focuses on the three major infectious diseases but also aims to tackle the growing challenge of chronic diseases with a dual market among the rich and the poor. *Sanofi-Aventis* has also

recently started extending its tiered pricing scheme, originally developed for malaria, to include epilepsy and mental health.

- ***Novo Nordisk's*** **pricing initiatives for diabetes***: Novo Nordisk* is implementing pilot projects targeting specific populations such as people in LDCs, the "Base of the Pyramid" in Brazil, India, China and Russia, migrant populations in the developed world, and children worldwide. The key component of Novo Nordisk's diabetes programs is partnerships in order to ensure that patients not only get access to the drugs but also get medical support, counseling and education.
- ***Cipla's*** **and** ***Ranbaxy*****'s willingness to reduce ARV price**: while generic companies traditionally offer low prices, they are still in a position to offer discounts to people in need. At the end of 2006, both Indian generic companies agreed to the Clinton Foundation's requests to significantly reduce the price of ARVs and in particular the price of formulations suitable for children.

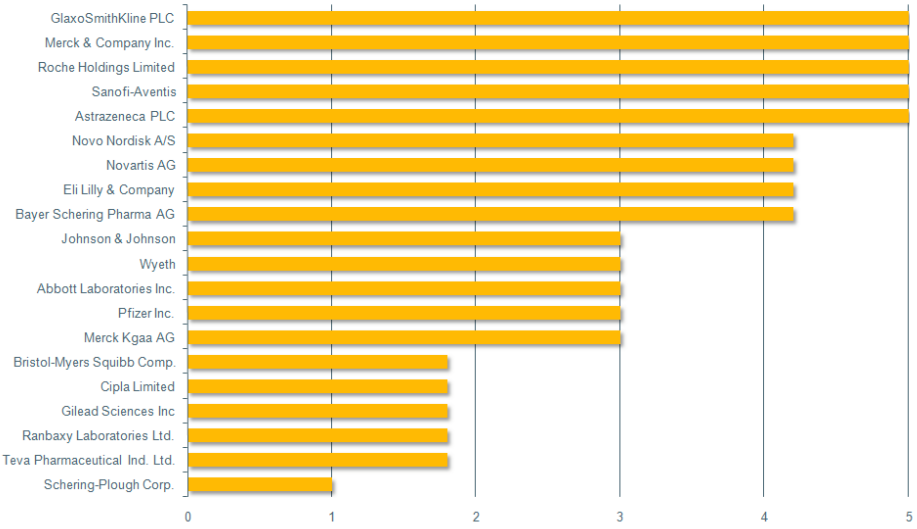
AREAS SUGGESTED FOR IMPROVEMENT

- **More data on registration:** while company's disclosure on registration for the main infectious diseases has improved, limited information is available in company reports and in third-party research regarding other diseases. Going forward, we would appreciate more reporting by governmental agencies, third parties and companies.
- **Measuring impact:** quantitative data such as the number of drugs sold or shipped at cost or at a discounted price allows for deeper analysis of the impact of pricing practices. However, little information is available.
- **Lack of transparency and predictability in middle-income countries:** most companies do not present the rationale behind pricing mechanisms in middle income countries and state that they negotiate with governments case by case. There is a need for more disclosure on the pricing mechanisms and implementations.
- **The development of innovative pricing policies:** pricing is a very complex issue due to the variety of players involved, different country contexts, the duality of markets within countries, the risk of diversion, the competition issue, and the different types of medicines. International initiatives are being conducted gathering views from a wide range of stakeholders on the pricing issue. A few companies have started developing new strategies in collaboration with specialized organizations to address the pricing issue targeting chronic diseases and specific populations in low-, middle- and high-income countries. Going forward, we hope to see more dialog between stakeholders on pricing.
- **Evidence of rebranding:** the issue of rebranding is not well addressed in companies' literature but is seen by stakeholders as a relevant way to prevent

product diversion and reduce the risks of reference pricing especially where there is a growing concern in developed nations about perceived unfair discounts in the developing world.

G. Drug Donations

Most, but not all, companies have active drug donation programs. They often rely on such practices as part of disaster relief assistance programs or in programs for disease eradication.



BEST PRACTICES FOR DRUG DONATIONS

- **Policy in line with the WHO's guidelines on drug donations:** leading practices include a public statement of adherence to the WHO's guidelines; Innovest 's research did not uncover any violations of the WHO's guidelines by leading companies.
- **Clear rationale behind drug donation programs**: Industry leaders consider that drug donations do not provide a sustainable solution to the access to medicine issue. However, they recognize that drug donations can be effective if part of a clear strategy such as in emergency situations or as part of a disease eradication program.
- **Disclosure of the number of doses donated and patients reached**: Industry leaders disclose the number of doses donated and the number of patients reached or lives saved which are relevant indicators to measure the effectiveness of programs on the ground.

Examples of leading edge practices:

» ***Merck & Co.'s* river blindness programs:** since 1987, *Merck & Co.* has been involved in the donation of Mectizan for the treatment of river blindness. The company is committed to donating the drug to all who need it for as long as required. *Merck & Co.* is working with numerous partners to ensure appropriate infrastructure, distribution and support. The program has successfully reached millions at risk in the developing world including more than 100 million in 2007.

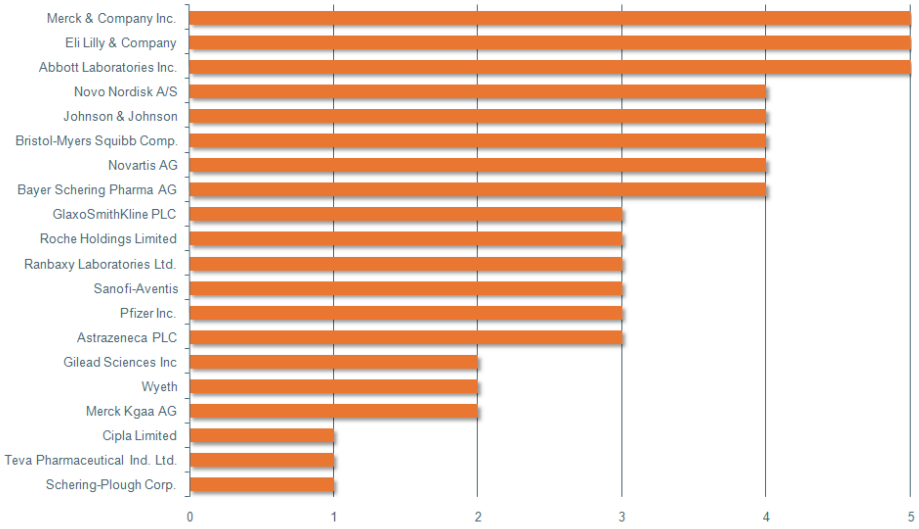
AREAS SUGGESTED FOR IMPROVEMENT

» **Consistent reporting amongst companies**: companies report on their drug donation programs using different metrics, which makes it difficult to benchmark practices. More consistent reporting on the number of doses donated in current and past years as well as the total value of drug donations as a percentage of special tax allowances would be helpful.

