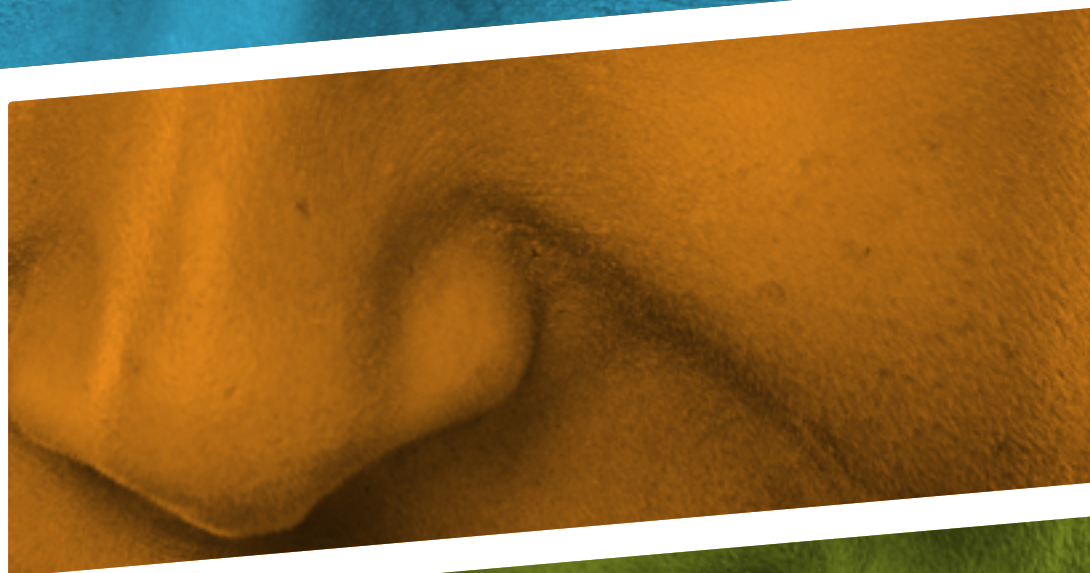


# The Access to Medicine Index 2012





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MSCI ESG Research is responsible for the scoring and ranking of company performance and the company profiles for the Access to Medicine Index 2012. MSCI ESG Research is a leading source of environmental, social and governance (ESG) ratings, screening, analysis, benchmarking and compliance tools to advisers, investment managers and asset owners worldwide. MSCI ESG Research builds on the expertise and achievements of sustainability pioneers KLD, Innovest, and IRRC, acquired through MSCI's acquisition of RiskMetrics Group.

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# The Access to Medicine Index 2012

**Access to Medicine Foundation**

November 2012

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final methodology, the analysis or results. Decisions regarding inclusion of all feedback were ultimately made by the Access to Medicine Foundation.

## Message from the Founder and CEO

---

I see around us a willingness and readiness for action to really attack the global health crisis, despite the fact that finding our way out of the global financial crisis is clearly the priority item on the international agenda. It seems as if almost every day somewhere in the world a global health seminar, gathering, or congress focussing on how to improve access to health care in the developing world is taking place or being planned. Against this backdrop, the Access to Medicine Foundation offers what we hope is a useful and constructive tool.

Although there's still a world to win, I am happy to see that the 2012 Access to Medicine Index finds that companies are continuing to take the path – and sometimes take the lead – in co-operating with the global health community, and increasingly with each other, to improve access to health care in the developing world.

This year's Index makes it even clearer that Big Pharma is able to share, and is open to sharing, its expertise, know-how and commitment with each other and with us.

This increased transparency has allowed us to hold a better quality mirror up to the industry, and to show individual companies how far they have come in comparison with their peers and how they can play an exemplary role with specific practices.

I am very happy to report that the Index has graduated from its pioneering phase and that, thanks to the UK Department for International Development, the Bill & Melinda Gates Foundation and the Dutch Ministry of Foreign Affairs, we can now plan for future iterations of the Index and refine the Index processes for the coming years.

The point of the Index is not to blame or shame the private sector for its practices, but to provide insight for companies, the global health and the investor communities, and to stimulate and facilitate the very necessary co-operation among all stakeholders focussed on improving health care in the developing world.

Companies will see the effort they have put in over the past few years reflected in the results of the 2012 Index, and you will see from the rankings that there has been quite a bit of movement. But for all companies this Index must be a wake-up call, for this Index is not only a barometer of the companies' willingness and dedication, and how they cope with the complexities on their path, but it also demonstrates that there still is a world to win and that they can make a difference.

Sincerely,



Wim Leereveld  
Access to Medicine Foundation



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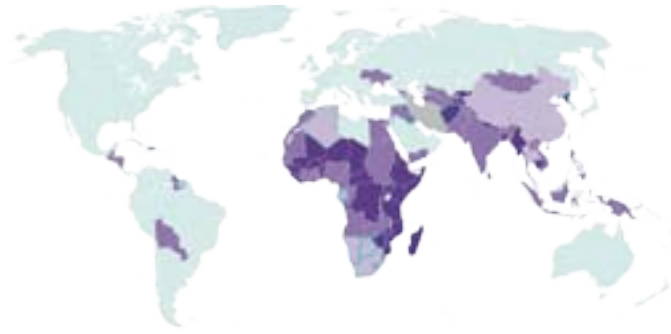
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## About the Access to Medicine Index

The Access to Medicine Index is an independent initiative that ranks the world's 20 largest companies according to their efforts to improve access to medicine in developing countries, highlighting policy and practice that either facilitate or hinder access. It is published every two years by the Access to Medicine Foundation, which aims to encourage pharmaceutical companies to make their products more available, affordable and accessible for the millions of people worldwide who do not have reliable access to medicine. > 14



## At a glance



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*“This year's Index finds that companies are continuing to take the path – and sometimes take the lead – in co-operating with the global health community, and increasingly with each other.”*

*Wim Leereveld, Founder and CEO*

**7** companies initiated **intra-country tiered pricing**

- GlaxoSmithKline
- Novartis
- Sanofi
- Merck & Co.
- Pfizer
- Eli Lilly
- Daiichi Sankyo > 48

### Opening Up Research

Collaborative R&D is growing, with companies opening up access to their knowledge and innovation, engaging in partnerships to meet public health challenges. > 38

## What and how we measure

The Index uses a framework that evaluates company activities in seven areas of activity considered to be key to enhancing access to medicine in developing countries. It analyses 101 indicators across these areas, and within each, the indicators are distributed across four types of action to assess the level of commitment the company demonstrates, how transparent it is about what it is doing, what specific activities it is engaged in and how innovative its approach is.

**20** companies      **103** countries      **33** diseases

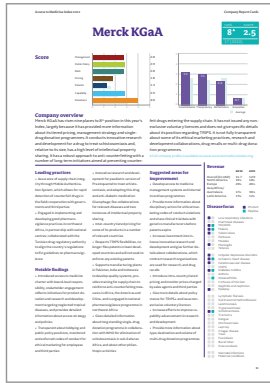
The Index covers 20 companies, 103 countries, and a broad range of products such as drugs, vaccines, diagnostic tests and other health-related technologies necessary for preventing, diagnosing and treating disease. A total of 33 diseases are covered, and the disease scope this year includes maternal conditions and neonatal infections.

[For more information on what and how we measure, see > 14](#)

## 60%

*More than 60% of companies now have direct board ownership of access to medicine and more companies are setting meaningful targets. Among the highest-ranked companies, leadership is coming from the very top. > 26*





## Company report cards

Noteworthy findings for each company are presented in a one-page report card, which also highlights any industry-leading practices and outlines suggested areas for improvement. Scores for each of the seven areas of activity the Index considers key to advancing access to medicine, as well as cumulative scores for commitments, perfor-

mance, transparency and innovation, are presented as graphs. A company overview summarizes the explanation for its position in the Index ranking. Current and future products are identified per disease to give a sense of the company's portfolio. > 79

## State of the disease focus of the industry

Important advances have been made in the major communicable disease areas of HIV/AIDS, tuberculosis and malaria, and R&D pipelines addressing lower respiratory infections, diarrhoeal disease, diabetes, cirrhosis, heart disease, asthma and cerebrovascular disease are growing. Attention to neglected tropical diseases is slowly improving, with, for example, the development of children's formulations for Chagas disease and schistosomiasis. There have also been notable price reductions, specifically for anti-retrovirals. There are few products in the pipeline for maternal health and neonatal infections, although industry is increasingly involved in collaborative safe-motherhood interventions. > 46



## Key findings > 17

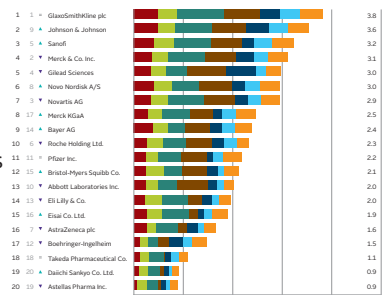
- GlaxoSmithKline remains top of the league, but by a narrower margin. Two newcomers, Johnson & Johnson and Sanofi move into the top three.
- Companies are becoming more organised in their approach and the Index leaders are increasingly viewing access as a strategic issue.
- More companies are developing more products, and some now devote 20% of their pipeline to products needed in developing countries.
- More companies are using tiered pricing schemes, for a broader range of products and countries, but what is their value?
- The majority of companies provide no evidence of exerting real influence over the way Contract Research Organisations conduct trials on their behalf.

## Scoring and Indicators

For an overview of the ranking and scoring process > 109  
And for the weighting of specific areas of activity and indicators > 112

## Company rankings 2012

The industry is doing more to improve access to medicine than it was doing in 2010. Seventeen out of the 20 companies saw their scores increase and leaders at the top end of the ranking appear to be jostling for position, with score differences between them smaller than it was in the 2010 Index. Find the leaders, risers and fallers on > 20





# The Access to Medicine Challenge

Over the last few years, much progress has been made in improving access to medicines, vaccines, diagnostic tests and other health technologies in developing countries. Four of the eight United Nations' Millennium Development Goals (MDGs) relate to improving health in the developing world, and more than a decade of increased international attention on improving the health of people in the developing world has borne fruit. Significant injections of financing into a raft of new institutions, global partnerships and initiatives have been central to progress, and the leading pharmaceutical companies have also played a significant role, collaborating with the global health community to address the needs.

However, tropical diseases continue to be a significant health burden, while research to develop treatments for them remains limited. Diarrhoeal diseases and pneumonia continue to be leading child killers in low-income countries, HIV/AIDS, tuberculosis and malaria remain endemic in a large part of the world and developing countries are experiencing an increasing burden of non-communicable diseases such as heart disease, stroke and diabetes.

Medicines are regarded as being essential to delivering better health<sup>1</sup>, but access to medicine remains a fundamental issue for many of the world's poorest people. Despite the progress that has been made, around a third of the world's population still has no regular access to medicine.<sup>2</sup> Many of the most neglected people in terms of health care live in the poorest countries, often in Sub-Saharan Africa, but it is estimated that the 'bottom billion'<sup>3</sup> people live in the emerging economies where the gulf between the growing middle classes and the poor living on less than a dollar a day is growing.

Efforts to continue making progress are ongoing, with HIV/AIDS, malaria and tuberculosis still a focus of attention, neglected tropical diseases increasingly so, and new commitments being made to address the enormous burden caused by non-communicable diseases and maternal and neonatal health.

However, numerous barriers hamper access to medicine for millions of people in developing world communities. Firstly, lack of research investment or scientific knowledge may mean that medicines for their condition

*For millions of people worldwide, medications are expensive, non-existent, inaccessible or of low quality.*

## Access to medicine depends on a number of things:

### Availability

Ensuring that new products are developed or existing products are adapted for local use

### Accessibility

Ensuring that people can receive the product and understand how to use it

### Affordability

Ensuring that the patients, healthcare providers and governments can afford the product

### Quality / Acceptability

Ensuring that the product works as intended, is efficacious and safe

1 WHO (2007) Everybody's Business. Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action. WHO. Geneva

2 WHO (2011) The World Medicines Situation. WHO, Geneva

3 Berger, M; Murugi, J; Buch, E; IJsselmuiden C; Moran, M; Guzman, J; Devlin, M; Kubata, B. Strengthening pharmaceutical innovation in Africa. Council on Health Research for Development (COHRED); New Partnership for Africa's Development (NEPAD) 2010.

do not exist. Even when a medicine can treat them, it may be too expensive, may not be available in the country, or may not reach them in time or at all due to ineffective supply chains. It also may not be of high quality, safe or effective, or may be formulated in a way that makes it difficult for them

*The challenge is multi-faceted and therefore the responsibility for rising to it lies with many actors.*

to take appropriately. In addition, the packaging may make it difficult for them to understand how to use the medicine.

The challenge is multi-faceted and therefore the responsibility for rising to it lies with many actors: the scientific research community; local governments; public health and regulatory agencies; overseas development agencies; philanthropists; trade administrators; the non-profit sector including product development partnerships; and the pharmaceutical industry – both research-based companies and manufacturers of generic medicines.

The 20 largest pharmaceutical companies evaluated in this Index have a crucial role to play in rising to this challenge.

The industry has made some important advances over the last two years, with the development of simpler and more affordable HIV and malaria diagnostics, and dramatic advances in laboratory-based tuberculosis diagnostic technology. In addition to engaging in innovative research, product development partnerships have made significant progress in adapting existing products with the development, for example, of a children's treatment for Chagas disease, a new meningitis vaccine for a strain of the disease that affects Africa, and a fixed-dose combination malaria drug.

Such examples show how large the impacts of pharmaceutical innovation, development and good practice can be, and it is due to such impacts that pharmaceutical companies have become increasingly important in tackling the MDGs related to health, being specifically identified in MDG 8.

Unfortunately the challenge will only grow. Looking beyond the expiration of the MDGs in 2015, the increasing burden of non-communicable diseases, along with continued challenges with HIV/AIDS,

co-infections with TB and other diseases, will only increase the complexity of disease interactions and medicine interactions. With an expanding global population, particularly in the developing world, the true extent of the problem – and opportunities – remains to be seen.

What is certain is the need for an innovative, thriving pharmaceutical industry, working collaboratively alongside public health and other actors, to rise to the challenge described above, and focus on creating, developing and meeting standards of excellence that will deliver healthcare and access to medicine for all.

## The pharmaceutical industry context

**Industry performance in increasing access to medicine must be understood in the context of the recent unstable economic climate, which has affected virtually all aspects of industry. In addition, 2012 is the peak year for expiries of patents on key products, and pipelines have not been sufficiently replenished, which means there are few valuable patents left to generate significant revenues.**

Scientific innovation challenges and changing regulatory, pricing and government reimbursement policies have presented further hurdles to the pharmaceutical business. Furthermore, there is increasing competition from generics companies, which are becoming innovators and threatening commercial returns for research-based pharmaceutical companies. In the context of these challenges, companies have made a number of strategic and tactical changes to the way in which they conduct their core business that are now beginning to play out.

**Relocating the focus of research, production and sales operations from Europe and the US to Asia and South America.** With emerging economies investing heavily in research and development and scientific infrastructure, and governments vying for inward investment, the trend of pharmaceutical companies shifting research and production from Europe and the United States to Asia and South America has been intensifying. The so-called 'pharmerging' markets - e.g. Brazil, Russia, India, China, Russia, Mexico and Turkey - are also major new sources of sales revenue, with a forecasted growth of approximately 14% by 2014, which compares with an estimated growth of less than 10% over the same period for the global pharmaceutical market.

**Shift towards rare diseases.** To respond to pressures to develop more innovative, targeted products, companies have invested more in rare diseases that, it is hoped, will increase productivity in research and development and replenish denuded pipelines. The one-size-fits-all blockbuster drug may be in decline.

**Patient 'crowdsourcing'.** Companies now recognise that getting closer to patients is essential for advocacy as well as for gaining insights into diseases, effectiveness of treatments and packaging adaptations. Patient groups now also have greater say when regulators assess the risks and benefits of new drugs and feed into reimbursement decisions.

**New ways of collaborating.** Companies are also taking a strategic approach to partnering with academics to tap into novel biology emerging from universities, working in concert with biotechnology firms rather than acquiring them, and carrying out joint research with rivals.

**Outsourcing early-stage discovery and development work.** New types of alliances with biotechnology firms are amounting to outsourcing discovery and early-stage development work, where companies pay biotech partners to carry out research and then take options on compounds that may be generated as a result.

**Reorganising research and development internally.** Companies are trying to replicate biotechnology firms in-house by reorganising researchers into flat and focussed teams designed to operate like small biotech companies, submitting business plans with defined objectives and competing with each other for funding.

**Opening up research.** To address productivity, the industry has been moving to a new paradigm of collaborative, 'open' or dispersed innovation, which is now managed as a centrally directed business issue, rather than an ad hoc process.

These changes are happening along with increasing and ongoing trends to outsource clinical trials and production, attempt novel forms of partnerships in the public and private sectors, and acquire generic manufacturers in the emerging economies. Within the context of these changing practices, some companies are also beginning to integrate an access to medicine strategy into their central business model as another way to reach new markets.

# What role does the Index play?

## Company Scope\*

- Johnson & Johnson
- Pfizer Inc.
- Novartis AG
- Roche Holding Ltd.
- Merck & Co. Inc.
- GlaxoSmithKline plc
- Sanofi
- Abbott Laboratories Inc.
- Novo Nordisk A/S
- AstraZeneca plc
- Bristol-Myers Squibb Co.
- Bayer AG
- Eli Lilly & Co.
- Takeda Pharmaceutical Co.
- Gilead Sciences
- Merck KGaA
- Astellas Pharma Inc.
- Daiichi Sankyo Co. Ltd.
- Eisai Co. Ltd.
- Boehringer-Ingelheim

\* by Market Cap as of December 31<sup>st</sup>, 2011

The Access to Medicine Index is an independent initiative that ranks the world's 20 largest companies according to their efforts to make their products more available, affordable and accessible in developing countries, highlighting policy and practice that either facilitate or hinder access to medicine.

It aims to help companies play their part in addressing the challenge of access and to offer them insight into the activities of their peers. By helping them to better understand their role, improve their approach and drive more value out of their access-related investments, the Index seeks to create value for pharmaceutical companies in addition to improving access to medicine for developing world populations.

By publishing the Access to Medicine Index every two years, the Access to Medicine Foundation seeks to create a platform that stakeholders across industry, government, civil society and academia can coalesce around to form a common view of how these companies can make further progress. The Index analysis and findings are based on information that is reported by companies in the Index questionnaire and cross-checked

with other sources and peer reviewed by experts in the relevant field. The Index is funded primarily by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs and the UK Department for International Development (DFID), as well as by other charitable organisations.

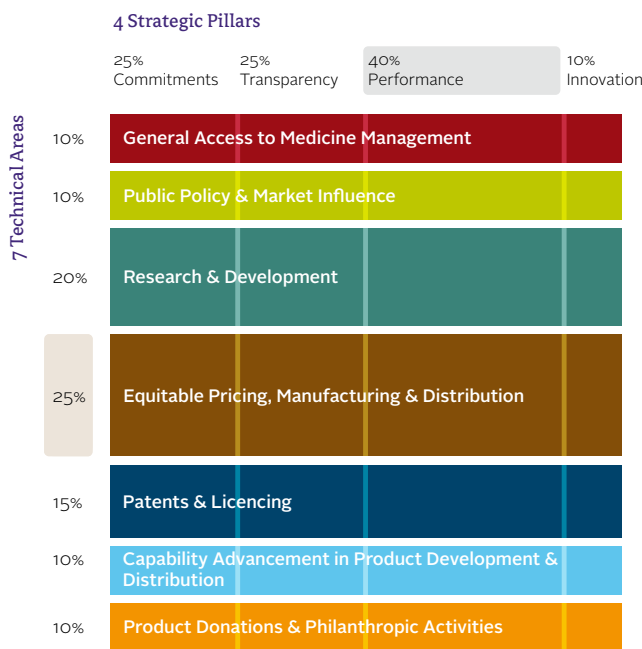
## How we measure

The Index uses a framework that evaluates company activities in seven areas of activity, or technical areas, considered to be key to enhancing access to medicine in developing countries, and across four important aspects of action, or strategic pillars. The technical areas and strategic pillars are weighted according to their relative importance for improving access to medicine. We analyse 101 indicators across the technical areas, and within each, indicators are distributed among the strategic pillars, which measure the level of commitment the company demonstrates, how transparent it is about what it is doing, what specific activities it is engaged in and how innovative its approach is.