» **Sustainability and drug donations**: there is a need for a better integration of drug donation programs into a sustainability plan in collaboration with local governments and NGOs to limit distortion on the market and ensure the long-term supply of drugs.

H. Philanthropic Activities

Most companies have miscellaneoous philanthropic programs aimed at improving access to medicine in the developing world.



BEST PRACTICES FOR PHILANTHROPIC ACTIVITIES

» **Strong philanthropic projects:** best practices include integration of philanthropic activities into the company's long-term plans, implementation through a consistent and well-managed program with clear targets, mechanisms to measure effectiveness, and close collaboration with local NGOs and governments.

Examples of leading edge practices:

» ***Abbott Lab* in Tanzania:** as part of a project called Tanzania Care, *Abbott Lab* provided funds to modernize the Tanzanian healthcare system and created several facilities to treat patients and educate them. Since 2003, the company has trained more than 10,500 health workers, including 7,200 in HIV patient care, 2,500 on new information technology, 250 on laboratory equipment operations and laboratory science, and 600 senior doctors and hospital directors on management. The Abbott Fund also upgraded 80 hospitals and health centers and provided access to voluntary HIV counseling and testing of 130,000 people.

- **AstraZeneca's collaboration with Axios in Ethiopia*:*** since 2005, AstraZeneca has been working on a project in Ethiopia, designed to build local capability in managing breast cancer. The company has worked closely with Axios, which has experience in working with the private sector to advance healthcare in developing countries. Results are positive and include monthly reporting on patients treated, development of treatments and management guidelines, installation of medical equipment, reduction of time between diagnosis and surgery, and donation of medicines.

AREAS SUGGESTED FOR IMPROVEMENT

- **Greater integration of philanthropic activities into companies' strategies:** most, but not all, companies run sound philanthropic programs as part of their global Access to Medicine strategy, and we expect to see stronger integration of philanthropy in the companies' long-term plans going forward.
- **Close collaboration with local governments:** philanthropic programs are more effective when conducted in alliance with or within the public health programs of developing countries' ministries of health, so that they support and enhance governmental efforts, not undermine them. More evidence of the impact of collaborative approaches on the ground would be appreciated by stakeholders.

Next Steps for the Access to Medicine Index

ANNUAL REVIEW

The Access to Medicine Index will continue to evolve over the coming years. Evaluation, review and adjustment of the Index will be overseen by an Index Executive Committee, which was added to the Foundation's Governance Charter in April, 2008; the Foundation is currently seeking to fill the Committee's positions.

The Index Executive Committee will oversee the maintenance of the Access to Medicine Index. As such, it will in the future be responsible for updating the Index methodology as well overseeing measurement, monitoring, review and publications by staff members and outside contractors. Its membership will reflect the range of stakeholders sharing the objective of improving global access to medicines. Committee members will be knowledgeable in the area of improving global access to medicines. Representatives from the pharmaceutical industry may be members of the Committee, but they do not vote on matters related to Index scores or measurements.

The Index Executive Committee ensures that the Index remains responsive to and consistent with market expectations and global developments. It collects and evaluates comments on the Index from stakeholders and decides on any necessary adjustments.

Tasks of the Index Executive Committee will include:

- Monitor, review and publish Index criteria, indicators and metrics;
- Monitor, review and publish rules under which research is carried out;
- Monitor, review and publish rules under which the index is published;
- Review Index outcomes before publication;
- Invite comments on all aspects of the Index;
- Evaluate comments;
- Publish evaluation results and conclusions;
- Oversee outside data suppliers and/or other contractors;
- Rule on appeals by third parties against Index components or their implementation.

Appendix 1: The Access to Medicine Index Evaluation Methodology

BENCHMARKING PHASE

The benchmarking process was conducted in six different steps:

1. **Selection of 20 Companies:**
   The largest companies by market capitalization in the healthcare sector have been selected in addition to four small key players in ATMs including Novo Nordisk, Gilead and two Indian generic companies Cipla and Ranbaxy (see Appendix 2).
2. **Collection of Data:**
   Corporate documents, government data, on-line news databases, industry sources NGOs and non-profit organizations, third party sources (see References).
3. **Interviews with Company Representatives:**
   Each company was contacted for an interview and 10 of them responded positively (see Appendix 3).
4. **Identification of Best Practices:**
   We determined best practices for all indicators included in the AtM Index framework and developed scoring guidelines (see Appendix 4)
5. **Production of Company Profiles:**
   A profile was written for each company summarizing the company's performance relating to the list of criteria/indicators/metrics. Each company was given the opportunity to comment on its profile. Eleven did so (see Appendix 3).
6. **Scoring:**
   Each company was scored at the indicator level and ranked based on the weighting system determined in the previous phase of the AtM Index project.

SCORING METHODOLOGY

The 20 companies we selected as part of the first AtM Index have different business models. Innovest drew on its experience as a globally recognized investment research firm with specialized expertise in analyzing all healthcare sectors, to develop an objective evaluation system. A detailed analysis of a company's business model (disease focus and product pipeline) was conducted at the outset, which helped to identify what could

realistically be expected from a company with regard to the eight criteria developed by the industry and its stakeholders. The weighting system was adjusted to reflect the companies' business models.

Below are a few examples to illustrate the methodology:

» **Generic versus originator companies**: generic companies have limited R&D capability, their core activities being drug manufacturing and distribution. Therefore the weighting of the criteria on "R&D that Reflects both the Global Disease Burden and Neglected Diseases" and "Patents & Licensing" were reduced by half, while "ATM Management" and "Drug Manufacturing, Distribution and Capability Advancement" increased from 20 to 25% and from 15 to 25% respectively (see figure below)

	Originator Companies	Generic Companies
A. ATM Management	20%	25%
B. Public Policy Influence & Advocacy	10%	10%
C. R&D that Reflects both the Global Disease Burden and Neglected Diseases	20%	10%
D. Patents & Licensing	10%	5%
E. Drug Manufacturing, Distribution and Capability Advancement	15%	25%
F. Equitable Pricing	15%	15%
G. Drug Donations	6%	6%
F. Philanthropic Activities	4%	4%

The weighting of the indicators included in "Drug Manufacturing, Distribution and Capability Advancement" has been modified as follows:

	Originator Companies	Generic Companies
E1. The company demonstrates efforts to	20%	40%

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

» **Lack of expertise relevant to R&D for neglected diseases:** companies such as *Novo Nordisk*, *Roche*, *Abbott Lab*, *Teva* and *Cipla* do not have expertise relevant to R&D for neglected diseases. Therefore we made slight changes in the weighting in the R&D section (see figure below).