## What we measure

The Index focusses on what pharmaceutical companies are doing to bring not only medicine, but also vaccines, diagnostic tests and

Figure 1 Methodology Framework



## The seven areas of activity cover:

- Overall organisation and management of access programmes
- The conduct of relationships with policy-makers, competitors, customers and the general public on matters that have an impact on access to medicine.
- Research and development aimed at producing relevant products
- Pricing policies and supply chains
- Policies and practices around patents and licencing
- Supporting developing countries to build capacities to develop and distribute their own drugs and to monitor drug effects.
- Product donation initiatives and philanthropic activities

other health technologies to people in what the World Bank considers to be low-income and lower-middle-income countries. The Index also includes an additional 10 countries the World Bank classifies as upper-middle-income, but that the UN Human Development Index identifies as still having wide disparities in human development and well-being. This brings the number of countries covered by the Index to 103.

The diseases covered in the Index include the top 10 communicable diseases based on disease burden (disability-adjusted life years); the top 10 non-communicable diseases and 14 of the 'neglected tropical diseases', and maternal conditions and neonatal infections.

**Refining the 2012 Methodology**

The 2012 Index is the third. The Index methodology was developed, and is continually refined, in consultation with multiple stakeholders including the World Health Organization, NGOs, governments and universities, as well as investors and companies themselves.

To enable comparability with the 2010 Index, the development of the methodology for the 2012 Index has been evolutionary rather than revolutionary, and the analytical framework remains the same as it was in 2010. This means we can now provide valu-

able insight into the progress made by the various pharmaceutical companies over the past two years in terms of their access to medicine initiatives.

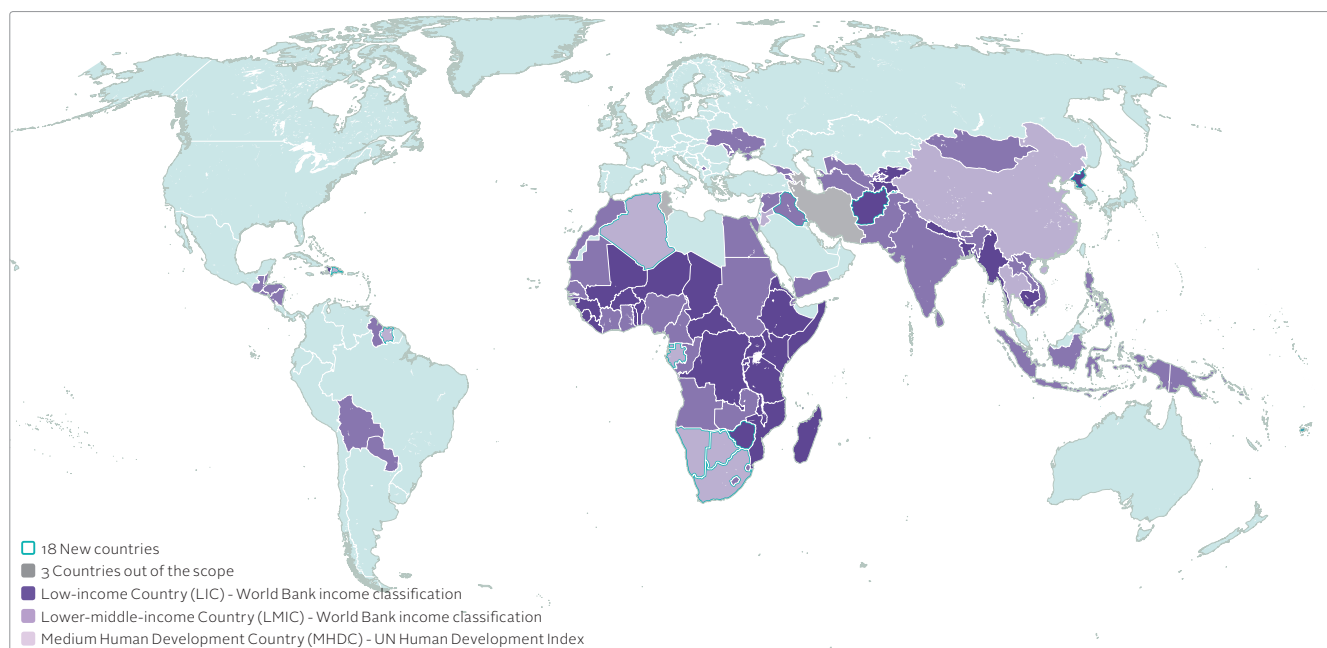
Following the suggestions of stakeholder groups, the weights of the key areas were adjusted, increasing Pricing, Manufacturing and Distribution by 5%, bringing it to 25%, and decreasing Research & Development by 5%, bringing it to 20%. The scoring now reflects that more activities are covered in Pricing, Manufacturing and Distribution relative to others. Additionally, the Performance pillar has increased to 40%, reflecting a focus on outcomes and impacts of company initiatives more than inputs, matching the widely-held view that monitoring and evaluating performance drives results.

Furthermore, in alignment with major global health objectives and the Millennium Development Goals, the disease scope of the Index has been expanded to include maternal health and neonatal infections. The geographical scope has also been expanded to 103 countries, which means that the companies' activities are now being measured in 18 additional countries.

**Limitations of methodology**

As does any study, the Access to Medicine Index has limitations, some of which are outlined below. A more detailed overview

Figure 2 Geographical Scope



limitations is presented in the Appendix. Further improvements will be made across all technical areas for the 2014 Index, to add more stringency and continuously improve the measures used.

### Measuring impact

As few companies disclosed the prices for each of the tiers in specific differential pricing programmes, and as there was no commonality in the way companies structured their tiered pricing programmes, or the reference prices they used to calculate their percentage reductions, the ability to draw conclusions about access was limited. Moving towards a more standardised way of gathering pricing data in order to facilitate better insight will be a major area of focus for the 2014 Index.

### Disease scope

Some companies may not have received credit for access-oriented activities targeting diseases that were not covered by the Index. The disease scope will be reviewed for the 2014 Index, and new DALY information will be balanced with the need to maintain comparability between Indices.

### Capturing breaches of codes of conduct

In the 2012 Index, only breaches in relevant countries were counted quantitatively. As some of these countries may have weaker regulatory and enforcement resources available, or out-of-court settlements may be more common, these breaches are sometimes difficult to capture, as is the level of transparency around them.

### Data availability

Another limitation was the lack of available and/or reliable data, particularly in the pricing and R&D areas, where companies are often unwilling to disclose data, or do so only partially. Occasionally, where sensitive data can be analysed, results cannot be published due to legal constraints. This has been a significant obstacle in finding and reporting trends in certain areas.

See our website for a detailed description of the process of preparation and quality control of the Access to Medicine Index 2012. ■



# Key Findings

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GlaxoSmithKline remains top of the league table, but by a narrower margin than in 2010. Two newcomers have moved into the top three closely behind and more companies have joined the ranks of the leaders, expanding the leading group from three companies in 2010 to seven this year. The industry as a whole is gradually progressing, with 17 out the 20 companies improving their scores against tougher standards.

The 2012 Index also reveals that companies are becoming more organised in their approach. Access to medicine has landed in more boardrooms and the Index leaders are increasingly coming to view access as a strategic issue.

Many companies have increased investment in relevant research and development, and some now devote as much as 20% of their pipeline to developing new products and adapting existing ones to address the needs of the poor. Meanwhile, more companies are using tiered pricing schemes, and applying them to a broader range of products and in more countries, but it is unclear whether the price reductions are enough to meaningfully increase affordability.

Finally, current industry performance in the area of accountability for the behaviour of Contract Research Organisations they hire is far from meeting Index expectations for clinical trial participant well-being in developing countries. Few companies report having robust measures to ensure clinical trials conducted by contractors are safe and ethical, with the majority providing no evidence of exerting real influence over the way their contractors conduct trials.

## *GlaxoSmithKline leads by narrower margin*

GlaxoSmithKline remains top of the league table, but its lead is shrinking, with two newcomers moving into the top three closely behind and more companies joining the ranks of the leaders. The industry as a whole is gradually progressing.

GlaxoSmithKline remains at the top of the Index, with a marginal improvement in performance since 2010, and this year, Johnson & Johnson and Sanofi follow closely in 2<sup>nd</sup> and 3<sup>rd</sup> positions. Seventeen out of the 20 companies are doing more than they were at the time of the 2010 Index to bring medicine to those who need it the most. At the top end, membership of the leading group has expanded from three companies in 2010 to seven, and there is a smaller difference between their scores than there was in 2010. Meanwhile, the gap has also narrowed between the bottom few companies and the top performers. This is notable given the fact that the Index set the bar higher this year in many areas.

The position of Gilead, in 5<sup>th</sup> place, and Novo Nordisk, in 6<sup>th</sup> place, in the leading group illustrates that companies don't necessarily need to have scale to perform well in access to medicine. The leading group are also the most transparent about their access activities, which contributes to higher scores because the initiatives are more visible, and therefore amenable to scoring.

## *Access approach is more organised*

Companies are becoming more organised in their approach and the Index leaders are increasingly coming to view access as a strategic issue. Access to medicine has landed in more boardrooms.

The 2012 Index finds that more than 60% of companies now have direct board ownership of access to medicine and that more companies are setting meaningful targets. Among the highest-ranked companies, leadership is coming from the very top, and there's an ever-increasing organisational focus. Dedicated access functions are being established and incentives to deliver access objectives are becoming more common, and are increasingly supported by performance management systems.

For instance, Index leader GlaxoSmithKline has, since the last Index report in 2010, established a Developing Countries and Market Access unit as a department dedicated to access, bringing all its businesses in Least Developed Countries under one umbrella, supported by a new lower price/higher volume business model. Notably, the bonus system for managers in this new unit is structured in a fundamentally different way, to reward volume growth rather than profit growth. Three other companies in the top five - Johnson & Johnson, Sanofi and Gilead – as well as Eisai, have also created similar dedicated departments.

## *Products and pipeline are meeting more needs*

More companies are developing more products.

Many companies have increased investment in relevant research and development since the last Index report, and some now devote as much as 20% of their pipeline to developing new products and adapting existing ones to address the needs of the poor. As well as investing more, companies are working together more often and sharing different types of information that can help advance various stages of research and development.

The primary focus continues to be communicable diseases with the highest health burden – lower respiratory infections, diarrhoeal diseases, HIV/AIDS, malaria and tuberculosis. Although the neglected tropical diseases still receive insufficient investment, they are less neglected than in 2010 and have received a significant funding boost from the private sector. Among this group, African trypanosomiasis, leishmaniasis and Chagas disease receive the most investment but there continues to be little, if any, investment for leprosy, soil-transmitted helminths, yaws, Buruli ulcer, dracunculiasis or fascioliasis.

## *More tiered pricing schemes, but what is their value?*

**More companies are using tiered pricing schemes, and applying them to a broader range of products and in more countries, but it is unclear whether the price reductions are enough to meaningfully increase affordability.**

The use of inter-country and intra-country tiered pricing, where companies set different prices for the same product depending on the target country or population group within a country, is increasing, with more than three quarters of companies now engaged in it. The number of companies applying the approach within countries has increased from five in 2010 to 12 in 2012. The affordability impact of these schemes is uncertain partly because not all companies disclose the extent of their price reductions, but also because across companies that do disclose, there is little commonality in the way that pricing tiers are constructed and in the reference points used to calculate price reductions. It is therefore not possible to compare schemes in order to assess which companies are delivering affordability.

An additional two factors interfere with the industry's attempt to use tiered pricing to lower prices. Firstly, companies often do not monitor the extent of mark-ups that third-party sales agents add to the price of their drugs, which means that even if the company sets low prices, the patient might still be paying high marked-up prices. Secondly, while so few companies use differentiated packaging to prevent drugs meant for the poor being diverted and ending up in the hands of richer patients, there is a risk of medicines not being available for the intended communities and that revenues lost through such market leakage could jeopardise the very sustainability of these schemes.

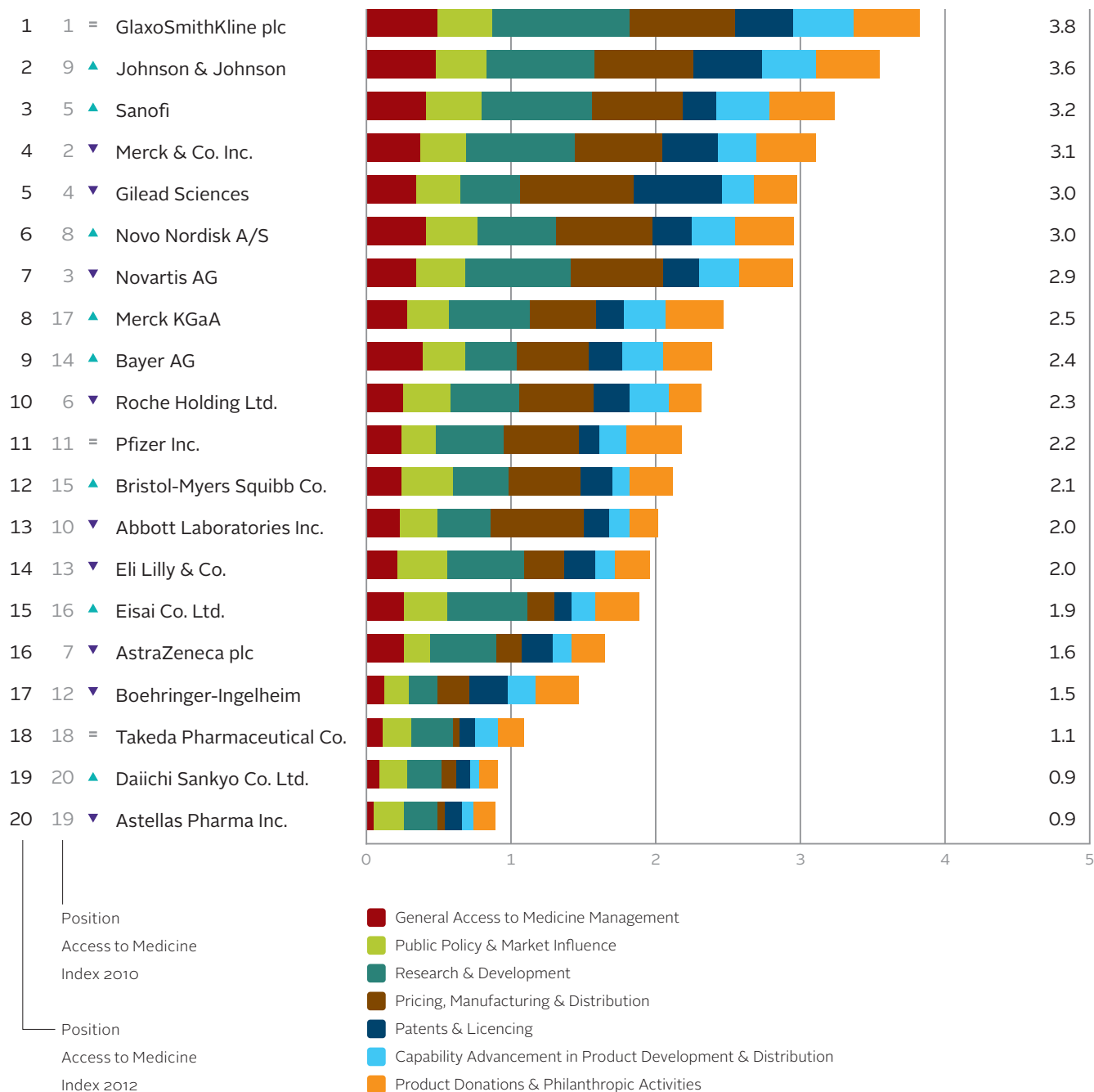
## *Accountability for CROs is weak*

**Few companies report having robust measures to ensure clinical trials conducted by contractors are safe and ethical, with the majority providing no evidence of exerting real influence over the way their contractors conduct trials.**

Only four companies provide evidence that they use disciplinary measures to enforce codes of conduct in relation to the Contract Research Organisations (CROs) they employ to conduct clinical trials on their behalf in developing countries. Without adequate due diligence in selecting contractors, monitoring of their conduct, or enforced disciplinary action, patients are left vulnerable to clinical malpractice with little recourse to justice.

While many companies have codes of conduct consistent with the basic minimum standard of the Helsinki Declaration, more than three quarters of them have not provided evidence of enforcement. Furthermore, in general, companies do not provide information about the CROs they hire, making it impossible for interested parties to monitor their behaviours. Current industry performance in the area of accountability for CRO behaviour is far from meeting Index expectations for clinical trial participant well-being in developing countries.

Figure 3 **The Access to Medicine Index 2012 - Overall Ranking**



A score of zero means lowest and five signifies highest indicator score among the company set.

# Leaders raise the bar

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Seventeen out of the 20 companies are doing more than they were at the time of the last Index report in 2010 to enhance access to medicine in developing countries. At the top end, more companies have joined the ranks of the leaders and there is a smaller difference between their scores than there was in 2010. Meanwhile, the gap has also narrowed between the bottom few companies and the top performers. This is notable given the fact that the Index set the bar higher this year in many areas.

There is evidence that, as an industry, companies are developing more products for more diseases that particularly affect the world's poor, and collaborating more in the process.

There is more target setting and increased attention to codes of conduct, and companies are starting to reward access-orientation in employees.

However, there are still several areas where all companies could improve their approaches significantly. These include being more transparent about their lobbying practices and clinical trial conduct and outcomes, expanding their tiered pricing schemes, adapting packaging to local needs, making their drug donations more needs-based, and allowing developing country regulators to use their clinical trial data to accelerate the approval of generic medicines.

## Leading group expands, with two newcomers in the top 3

### Leaders

- 1 **GlaxoSmithKline**
- 2 **Johnson & Johnson**
- 3 **Sanofi**

GlaxoSmithKline remains at the top of the Index, with a marginal improvement in performance since 2010, and this year, Johnson & Johnson and Sanofi follow closely in 2<sup>nd</sup> and 3<sup>rd</sup> positions. The top two companies have the most consistent approach to improving access to medicine, in terms of Index measurements - GlaxoSmithKline leads in four out of the seven key areas and is in the top three in others, and Johnson & Johnson is among the top five performers across all categories. Sanofi leads in public policy, and is second in three other areas; only its ninth position in patents and licencing and eighth position in pricing, manufacturing and distribution puts its overall score at third.

With visible leadership from the top, GlaxoSmithKline continues to outperform the field, with consistent good practice relative to peers across all areas. It is transparent about its activities and is the most innovative company in terms of the way in which it manages access to medicine and approaches research and development and building capability in developing countries. The company benefits from an integrated approach with a vision of sustainable involvement in access to medicine.

Johnson & Johnson is one of the two fastest risers in the Index, moving up seven places. This is largely due to the fact that it has consolidated its access activities under one business unit, which has resulted in a more strategic and integrated approach, and to its acquisition of Crucell, which has increased the relevance of its research and development investments. It has also disclosed more about its approach to access activities overall.

Sanofi has a proactive approach to increasing access with a CEO-led strategy that results in strong performance in public policy and market influence, a large investment in research and development and good practice in the management of clinical trials. It also has a particular commitment to advancing capabilities in developing countries, and to relevant product donation and philanthropy. The company is less consistent in its approach to equitable pricing, where it is an average performer and although only ranked middle of the field in patents and licencing, it has made improvements in this area against tougher measures.

### Risers

- 1 **Merck KGaA (+9)**
- 2 **Johnson & Johnson (+7)**
- 3 **Bayer (+5)**

A notable riser in the Index is Merck KGaA, up nine places and into the top 10. Despite being only a mid-sized company, it has improved performance in all areas. Its score improved considerably due to its detailed disclosure around its tiered pricing schemes. Significant progress can be seen in its approach to building developing world capacities in anti-counterfeiting and drug safety monitoring (pharmacovigilance), and also in product donation and philanthropy, research and development.

Bayer has risen five places since 2010, ranking 9<sup>th</sup> in this Index, largely due to an improved management approach, the establishment of targets for access initiatives, and an intra-country four-tiered differential pricing scheme. Its score also benefited from increased transparency about its approach and initiatives and about its stance on intellectual property issues.

## Standing still means falling backwards

Among the fallers in the Index, most remarkable is AstraZeneca, which fell nine places from a position within the top 10 performers in 2010. It is one of three companies to have scored fewer points this year than it did in the last Index.

This is due to its limited investment in relevant research and development, including below-average clinical trials management. In other areas, the company has not made progress, and therefore has been overtaken by peers that have improved their performance in governance of access, public policy, pricing, advancing relevant capabilities in the developing world, and product donation and philanthropy.

Novartis and Boehringer-Ingelheim have also fallen in the Index for quite different reasons. Boehringer-Ingelheim disclosed less information about its activities than other companies did, making it more difficult for the Index to give credit for progress. Novartis, which does not have a pro-access approach to patents and licencing, and also fell in rank in pricing and capability advancement, was knocked out of the top three by better-performing companies.