Companies with expertise relevant to R&D for neglected diseases	
C1. The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases.	5%
C2. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases.	30%
C3. The company with in-house investment in R&D into new treatments for neglected diseases provides evidence of partnership with groups with developing-country health expertise, such as product development public-private	40%

partnerships, academic institutions and/or the World Health Organization.	
C4. The company shows temporal evidence that its research programs into both the global disease burden and neglected diseases consider research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups.	25%
Companies without expertise relevant to R&D for neglected diseases	
C1. The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases.	10%
C2. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases.	15%
C3. The company with no in-house neglected diseases R&D investment provides evidence of investment into such R&D conducted by others.	45%
C4. The company shows temporal evidence that its research programs into both the global disease burden and neglected diseases consider research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups.	30%

» **Limited range of commercial treatments that primarily affect people in the developing world:** companies such as *AstraZeneca* and *Schering Plough* have a very limited range of products for the developing world. Therefore the weighting of "Equitable Pricing" and "Drug Manufacturing, Distribution and Capability Advancement" has been reduced (see figure below).

	Companies with commercial products for the developing world	Companies with few commercial products for the developing world

A. ATM Management	20%	23%
B. Public Policy Influence & Advocacy	10%	12%
C. R&D that Reflects both the Global Disease Burden and Neglected Diseases	20%	23%
D. Patents & Licensing	10%	12%
E. Drug Manufacturing, Distribution and Capability Advancement	15%	10%
F. Equitable Pricing	15%	10%
G. Drug Donations	6%	6%
F. Philanthropic Activities	4%	4%

» **Insulin manufacturers:** although there are active patents on the insulin analogs, the patents on recombinant human insulins have already run out. However, no generic version of human insulin exists. The main reason is that biologics and their manufacturing processes are too complex for most generic manufacturers to replicate. Therefore, as an insulin manufacturer, *Novo Nordisk* is hardly in a position to enter into technology transfer agreements with local manufacturers in the developing world, unlike its peers manufacturing treatments for infectious diseases. Additionally, Novo Nordisk's risks of counterfeiting are lower. The weighting of "Drug Manufacturing, Distribution and Capability Advancement" has therefore been reduced to 10%. We decided to distribute the remaining 5% to "ATM Management", "R&D that Reflects both the Global Disease Burden and Neglected Diseases," and "Equitable Pricing". "Patent & Licensing" is less of an issue, because human insulin is off patent, and due to its size *Novo Nordisk* seems to have less lobbying power than its counterparts.

	Companies (non purely insulin manufacturers)	Novo Nordisk
A. ATM Management	20%	22%
B. Public Policy Influence & Advocacy	10%	11%

C. R&D that Reflects both the Global Disease Burden and Neglected Diseases	20%	22%
D. Patents & Licensing	10%	10%
E. Drug Manufacturing, Distribution and Capability Advancement	15%	10%
F. Equitable Pricing	15%	16%
G. Drug Donations	6%	6%
F. Philanthropic Activities	4%	4%

For more information on the scoring, please see the scoring guidelines in Appendix 4.

Appendix 2: List of Companies

This list of 20 companies was developed in December 2007 using data from Thomson Financial. The largest pharmaceutical and biotechnology companies by market capitalization have been selected. Genentech, Amgen and Takeda have been removed from the initial list due to a portfolio targeting people in the developed world and two major Indian generic companies Cipla and Ranbaxy have been added.

	Ticker	Company	Country	Sub-industry Category	Market Cap in Billion USD
1	JNJ-N	Johnson & Johnson	USA	Pharmaceutical/ Originator	186,471.6242
2	PFE-N	Pfizer	USA	Pharmaceutical/ Originator	155,924.4498
3	ROG-VX	Roche	Switzerland	Pharmaceutical/ Originator	146,166.8053
4	GSK-LN	GlaxoSmithKline	UK	Pharmaceutical/ Originator	136,029.1935
5	SAN-FR	sanofi-aventis	France	Pharmaceutical/ Originator	122,784.9381
6	MRK-N	Merck & Co.	USA	Pharmaceutical/ Originator	121,670.1226
7	NOVN-VX	Novartis	Switzerland	Pharmaceutical/ Originator	120,175.8365
8	ABT-N	Abbott Lab	USA	Pharmaceutical/ Originator	83,630.14862
9	AZN-LN	AstraZeneca	UK	Pharmaceutical/ Originator	64,866.13069
10	WYE-N	Wyeth	USA	Pharmaceutical/ Originator	60,288.06713
11	LLY-N	Eli Lilly	USA	Pharmaceutical/ Originator	58,428.45135
12	BMY-N	Bristol-Myers Squibb	USA	Pharmaceutical/ Originator	55,972.08821
13	SGP-N	Schering-Plough	USA	Pharmaceutical/ Originator	47,619.82289
14	GILD-O	Gilead	USA	Biotechnology	40,553.73543

15	NOVO'B-KO	Novo Nordisk	Denmark	Pharmaceutical/ Originator	40,409.38829
16	TEVA-TV	Teva	Israel	Pharmaceutical/ Generic	33,745.44432
17	SCH-FF	Bayer	Germany	Pharmaceutical/ Originator	29,795.55571
18	MRK-FF	Merck KGaA	Germany	Pharmaceutical/ Originator	25,842.20941
19	RANBAXY-BY	Ranbaxy	India	Pharmaceutical/ Generic	4,098.860237
20	CIPLA-BY	Cipla	India	Pharmaceutical/ Generic	3,507.959422

Appendix 3: Company Interviews

Following the data collection phase, Innovest contacted all 20 companies to get additional information on their AtM programs. Interviews were conducted with representatives from the following companies:

1. **ASTRAZENECA**
2. **BAYER AG**
3. **GLAXOSMITHKLINE**
4. **JOHNSON & JOHNSON**
5. **MERCK & CO.**
6. **NOVARTIS**
7. **NOVO NORDISK**
8. **ROCHE**
9. **SANOFI-AVENTIS**
10. **WYETH**

All companies also had the opportunity to comment on their drafts. The following did so:

1. **ASTRAZENECA**
2. **BAYER AG**
3. **BRISTOL-MYERS SQUIBB**
4. **GLAXOSMITHKLINE**
5. **MERCK & CO.**
6. **MERCK KGAA**
7. **NOVARTIS**
8. **NOVO NORDISK**
9. **ROCHE**
10. **SANOFI-AVENTIS**
11. **WYETH**

Appendix 4: Scoring Guidelines

The table below presents the list of criteria, indicators, metrics and weighting as well as the scoring guidelines. Note that 5 is the best possible score and 1 the worst possible score.