## Closing the gap

The bottom of the Index is dominated by the Japanese companies Daiichi Sankyo, Astellas and Takeda. They are showing signs of improving their policies and programmes related to improving access to medicine, but tend to concentrate on needs in Japan and fare poorly across almost all areas. Eisai leads the field among the Japanese companies, rising one place to 15<sup>th</sup>, leapfrogging larger companies AstraZeneca and Boehringer-Ingelheim and, along with Takeda, is showing increased commitment to enhancing access. It is moving to improve the management of its access initiatives and shares the most intellectual property relative to its size (by revenue). It also became in 2010 the first Japanese company to announce a single-drug donation programme to combat a neglected tropical disease. Takeda is also investing in research and development, now operates in a larger number of relevant countries, and has a greater focus on philanthropy and anti-counterfeiting, which brings it closer to its peers.

This year's Index demonstrates how important it is for companies to continue to step up their efforts in order to keep up in what is increasingly becoming a very competitive field.

## Fallers

- 1 **AstraZeneca (-9)**
- 2 **Boehringer-Ingelheim (-5)**
- 3 **Novartis (-4)**  
**Roche (-4)**

## Highlights

- **GlaxoSmithKline still top by narrower margin**
- **Whole field improved**
- **Laggards closing the gap**
- **The static tend to be overtaken**
- **Tougher bar**

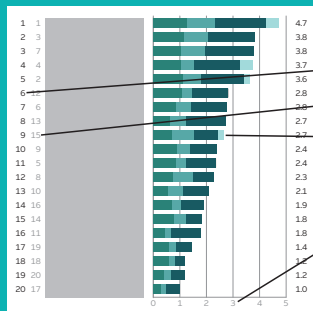




# Technical Areas

## Analysis Chapters

The Index uses a framework that evaluates company activities in seven areas of focus, or technical areas, considered to be key to enhancing access to medicine in developing countries, and across four key aspects of action, or strategic pillars. The following chapters present comparative analyses of company activities within each key area, and with relevant sub-themes identified and discussed. Chapters describe what matters - and therefore what is measured - and how companies perform against this. Each chapter includes a separate ranking for that key area of focus, presented in the same format as the overall ranking.



### Company Ranking per Technical Area

Position ATM Index 2012  
 Position ATM Index 2010  
 Four aspects of action:  
 Commitments  Transparency  
 Performance  Innovation  
 A score of zero means lowest and five signifies highest indicator score among the company set.

Relevant Indicators



### Key Sub-themes

In each chapter, key sub-themes provide a snapshot of how companies fare within the key areas of activity. They should be regarded as a general reflection of trends, and not exhaustive representations of the chapter or the indicators. Each sub-themes' results are based on scores from relevant indicator(s) within the corresponding area. All companies are presented relative to one another.

Score:  
 Low  Medium  
 High  Non-applicable

# A General Access to Medicine Management

## What matters

- Board ownership of and involvement in access to medicine strategy, approach and initiatives
- Quantitative and qualitative time-bound targets supported by performance management systems and access-oriented incentives
- Proactive stakeholder engagement, with coherent engagement strategy that is used to inform access strategy, approach and initiatives and to shape stakeholder expectations
- High degree of public visibility of access-related materials

## Key trends

### Ownership

Access is increasingly being owned and monitored by company boards, with leading companies allocating responsibility for access strategy, co-ordination and management to a single department.

### Targets

More companies are setting targets, using structured performance management systems and incentivising good performance.

### Better Reporting

Public transparency of access-related information is increasing, with approaches, initiatives and targets available via the Internet and company publications.

## Company performance

### Leaders

- 1 GlaxoSmithKline
- 2 Johnson & Johnson
- 3 Novo Nordisk

### Risers

- 1 Johnson & Johnson
- 2 Eisai
- 3 Merck KGaA

### Fallers

- 1 Abbott
- 2 Merck & Co., Gilead, Roche, Eli Lilly

## Centralising Access

Set up in 2010, GlaxoSmithKline's Developing Countries and Market Access (DCMA) unit brings its businesses in all Least-Developed Countries under one umbrella, with more than 650 employees managed through seven hubs. The company incentivises managers of its DCMA unit to increase volume growth rather than profit growth. > 30



**Overall, companies are performing well in this area. Significant progress has been made since 2010 in spite of the more challenging set of measurement criteria used in 2012.**

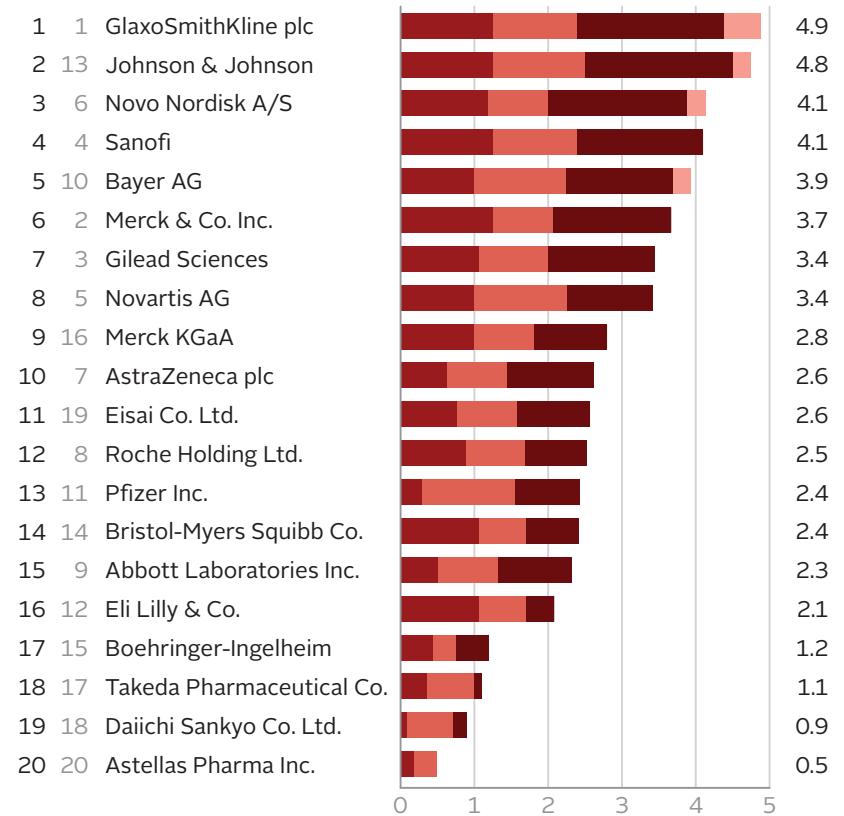
GlaxoSmithKline leads in this area, demonstrating very good performance across all measures. Access is owned and regularly reviewed at board-level and managed across the business by a single department. Tangible targets are set and well supported by performance management and incentive schemes directly oriented at furthering access. The company engages a wide range of stakeholders and actively seeks to shape and manage stakeholder expectations, as well as to inform the company approach to access. Good quality information about the company's access activities is publicly available.

Johnson & Johnson follows very closely in 2<sup>nd</sup> place, performing to a similar level and having made significant progress across many measures since 2010 in this area, rising 11 places in rank.

Novo Nordisk has also improved since 2010, rising three places to rank 3<sup>rd</sup>. It has a good level of board ownership, performance management and incentives but could improve its score by publicly disclosing targets for more of its access initiatives. The company's has active engagement programmes across its main access platforms but at a lower level of engagement than the two leading companies.

Eisai has also risen in rank, by eight places to 11<sup>th</sup>. The company has improved across many measures, now having board ownership of access, having established a Global Access Strategies unit and by having made some improvements in target setting and performance management. Further work in these areas would improve its score, as well as more extensive stakeholder engagement and making more of its access rationale public.

Figure 4 **Company Ranking General Access to Medicine Management**



The other notable riser is Merck KGaA, which rises seven places to rank 9<sup>th</sup>. The company has introduced a new access to medicine charter, which includes reporting, rationale, objectives, targets and progress measurement.

The fallers in this area have decreased in rank because they maintained their level of performance or have made progress less rapidly than their peers. Against the background of others making rapid progress and in the context of more demanding measures, they have therefore comparatively fallen back.

**Governance**

In their approach to governance, the highest-ranking companies have high levels of board ownership with directors involved in the access strategy and with regular reviews of performance. In GlaxoSmithKline for example, the President of Emerging Markets is accountable for access and the board

- Commitments
- Transparency
- Performance
- Innovation

reviews progress quarterly. In Novo Nordisk, ownership of access sits with a committee headed by the Chief Operating Officer, which reviews progress every six months. This contrasts with companies that rank lower in this area. For example, Pfizer provides no evidence of a single board director responsible and accountable for access and its board reviews access progress only annually. At Daichii, access is not owned or reported at board-level at all.

Many companies have made significant progress since the 2010 Index. Johnson & Johnson, for example, has improved its governance methods considerably through the establishment within the Janssen pharmaceutical business of a Global Pharmaceutical Access Committee, responsible for creating and managing a coherent approach to access. The committee includes several board members and its establishment, together with similarly senior ownership of access within its Crucell vaccines business, is the principal reason Johnson & Johnson has risen to rank 2<sup>nd</sup> in this area. Eisai has also made impressive improvement since 2010,

with board-level governance of access and a dedicated Global Access Strategies unit co-ordinating access strategy and initiatives. A contrasting example can be found in Abbott Laboratories, which in 2010 made a commitment to board-level representation for access and executive ownership of access. Although board representation at the director or vice president-level was achieved, there is no ownership of access. The company's comparative lack of progress in both this regard and in creating access-directed performance management means that its performance was lower than that of others, and the company has dropped in rank to 15<sup>th</sup> in this area.

It will be instructive to examine over time whether having a single department formulating strategy and approach for access leads to more global and integrated approaches than the current dispersed accountability for access seen in many of the other companies. The single-department approach can be seen in GlaxoSmithKline, which has, since the last Index, established its Developing Countries and Market Access unit as a department dedi-

## Background

### What we examine

Companies are increasingly realising the importance of emerging and developing country markets to their future business, and some are moving towards a lower-margin, higher-volume business model in order to gain and increase sales in these markets. This business approach offers opportunities to increase access to medicine for a much broader spectrum of the population in those countries than hitherto, and company boards of directors are apparently increasingly coming to regard access to medicine as a core part of their market development business strategy, where 'doing well' and 'doing good' are compatible for them.

It should be noted, however, that the new business model is not in itself the same as improving access for the whole of the population. While moderate price reductions may assist in making medicines more affordable for some, especially in countries where there

is an emerging middle class, they will remain unaffordable for many millions of people.

As for any other business strategy, a number of platforms and approaches are required to manage this effectively:

- Board-level ownership, commitment and visibility
- Tangible and measurable targets supported by internal incentives and performance management methods
- Engagement with a wide range of relevant stakeholders
- Public visibility of approaches, objectives, targets and progress

The indicators and methodology of the 2010 Index were based on these principles. The 2012 Index takes this further, with more demanding and new indicators reflecting the increased levels of management, delivery and visibility required to ensure that progress continues.

cated to access, bringing all its businesses in Least-developed countries under one umbrella, supported by a new lower-price/higher-volume business model. Johnson & Johnson, Sanofi, Gilead and Eisai have also created similar dedicated departments.

### Setting Targets and Managing Performance

As companies mature in their approach to managing access, a key enabling factor is the establishment of structured and robust methods for managing performance of access-related activities, involving:

- Setting relevant qualitative and quantitative access targets, long-term and, crucially, short-term, to allow performance management to be effective
- Utilising effective progress review and performance management methods
- Incentivising and rewarding access-orientation and results across the business

Among the leader group, good progress is being made toward this destination. In GlaxoSmithKline, Sanofi, Johnson & Johnson, Novo Nordisk, Bayer and Merck & Co., access initiatives have relevant qualitative and quantitative targets, often expressed in terms of short-, medium- and long-term targets. Progress is regularly reviewed and reward methods incentivise individuals working in access-relevant roles. Work has also been or is being undertaken to make these incentives more access-oriented. In GlaxoSmithKline, for example, since the 2010 Index the bonus of managers working in its Developing Countries and Market Access unit has been structured in a fundamentally new way to focus on driving volume growth, consistent with a low-margin, high-volume business model appropriate for these markets. In Merck & Co.'s Infectious Diseases franchise too, work is underway to change the reward structure to incentivise performance around the number of patients treated.

Companies such as Gilead and Novartis are using structures and methods that follow closely behind those of the leaders, and work is underway at Merck KGaA to develop a central incentive scheme directly related to access.

Other companies are making slower progress in this area, setting objectives without time-scales or indicators, or reporting progress

achieved to-date but not setting qualitative, quantitative and time-bound targets for the future. For example, while Bristol-Myers Squibb assesses access performance against a set of objectives, these are not quantified or time-bound. In other companies, targets exist but are expressed in terms of long-term goals rather than the near-term targets seen in the higher-ranked companies. In AstraZeneca's Young Health Program (YHP), for example, the goal is to launch programmes with the aim of reaching a million young people directly and indirectly by 2015, but there is no evidence of short-term targets that will be used to manage progress towards this goal. In the context of common experience both inside and outside of business indicating that progress is more readily achieved when goals are 'SMART' (Specific, Measurable, Attainable, Relevant and Timely), long-term general goals are less likely to be achieved if they are not supported by shorter-term targets.

Commonly, the companies using structured performance management and incentive schemes refer to remuneration and reward based on a mixture of company/business unit-level performance and personal contribution, which for access-related staff can include contribution to access initiatives. While broadly positive in driving access-orientation and behaviour, without company-level access objectives the proportion of an individual's reward package that is access-related is necessarily limited. Additionally, as individuals in directly access-related roles are in a minority, the proportion of the overall reward pool which incentivises access is likely to be small. The Index believes that making access a systemic business-wide reward factor, incentivising staff across the entire company value chain and setting company as well as business unit and personal objectives around access better promotes access to medicine.

Companies in the lagging group for this area, such as Boehringer-Ingelheim, Takeda, Daichii and Astellas, do not disclose measurable targets for access initiatives, nor do they measure or reward contribution to access initiatives through a formal performance management system. It is worthy of

*GlaxoSmithKline fundamentally restructured bonuses in its access unit to reward volume growth instead of profits.*

# 1st

Eisai is the Japanese company to tackle access to medicine as a **board issue**.

note, however, that progress can be made from this lagging position with relative ease. Eisai has made substantial progress since the 2010 Index, creating a management system to track and reward progress in access-related initiatives. While further work is required to set tangible short-term targets, this demonstrates that relatively straightforward changes in management approach can engender significant progress.

### Stakeholder Engagement

Stakeholder engagement that maximises positive access outcomes and develops a more access-oriented environment, involves many elements, including:

- A high level of proactive and reactive engagement with a coherent underpinning approach, engaging with senior individuals from appropriate stakeholder groups and documenting outcomes and their delivery
- Using engagement actively to inform and shape company approaches to access and to create relevant initiatives, measures, targets and outcomes
- An access strategy that is not subordinate to a corporate social responsibility/public relations (CSR/PR) strategy but that is seen within the company and externally as a core business strategy in its own right
- Companies seeking to act as a source of information, experience and knowledge in order to collaborate positively, shape

expectations, influence stakeholders and solve public policy problems

In order to create an evidence-based measurement in this area, the Index uses quantitative measures for how much stakeholder engagement of what type has taken place. In addition, qualitative information is used to create a more holistic view of the nature of that engagement.

Against these measures, all companies taking part in the 2012 Index engage with stakeholders to some degree in relation to access issues. GlaxoSmithKline, Johnson & Johnson and Sanofi rank as the lead group in terms of an access approach leading to their sponsorship of and attendance at access-related conferences, workshops, expert groups and so on. GlaxoSmithKline, for example, engage with stakeholders in relation to multiple access issues including tiered pricing, voluntary licencing, R&D and its drug donation programmes and has sponsored more than 30 access-related conferences and workshops since 2010. Company members attended many more events and GlaxoSmithKline executives took active roles in senior stakeholder events including co-chairing the Bill & Melinda Gates Foundation/CEO roundtable, co-chairing the UK's Industry-Government Forum on Access to Medicines and participating as members of the GAVI Alliance and Roll Back Malaria boards.

## GlaxoSmithKline Centralises Access

Set up in 2010, GlaxoSmithKline's Developing Countries and Market Access (DCMA) unit brings its businesses in all Least-developed countries under one umbrella, with more than 650 employees working out of seven hubs. The unit serves a total population of about 800 million in 50 countries, with the goal of building a lower-price/higher-volume business to reach more patients. The company

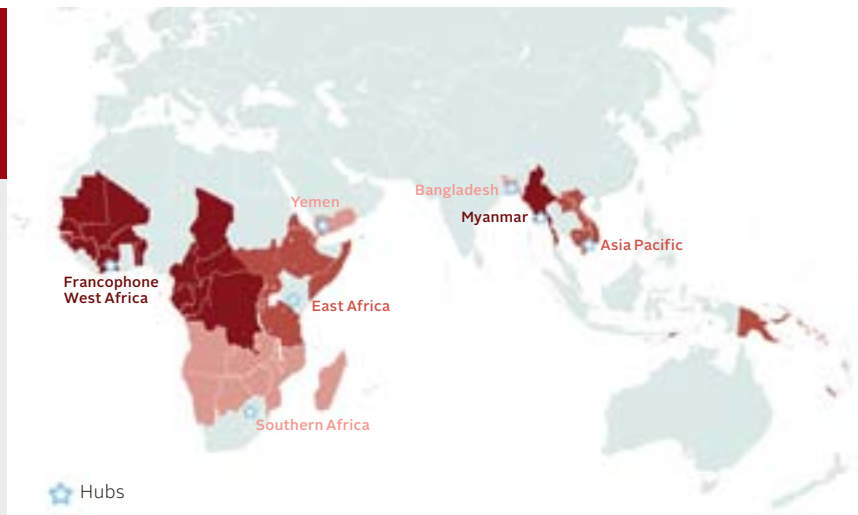


Figure 5 Geographical Scope: GlaxoSmithKline Developing Countries and Market Access

incentivises managers of its DCMA unit to increase volume growth rather than profit growth. Given that bonus payments can be up to 35% of an employee's

salary, there is a significant incentive to focus on access. GlaxoSmithKline also commits to reinvesting 20% of its profits from

Least-developed countries directly in projects that strengthen the health care infrastructure in these countries.

Johnson & Johnson has conducted stakeholder engagement events at a similar level and on similar topics and Sanofi in particular has improved the extent of its stakeholder engagement since 2010, holding more than 200 access-related workshops and meetings, increasing engagement with governments in access-relevant countries and with patient associations, health care professionals, academics and access-oriented UN organisations. It has also engaged via research and development partnerships in groups such as the Drugs for Neglected Diseases initiative and the Medicines for Malaria Venture, and Sanofi executives have engaged in senior stakeholder events.

Some companies outside the leading group, such as Merck & Co., Novo Nordisk and Merck KGaA are notable for the extent to which they use engagement to shape their access approach; diabetes for Novo Nordisk, maternal health and HIV access in the case of Merck & Co., and across a range of access topics for Merck KGaA. For other companies, for example Eli Lilly, the value of their numerous stakeholder engagement activities is rendered uncertain by a lack of documented outcomes from these engagements.

Gilead also sets a very good example by taking an advocacy position within the industry regarding the Medicines Patent Pool and its novel licencing strategy, seeking actively to shape opinions within the industry and to drive adoption of what it sees as good practice. GlaxoSmithKline too performs well, seeking actively to drive access efforts and publicly advocating a pro-access position.

At the lower end of the rankings, Roche, Daichii and Astellas perform poorly against these measures, with no co-ordinated engagement effort and little engagement beyond the local level.

**Public Visibility**

A crucial component of access is enabling public availability of information about company intents, approaches, activities and progress.

The highest-ranking companies in this area are Bayer, Johnson & Johnson, Pfizer and Novartis, followed very closely by Glaxo-SmithKline and Sanofi.

Novartis remains in the leading group of companies by continuing and enhancing its public reporting of access activities, reporting the rationale, policies and practices on its website and in its annual report and by setting and disclosing tangible targets.

Johnson & Johnson and Pfizer have similar levels of disclosure of their approach, rationale, initiatives and targets. Bayer has improved significantly in this area by publishing information relating to its access activities, including quantitative/qualitative targets and performance in its Sustainability Report and on its website.

GlaxoSmithKline and Sanofi perform to the same level as the leading companies in this area in their disclosure of their access approach and practices, but score slightly lower on their quantitative and qualitative targets.

At the lower end of the rankings in this area, the visibility of access-related information by Takeda, Daichii, Astellas and Boehringer-Ingelheim is very limited, with targets either not set or not publicly disclosed.