A. Access to Medicine Management (20%)

A1. Governance: The company has a governance system that includes direct board level responsibility and accountability for its AtM strategy.	■ Existence and disclosure of a committee or a member of the board or the executive board that has AtM issues included in its mandate. ■ External board positions that include AtM initiatives.	5 - The company has a board member or a committee responsible for AtM policies. 4 – The board or the executive board is responsible for AtM but there is no existence of a clear member or committee. 3 – The company has a committee at the board or executive board level in charge ESG/CSR issues but AtM is not clearly included in its mandate. 2 – The board or the executive board is responsible for CSR, but no clear mention of AtM. 1 - The company has no board-level responsibility and accountability for AtM strategy.
A2. Policy and Disclosure: The company has a public global policy in place, in which it explains its rationale for AtM, its contents and details its specific objectives.	■ Existence and disclosure of a global policy to ensure the long-term availability of a sustainable supply of drugs, including disclosure of geographical and organizational scope. ■ Adherence to the Human Rights Guidelines for Pharmaceutical Companies in relation to AtM. ■ Evidence of policy endorsement at the board level. ■ Disclosure of the rationale via case studies.	5 – The company has a global policy backed at the board or executive board level, details the rationale and the sustainability of its AtM strategy, and discloses evidence via case studies. 4 – The company has a global policy backed at the board or executive board level and details the rationale and the sustainability of its AtM strategy. 3 – The company has a global strategy backed at the board or executive board level but does not detail the rationale of its policy. 2- The company has a global strategy, but it is not backed at the board or executive board level and does not detail the rationale and the sustainability of its policy. 1 – The company does not disclose information or does not have a global AtM policy.

A3. Systems and Reporting: The company has a management system, including quantitative targets, to implement, monitor and report on its AtM strategy.	■ Existence and disclosure of quantitative targets and target attainment when a program is implemented solely by the company. ■ Requirement that AtM public-private partnerships have stated targets. ■ Disclosure of how the effectiveness of the system is measured. ■ Existence of a public annual report on AtM. ■ Existence of an external verification system.	5 – The company has a clear management system and regularly reports on targets, target attainment for its programs and programs conducted in PPP. The company also discloses information on how the effectiveness of the programs is measured and its report is certified by an external party. 4 – The company has a management system and annually reports on impacts but fails to set targets for its own activities. The company also discloses information on how the effectiveness of the programs is measured, but its report is not certified by an external party. 3 – The company has a management system and annually reports on impacts but fails to set targets for its own activities. The company's report is not certified by an external party. 2 – The company does not have a management system but reports on impacts of its activities. There is no evidence of targets and effectiveness. 1 – The company does not disclose information on AtM programs or information is hard to find.
A4. Stakeholder Input: The company has a mechanism for stakeholder engagement which inputs into AtM management.	■ Existence and disclosure of programs/channels which raise the awareness of employees on AtM and allow feedback to be received. ■ Disclosure of evidence that stakeholder feedback has been used to improve, develop and refine a company's AtM strategy. ■ Range of major initiatives and policy debates to which the company contributed in the previous year.	5 – The company has a clear mechanism for stakeholder engagement and discloses evidence of stakeholders' input into the company's strategy. It also reports on the impact of employee awareness programs and is very active in policy debate around AtM. 4 – The company has a clear mechanism for stakeholder engagement and discloses evidence of stakeholders' input into the company's strategy, but does not report on the impact of employee awareness programs. The company is very active in policy debates. 3- The company claims to communicate with employees and stakeholders, but does not provide details about these activities. 2 – The company discloses who its stakeholders are, but does not detail on how they input into its strategy. Nor does the company provide detail on employee awareness programs or participation in debates 1 – The company does not disclose information on stakeholder relations.
A5. The company has globally applicable ethical business practices and marketing policies that conform to appropriate standards.	■ Adherence to international codes on responsible business conduct (UN Global Compact and/or OECD Guidelines for Multinational Enterprises).	5- The company discloses its adherence to international codes, to the IFPMA Code of Pharmaceutical Marketing Practices and to the WHO's Ethical Criteria for Medicinal Drug Promotion. 1 – The company does not disclose adherence or does not adhere to the IFPMA Code of Pharmaceutical Marketing Practices and to

	■ Compliance and breaches of the IFPMA Code of Pharmaceutical Marketing Practices.	the WHO's Ethical Criteria for Medicinal Drug Promotion.
	■ Adherence to the WHO's Ethical Criteria for Medicinal Drug Promotion.	
	■ Number and content of EMEA and US FDA Warning Letters for Advertising and Promotional Violations.	

B. Public Policy Influence & Advocacy (10%)

B1. The company has a position on public policy advocacy and transparency.	■ Existence and disclosure of a commitment towards transparency in public policy advocacy.	5- The company has a clear public statement on transparency in public policy influence and advocacy. 3- The company recognizes the need for a public statement on transparency in public policy influence and advocacy and plans to formalize one; or the company does not have a statement but appears to be transparent in its lobbying activities. 1- The company does not disclose information on transparency in public policy influence and advocacy.
B2. The company and subsidiaries disclose major public policy positions at regional, national and international levels related to the AtM debate.	■ Existence and disclosure of a position on major AtM issues. ■ Disclosure of positions companies seek to promote within industry organizations. ■ Disclosure of national perspectives by local subsidiaries.	Best practices include disclosure on: - Data exclusivity - Intellectual property - TRIPS and compulsory licenses - Public-private partnerships - Product diversion and counterfeiting - Registration - Pricing - Drug donations - Philanthropy - R&D for neglected diseases - Clinical trials - Ethical marketing practices and code of conduct - Access to health 5 – The company discloses its position on at least nine topics and provides examples of positions it seeks to promote within industry organizations. 4 - The company discloses its position on at least nine topics. 3 - The company discloses its position on at least six topics. 2 - The company discloses its position on at least three topics. 1 - The company does not disclose information on any public policy positions.
B3. The company and subsidiaries actively advocate health reforms that foster AtM and policies that would result in improvements in public health.	■ Existence and disclosure of a commitment not to advocate for data exclusivity.	Best practices include advocacy on: - Better healthcare infrastructures in the developing world - Shortage of health workers - Political commitment and sustained funding for the global disease burden and neglected diseases - Drug quality