For all companies, higher scores can be achieved by enhancing public visibility by making access reporting available in a single place. Currently, within some companies, access-relevant information is reported piecemeal in diverse outlets such as annual reports, CSR-related reports, in the reports of foundations or similar entities, within project updates and within financial contributions reports. ■

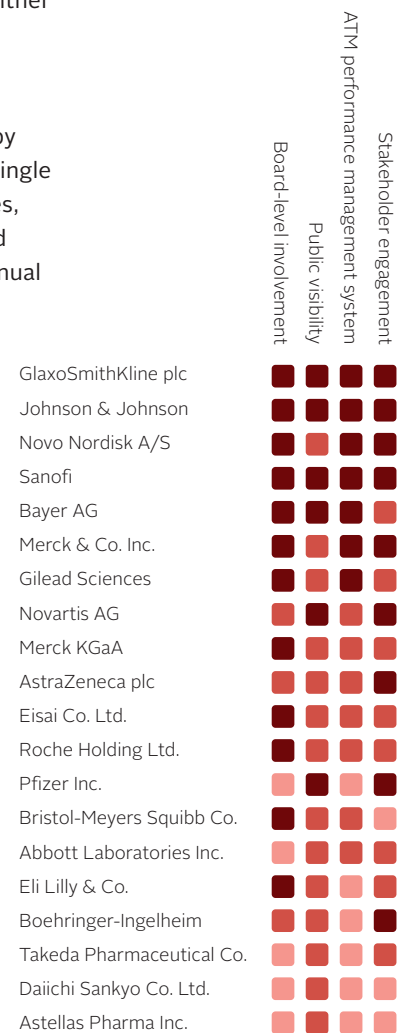
**3** companies have no co-ordinated **stakeholder engagement** effort:

- Roche
- Daichii
- Astellas

**Figure 6 Key Sub-themes**

Increased board-level ownership and reporting of access activities are reflected here. Management performance combines targets, incentive structures and performance measures. Stakeholder engagement is rarely used to inform access approaches.

- High
- Medium
- Low



# B Public Policy & Market Influence

## What matters

- Ethical and transparent lobbying practices that are monitored and enforced
- Ethical and transparent marketing and anti-bribery/anti-corruption practices that apply internally and to third parties and are monitored and enforced
- Engaging with external parties and memberships proactively to promote access
- Non-pursuit of anti-competitive policies or practices

## Key trends

### More commitment

Companies generally show more commitment to increased public accountability, stakeholder engagement, high standards for lobbying, ethical marketing and anti-bribery and corruption.

### Improving standards

Anti-corruption policies and ethical marketing standards are more robust and codes of conduct are increasingly applied to employees and others, with more meaningful monitoring and enforcement.

### Opaque lobbying

No company discloses how much it spends on lobbying specifically in developing countries covered by the Index.

## Company performance

### Leaders

- 1 Sanofi
- 2 GlaxoSmithKline
- 3 Novo Nordisk

### Risers

- 1 Novo Nordisk
- 2 Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson
- 3 Sanofi

### Fallers

- 1 AstraZeneca
- 2 Abbot
- 3 Pfizer

## Improving compliance with ethics codes

Sanofi's Global Compliance Department provides face-to-face and e-learning training and guidance to employees and third parties on anti-bribery laws and international conventions, tailored to local contexts. >36





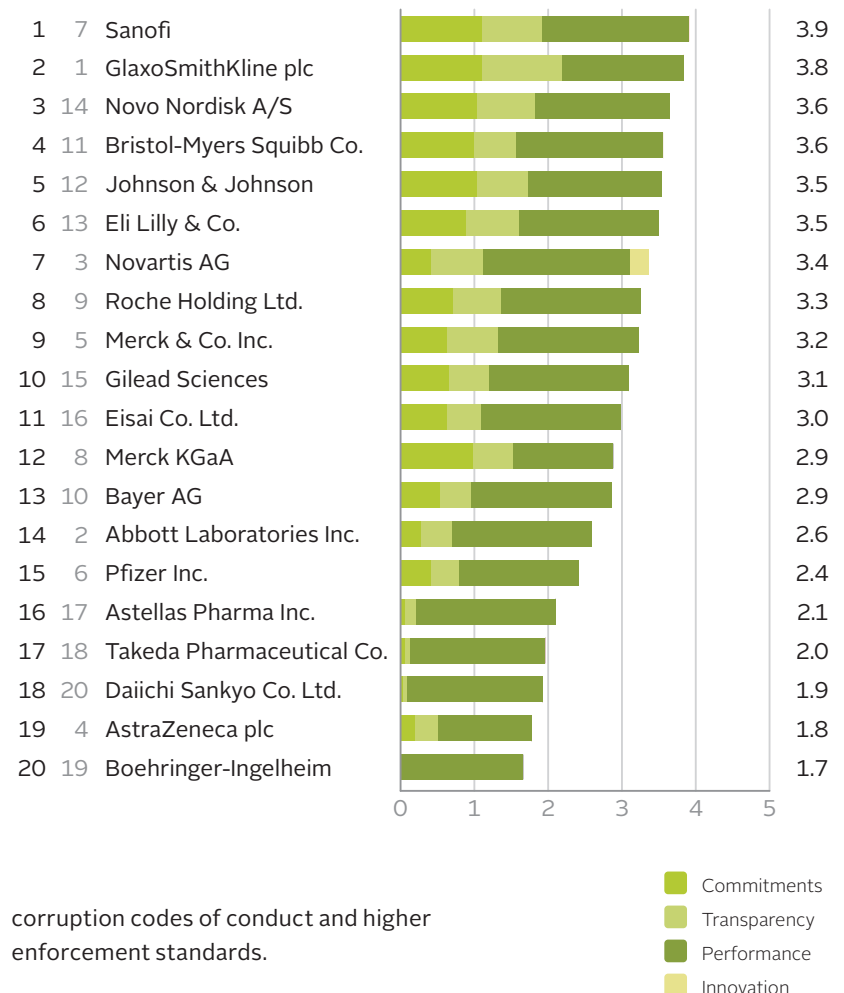
The leading companies, Sanofi and GlaxoSmithKline, meet higher standards for lobbying, marketing, bribery and corruption than their peers. These are reflected in their having internal codes of conduct and mechanisms to monitor and enforce them, as well as in their memberships of international arrangements such as the UN Global Compact. This is evidence that, among the leading companies at least, we are seeing a stronger public commitment than in the past to ethical practice.

Novo Nordisk's performance has improved markedly since 2010, moving it up 11 places to 3<sup>rd</sup>. It has access-orientated policy commitments related to competition and is the only company to commit fully to not applying data exclusivity. The company has also improved against more stringent measures relating to bribery and corruption.

Among the companies showing the biggest improvements since 2010, Sanofi has moved up six places because it has no pending litigation or regulatory proceedings relevant to breaches of any ethical marketing, lobbying or anti-bribery standard. Bristol-Myers Squibb, Johnson & Johnson and Eli Lilly also rose in rank by improving transparency and implementing more explicit codes of conduct, and Bristol-Myers Squibb meets higher anti-corruption standards. These companies do, however, have further to go in creating enforcement mechanisms.

Gilead and Eisai are less developed in terms of the scale and scope of enforcement around their lobbying and marketing efforts but have better standards for bribery and corruption than in the past, including anti-

Figure 7 Company Ranking Public Policy & Market Influence



corruption codes of conduct and higher enforcement standards.

Abbott, AstraZeneca and Pfizer fell in rank through a relative lack of transparency around their lobbying and marketing practices compared with the leaders in this area. Although Abbott and AstraZeneca show some commitment to fighting bribery and corruption and have improved their internal standards for ethical practices, there is further for them to go to meet a high standard of monitoring and enforcement mechanisms for preventing corruption.

Boehringer-Ingelheim, Daiichi Sankyo, Astellas and Takeda continue to lag, with little improvement since 2010 in relevant lobbying, marketing and anti-corruption commitments. They also have limited transparency around their lobbying and marketing practices, and Boehringer-Ingelheim had a breach of ethical conduct codes.

In the reporting period, four companies were found to have breached codes of conduct in countries relevant to the Index. GlaxoSmithKline's score was affected by six breaches, ranging from the sale of unregistered pharmaceutical products to improper product advertising, occurring in relevant countries in 2010-2011. Johnson & Johnson's score was affected by an April 2011 Securities and Exchange Commission (SEC) charge that subsidiaries gave kickbacks to Iraqi authorities to secure 19 contracts in the United Nations Oil for Food Programme. However, both scored highly for transparency around such infractions. AstraZeneca's score was affected by 28 marketing and sales breaches it reported took place globally in 2010-2011, and by its lack of disclosure regarding what proportion of these occurred in countries relevant to the Index. Boehringer-Ingelheim was fined in the Ukraine in 2010 for making false claims about a drug, but denied the allegations. The actual number of breaches may be higher given the difficulty of collecting such data in less-regulated markets. Certain troubling aspects of company behaviour are

captured in other chapters of this report, including breaches in relation to other areas such as intellectual property rights or clinical trials in countries covered by the Index.

*GlaxoSmithKline and Bayer have publicly committed to stop making political contributions in Index countries where they operate.*

### Lobbying and advocacy/competition behaviour

The Index looks for evidence that any lobbying, which could have relevance to access to medicine, is carried out in an ethical manner. It evaluates both the processes governing lobbying activities and the policy positions for which companies lobby. The Index expects companies to undertake at least the following actions to provide assurance that their lobbying activities are ethical:

- Publicly disclose any potential governance conflicts of interests, financial support and advisory functions to other organisations
- Publicly disclose policy positions being lobbied for, particularly around competition and data exclusivity
- Publicly disclose any breaches of relevant codes of conduct
- Apply stringent standards to deter breaches of codes of conduct

The leading companies in this area demonstrate a relative high level of disclosure and commitment to having ethical competition and lobbying practices in developing countries. For example, both GlaxoSmithKline and Sanofi have a transparent approach to policy positions, making public their position in areas such as intellectual property (TRIPS), technology transfer, tiered pricing, patents, compulsory licences, donations and clinical trial and pharmacovigilance processes.

Since 2009, GlaxoSmithKline has also ceased making political contributions in all countries relevant to the Index where it operates, although this does not apply to developed countries. Bayer reports a similar policy of not making campaign contributions to politicians. Both also disclose how they promote public policy positions relevant to access to medicine at the local, regional, and international levels and proactively interact with legislators and other stakeholders.

Across the industry, there is no transparency around lobbying payments specifically in developing countries. No company discloses its activities in the relevant countries, although the leaders' lobbying spend in high-income countries is transparent.

Novo Nordisk is the leader when it comes to allowing its clinical trial data to be used in

## Background

### What we examine

The Public Policy and Market Influence area requires companies both to sustain a proactive policy stance supportive of access to medicine, particularly around competition, and avoid breaches of ethical standards in lobbying and marketing. For companies to demonstrate commitment to high standards and compliance with lobbying, marketing and anti-bribery/corruption codes, they are required to provide evidence of having sound policy enforcement processes and disciplinary mechanisms. To show good performance, they must demonstrate very few violations of codes of conduct and accepted industry standards and laws and voluntarily disclose these.

the approval process for generic medicines, which is an important indicator of competition behaviour focus to access to medicine. It is the only company that states it does not apply data exclusivity in countries covered by the Index, nor does it apply for patent rights in more than 97% of focus countries. Several other companies - such as Gilead, Eli Lilly, Bristol-Myers Squibb, Johnson & Johnson, GlaxoSmithKline and Sanofi - have become more transparent in this area, disclosing a conditional commitment, for instance not to apply data exclusivity for specific diseases or under specific conditions. Also, Eisai specifically commits not to apply data exclusivity in the Least Developed Countries (UN LDCs), although the company has previously excluded Bangladesh from this commitment.

Companies that score below average, such as AstraZeneca and Abbott, lobby on access-related issues but are not transparent about the nature of policy positions and financial contributions in emerging markets. In addition, Abbott has disclosed only a partial list of trade memberships on its website, and has not publicly disclosed what board seats it holds at industry associations. Similarly, Gilead and Boehringer-Ingelheim have not disclosed board seats held in industry associations. This is in contrast to Bayer, GlaxoSmithKline and Johnson & Johnson, which are the leaders in this regard, disclosing all board seats at industry associations and advisory roles related to access to medicine for diseases and countries covered by the Index.

### Marketing

An ethical approach to marketing is essential for ensuring that patients and health care providers are able to make optimum choices and avoid potential hazards through incorrect or misinformation. Companies and their sales agents are expected to act in the best interests of patients, ensuring that their promotional methods do not mislead doctors, other healthcare providers, students, or patients. Guidance exists to ensure marketing practices are not in conflict with education and information dissemination goals, with the minimum accepted standard being the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) marketing code. However this covers only company employees and does not extend to sales agents.

In this respect, the Index looks for evidence that companies undertake, at a minimum, the following activities:

- Comply with the IFPMA marketing code
- Extend the application of this code to third party sales agents and other relevant parties
- Develop internal processes to monitor and enforce related codes
- Disclose codes and processes for their enforcement along with any breaches and related disciplinary actions.

### GlaxoSmithKline unique in exceeding IFPMA code

The majority of companies comply with the IFPMA marketing code. However, following its agreement in 2011 to plead guilty to unlawfully promoting two of its antidepressant drugs (Paxil<sup>®</sup> and Wellbutrin<sup>®</sup>) for unapproved uses in the United States, GlaxoSmithKline introduced more advanced ethical marketing codes of conduct through the revision in 2012 of its Global Code of Practice for Promotion and Customer Interactions and set standards for itself that significantly exceed the IFPMA marketing code.<sup>4</sup> Its Global Code of Practice for Promotion and Customer Interactions, revised in 2012, covers a wide range of areas, including fees for service payments to health care providers, and draws a clear distinction between promotional activities and legitimate scientific exchanges. It also maintains specific third-party codes of conduct for suppliers, including specific regional criteria. In addition, it is the only company with a policy of full disclosure of all marketing breaches in developing countries.

Though not to the same level as GlaxoSmithKline, Sanofi, Bristol-Myers Squibb, Johnson & Johnson, Merck & Co., Novo Nordisk, Pfizer, Novartis, Roche and Merck KGaA also have extensive ethical marketing codes of conduct

*Novo Nordisk allows its clinical trial data to be used to facilitate approval of generic medicines and does not apply for patent rights in more than 97% of them.*



Training session in Machacos district, Kenya

Novartis has strengthened its corporate citizenship programme for suppliers in an effort to foster **higher ethical standards**. Activities include engagement, collaboration, training and joint capacity building on bribery, corruption and data privacy. Site visits and audits aim to hold **suppliers accountable** and improve their adherence to the company's code of conduct.

that include monitoring and enforcement mechanisms for all sales agents and local third-party distributors and contractors, and hold their employees accountable to related policies, having disciplinary actions in place and active reporting of violations.

#### Holding suppliers accountable

Novartis stands out in the area of supplier accountability, as it has proactively implemented an extensive local review and approval process that ensures adherence to relevant codes of conduct, accompanied by stringent division compliance practices and multi-tiered company-level audits. This process extends to third parties to enhance transparency, active engagement and collaboration. Supply chain audits include focussed interventions if there is suspicion, for instance, of bribery, corruption, or data privacy; as well as supplier visits, regular audits and joint capacity-building projects. Novartis is the only company that receives recognition for Innovation in Public Policy and Marketing for these explicit best-in-class third-party auditing and enforcement mechanisms as outlined in its January 2012 revised code of conduct.

Companies at the lower end of the ranking, such as Daiichi Sankyo and Takeda, would benefit from better transparency on:

- Internal benchmarks or auditing systems concerning codes of compliance
- Marketing practices in developing countries
- Relationships with health care providers

#### Bribery and Corruption

Bribery and corruption have a wide range of negative impacts on developing countries and the Index expects companies to take all necessary steps to prevent employees and third-party contractors or sales agents from engaging in any corrupt practices. This involves:

- Publicly committing to fight corruption through adopting global arrangements such as World Economic Forum's Partnering Against Corruption Initiative (PACI) and UN Global Compact
- Implementing and enforcing codes of conduct in support of these arrangements
- Disclosing any breaches and related disciplinary actions

This year's Index sets higher standards regarding enforcement, auditing and disciplinary mechanisms for upholding global anti-corruption standards. Against these more stringent measures, Merck & Co. meets the highest standard in anti-corruption, auditing its code related to ethical practices and anti-corruption, as well as having memberships to the global conven-

*The Index asks for more on combatting corruption.*

## Sanofi's training programme on ethics compliance



Photo: Sanofi China

Sanofi's Global Compliance Department provides training and guidance to employees and third parties on anti-bribery laws and international conventions,

tailored to local contexts. As part of a China Compliance Day initiative, applied in each region, the company's China compliance team conducted more than

100 face-to-face training sessions and launched eight e-learning courses to train more than 5,000 employees on compliance with anti-bribery codes.

Sanofi has not been found to be in breach of any codes of conduct.

tions referred to above and being the only company to be a signatory to PACI.

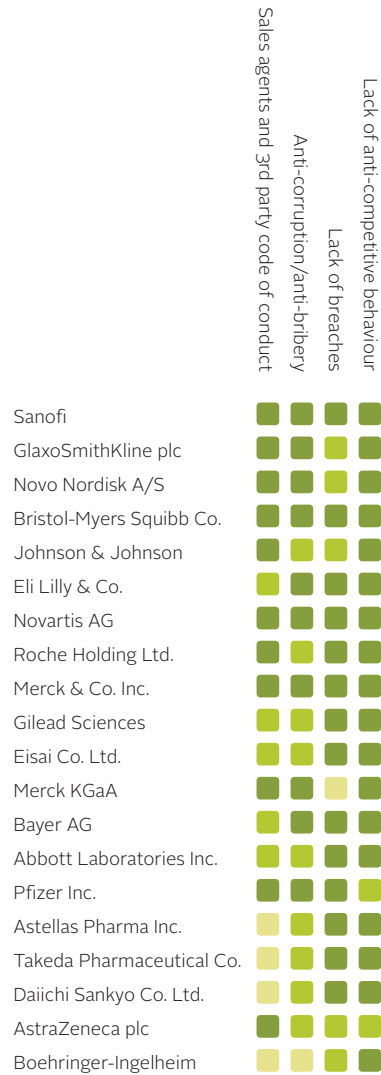
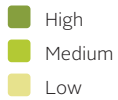
Other leaders such as GlaxoSmithKline, Sanofi and Novo Nordisk also have explicit anti-corruption policies meeting high auditing standards. These companies also provide training to employees and third parties on anti-bribery laws and relevant international conventions and voluntarily disclose breaches related to international anti-corruption standards as noted below.

The majority of companies, such as Abbott, AstraZeneca and Eli Lilly, are moving towards having more explicit anti-corruption codes of conduct but lack depth and quality of monitoring and enforcement mechanisms.

The lowest-ranked companies, such as Astellas, Daiichi Sankyo, and Boehringer-Ingelheim, have weaker codes of conduct for addressing corruption, and no internal enforcement mechanisms for those codes. ■

**Figure 8 Key Sub-themes**

Increased commitment to ethical marketing and anti-corruption standards, but overall still much room for improvement.



4 The high-profile US case has not affected the company's score in the Index because it occurred in a country not covered by the Index and the breach took place outside the five-year cut-off for inclusion.

# C Research & Development

## What matters

- Addressing the needs of poor and neglected populations through ‘innovative’ R&D to create products, and ‘adaptive’ R&D to modify existing ones
- Collaboration through partnerships or sharing of knowledge and intellectual property
- Excellent standards of clinical trial conduct, monitoring and transparency, whether the trials are conducted in-house or by contractors
- Innovative approaches to R&D

## Key trends

### Access-oriented R&D

Investment in R&D for diseases that particularly affect the world's poor is increasing, with the top five ranked companies now orienting more than a fifth of their pipeline towards relevant disease areas.

### Collaborative R&D

Companies are increasingly sharing know-how and intellectual property with the scientific community in the public and private sectors, whether through product development partnerships or other pre-competitive intellectual property sharing mechanisms.

### Ethical clinical trials

Few companies have robust measures to ensure clinical trials conducted by contractors are safe and ethical with the majority providing no evidence of exerting real influence over the way their contractors conduct trials or adequate assurance of benefits returned to host communities.