	■ Advocacy of a range of policies and initiatives.	- Pharmacovigilance - More investment in pediatric R&D - Enhanced basic health coverage for the uninsured - Faster regulatory registration - Transparency in lobbying in Europe - Chronic diseases 5 - The company provides more than two examples of advocacy activities. 3 - The company provides two examples of advocacy activities. 1 - The company does not disclose information on advocacy activities.
B4. The company annually discloses which individuals, patient associations, political parties, trade associations and academic departments it supports with which it might advocate on public policy positions and practices at a regional, national and international level.	■ Amount spent on federal lobbying activities in the US in current and past years. ■ Amount spent on lobbying activities in the EU in current and past years. ■ Amount spent on lobbying governments in developing and least developed countries in current and past years. ■ Contributions to political organizations in the US, Canada and Australia in current and past years. ■ Funding to patient groups, medical associations, and academic centers in the US and Europe. ■ Existence and disclosure of board seats at industry associations and advisory bodies.	Best practices include disclosure of: - List of state and local candidates supported by the company - Donations to political organizations in the US, Canada and Australia - Lobbying expenditures in the US - The number of lobbyists in the US and Europe - List of patient groups supported in the UK - List of patient groups in Europe or in the US - Details of the funding and in particular corporate funding should not exceed 25% of a patient group's overall funding - Disclosure of cash amounts donated to each grant request or organization - For each trade association that receives more than USD100,000 in dues or other payments from a company during a given year, the company discloses the portion of such payments that is identified by the trade association as being used for non-deductible political expenditures 5 – The company discloses at least five elements identified as best practices. 4 – The company discloses at least four elements identified as best practices. 3 – The company discloses at least three elements identified as best practices. 2 – The company discloses at least one element identified as best practices. 1 – The company does not disclose any best-practice information.

	■ Evidence of inconsistency between the company's positions (see B2) and its support to various groups.	
B5. The company demonstrates a process of board approval of the approach to public policy advocacy, its transparency, and reporting.	■ Evidence of a board or executive board approval process for advocacy activities and public policy positions.	5 - The company clearly discloses a board-approval process. 1 - The company does not disclose information on a board-approval process or does not have one.

C. Research & Development that Reflects both the Global Disease Burden and Neglected Diseases (20%)

C1. The company has a policy on R&D investment that reflects both the global disease burden and neglected diseases.	■ Existence and disclosure of a policy that considers investment into treatments for neglected diseases and into suitability for the global disease burden. ■ Compliance with the WHO Ethical Guidelines on Clinical Trials.	5- The company has a clear policy on investment into treatments for ND and into suitability for GBD. 3- The company does not have a clear public policy on the need for new treatments for ND and for new formulations for GDB. 1- The company does not have a policy or does not disclose information on a policy that reflects the GDB and ND.
C2. The company provides evidence of in-house investment in R&D into new treatments for neglected diseases.	■ Existence of a dedicated neglected diseases division. ■ Number of scientists dedicated to neglected diseases. ■ Number of compounds in the neglected diseases portfolio. ■ Number of papers contributing to scientific debates on neglected diseases.	5 – The company is working on two or more ND. 3 – The company is working on R&D for one ND. 1- The company does not provide evidence of in-house investment in R&D into new treatments for ND.
C3. The company with in-house investment in R&D into new treatments for neglected diseases provides evidence of partnership with groups with developing-country health expertise, such as product development public-private partnerships, academic institutions and/or the World Health Organization.	■ Evidence of R&D programmatic collaboration with groups with developing-country health expertise (e.g. development of product profiles). ■ Number of clinical trials involving collaboration with groups with developing-country health expertise.	5- The company has a long tradition of collaborations with R&D groups focused on development of product profiles and/or conduct of clinical trials on several diseases. 4 – The company has robust collaborations with R&D groups on one disease focused on development of product profiles and/or conduct of clinical trials. 3- The company provides evidence of recent collaborations. 2 – The company provides evidence of recent collaborations but discloses limited information. 1- The company does not provide evidence of collaboration.

C3. The company with no in-house neglected diseases R&D investment provides evidence of investment into such R&D conducted by others.	■ Evidence of consultation with organizations with a view to contributing to R&D. ■ Evidence of sharing of library compounds. ■ Evidence of IP rights given to research institutes. ■ Evidence of participation on scientific advisory or management boards of external organizations conducting neglected disease R&D. ■ Evidence of provision of expertise to such organizations (e.g. chemistry and regulatory expertise, and staff sabbaticals). ■ Evidence of provision of training to such organizations.	Best practices include: - Evidence of library sharing - Evidence of IP rights given to research institutes - Evidence of participation on scientific advisory or management boards of external organizations conducting neglected disease R&D - Evidence of provision of expertise to such organizations (e.g. chemistry and regulatory expertise, and staff sabbaticals). - Evidence of provision of training to such organizations - Evidence of donation of ingredients 5 - The company provides evidence of three of the above. 4 - The company provides evidence of two of the above. 3 - The company provides evidence of one of the above. 2 - The company provides evidence of consultation with organizations with a view to contributing to R&D. 1- The company does not provide evidence of support given to other organizations to foster R&D for ND.
C4. The company shows temporal evidence that its research programs into both the global disease burden and neglected diseases consider research into existing medicines and formulations suitable for use in developing and least developed countries and for affected patient groups.	■ Evidence of research programs on suitability (oral formulations, dosing intervals, length of treatments, and requirement for cold chain). ■ Evidence of clinical trials to support treatment indications aimed at children and people living in developing and least developed countries. ■ Number of approvals in the last year for compounds and formulations useful in developing world settings and for affected patient groups.	Best practices include: - Development of fixed-dose combination - Development of pediatric formulation - Development of heat-stable formulations - Development of formulation that do not require taking food with the treatment - Development of formulation to reduce the length of the treatment - Development of formulation to improve the dosing intervals 5 - The company provides evidence of at least three of the best practices above for more than one treatment. 4 - The company provides evidence of three of the best practices above for one treatment or the company provides evidence of at least two of the best practices for more than one treatment. 3- The company provides evidence of at least one of the best practices above for more than one treatment, or the company provides evidence of at least two of the best practices for one treatment. 2- The company provides evidence of at least one of the best practices above for one treatment. The company provides evidence of consultation with organizations with strong expertise of the developing world. 1- The company does not provide evidence of support given to other organizations to foster R&D for new formulations.