## Company performance

### Leaders

- 1 GlaxoSmithKline
- 2 Sanofi
- 3 Johnson & Johnson

### Risers

- 1 Eli Lilly
- 2 Merck KGaA
- 3 Novo Nordisk

### Fallers

- 1 Pfizer
- 2 Bayer
- 3 AstraZeneca

## Sharing knowledge at the Open Lab

GlaxoSmithKline's establishment of the Open Lab, based at its Medicines Development Campus in Tres Cantos, Spain, is an innovative, unique approach to R&D that aims to stimulate research on diseases of the developing world. >44



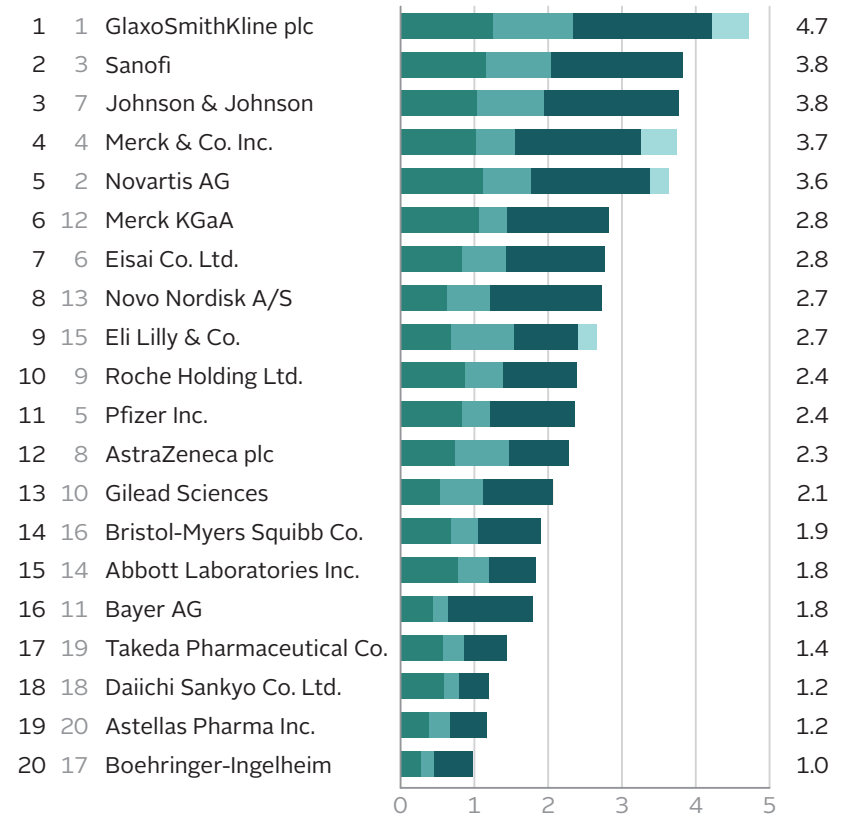
Many companies are investing more in research and development (R&D) than they were in 2010 for diseases that particularly affect people in developing countries. The leaders in this area – GlaxoSmithKline, Sanofi and Johnson & Johnson – invest most heavily in the development of new and adapted products for developing world markets. They are also more transparent than their peers regarding clinical trials conducted in developing countries. These companies, as well as smaller ones such as Gilead, also invest heavily in R&D partnerships.

**Leaders**

GlaxoSmithKline ranks 1<sup>st</sup> by quite a wide margin, demonstrating leadership across nearly all indicators. Its pipeline is fuller than previously for new medicines and for adaptive research directed at the needs of the poor, and this is complemented by R&D partnerships and sharing of intellectual property. Its transparency in all major areas of R&D that affect access is better than that of any other company. Its mechanisms for ensuring clinical trials are conducted ethically, including allowing for continued access post-trial to medicines for clinical trial participants, are also superior.

Sanofi, ranking 2<sup>nd</sup>, has a good pipeline in both innovative and adaptive R&D that covers a broad range of relevant diseases. At the time of the 2010 Index it had no adaptive products. The company also has numerous R&D partnerships. Compared to 2010, it has improved its position in relation to ensuring patient access to medicines after clinical trial participation and its disclosure of the results of clinical trials. It shows a strong commitment

Figure 9 **Company Ranking Research & Development**



to ensuring that contract research organisations (CROs) conducting clinical trials on its behalf uphold ethical standards, and follows through by monitoring and enforcing its standards for clinical trial conduct.

Johnson & Johnson has risen by four places to 3<sup>rd</sup> by adding relevant compounds to its pipeline and through its acquisition of Crucell, which has brought relevant vaccines into its portfolio. A large number of product partnerships and a high level of intellectual property sharing have also significantly improved its position.

Novartis, although dropping three places to 4<sup>th</sup>, is still among the leading companies in many of the R&D-related indicators, including making significant investments in R&D for neglected tropical diseases (NTDs), engaging in several relevant R&D partnerships, taking responsibility for the conduct of CROs involved in clinical trials and having in place clear processes for assuring post-trial access

to medicine for trial participants. Despite this, Johnson & Johnson and Sanofi have overtaken Novartis this year because they made relatively better progress since 2010.

### Most improved

Merck KGaA, which jumped six places to 6<sup>th</sup>, increased investments in both innovative and adaptive R&D with products of both types in the pipeline in 2012, compared to having neither in 2010. The company is also among the leaders in terms of intellectual property sharing relative to company size. It is also one of the few companies to move beyond having CRO codes of conduct to actively monitoring and enforcing them, although it lacks transparency around the details of who those CROs are, clinical trials registration and results.

Eli Lilly, which has likewise improved its position by six places in this Index, also

shows a significant commitment to intellectual property sharing for its size and now has relevant new products in the pipeline, whereas at the time of the last Index it had none. The company is one of only four to be relatively more transparent about the details of licences with the Product Development Partnerships (PDPs). Its improved position is also related to its innovative Open Innovation Drug Discovery programme, a web platform to open up data to the scientific community to advance research. However, the company is not fully transparent with respect to its use of CROs.

### Fallers

Some companies that slid in ranking, such as Boehringer-Ingelheim, Pfizer, Bayer and AstraZeneca, have no significant relevant investments in Phases II and III trials and fare poorly against the more stringent indicators relating to clinical trials conduct. For example:

## Background

### What we examine

Company investments in R&D often signal their future strategic direction, and an examination of company R&D efforts in relation to diseases of poor and neglected communities can therefore be useful in assessing their stance towards access to medicine.

To focus this on relevant areas, the Index uses the G-FINDER tracking tool of Policy Cures to examine R&D for communicable diseases

- In areas of high health burden in relevant countries
- That can have a significant impact on health outcomes for the poorest populations
- For products that lack strong market incentives

Given the strong market incentives that exist for non-communicable disease research relevant to developed countries, R&D for these is examined following the exclusions as detailed in the methodology. Four key aspects of company practice are assessed:

#### Adaptive and innovative R&D

To address the health needs of poor and neglected populations, new therapeutic, diagnostic and preventive technologies,

developed through 'innovative' R&D, are needed. However, modification of existing products and technologies, through 'adaptive' R&D, is also needed, to make them more suitable for developing world conditions and needs. Examples include paediatric formulations, heat-stable formulations and fixed-dose combination drugs.

#### Partnerships and knowledge sharing

As the R&D process can be long, risky and expensive, with high failure rates, R&D partnerships have been for some years growing in importance to companies. As well as helping to counter falling productivity in R&D<sup>5</sup>, they can offer opportunities to share cost and risks and to enhance quality by combining capabilities. In relation to developing world-oriented R&D, product development partnerships (PDPs) play an important role because they can offer funding and an organised structure for company participation. Collaborative approaches to R&D have also become increasingly important. These include pools, opening of molecule/compound libraries, and initiatives for sharing pre-competitive intellectual property, such as WIPO Re:Search. They allow an alternative (or sometimes complementary)



- Pfizer, dropping six places to 11<sup>th</sup>, does not perform well across many measures related to enhancing the safety of developing world clinical trials, and scores poorly in terms of transparency about trial registration details, use of CROs and clinical trial results. The company's score was also affected by a clinical trial regulatory breach in Nigeria.
- Bayer, declining five places to 16<sup>th</sup>, has no relevant innovative compounds in its pipeline and performs poorly against many measures around ethical clinical trials conduct. It provides no evidence of conducting due diligence prior to using CROs or of robust methods for controlling them. It also applies access-oriented licence terms to only two out of four research collaborations.
- AstraZeneca, declining four places to 12<sup>th</sup>, still has limited R&D relevant to developing country needs.

### Innovative and adaptive R&D

Company scores are based on the financial investments they make in relevant R&D and on the size of their pipeline. This is adjusted for company size based on total number of compounds and scaled, in order to achieve revenue-standardized scores to ensure that large and small companies are treated fairly. Separate measures are used for investment in innovative and adaptive R&D activities – conducted in-house and through third party partnerships – to acknowledge the different needs that these activities fulfil.

Investment in a pipeline of relevant innovative or adaptive products is increasing. Several companies commit more than 20% of their pipeline in terms of number of compounds to disease areas covered by the Index. The majority of the products and R&D pipeline investments correlate with the highest communicable disease burdens:

model to partnership for sharing of risk, cost and knowledge and increase the likelihood of creating successful new products at lower overall cost.

### Clinical trial conduct

Regardless of trial location, companies have a responsibility to minimise risks posed to trial participants and to ensure that host communities are able to benefit from them. All companies state their support for the Declaration of Helsinki<sup>6</sup>, but a number of factors argue for the bar being raised beyond that standard:

- The Declaration is not binding and companies are at liberty to apply it within their codes of conduct as they see fit. It is also typically regarded as a basic level of practice rather than a best-practice standard – a floor rather than a ceiling.
- Clinical trials are increasingly being conducted in developing countries, with typically poorer regulatory enforcement environments than in the developed world. Internal monitoring and enforcement will therefore be required.
- Trials are increasingly being carried out on behalf of companies by third parties such as contract research organisations

(CROs), with potentially different clinical practices and a lower level of reputational and financial exposure in the event of problems with the trial. Codification and formalisation of the standards of practice and responsibility for participant safety are therefore required.

The Index looks for evidence that, at minimum, the company follows ethical standards such as the Declaration of Helsinki and of adoption of standards that go beyond, including monitoring and auditing for compliance.

### Innovation in approaches to R&D

In the context of the length, risk, high rates of failure and huge levels of investment required by traditional models of R&D, it is fundamentally important for companies to innovate models of R&D. This is even more important for medicines aimed at the poorest communities, in view of the commercial challenges. The Index therefore assesses the extent to which companies innovate in their approach to R&D.



Photo: Prashant Panjari

Children living at the Guinea Worm Case Containment Center while receiving medical attention.

**13 companies** - Abbott, AstraZeneca, Bayer, Bristol-Meyers Squibb, Eisai, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Pfizer and Sanofi - committed in the London Declaration to coordinated action to **combat NTDs**, together with NGOs, multilateral organisations, the Bill & Melinda Gates Foundation and governments. (January 2012)

HIV/AIDS, tuberculosis, malaria, lower respiratory infections and diarrhoeal disease. Maternal conditions appear not yet to be an R&D priority, despite the strong need for interventions that are adapted to local contexts.

### Neglected diseases less neglected

NTDs are receiving more attention from industry than in the past, with GlaxoSmithKline, Johnson & Johnson, Sanofi, Merck & Co., Novartis and Merck KGaA making significant pipeline investments, from basic research to pre-clinical molecules, for these diseases. Among the

14 NTDs, most companies are focussed on African trypanosomiasis, leishmaniasis and Chagas disease. However, none of these investments is yet having an impact on disease outcomes and there continues to be little, if any, R&D pipeline investment for leprosy, soil-transmitted helminths, yaws, Buruli ulcer, dracunculiasis, or fascioliasis.

In the last Index, the level of R&D investment in relevant diseases was highest among the largest companies (by revenue) even after adjusting for company size, and in 2012 the same holds true, with large companies such as GlaxoSmithKline, Merck & Co., Johnson & Johnson, and Sanofi leading. Given the apparent lack of commercial incentives for R&D in NTDs, this is significant and, taken together with the good performance of these companies across other Index

measures relating to enabling market access in developing countries, suggests a systemic intent by these companies to make progress in these disease areas and markets.

This is not exclusive to large companies, with tangible improvements also visible among some smaller companies with less mature access to medicine approaches. Eisai, for example, has delivered against its 2010 commitment to invest in innovative R&D and has improved its investment in research into NTDs since that time.

### Mixed performance in adaptive R&D

For adaptive R&D, the top performers are GlaxoSmithKline, Johnson & Johnson, Merck & Co. and Bayer.

This group is followed by Sanofi, Novartis, Novo Nordisk and Roche, which also have significant amounts of adaptive R&D ongoing and have increased their pipelines in this respect since 2010.

All other companies have less than 5% of their pipeline oriented towards adaptive R&D, with AstraZeneca, Eli Lilly, Gilead, Astellas, Abbott, Daichii and Takeda having no relevant adaptive R&D.

Companies have tended to be more transparent in this Index than in 2010 about details of which compounds are in which stages of the pipeline, but not about financial and human resource investments, which companies consider highly sensitive information. Companies provided varying and therefore, incomparable data for in-house R&D investments specifically for relevant diseases, preventing analysis of trends of these investments.

### Sharing intellectual property

In terms of their participation in intellectual property sharing initiatives, many companies have opened their compound libraries for NTD and infectious disease molecules. Johnson & Johnson have seven examples of sharing, the highest in absolute number, but the leaders in terms of intellectual property sharing<sup>7</sup> are Eli Lilly, Gilead, Merck KGaA and Eisai, whose instances of sharing compared to their revenue is the highest. These are companies that also tend to have smaller in-house pipeline investments relevant to the Index, suggesting that participation in

Girl with multiple active CL lesions, Bolivia.

Reducing hospital visits through self-administration: Sanofi is adapting its **leishmaniasis drug**, which currently requires repeated injections, to develop a product that patients can apply to their skin at home.



Photo: Dr Philippe Desjeux

intellectual property sharing initiatives can act as a useful addition to in-house R&D.

Companies in the lagging group in this area, such as Astellas, Daiichi Sankyo, Takeda and Boehringer-Ingelheim, report no instances of intellectual property sharing.

### R&D partnerships

Given the long timescales in R&D, it is difficult to measure the results, such as new products developed, within the two-year reporting cycle of the Index. As a proxy, the Index continues to use input measures as a signal for company commitment to advancing the availability and affordability of needed drugs, vaccines and diagnostics through partnerships. Companies have therefore been scored against the quantity of relevant R&D public-private partnerships or PDPs in which they engage; the duration of such engagements; evidence of access-oriented licencing terms related to the partnerships, assuring timely, affordable access in relevant markets; and transparency around the conditions of such partnerships.

GlaxoSmithKline, Johnson & Johnson and Novartis engage in the most research collaborations, with GlaxoSmithKline being involved in around 12 relevant PDPs and R&D partnerships that have a clear link to health burden in relevant countries.

The weakest performers in this area (Takeda, Boehringer-Ingelheim, Daiichi Sankyo and Astellas) report no relevant collaborations.

In terms of details of partner licences, more than half of companies provided the Index with very little or no information about the terms, but four companies (Sanofi, Eli Lilly, GlaxoSmithKline and Johnson & Johnson) make this information partially or completely publicly available.

Among the companies that did disclose details of their licencing arrangements, GlaxoSmithKline demonstrates the best approach to licencing, applying access-oriented licencing terms to a large number of partnerships across a range of disease areas and disclosing the terms of licences, including for pricing, supply commitments and royalty rates. It is closely followed by Johnson & Johnson and Sanofi, which apply such terms to the majority of their partner-

ships. In some cases companies implement tiered pricing for products created through PDPs in eligible countries. Only GlaxoSmithKline applies access-oriented licencing terms to all PDPs for all relevant diseases in all developing countries in which it has sales, while the majority of companies employ such terms in none or, at best, to 50% or fewer of their licences.

### Clinical Trials Conduct

Companies are measured against their compliance with the letter and the spirit of the Declaration of Helsinki and similar standards of practice and the degree to which they move beyond them to develop excellent clinical practice through:

- Using codes of conduct to ensure safe and ethical delivery of clinical trials, whether by employees or CROs, including conducting monitoring and enforcement when required
- Due diligence activities in the selection of the CROs
- Ensuring post-trial access to medicine in all cases where there is a need
- Working to improve transparency and accountability through timely disclosure of clinical trial results, controversies related to clinical trials, details of any CROs used and details of codes of conduct and supporting monitoring and enforcement
- Not being in breach of the Declaration of Helsinki or similar standards

### Evidence for oversight of CROs is weak

Although the use of codes of conduct is widespread, there is less evidence of active monitoring and auditing of compliance, with Bayer, Abbott and Boehringer-Ingelheim providing no evidence of such activities. Furthermore, more than three-quarters of companies provide no evidence of having employed disciplinary action to enforce these codes of conduct. Only four companies – GlaxoSmithKline, Sanofi, Merck & Co. and Eisai – provide evidence that they use such measures to enforce codes of conduct in relation to the CROs they employ.

Merck & Co. publicly discloses details about the CROs it employs, with GlaxoSmithKline, Sanofi AstraZeneca, Bristol-Myers Squibb, Gilead, Johnson & Johnson, Novartis, Novo Nordisk, Roche, Astellas, Eisai and Takeda disclosing these details to the Index. However, other companies, such as Bayer, Eli Lilly, Merck KGaA, Pfizer, Daiichi Sankyo

# 14,000

**novel compounds**

from laboratories in 27 countries have been screened through Eli Lilly's 'Open Innovation Drug Discovery' initiative, resulting in several agreements for further evaluation of newly discovered compounds.

# 40%

of funding for R&D targeting neglected tropical diseases comes from **Product Development Partnerships**.

# 25%

of the companies enforce standards of **ethical conduct** in their clinical trial contractors, in line with the Declaration of Helsinki.

**9** companies are transparent on clinical trial results, regardless of the outcome:

- GlaxoSmithKline
- Sanofi
- Johnson & Johnson
- Novartis
- Novo Nordisk
- Eli Lilly
- Roche
- Gilead
- Bristol-Meyers Squibb

and Boehringer-Ingelheim, do not disclose information about CRO partners. This is noteworthy given the risks that poorly conducted clinical trials can pose to patients and the reputational damage that could result for companies seeking to gain access to those markets. The Index believes that accountability for CRO behaviour is where one of the widest gaps exists between current industry performance and Index expectations for clinical trial participant well-being in developing countries, and will closely monitor future company commitments and activities in this area.

Only half the companies make a commitment to ensuring that trial participants continue to have access to medicines when the trial is over. However, six companies (AstraZeneca, Johnson & Johnson, Merck & Co., Novartis, Pfizer and Eisai) did not provide specific details of how employees or CROs will ensure access. GlaxoSmithKline, Sanofi, Roche and Novo Nordisk, on the other hand, disclose specific, detailed approaches to post-trial access for trials conducted in relevant countries, assuring access under a wide variety of circumstances.

#### Trial registration transparency variable

Nine companies are fully transparent in relation to initial trial registration information

and results, which they disclose within one year of trial completion for all clinical trials conducted in relevant countries, whether in-house or by CROs. AstraZeneca scores slightly lower than the most transparent companies, giving more general trial details but still showing a relatively strong commitment to disclose this information.

In contrast, other companies revealed a much weaker level of commitment to being transparent, often disclosing only partial information with the following types of omissions:

- Not publishing results on their websites (e.g. Boehringer Ingelheim, Daiichi Sankyo, Astellas)
- Missing some trial details, such as names of collaborators (e.g. Bayer, Pfizer), CROs (e.g. Pfizer), trial sites, the principal investigator, duration of the trial, target sample size, recruitment status (e.g. AstraZeneca, Merck KGaA)
- Disclosing outcomes of clinical trial registry only after the compound is approved, which may lead to only positive outcomes being reported (e.g. Eisai, Merck KGaA)
- Disclosing only partial outcomes (e.g. Abbott, Bayer, Merck & Co., Pfizer, Takeda)

Notwithstanding the above, most companies were not in breach of international codes and were not the subject of lawsuits filed

## Sharing knowledge at the Open Lab in Tres Cantos, Spain

GlaxoSmithKline's establishment of the Open Lab, based at its Medicines Development Campus in Tres Cantos, Spain, is an innovative, unique approach to R&D that aims to stimulate research on diseases of the developing world. It fosters collaboration by hosting visiting scientists from universities, not-for-profit partnerships, and other research institutes to work on their own projects for the developing world

while using the company's expertise and facilities. The Open Lab hosted six projects in 2011, including the Pool for Open Innovation against Neglected Tropical Diseases (POINT),

administered by BIO Ventures for Global Health. GlaxoSmithKline contributed its patents and a patent application to POINT. Under the terms, any medicines or

treatments for neglected diseases developed using the pooled patents and intellectual property will be available for use in Least Developed Countries royalty-free.



during the last five years around clinical trial practices in relevant countries. Pfizer, however, reached an out-of-court settlement with 200 plaintiffs during the reporting period, for a breach related to its trial of Trovan® in Nigeria. Eli Lilly has also been the subject of several legal cases that have resulted in negative rulings or regulatory notices.

**Innovation in approaches to R&D**

The traditional R&D model is yielding lower levels of productivity across the industry,<sup>8</sup> which is therefore adopting increasingly innovative approaches across the disease portfolio. In relation to enhancing access to medicine, innovation in approaches to R&D may come in a variety of forms, including:

- Technological advances in R&D processes
- Novel collaborations in R&D
- Use of digital technologies to open up access to data
- Funding for targeted NTD research

On this basis, GlaxoSmithKline and Merck & Co. lead as the most innovative companies in relation to their approaches to R&D, followed by Eli Lilly and Novartis.