D. Patents & Licensing (10%)

D1. The company demonstrates the existence of, and discloses the terms of, non-exclusive voluntary license agreements to increase AtM in developing countries.	■ Disclosure of terms of agreement (non exclusivity, royalty-free conditions, sourcing, manufacturing limits and exports).	Best practices include: - Non exclusivity - Royalty- free conditions - License that allow for sales in a wide range of markets - No restriction on sourcing - Pricing established by the generic company - Co-formulation with other brands to develop appropriate fixed-dose combinations allowed by the company 5 - The company has at least three licenses that satisfy four of the above criteria. 4 - The company has at least two licenses that satisfy three of the above criteria. 3 - The company has fewer than two licenses and discloses limited information on the terms of agreement. 2 –The company does not enforce patents in LDCs, and/or drugs for neglected diseases are off patent. 1- The company does not have voluntary licenses with generic companies or does not provide evidence of licensing agreement.
	■ Number and type of collaborations with peers.	
	■ Number of drugs and treatments produced by licensees.	
D2. The company publicly commits itself to respecting the right of developing countries to use the provisions in the TRIPS agreement.	■ Involvement in country-specific TRIPS flexibility use.	5 - There is a clear commitment not to enforce patents in LDCs and to support TRIPS in case of emergency, and no involvement in countries' right to use TRIPS has been found. 4 – There is a no clear statement on TRIPS but the company is committed not to enforcing patents in LDCs. No involvement in countries' right to use TRIPS has been found. 3 – There is no information regarding TRIPS and the enforcement of

	■ Existence and disclosure of a commitment not to enforce patents in least developed countries.	patents in LDCs. No involvement in countries' right to use TRIPS has been found. 2 - There is evidence of lobbying activities to limit the country's ability to use TRIPS but the company is involved in discussions with local governments. 1- The company relies on various means to limit the country's ability to use TRIPS.
	■ Existence and disclosure of a commitment not to extend patent duration for new indications for existing medicines that are not innovative.	

E. Drug Manufacturing, Distribution and Capability Advancement (15%)

E1. The company demonstrates efforts to manufacture drugs to the highest quality standards.	■ Existence and disclosure of a policy that considers the inadequate infrastructure in developing and least developed countries.	5 – The company has quality standards in line with the FDA, EMEA and the WHO and/or recognizes the need for quality control in the developing world. 3 – The company claims to adhere to the highest quality standards but does not recognize the need for more quality control in the developing world. 1 – There is evidence of quality breaches involving the company, and/or the company does not have a policy on quality in manufacturing.
	■ Existence and disclosure of a policy on drug manufacture that is in line with the quality requirement of the FDA, the EMEA, the WHO or better, for use in developing and least developed countries.	
	■ Evidence and type of violations and disclosure of fines.	
E2. The company enters into technology transfer agreements with local companies in developing and least developed countries.	■ Existence and disclosure of mechanisms for sharing of manufacturing skills in developing and least developed countries.	5 - The company has entered into several technology transfer agreements and has robust mechanisms in place to ensure the positive impact of these programs on AtM. 3 - The company has entered into several technology transfer agreements, but discloses limited information on the impact and the existence of quality control measures. 1 – The company does not enter into technology transfer agreements with local companies in the developing world.
	■ Existence and disclosure of quality control mechanisms in developing and least developed countries.	
	■ Existence and disclosure of support provided for registration in developing and least developed countries.	
	■ Number of drugs and treatments produced.	

E3. The company undertakes external activities to support the monitoring of drugs that reflect both the global disease burden and neglected diseases including participation in public private partnerships.	■ Existence and disclosure of support to implement a pharmacovigilance system in developing and least developed countries.	5 – The company discloses several examples of programs aiming to improve pharmacovigilance systems in the developing world. 3 – The company participates in projects to improve pharmacovigilance in the developing world but provides limited details on the implementation and impact. 1- The company does not disclose information on pharmacovigilance or does not collaborate with others on programs to improve pharmacovigilance.
E4. The company has mechanisms in place to help prevent product diversion and to address counterfeiting, in collaboration with states.	■ Existence and disclosure of a corporate policy on diversion and counterfeiting. ■ Existence and disclosure of processes in place to prevent diversion and counterfeiting. ■ Evidence of cooperation with states and peers on anti-counterfeiting initiatives. ■ Existence and disclosure of a policy on primary, authorized distributors. ■ Existence and disclosure of examples of legal strategies to deter counterfeiting.	Best Practices include: - Existence and disclosure of processes in place to prevent diversion and counterfeiting. - Evidence of cooperation with states and peers on anti-counterfeiting initiatives. - Existence and disclosure of a policy on primary, authorized distributors. - Existence and disclosure of examples of legal strategies to deter counterfeiting. 5 – The company has a policy and discloses three of the above. 4- The company has a policy and discloses two of the above. 3 – The company has a policy and discloses one of the above. 2 – The company has a policy on diversion and counterfeiting. 1 – The company does not disclose information on counterfeiting and/or does not have a policy on counterfeiting.
E5. The company demonstrates efforts to provide AtM to its employees and their relatives in developing and least developed countries.	■ Percentage of employees in developing and least developed countries covered by healthcare benefits. ■ Type of benefits offered.	5 - The company has operations in the developing world and more than 90% of its employees and their relatives have access to healthcare benefits. 4 – The company claims to offer benefits to employees in the developing world and has an HIV/AIDS policy in the workplace which includes the provision of ARVs to employees and their relatives. 3 – The company claims to offer benefits to employees in the developing world but does not provide evidence of the type of benefits offered and who is entitled to receive them. 2 – The company discloses limited information on its employees worldwide. 1 – The company does not disclose information on employees.