With respect to novel collaborations in R&D, GlaxoSmithKline established the Tres Cantos Open Lab Foundation with an initial donation of £5 million (USD 1.9 million) to kick-start research at the Lab.

Focussed on accelerating technology development in the area of maternal health, Merck & Co. started in September 2011 the Merck for Mothers Initiative, which will engage external partners to develop technologies that will primarily focus on prevention

of haemorrhage and pre-eclampsia during pregnancy, as well as on family planning.

Meanwhile, Eli Lilly has a new ‘Open Innovation Drug Discovery’ programme, which is a web-based tool that allows external researchers to register their molecules. Eli Lilly in turn allows the researchers to use its expertise in the drug discovery and development process and compensates the researchers with external funding. Eli Lilly discloses that this programme allows global affiliated institutions to continue their work in a cost-effective manner by lowering the barriers for accessibility and providing immediate data and feedback. ■

**2** companies had **clinical trial breaches** during the Index period: Pfizer and Eli Lilly.

And more than **75%** provide **no evidence** of using disciplinary action to enforce codes of conduct in CROs.

**Figure 10 Key Sub-themes**  
Collaboration and sharing in research is improving but still limited. More accountability for ethical trial conduct by third party contractors needed.

- High
- Medium
- Low



5 J. Hewitt, Campbell J. D., Cacciotti J., (2011), Beyond the Shadow of a Drought The need for a new mindset in R&D, Oliver Wyman Health and Life Sciences 2011.

6 Along with the WHO’s International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982) and other recognised standards, listed in the Scoring Guidelines.

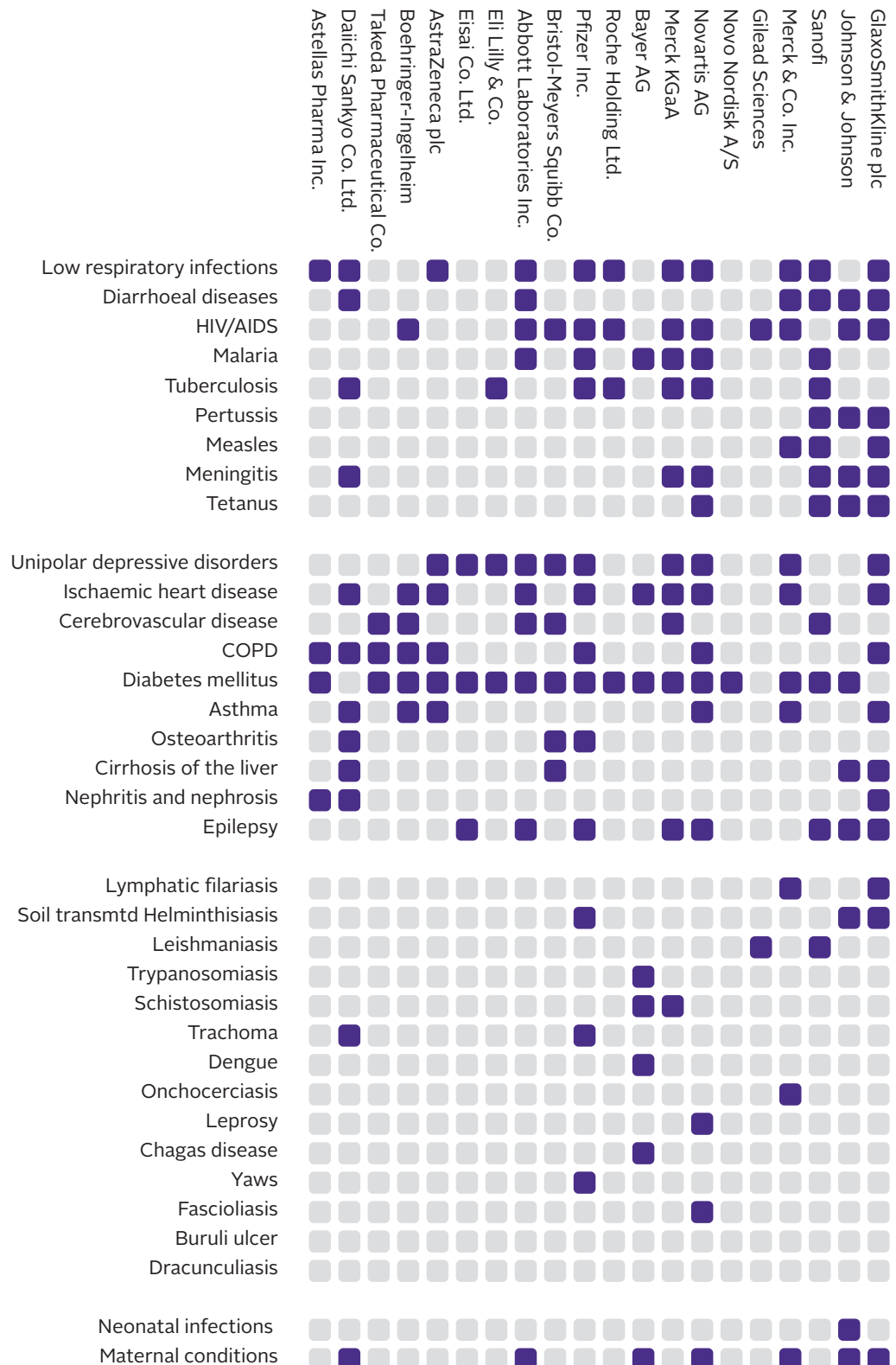
7 Companies are assessed for the quantity of IP-sharing arrangements in which they are involved, adjusted for company revenue and scaled, in order to achieve revenue-standardized scores. This approach is new in the 2012.

8 J. Hewitt, Campbell J. D., Cacciotti J., (2011), Beyond the Shadow of a Drought The need for a new mindset in R&D, Oliver Wyman Health and Life Sciences 2011.

## Disease products

Below is a snapshot of commercial product types in scope to support prevention, diagnosis and treatment for relevant diseases, irrespective of quantity or other qualifying factors. The figure below provides a general sense of where companies are currently focussing efforts.

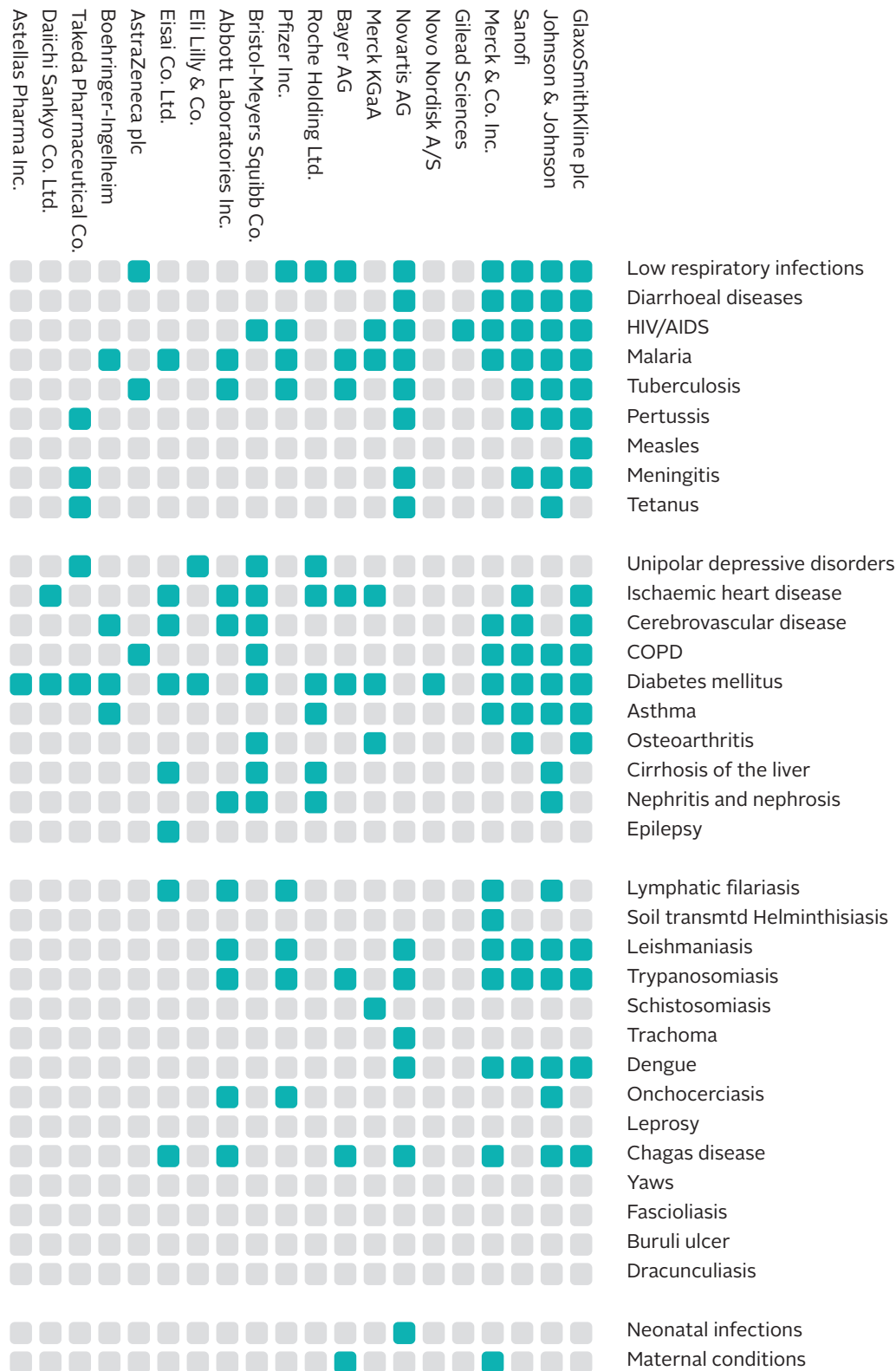
Figure 11 **Index Company Disease Scope for Commercial Products**



# Disease pipeline

Below is a snapshot of existing developmental innovative and adaptive molecules that have reached clinical trial stage, irrespective of quantity, partnerships, or other qualifying factors. The figure below provides a general sense of where companies are currently focussing efforts. Molecules in initial developmental stages are not included. Others are not included here, because they are not publicly disclosed.

Figure 12 **Index Company Disease Pipeline**



# D Pricing, Manufacturing & Distribution

## What matters

- Using tiered pricing schemes, anti-diversionary product adaptation and monitoring sales agent mark-ups in order to increase affordability of medicines
- Monitoring of and transparency around compliance with international manufacturing and quality standards, with policies, practices and transparency around product recalls
- Seeking early product prequalification and market registration to enable maximum availability to those in need

## Key trends

### Pricing transparency

Poor and/or inconsistent disclosure of pricing information makes real insight and trend analysis extremely difficult. Even when data are disclosed, comparability and insights across companies are limited because of varying approaches, reference points and reporting.

### Affordable pricing

More companies have made commitments towards both inter- and intra-country tiered pricing, particularly intra-country. Commitments to monitor pricing practices of sales agents and price mark-ups along the supply chain have also improved.

### Product registration

Companies have performed marginally better on WHO prequalification, but their commitments to file for marketing approval, or product registration, lack specific timeframes.

## Company performance

### Leaders

- 1 Gilead Sciences
- 2 GlaxoSmithKline plc
- 3 Johnson & Johnson

### Risers

- 1 Merck KGaA
- 2 Johnson & Johnson
- 3 Pfizer

### Fallers

- 1 AstraZeneca plc
- 2 Boehringer-Ingelheim
- 3 Merck and Co.

## Tiered pricing for contraceptives

In partnership with the USAID Contraceptive Security Initiative, Bayer is seeking to make contraception more affordable for women in 11 Sub-Saharan countries by selling its oral contraceptive Microgynon® Fe using an innovative tiered pricing model. > 53





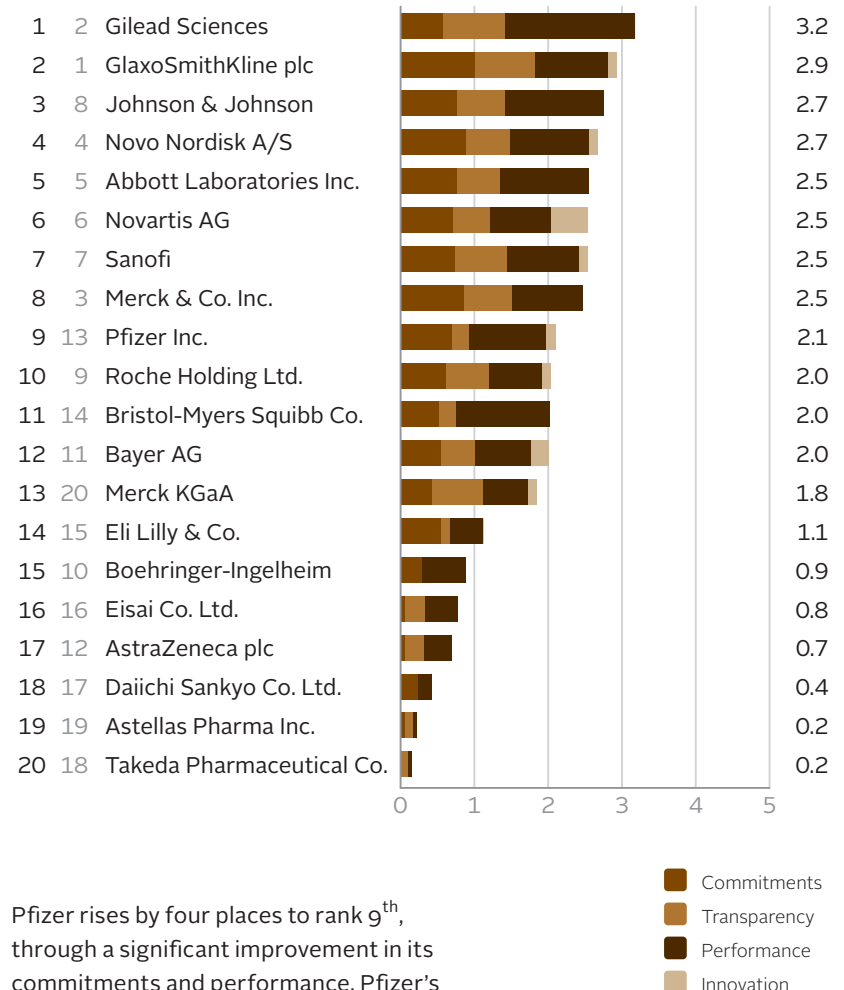
**Gilead rises in rank by one place to lead in this area overall, with tiered pricing programmes for its anti-retrovirals in a large number of countries, packaging differentiation for tiers and full public disclosure of pricing differentials. The company also excels in obtaining WHO prequalification for its products and by being transparent in its processes for product registration.**

GlaxoSmithKline falls in rank by one place to 2<sup>nd</sup>, with tiered pricing covering a large number of products but with a narrower geographic scope than Gilead and without anti-diversionary packaging differentiation for all its applicable products. Glaxo-SmithKline has also had product recalls due to quality issues and has only disclosed details of these recalls upon engagement with the Index. However, the company has strong commitments in multiple areas, including for monitoring pricing practices of sales agents and third parties, for quality control and for distribution. In addition, the company has generally high levels of disclosure.

Johnson & Johnson comes 3<sup>rd</sup>, moving up five places since 2010. This is based on increased disclosure of its tiered pricing programmes. The company is a strong performer on WHO prequalification and quality control.

Merck KGaA has also improved significantly since 2010, rising by seven places to 13<sup>th</sup> by disclosing for the first time its tiered pricing programme, a scheme that is average in terms of products and geographic scope. Additionally, the company has robust performance on quality control. It however lacks concrete commitments for monitoring product price across its supply chain and for product registration.

Figure 13 **Company Ranking Pricing, Manufacturing & Distribution**



Pfizer rises by four places to rank 9<sup>th</sup>, through a significant improvement in its commitments and performance. Pfizer's tiered pricing programme is extensive in its product and geographic scope, but the company lacks transparency regarding drug recalls, registration policy, quality control, and monitoring of product pricing along the supply chain.

Boehringer-Ingelheim drops five places to rank 10<sup>th</sup>, remaining static in its approach to tiered pricing and not disclosing information regarding its quality management system, drug recalls or product registration strategy.

AstraZeneca falls five places to rank 17<sup>th</sup>, with no tiered pricing programmes in scope and no commitment to register products in countries covered by the Index. The company has also had product recalls and is not transparent about them.

Merck & Co. loses five places and now ranks 8<sup>th</sup>, due to lack of disclosure on both drug recalls and quality management systems in countries of relevance to the Index.

#### Limitations of Pricing Data

Despite intensive efforts by the Index research partners to source accurate and consistent pricing data, it has not been possible to achieve this for the 2012 Index. Disclosure of pricing data by some companies was very poor and in some cases it appeared that the data did not exist within the company. Where data were disclosed, comparability and insights across companies are made very difficult due to wide variations in the way companies build tiered pricing models and the reference price, or reference point, they use as the basis for their price reductions. Moving to a more standardised way of gathering pricing data in order to

drive better insight will be a major area of focus for the 2014 Index.

#### Inter-Country Tiered Pricing

Overall there has been improvement in commitment to inter-country pricing since 2010, with more products being covered by schemes in more countries.

The focus of the schemes remains largely on anti-retrovirals, diabetic medication, vaccines and antibiotics, but the inclusion of maternal health in the 2012 Index means that products relating to these areas are now included, benefitting companies such as Bayer that have tiered pricing schemes covering these types of products.

The companies that apply inter-country tiered pricing to the highest number of products in absolute terms are Pfizer,

## Background

### What we examine

The assessment of companies in this area covers two broad areas:

#### Pricing

Pricing remains a fundamental access issue, putting medicines out of reach for millions of people in the developing world for whom treatments are available but are simply unaffordable. Most people in developing countries pay out-of-pocket for medicines, and often the costs of needed drugs are higher in these countries than in more affluent countries, in relation to income levels but also sometimes in absolute terms.

Pharmaceutical companies can improve affordability by setting lower base prices. However, because of government tariffs and mark-ups in the supply chain, prices paid by patients are significantly higher. Nonetheless, companies can influence behaviour down the supply chain, for instance by indicating intolerance of excessive mark-ups, by clarifying expectations, and by incentivising and monitoring price activity through the supply chain.

More comprehensive approaches are available through 'tiered' pricing schemes,

which operate between countries (inter-country) and within countries (intra-country) and which can be effective at lowering prices for and improving access in low-income communities while still offering a model with potentially higher profits for companies involved<sup>9</sup>.

In principle, to maximise positive impacts on access, tiered pricing schemes should cover all relevant products, and operate in all relevant countries, with price reduction levels that make products affordable. Schemes should also involve efforts to reduce the risk of products meant for lower price tiers being diverted to users targeted by the higher price tiers, removing medicines from the intended communities as well as running the risk of undermining revenue potential from the richer markets. Adapting packaging for different markets is one means of reducing these risks.

In practice, tiered pricing decisions often require complex strategic decisions to be made in response to a variety of forces, including market conditions, the presence of generic competitors, civil society expectations and public health pressures, product and disease idiosyncrasies, and

GlaxoSmithKline, Novartis, Sanofi, Merck & Co. and Merck KGaA. However, as this favours companies with large product portfolios, it is useful to look at the proportion of their relevant product portfolio covered by schemes. Against this measure, the leading companies are Pfizer, GlaxoSmith-Kline, Johnson & Johnson, Gilead and Novo Nordisk, followed closely by Novartis and Merck & Co.

In terms of geographic coverage Novo Nordisk, Pfizer and Merck & Co. have the highest proportion of countries of relevance to the Index covered by schemes, followed very closely by Boehringer-Ingelheim and then by Gilead, Sanofi and Bristol-Myers Squibb.

The performance of Pfizer since 2010 is particularly noteworthy. The company

has gone from having no tiered pricing of relevant products in 2010 to having its entire portfolio of relevant products covered by schemes in every country where it is present. Merck KGaA's performance improvement since 2010 has also been significant, although not to the same level as Pfizer's.

*Pfizer's tiered pricing programme covers all its products in relevant countries where it operates.*

Noteworthy efforts of companies further down the rankings include that of Eisai, which has introduced tiered pricing programmes for its breast cancer drugs and has introduced affordable pricing schemes for its epilepsy and unipolar depressive disorder drugs in India. However, these do not fall within the scope of the 2012 Index because they are not tiered pricing schemes, and Eisai has therefore gained no scoring credit for these initiatives.

patient needs. A balance must be found between these forces, to meet public health needs, maintaining commercial viability and finding the optimal route to reach target patients at lowest cost.

In reference to pricing, the 2012 Index assesses the extent to which companies:

- Create inter-country and intra-country tiered pricing schemes and seek to limit mark-ups through the supply chain in order to make medicines more affordable for people and communities in need,
- Adapt packaging to prevent product diversion in order to support tiered pricing.

### **Manufacturing and Distribution**

In an increasingly global landscape for production, distribution and quality control of medicine, companies must have effective strategies in place to ensure the safety and efficacy of medicine reaching consumers. The following areas of practice are measured by the 2012 Index:

- Monitoring of and transparency around compliance with international quality standards such as World Health Organization Good Manufacturing Practices (GMP)

and transparency regarding the company's Quality Management System (QMS)

- Policies and practices for product recall and disclosure regarding product recalls

Additionally, packaging must be suitable for use by the target communities, particularly in the context, for example, of around 38% of the adult population in Sub-Saharan Africa lacking basic literacy skills. The Index therefore assesses:

- Adaptation of product brochures and packaging in order to facilitate rational use and increase patient adherence.

Lastly in this area of measurement, the Index examines the extent to which companies:

- Seek WHO, FDA or EMA prequalification and market registration of relevant products in order to improve efficiencies in regulatory approval and market entry.

Daiichi Sankyo now has **>50%** of its relevant products covered by **tiered pricing** schemes.

Also of note is the improvement of Daiichi Sankyo in tiered pricing since 2010. The company has implemented tiered pricing schemes covering more than half of its relevant products, although in a limited number of markets. The company did not disclose programme outcomes or pricing across tiers, but is to be commended for making progress.

The performance of AstraZeneca, Astellas and Takeda has not improved since 2010 as they have no tiered pricing schemes. These companies also lack transparency in other aspects of this technical area.

### Intra-Country Tiered Pricing

Intra-country schemes are ideally suited to countries where an expanding middle class co-exists with a large population with high levels of poverty and for whom medicine remains unaffordable. Implementing these schemes is challenging for companies due to the risk of product diversion to affluent markets.

Since 2010, seven additional companies have started to implement intra-country tiered pricing, bringing the total with intra-country schemes to 12.

- Novartis is the leading company, with intra-country programmes covering a large number of products in a large number of countries.
- GlaxoSmithKline and Sanofi have rolled out intra-country schemes in a large number of countries but for a limited number of products.
- Merck & Co., Pfizer, Eli Lilly and Daiichi Sankyo are less developed in this area, having a limited number of products covered by schemes in a few markets. Although Bayer has intra-country schemes covering a limited number of countries and products, the company's intra-country tiered pricing structure for contraceptives is innovative.
- AstraZeneca committed to intra-country tiered pricing in 2010 and has established schemes, but these lie outside the scope of the Index.

### Influencing Pricing through the Supply Chain

In order to maximise the impact of tiered pricing programmes, companies need to monitor the price of their products through the supply chain in order to prevent high mark-ups by sales agents.

Companies were evaluated on the presence of pricing monitoring processes and training and audit mechanisms for sales agents.

The leaders in this area are GlaxoSmithKline and Eli Lilly, which have mature policies and processes in place. GlaxoSmithKline does this through its Developing Countries and Market Access (DCMA) unit, which works with other groups in the distribution chain and the Medicines Transparency Alliance (MeTA) to ensure that prices are controlled along the supply chain. Eli Lilly sets prices for its products so that local sales agents cannot adjust prices beyond those set, enforced by contractual agreement and periodic audit, thereby holding sales agents accountable for its pricing practices.

In six companies – Johnson & Johnson, Abbott, Bristol-Myers Squibb, Merck & Co., Novartis and Novo Nordisk – a systematic approach to training and auditing is taken but is presently limited in geographical scope. For example, Novartis consults ACTwatch, a research group that measures accessibility and affordability of anti-malarials, to track retail price levels across seven countries. With respect to its participation in the Affordable Medicines for Malaria (AMFm) initiative, Novartis works with purchasers (e.g. wholesalers) who have signed a 'first-line buyer' undertaking with the Global Fund to Fight AIDS, Tuberculosis and Malaria. Abbott also engages with local community organisations to inform it if prices exceed those that have been set, and conducts audits of distributors and their mark-ups.

Other mechanisms include that used by Novo Nordisk. In 2008, the company began pilot projects in Cameroon, the Democratic Republic of Congo, Guinea, Mozambique and Tanzania to improve the distribution process and ensure that the differential prices enable insulin to reach medical centres and are used to treat people with diabetes. All warehouses are audited every year, and all distributors are audited every two years.

Companies such as AstraZeneca, Astellas, Boehringer-Ingelheim, Daiichi Sankyo, Eisai, Merck KGaA and Takeda do not make efforts to control third-party pricing practices.

## 7

companies initiated **intra-country tiered pricing**

- GlaxoSmithKline
- Novartis
- Sanofi
- Merck & Co.
- Pfizer
- Eli Lilly
- Daiichi Sankyo

### Packaging Adaptation

Product packaging is adapted for two main reasons:

- To reduce the risk of product diversion, which undermines tiered pricing schemes
- To facilitate rational use and improve patient adherence

Companies are evaluated on their commitment to adapt brochures and packaging to facilitate rational use and on their ability to at least meet local regulatory requirements. Company commitment is based on the extent to which such package adaptation is applied to its tiered pricing products.

Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Merck KGaA, Novo Nordisk, Pfizer and Roche have explicitly committed to packaging adaptation for rational use for a vast proportion of their products.

Other companies such as Abbott, Bayer, Novartis, Sanofi and Boehringer-Ingelheim have commitments for a sub-set of their

products only. Eli Lilly, Bristol-Myers Squibb and AstraZeneca do not disclose whether they adapt their packaging to local contexts.

In the area of anti-diversionary packaging adaptation, companies are evaluated on what proportion of their products that are covered by tiered pricing and the WHO Essential Drugs List (EDL) have packaging adapted to prevent product diversion.

Merck & Co. leads in this area, applying differential packaging for product diversion prevention to a majority of its products on the WHO EDL. Abbott, Gilead, Bristol-Myers Squibb and Bayer also apply differential packaging to the products they have on the EDL.

Sanofi, Daiichi Sankyo, and Boehringer-Ingelheim have products on the EDL with tiered pricing schemes. They do not adapt packaging for these to prevent product diversion, although they do adapt packaging to facilitate rational use.

8

companies explicitly committed to **adapt packaging** to facilitate rational use

- Gilead
- GlaxoSmithKline
- Johnson & Johnson
- Novo Nordisk
- Merck & Co.
- Pfizer
- Roche
- Merck KGaA

## Bayer sells contraceptives using four pricing tiers

In partnership with the USAID Contraceptive Security Initiative, Bayer is seeking to make contraception more affordable for women in 11 Sub-Saharan countries by selling its oral contraceptive Microgynon® Fe using a tiered pricing model. The programme started in 2010 with a pilot in Ethiopia and is progressively rolling out in the remaining countries before 2015.

The company's approach to its tiered pricing model is innovative, in that it is designed around four market segments and distribution tiers:

- The Private market (Tier 1), served by full price commercial products
- The low/middle-income market (Tier 2), served by affordable commercial products created through public private partnership and targeted at low/middle-income earners
- The Social market (Tier 3), served by social marketing of donor-subsidised branded products
- The Public market (Tier 4), served by products free of charge or with minimal cost recovery

Each of these tiers is supported and differentiated from the others by different product packaging and distribution channels.



*Few companies provide information about product recalls.*

**Quality of Medicines**

While most pharmaceutical producers seek to comply with international quality standards as set by WHO or regulatory authorities such as the FDA or EMA, the application of these standards in the developing world is not consistent, which when combined with variable regulatory regimes for drug safety can place patients at risk of exposure to unsafe medicines.

Companies are evaluated on the following actions to assure quality:

- Following robust guidelines for enforcing QMS (e.g. EMA ICH Q10) and monitoring breaches in quality, including those of third-party manufacturers
- Having processes to recall products effectively in relevant countries, and disclosure of processes for quality and recalls

Companies that have a high level of commitment in terms of policies, procedures and resources needed to carry out effective drug recalls are GlaxoSmithKline, Novo Nordisk and Sanofi. These companies have disclosed their policies and procedures for drug recall in detail. For example, Novo Nordisk has committed to strive to limit its product recalls to no more than seven per year globally, and has disclosed details to the Index of how it maintains quality and achieves this target.

*Gilead and Merck & Co. publicly disclose product registration.*

Company disclosure regarding product recalls is not robust, with few companies providing information in this area. Sanofi is the only company that publicly discloses information on its product recalls. Abbott, Bristol-Myers Squibb, Gilead and Johnson & Johnson report that they have not had product recalls during the period of analysis.

Eli Lilly, Merck & Co., Pfizer, Astellas, Daiichi Sankyo and Boehringer-Ingelheim do not disclose details regarding drug recalls.

GlaxoSmithKline and Sanofi report that they are fully ICH Q10-compliant and have high levels of public disclosure on quality management systems including standards and processes. Abbott, Johnson & Johnson, AstraZeneca, Merck KGaA and Eisai follow GlaxoSmithKline by approaching these levels of quality in their processes.

**Product Approval and Registration**

In order to facilitate the earliest availability of products in developing world countries, companies can use a number of mechanisms, including:

- EMA Article 58 and WHO prequalification are reliable non-regulatory mechanisms for ensuring the safety, efficacy, and quality of medicines used primarily to treat HIV/AIDS, tuberculosis, and malaria and in reproductive health. As well as being an international quality standard, use of prequalification or US FDA tentative approval can accelerate market registration of products
- Proactively seeking registration of relevant products in markets based on need, filing within a set timeframe after launch in the developed world

Companies are evaluated on their use of these mechanisms, in addition to their transparency about the decision process regarding product registrations.

Abbott, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co. and Novo Nordisk have commitments for registering or filing for market approval for a sub-set of their products on a needs basis. However, no company assessed by the Index has made a commitment to a specific timeframe for such registration, stating that product registration durations vary significantly between countries.

The majority of companies do not disclose details of their decision criteria for and status of product registration. Gilead leads in the group of companies that do, with full public disclosure of this information. Merck & Co. follows in close 2<sup>nd</sup> place by publicly disclosing the registration status of its anti-retrovirals, contraceptives and vaccines, and Merck KGaA and Abbott follow with public disclosure of some details. GlaxoSmithKline, Johnson & Johnson and Novo Nordisk provided details to the Index but do not publicly disclose this information.

In relation to the use of mechanisms such as WHO prequalification, FDA tentative approval and other similar schemes, the leading group of companies is made up of Gilead, GlaxoSmithKline, Novo Nordisk, Johnson & Johnson, Roche and Boehringer-Ingelheim. These companies have applied

for WHO prequalification for all of their relevant products in countries covered by the Index.

Abbott, Bayer, Bristol-Myers Squibb, Merck & Co., Novartis, Pfizer and Sanofi have only applied for WHO prequalification for a subset of their relevant products.

AstraZeneca, Eli Lilly and Merck KGaA have not prequalified any of their relevant products.

No other companies have products eligible for prequalification. ■

**Figure 14 Key Sub-themes**

Increasing inter-country tiered pricing, with intra-country tiered pricing still nascent. Few companies with products eligible for WHO prequalification use it as a mechanism to ensure product quality and deliver swift market access based on need.

- High
- Medium
- Low
- ⊗ Non-applicable



9 Yadav, Prashant; Differential Pricing for Pharmaceuticals: Review of current knowledge, new findings and ideas for action; MIT-Zaragoza International Logistics Programme: Zaragoza Logistics Center, SPAIN; August 2010

# E Patents & Licencing

## What matters

- Transparency in company policy and support for Trade-related Aspects of Intellectual Property (TRIPS) and the Doha Declaration
- A constructive access strategy, incorporating non-exclusive voluntary licences, or equivalent, that have broad geographical scope and provide for milestone-based technology transfer
- Evidence of innovative activity in intellectual property and access to medicine

## Key trends

### TRIPS/Doha

The industry continues to take a conservative attitude towards the Doha Declaration and offers only qualified support for the flexibilities of the World Trade Organization's agreement on the Trade-related Aspects of Intellectual Property (TRIPS).

### Non-exclusive voluntary licencing

Companies have made progress in engaging in non-exclusive voluntary licences or equivalent practice. Greater emphasis should be placed on increasing product and geographical scope and inclusion of sustainable, pro-access technology transfer in these agreements.

### Patent pools

Companies display a cautious approach to engaging seriously with the Medicines Patent Pool. One company has signed on; four others are in active negotiation.

## Company performance

### Leaders

- 1 Gilead
- 2 Johnson & Johnson
- 3 GlaxoSmithKline

### Risers

- 1 Johnson & Johnson
- 2 Bayer
- 3 Sanofi

### Fallers

- 1 Eli Lilly
- 2 Astellas
- 3 Bristol-Myers Squibb

## Increasing Access to HIV Drugs

Gilead's progressive view of intellectual property facilitates access to a range of patented HIV drugs including tenofovir (TDF), emtricitabine (FTC), elvitegravir (EVG), cobicistat (COB), TDF/FTC, and its 'Quad' combination therapy that combines the four drugs. >61



Photo: Niamh Herlihy



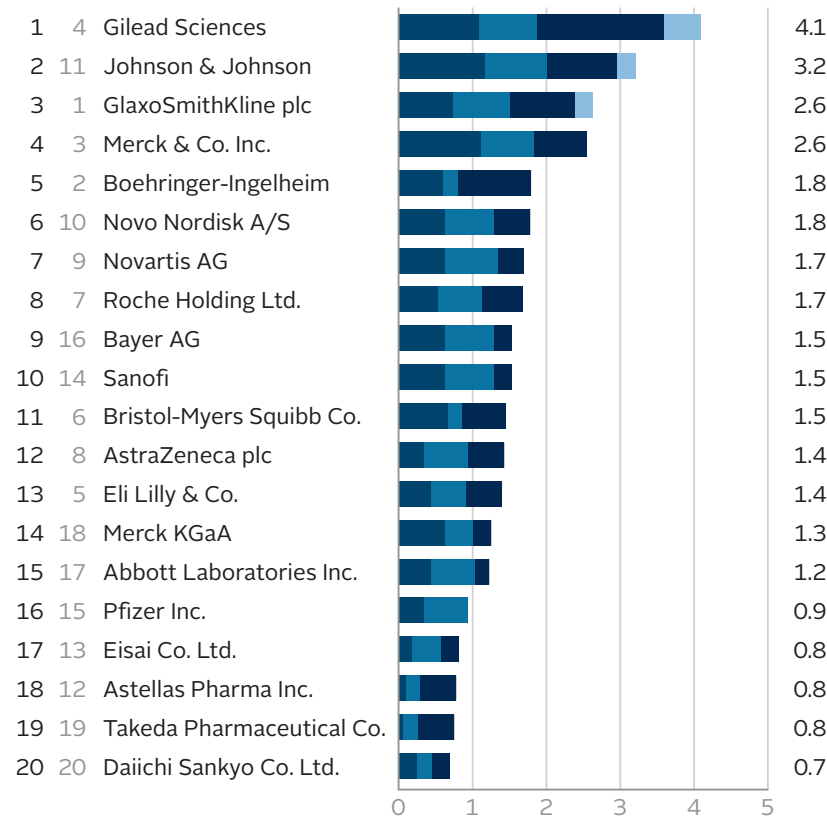
Research-based companies have traditionally been very concerned about protecting their intellectual property, which is the basis of their business model. They are wary of relaxing their attitude in this area, in case any single measure has unintended negative effects. Company activity since 2010 captured by the Index does not indicate a significant relaxation of the industry position.

Gilead leads the field in patents and licencing in 2012, displaying a progressive view of intellectual property as an enabling tool that can both facilitate access to medicine and contribute to business growth. Its improvement in ranking this year from 4<sup>th</sup> to 1<sup>st</sup> place is attributable to its engagement with the Medicines Patent Pool and its increasing use of non-exclusive voluntary licences (NEVLs) as a mechanism for tapping into the capacity of generic producers to support access to medicine.

Johnson & Johnson has significantly improved its performance to rise from 11<sup>th</sup> to 2<sup>nd</sup> in this area and this can be attributed to increased public transparency regarding its attitude towards TRIPS flexibilities and public disclosure of a limited range of patent statuses. Since the 2010 Index, Johnson & Johnson has issued NEVLs and is also engaged in related technology transfer. On the other hand, it has declined to enter into formal negotiations with the Medicines Patent Pool.

GlaxoSmithKline, ranked 3<sup>rd</sup>, still performs strongly across the board, relative to peers, and should be noted for its constructive, transparent approach across most patents and licencing measures. Its standing has fallen slightly since 2010 largely because it has stood still, with a lack of significant progression since 2010 on licencing activity,

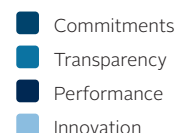
Figure 15 Company Ranking Patents & Licencing



particularly in licencing that incorporates technology transfer.

Besides Johnson & Johnson, other companies performing more strongly this year are Bayer (up seven places) and Sanofi (up five places). In both cases this is due to a greater degree of disclosure to the Index of their positions on TRIPS and its flexibilities and their stance on enforcement and filing of patents in the Least Developed Countries (LDCs).

In the face of tougher indicators, especially around NEVLs, the ranking of some companies has dropped because of a lack of significant additional activities. Astellas fell by six places because it has yet to follow through on the commitment it made in 2010 to engage in NEVLs and has no stated plans to engage in them in the future. Bristol-Myers Squibb (down five places) and Eli Lilly (down eight places) have also not demonstrated significant progress since 2010, with Bristol-Myers Squibb failing to disclose any detail of



patent status in LDCs, and Eli Lilly reporting an ambiguous stance on TRIPS.

The lowest-ranked companies (Astellas, Daiichi Sankyo and Takeda) are those that are silent on the relationship between intellectual property and access. They fail to engage in NEVLs or equivalent strategies and do not disclose their policy on TRIPS and the Doha Declaration. Some credit should be given for their openness regarding TRIPS lobbying activities. None of the three provide information about patent status in relevant countries, and Daiichi Sankyo and Takeda do not declare a commitment to refrain from patenting in LDCs.

### Attitude towards TRIPS and the Doha Declaration

The 2001 Doha declaration on TRIPS and Public Health<sup>10</sup>, which affirms the right of countries to use flexibilities within TRIPS to facilitate access to medicine, remains the lens through which TRIPS can be interpreted

in the context of access to medicine. While the TRIPS agreement is between World Trade Organization (WTO) member states, a company's behaviour in relation to it, including any commitments made and openness about them, can be regarded as a litmus test concerning its attitude towards access to medicine.

Companies generally do not show high levels of commitment to ensuring that TRIPS is not a barrier to access to medicine. They are not transparent about their lobbying practices concerning strengthening pharmaceutical intellectual property rights beyond what TRIPS prescribes. While there remains a similar level of commitment and transparency across the board since 2010 regarding the Doha Declaration and some progress in transparency, support remains qualified.

To ensure that intellectual property and the rights surrounding it are not a barrier to access, companies are judged against their:

## Background

### What we examine

To support efforts to give patients in developing countries better access to medicine, a flexible approach to intellectual property is essential both for allowing for generic competition to improve access to products and for facilitating technology transfer to develop new therapies.

Tension exists between the pricing opportunities and information control that patent monopolies confer for business, and facilitating access to patented medicines at affordable prices. Practices such as non-exclusive voluntary licencing (NEVL), where companies issue licences to multiple manufacturers for the production of cheaper drugs, and tiered pricing, where companies price the same medicine differently depending on socioeconomic levels either between or within countries, can mitigate this tension and bring more medicines to more of those who need them in these countries.

It is becoming clearer that to stimulate continued innovation in drug development, companies need to make a shift

from operating solely as islands of activity towards a more co-operative approach.<sup>11</sup> This is due to multiple factors: cutbacks in research and development spending, a lack of new medicines in the pipeline, and the complexity of the patent landscape. The example of the Medicines Patent Pool demonstrates how co-operation between intellectual property owners and licencees can be achieved in a field where new combination products that cover multiple patents are badly needed. This kind of co-operation capitalises on the intellectual property and know-how of research-based companies and the manufacturing capacity and quality of generic producers.

Companies that demonstrate forward-thinking and constructive engagement in the existing innovative approaches towards intellectual property, such as more use of NEVLs, either bilaterally or via the Medicines Patents Pool, stand out in the area of patents and licencing.