F. Equitable Pricing (15%)

F1. The company can demonstrate efforts to register treatments that reflect both the global disease burden and neglected diseases in developing and least developed countries.	■ Disclosure of the list of countries where marketing applications filed, not heard from and approved for major products. ■ Evidence and disclosure of rebranding.	5 - There is no evidence of registration issues involving the company in the developing world, and the company discloses the list of countries where at least one drug is registered. 4 - There is no evidence of registration issues involving the company in the developing world, and the company discloses a clear commitment to register all drugs worldwide. 3 – There is no evidence of registration issues involving the company in the developing world but no clear commitment on registration. 2 – There is evidence of registration issues involving the company in the developing world, but the company displays progress in this matter. 1 – There is evidence of registration issues involving the company in the developing world.
F2. The company has a policy to facilitate AtM in developing and least developed countries through pricing mechanisms which include reporting on scope, pricing levels and pricing reviews.	■ Evidence and disclosure of pricing mechanisms, their implementation and impact. ■ Evidence and disclosure of the rationale behind pricing policies. ■ Number of countries where a company does sell drugs at cost, as a percentage of all countries where a drug is received. ■ Number of countries where a company does provide a discount, as a percentage of all countries where a drug is received. ■ Decrease in drug prices over the year, as a percentage of the total original cost.	Best practices include: - Disclosure of pricing mechanisms - Disclosure of the rationale behind pricing mechanisms - Disclosure of implementation (public/private sector, LDCs, MIC) - Disclosure of impact of pricing practices in terms of number of drugs shipped, countries or patients reached - Evidence of decrease in drug prices over the years - Involvement in pilot projects to improve and extend pricing mechanisms - Affordable prices - Predictable prices 5 - The company discloses all of the above best practices. 4 - The company discloses five of the above best practices. 3 - The company discloses three of the above best practices. 2 – The company discloses one of the above best practices. 1 – The company does not disclose information on pricing mechanisms.

	■ Number of drugs sold or shipped at cost in current and past years.	
	■ Number of drugs sold or shipped at a discounted price in current and past years.	
F3. The company demonstrates that its discount schemes place the minimum administrative burden on the beneficiary health system.	■ Existence and disclosure of programs to facilitate transactions between the company and the beneficiaries of equitable pricing programs.	5 – There is no evidence of transaction issues between companies and the beneficiaries of the programs. 1 – The company has been criticized for not facilitating transactions between the company and the beneficiaries of equitable pricing programs.
F4. The company has a policy for the very poorest in countries with no public healthcare provision.	■ Existence and disclosure of a public policy.	5 – The company has several strong programs in place to benefit the poorest and discloses the eligibility rules. 3 – The company produces generic drugs. 1 – The company has limited programs in place to benefit the poorest but does not clearly disclose the eligibility rules. No information available but because of generic versions, people get access to the drugs.
	■ Number of treatments and patients benefiting from patient assistance programs (PAPs) in the US and other relevant countries in current and past years.	
	■ Disclosure of eligibility rules.	
	■ Additional programs to help the poorest.	

G. Drug Donations (6%)

G1. The company has a policy that fully conforms to the WHO's Guidelines for Drug Donations.	■ Existence and disclosure of a policy that considers the sustainability of each donation program.	5 – Existence of a policy on drug donation in line with the WHO's Guidelines that considers the sustainability of the donation programs. 3 – Existence of a policy on drug donation in line with the WHO's Guidelines, but no evidence of sustainability. 1 – No policy on drug donations and no mention of the WHO's Guidelines.
	■ Number and type of breaches per year.	
G2.The company discloses the absolute volume of its drug donations and, to the extent possible, the number of treatments approved for patient use per year.	■ Number of drug doses donated in current and past years.	5 –Drug donation programs are integrated into a sustainable strategy (disease eradication and emergency situation) and implemented in collaboration with stakeholders. 3 – Existence of donation programs but unclear integration into a long term strategy. The company does not have drug donation programs. 1 – Existence of drug donation programs without a clear sustainable strategy
	■ Total value of drug donations as a percentage of pre-tax profit.	
	■ Total value of drug donations as a percentage of special tax allowances.	

H. Philanthropic Activities (4%)

H. The company has philanthropic programs related to AtM not covered by any of the other criteria.	■ Community donation as a percentage of pre-tax profit excluding donations in current and past years.	5 – Community donations and/or philanthropic activities offered regularly, through a consistent and well-planned philanthropy program with set targets or commitments and in collaboration with local NGOs. Philanthropic programs are well integrated into the company's strategy (8% of pre-tax profit, or more, on a yearly basis). 4 – Community donations and/or philanthropic activities offered regularly, through a consistent and well-planned philanthropy program with set targets or commitments and in collaboration with local NGOs. Philanthropic programs are well integrated into the company's AtM strategy (less than 8% of pre-tax profit or no information on the amount spent). 3 – Community donations and/or philanthropic activities integrated into the company's AtM strategy but no long-term commitment (less than 8% of pre-tax profit or no information on the amount spent). 2 – Some community donations and/or philanthropic programs related to AtM, but little information (less than 8% of pre-tax profit or no information on the amount spent). 1 – Very limited philanthropic programs related to AtM.
	■ Breakdown of cash donations as a percentage of pre-tax profit in current and past years.	
	■ Existence and disclosure of support given to local NGOs in current and past years.	
	■ Number of health professionals trained (in current and past years).	
	■ Number of hospitals or healthcare facilities built or supported (in current and past years.	

Appendix 5: References

Third-Party Data Sources:

Benchmarking AIDS Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets' Interfaith Center on Corporate Responsibility, The Corporate Examiner, Vol. 34, No.6-7, August 1, 2006.

Clinton Global Initiative available at http://www.clintonglobalinitiative.org/NETCOMMUNITY/Page.aspx?pid=895&srcid=739

Drugs for Neglected Diseases Initiative available at http://www.dndi.org/index.asp

Investing for Life, Oxfam Briefing Paper, November 2007.

Medicines for Malaria Venture available at http://www.mmv.org/rubrique.php3?id_rubrique=15

Opensecret available at opensecret.org.

Partnerships to Build Healthier Societies in the Developing World, IFPMA, May 2007.

Pharmaceutical and Vaccine Research and Development for the World Medical Needs, IFPMA.

Pharmaceutical Links of NGOs, Essential Action, 2007

Pharmacovigilance in the Developing World, BMJ, September 2007 available at http://www.bmj.com/cgi/content/full/335/7618/462

TB Alliance available at http://www.tballiance.org/home/home.php

The New Landscape of Neglected Disease Drug Development, Pharmaceutical R&D Policy Project, September 2005.

The Regulatory status of the Antiretroviral Drugs Database, WHO, November 2005.

Untangling The Web of Price Reduction 10th Edition, MSF, July 2007.

Company's reports:

Abbott Lab: Generations: 2006 Global Citizenship Report

http://www.abbott.com/global/url/content/en_US/40:40/general_content/General_Content_00035.htm

AstraZeneca: AstraZeneca 2006 CR Summary Report

AstraZeneca 2007 Annual Report

http://astrazeneca.com/article/511606.aspx

Bayer: Bayer Sustainable Development Report 2006

http://www.bayer.com/en/Sustainability-and-Commitment.aspx

Bristol-Myers Squibb: 2007 Sustainability Website Contents available at http://bms.com/sr/data/index.html

Cipla: 71st Annual Report 2006-2007

Eli Lilly: Lilly Corporate Citizenship Report 2006/07

http://www.lilly.com/about/citizenship

Gilead: 2007 Annual Report

http://www.gilead.com/corporate_responsibility

GlaxoSmithKline: GlaxoSmithKline Corporate Responsibility Report 2006

GlaxoSmithKline Corporate Responsibility Report 2007 ("Answering the Questions that Matter")

GlaxoSmithKline Annual Report 2006

GlaxoSmithKline Annual Report 2007

www.gsk.com/responsibility

Johnson & Johnson: 2006 Sustainability Report

http://www.jnj.com/connect/caring/?flash=true

Merck & Co.: Corporate Responsibility 2004-2005 Report

http://www.merck.com/cr/

Merck KGaA: Responsibility for Employees, the Environment and the Community - Report 2007

http://www.merck.de/servlet/PB/menu/1006980/index.html

http://www.emdserono.com/index.html

Novartis: Novartis Annual Report 2006

Novartis Corporate Citizenship Review 2006

Novartis Code of Conduct

Novartis GRI report 2006

http://www.novartis.com/about-novartis/corporate-citizenship/index.shtml

Novo Nordisk: Novo Nordisk Annual Report 2007

http://www.novonordisk.com/sustainability/default.asp

Pfizer: 2007 Corporate Responsibility Report: Strong Actions/ Partnering for Positive Change

Corporate Social Responsibility in Global Health: the Pfizer Global Health Fellows International Volunteering Program [Published in March 2007 issue of Human Resource Planning Journal 30(1), pp. 30-35.]

Ranbaxy: Ranbaxy Annual Report 2007

http://ranbaxy.com/socialresposbility/mm.aspx

Roche: "Committed to Making a Difference" report and website (Sustainability: Least Developed Countries) - Roche

Roche Annual Report 2007

Communication brief sent by Roche in January 2008

Public Global Roche Statement on Counterfeiting

"Removing Barriers" p. 8
http://www.roche.com/pages/downloads/sustain/pdf/removing_barriers_e.pdf

Roche Drug Donations Policy:
http://www.roche.com/pages/downloads/sustain/pdf/drug_don_pol.pdf

Sanofi-Aventis: Sanofi-Aventis Sustainable Development Report 2006

Sanofi-Aventis Annual Report 2006

Sanofi-Aventis Humanitarian Brochure

Actwithasaq available at http://www.actwithasaq.org/en/asaq1.htm

Schering Plough: 2006 Annual Report

2006 Report on Safety, Health and Environment

http://www.schering-plough.com/schering_plough/corp/corporate_responsibility.jsp

Teva: http://www.tevapharm.com/

Wyeth: Corporate Citizenship 2006: Living Our Values

http://www.wyeth.com/aboutwyeth/citizenship

Acronyms

ABPI	Association of the British Pharmaceutical Industry
AIDS	Acquired Immune Deficiency Syndrome
AtM	Access to Medicine
AtM Index	Access to Medicine Index
AZN	AstraZeneca
BMS	Bristol-Myers Squibb
DFID	Department for International Development (UK Government)
DNDi	Drugs for Neglected Diseases initiative
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMEA	European Agency for the Evaluation of Medicinal Products
FDA	Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunization
GSK	GlaxoSmithKline
GDB	Global Disease Burden
HDI	United Nations Human Development Index
HIC	High-Income Country
HIV	Human Immunodeficiency Virus
ICCR	Interfaith Center on Corporate Responsibility
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IP	Intellectual Property
IPM	International Partnership for Microbicides
J&J	Johnson & Johnson
KPI	Key Performance Indicator
LDC	Least Developed Country

LIC	Low-Income Country
MMV	Medicines for Malaria Venture
MIC	Middle-Income Country
ND	Neglected Diseases
NDRA	National Drug Regulatory Authority
NGO	Non-Governmental Organization
PAP	Patient Assistance Program
PPP	Public-Private Partnership
PDP	Product Development Partnership
PhMRA	US Pharmaceutical Manufacturers and Research Association
R&D	Research and Development
SSA	Sub-saharan Africa
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WTO	World Trade Organization

Glossary

DEFINITIONS

Developed Countries

High-income Countries (HICs) in the UN Human Development Index (HDI):

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

Developing Countries

Middle-income Countries (MICs) and Low-income Countries (LICs) in the UN Human Development Index (HDI):

Albania	Egypt	Malaysia	São Tomé and

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

Global

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

Least Developed Countries

Low-income Countries (LICs) in the UN Human Development Index (HDI).

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

Neglected Diseases

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

Subsidiary

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

Very Poorest

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

Originator Company

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

Global Disease Burden

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

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

World Health Organization (WHO) Neglected Diseases

These are listed below.

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

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

Disclaimer

The Access to Medicine Index is an independent, multi-stakeholder and collaborative project. Findings, interpretations, and conclusions expressed in this report may not necessarily reflect the views of all companies, stakeholders or organizations that contributed to it. The report is intended for informational purposes only. It is not intended to be used as promotional material or 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.

The Access to Medicine Foundation has a conflict of interest policy, which is available on its website (www.atmindex.org).

Innovest Legal Disclaimer

Innovest Strategic Value Advisors, Inc., is registered (IARD/CRD nr 127021) with the US Securities and Exchange Commission (SEC) as an Investment Adviser. The information herein has been obtained from sources which we believe to be reliable, but we do not guarantee its accuracy or completeness. All opinions expressed herein are subject to change without notice. Innovest Strategic Value Advisors, Inc., its affiliated companies, or their respective shareholders, directors, officers and/or employees, may have a position in securities discussed herein. The securities mentioned in this document may not be eligible for sale in some states or countries, or suitable for all types of investors; their value and the income they produce may fluctuate and/or be adversely affected by exchange rates.

Spaarne 35
2011 CD Haarlem
The Netherlands
T. +31 (0)23 533 91 87

info@atmindex.org
www.atmindex.org