- Public endorsement of the Doha Declaration on TRIPS and Public Health
- Explicit endorsement of the rights of countries to respect TRIPS flexibilities such as compulsory licencing, exceptions (Bolar, experimental use) and transitional periods for LDCs
- Absence of lobbying for measures that exceed TRIPS standards, such as specific time periods for data exclusivity, or limiting the grounds for compulsory licencing
- Absence of litigation or regulatory proceedings against a company with respect to patents and licencing

The industry disputes how TRIPS has been integrated into national legislation by WTO members in particular countries, and lengthy court cases continue to be fought over the use of TRIPS flexibilities. For example, Novartis and Bayer, both of which publicly support TRIPS and Doha, have also contested decisions by the Indian Government over the application and TRIPS-compatibility of patentability criteria in one case (Novartis), and over issuing a compulsory licence for cancer medication in the other (Bayer). The outcomes of cases like these have an impact on access to medicine that could be felt far beyond the specifics of each case, particularly given India's position as a major supplier of medicines to developing countries.

#### Attitude towards TRIPS and the Doha Declaration: Pro-access behaviour

- Discloses support for TRIPS/Doha: Abbott, Bayer, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi, AstraZeneca
- Recognises at least one TRIPS flexibility that member countries have the right to use: Bayer, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk, Sanofi, Boehringer-Ingelheim

#### Attitude towards TRIPS and the Doha Declaration: Poor performance

- Fail to publicly disclose support for TRIPS/Doha: Astellas, Boehringer-Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Eli Lilly, Takeda
- Evidence of litigation and regulatory proceedings regarding patents and the application of TRIPS flexibilities: Abbott, Bayer, Novartis, Pfizer

The majority of companies demonstrate their commitment to the Doha Declaration in the same way: a general statement detailing their endorsement of TRIPS and the flexibilities it contains. GlaxoSmithKline takes the extra step of explicitly endorsing a further extension of the TRIPS waiver for LDCs. Some companies (e.g. AstraZeneca) acknowledge Doha, but with little or no mention of their attitude towards the flexibilities it affirms.

#### Qualified support for compulsory licencing

TRIPS and the Doha Declaration confirm that countries are free to determine the grounds for compulsory licencing, if those fulfil the conditions laid down in TRIPS. Under TRIPS, efforts should be made to reach agreement on a voluntary licence. If these are not successful in a reasonable period of time a compulsory licence may be issued. However the requirement for prior negotiation with the right holder may be waived in the case of national emergencies, other circumstances of extreme urgency, for public non-commercial use (often called government use) and when used as a remedy for anti-competitive practices.<sup>12</sup> Where companies have explicitly supported the concept of compulsory licencing, their support is usually qualified. For example, while Johnson & Johnson and Novartis accept the practice of compulsory licencing, they state it should only be used as a last resort and only in emergency situations. Gilead states that it believes an open, needs-based discussion should usually precede the use of compulsory licencing.

Johnson & Johnson has progressed its stance since 2010, when it had no public position. Astellas and Eisai have increased transparency too; they now publish their attitude towards TRIPS flexibilities, which is mainly negative. In the case of Eisai, while it is commendable that the company is more transparent about its position, they could go further to support the spirit of the Doha Declaration.<sup>13</sup>

#### Reticence to reveal lobbying activity around TRIPS

To better measure company performance in 2012, the Index developed a new indicator to assess whether company behaviour accorded with stated commitments. This indicator investigates whether companies are engaged in lobbying activities to secure

## 10 companies endorse at least one TRIPS flexibility

- Gilead
- Johnson & Johnson
- GlaxoSmithKline
- Merck & Co.
- Boehringer-Ingelheim
- Novo Nordisk
- Novartis
- Bayer
- Sanofi
- Merck KGaA

## 5 companies do not publicly disclose patent status

- Bristol-Myers Squibb
- Merck KGaA
- Eisai
- Astellas
- Daiichi Sankyo

(through trade negotiation processes) intellectual property protection that exceeds TRIPS (sometimes referred to as 'TRIPS+' protection) in countries covered by the Index. However, some companies contest whether or not specific actions – such as requiring time periods for data exclusivity – exceed TRIPS. For example, GlaxoSmithKline maintains that requiring a period of data exclusivity does not exceed TRIPS, while Merck & Co. states that it does 'not believe in the concept of TRIPS+'. Highlighting the continuing reticence of the industry in this respect, the bulk of companies provided very limited responses to this indicator, preferring to remain silent about their lobbying practices. A majority of the companies have only stated that they lobby through industry associations on this and related issues.

### Patent filing and enforcement in relevant countries

The Doha Declaration states that LDCs should not be obliged to grant or to enforce patents for pharmaceutical products until at least 2016. Despite this waiver, many LDCs already had in place patent provisions and have not chosen to reverse them. Simply having these systems in place does not indicate that the country is ready to benefit

from strong intellectual property rights, and it could, rather, be harmed through increased prices for pharmaceuticals and restricted access to technologies.<sup>14</sup>

The implication of TRIPS and the Doha Declaration is that patents should not be filed or enforced in LDCs and companies that seek to do so are acting against the spirit of the Doha Declaration in a manner that is not conducive to improving access to medicine.

GlaxoSmithKline is the only company clearly reporting support for the extension of the 2016 deadline for LDCs to comply with the requirements of TRIPS for pharmaceutical products. While this is a relatively low-risk strategy for a pharmaceutical company to take – LDCs for the most part not being valuable markets for research-based pharmaceutical companies – it perhaps indicates a recognition of the potential negative impact of intellectual property protection in such economies.

It is rare for companies to avoid entirely holding patents in LDCs. They may see longer-term market potential in a developing country for particular products, and thus seek or maintain patents, perhaps issuing non-assert clauses to facilitate access in the medium term. Patenting behaviour in LDCs thus needs to be unpacked carefully in terms of the disease category that is the subject of the patent, a company's efforts to ensure transparency, whether the patent is likely to block access, and whether the company employs additional mechanisms such as in-country tiered pricing arrangements to distinguish wealthier from poorer markets.

To assess to what extent a company files in LDCs and if this constitutes a barrier to access, companies are judged on the extent to which it commits not to file for patents in LDCs, and not to enforce existing patents.

There has been some progress towards greater transparency regarding patent status in relevant countries. Most companies provide a basic, though incomplete, public account of patent status. Daiichi Sankyo, Astellas, Merck KGaA, Eisai, Takeda, Boehringer-Ingelheim and Bristol-Myers Squibb do not publicly disclose product patent status.

The bulk of companies make a general commitment to either not file for patents in LDCs, or not to enforce existing patents. Only a few companies – Pfizer, Daiichi Sankyo, Takeda and AstraZeneca – do not make any commitment not to assert or file for patents in LDCs. AstraZeneca indicates that it files patents where it sees viable future markets, irrespective of access concerns. Merck & Co., on the other hand, explains that that it may file patents where it sees the potential for viable future markets, and in those cases it 'commits to working with government to ensure access needs are met'.

### Patent filing enforcement in LDCs: Example of a 2010 commitment yet to be met

- AstraZeneca: Committed in the 2010 Index to not filing or enforcing patents in LDCs. In 2012, it states it will consider filing if it sees a good market in LDCs.

### Patent filing in LDCs: New commitments

- Johnson & Johnson: Made no commitments in 2010. In 2012, it commits to not enforce any patents in the UN-defined

*GlaxoSmithKline unique in supporting giving LDCs more time to comply with TRIPS.*

LDCs for products related to diseases covered by the Index.

- Sanofi: Made no commitments in 2010. In 2012, it states it is committed to not filing/enforcing patents in LDCs.

#### Patent filing in LDCs: Need for improvement

- Daiichi Sankyo, and Takeda: No commitment in 2010, nor in 2012.
- Pfizer: No commitment in 2010 or 2012. In 2012, states that it files patents through ARIPO.

#### Access-oriented intellectual property strategy

Allowing alternative manufacturers with low-cost production facilities to produce products that will enable more equitable supply to developing country markets remains a central mechanism for improving access to medicine. Companies can make intellectual property available through NEVLs, socially responsible licencing terms and binding non-assert declarations. The Index believes these activities demonstrate good practice in relation to intellectual property strategy.

The Index has applied more stringent guidelines, and with respect to licencing practices

a company is judged on:

- Whether it engages in NEVLs or non-assert declarations
- Transparency about the terms and conditions of NEVLs
- Whether NEVLs are accompanied by milestone-based technology transfer strategy

#### Using non-exclusive voluntary licences

Although companies have made some progress since 2010, NEVLs and non-assert declarations are not part of an overall strategy for a majority of companies. Gilead, GlaxoSmithKline and Merck and Co. are the most advanced, with Gilead openly recognising the value of its engagement with the generic industry's capacity to produce high volumes of low-cost, high-quality medicines.

GlaxoSmithKline, Merck & Co. and Gilead display continued progress. For HIV products, Gilead has multiple licencees in India and one in South Africa. It has been transparent in its waivers of royalty payments, although it has been criticized by some groups for the anti-competitive nature of a clause encouraging use of an active pharmaceutical ingredient from a Gilead supplier. It should be noted that Gilead has publicly disclosed in full the licence agreements it has engaged in with the Medicines Patent Pool.

## Gilead Increasing Access to HIV Drugs

Gilead's progressive view of intellectual property facilitates access to a range of patented HIV drugs including tenofovir (TDF), emtricitabine (FTC), elvitegravir (EVG), cobicistat (COB), TDF/FTC, and its 'Quad' combination therapy that combines the four drugs. Its involvement in the Medicines Patent Pool and its increased use of non-exclusive voluntary licences helps HIV patients in developing countries gain access to treatment. The company views these mech-

anisms as tools for maximising access by leveraging the growing manufacturing capacity of generics companies. Although not a new concept, fixed-dose combinations facilitate treatment compliance, which reduces

the risk of drug resistance, and simplifies drug delivery in resource-poor settings. With TDF/FTC approved by the US Food and Drug Administration as preventative therapy, affordable access to this medicine has

the potential to strengthen comprehensive prevention of HIV in many developing countries.



Photo: Niamh Herlihy

Merck & Co. has granted four NEVLs over the last two years, including one for an anti-diabetic drug, and also states that it will not assert its patent for efavirenz in South Africa. The issuance of an NEVL for an anti-diabetic product expands product scope beyond the overwhelming dominance of anti-retroviral medication. Boehringer-Ingelheim has significantly increased the number (from 6 to 14) of non-assert declarations for its antiretrovirals.

Johnson & Johnson provided no evidence of engagement in NEVLs in 2010, but in 2012 it started issuing NEVLs for three of its HIV products. In the case of rilpivirine, its licences cover a high number (112) of low- and lower-middle-income countries. However, the agreement with Aspen only covers branding and distribution, not manufacture. For darunavir, the geographical scope is limited to India. To foster healthier generic competition in future, such licencing arrangements should extend further in geographic scope and incorporate manufacturing.

Licencing may not always be the most suitable strategy for a company. An effective licencing strategy requires a willing and able licensee that meets the company's requirements. Where licencing is not possible, legally binding non-assert declarations could be used to ensure that intellectual property rights do not block access to a technology.

Some companies, such as Abbott and Novartis, are explicit that they do not try to improve access through intellectual property strategies at all, stating, for example, that they remain focussed on delivering low-cost medicines through tiered pricing strategies.

Six companies now utilise NEVLs. Only three report going further by incorporating knowledge transfer into their agreements. Merck & Co. ensures that its technology transfer in at least one instance is milestone-based. Johnson & Johnson provides technical assistance and know-how to Emcure Pharmaceuticals to enable the manufacture of darunavir – though as noted earlier, this licence is geographically restricted to India. Gilead has entered a partnership with Aspen to produce tenofovir and tenofovir-emtricitabine. However details provided concerning these transfers are limited.

### NEVLs: Examples of progress made on commitments since 2010

- Gilead: In 2010, committed to issuing NEVLs for products that target relevant diseases across its portfolio. By 2012, it had issued NEVLs for two ARVs.
- GlaxoSmithKline: Committed to issue NEVLs for products that target relevant diseases across its portfolio in 2010. By 2012, it had issued NEVLs for HIV medicine only, and through a GSK-Pfizer joint initiative, ViiV.

### NEVLs: No progress made on commitments since 2010

- Astellas: Committed to consider voluntary licences (VLs) for a subset of products, without terms mentioned. In 2012 it did not report issuing any VLs, and made no commitment to do so in the future.
- Novartis: Made a general commitment in 2010 to consider NEVLs on a case-by-case basis. It has not yet issued NEVLs on any of its products in the countries relevant to the Index. It argues that due to its engagement in tiered pricing and generic manufacture there is a limited benefit to be gained from engaging in NEVLs.
- Eisai: Committed in 2010 to engage in VLs for relevant disease products. By 2012, it had not issued any NEVLs.

### Other innovative approaches towards intellectual property

The Medicines Patent Pool was launched to reduce the prices of HIV medicines and facilitate development of better-adapted HIV medicines, such as simplified fixed-dose combinations and special formulations for children, by creating a pool of relevant patents for licencing to generic manufacturers and product development partnerships. Its goal is to increase access to quality, safe, effective, appropriate and affordable treatment for HIV in low- and middle-income countries. Created under the aegis of UNITAID, it is now an independent Swiss-based foundation.

Since 2010 a number of companies with relevant HIV drugs in their portfolios have entered into formal negotiations with the Pool, such as Boehringer-Ingelheim, Bristol-Myers Squibb, ViiV and Roche. To date Gilead is the only company to reach an agreement with the Medicines Patent Pool, contributing a range of ARV patents, including tenofovir,

## 6

### companies use NEVLs

- Gilead
- Johnson & Johnson
- GlaxoSmithKline
- Merck & Co.
- Boehringer-Ingelheim
- Bristol-Myers Squibb

## 3

### companies have transferred knowledge to NEVL holders

- Gilead
- Johnson & Johnson
- Merck & Co.

tenofovir-emtricitabine, elvitegravir, cobicistat and the quad single tablet regimen. It also openly advocates for the use of the Medicines Patent Pool.

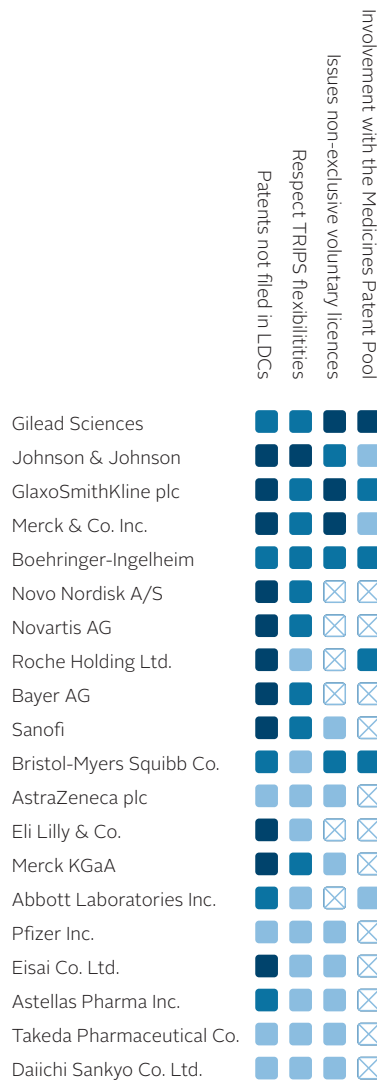
Other companies with relevant HIV molecules which could benefit the pool have so far declined to enter into formal negotiations. These include Johnson & Johnson, Abbott, and Merck & Co.

Besides participation in the Medicines Patent Pool, companies were asked about other innovative approaches they were engaging in through patents and licencing. The results showed few truly new initiatives being pursued. GlaxoSmithKline has expanded the scope of its ViiV initiative, in which it is the majority partner with Pfizer. ■

**Figure 16 Key Sub-themes**

Some progress has been made, but a conservative stance towards patents & licencing overall is reflected here.

- High
- Medium
- Low
- ⊠ Non-applicable



10 [http://www.wto.org/english/thewto\\_e/minist\\_e/mino1\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/mino1_e/mindecl_trips_e.htm)

11 <http://www.kellogg.northwestern.edu/biotech/faculty/articles/newrdmodel.pdf>

12 [http://www.wto.org/english/tratop\\_e/TRIPs\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm)

13 <http://www.eisai.com/company/atm/approach/06.html>

14 Keith Maskus & Jerome Reichman, 2004. 'The Globalization Of Private Knowledge Goods And The Privatization Of Global Public Goods,' Journal of

International Economic Law, Oxford University Press, vol. 7(2), pages 279-320, June.

# F Capability Advancement

## What matters

- Working with developing countries to enhance their QMS, supply chain capabilities, health research capacities and pharmacovigilance programmes
- Engagement with in-country stakeholders to understand requirements for local capability building
- Sustained, long-term commitment to and delivery of capability building initiatives
- Initiatives throughout the pharmaceutical value chain and outside it where possible

## Key trends

### The bottomline

The overall picture is not encouraging, with most companies engaging in short-term or ad hoc capability advancement activities and fewer than half of companies conducting activities in low-income countries. Marginal increase in fostering R&D capacity through partnerships.

### Weak pharmacovigilance

Very few companies systematically build manufacturing and quality assurance capacity in a sustainable manner and almost no companies are involved in work to develop pharmacovigilance systems.

### Attention to supply chains

There is, however, an emerging and encouraging trend of companies committed to improve supply chain capacities. This is an improvement since 2010, although the scale and scope of these activities is still limited and ad hoc in nature.

## Company performance

### Leaders

- 1 GlaxoSmithKline
- 2 Sanofi
- 3 Johnson & Johnson

### Risers

- 1 Novo Nordisk
- 2 Sanofi
- 3 Merck KGaA

### Fallers

- 1 AstraZeneca
- 2 Eli Lilly
- 3 Merck & Co. and Novartis

## Strengthening supply chains

Johnson & Johnson has partnered with i+solutions to provide training in the Democratic Republic of Congo and South Africa to local workers involved in managing the HIV/AIDS medicine supply chain. >69





In many companies there has been an increase in activity, although when examined against the extensive needs of relevant countries, companies are still doing relatively little. It should be noted that the bar is set low, with companies only needing to demonstrate that between 2010 and 2012 they were involved in more than five partnerships, training workshops or other ad hoc events for a particular area to get the highest score.

**Leaders**

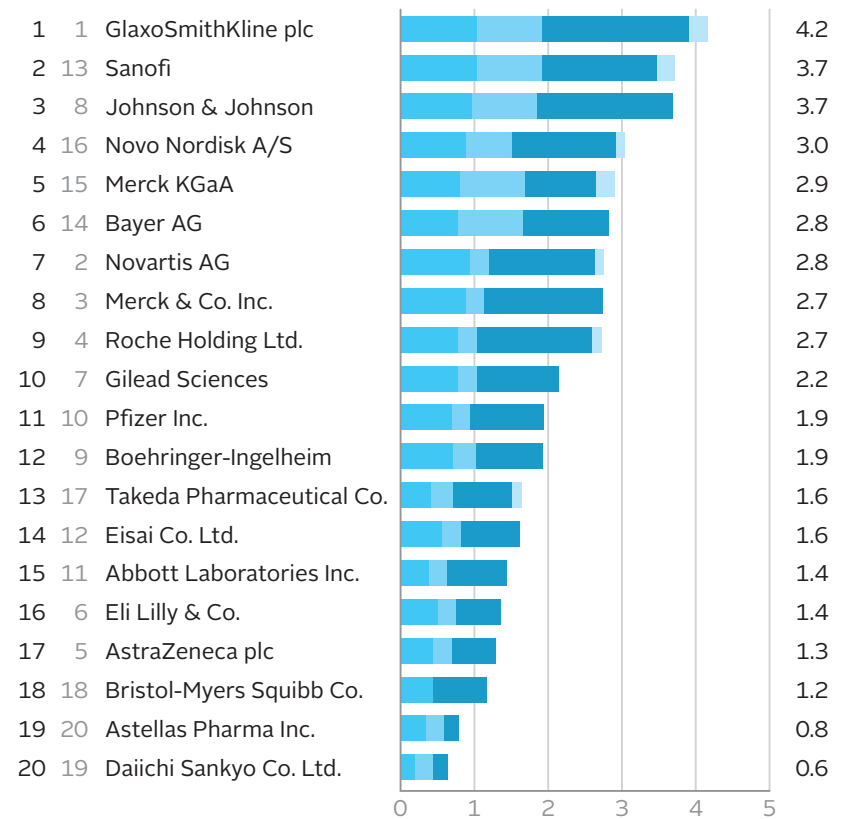
GlaxoSmithKline leads in this area overall, being among the leaders in in-country training and workshops related to Quality Management Systems (QMS) and Good Manufacturing Practice (GMP) and by being active across other the areas, building capabilities in pharmacovigilance, supply chains and research and development (R&D).

Sanofi follows in 2<sup>nd</sup> place, by also being in the lead group for training and workshops on QMS and GMP, by being active in R&D capability building and in initiatives outside the core pharmaceutical value chain. The company also scores well in innovation in its approach to building mental health treatment capabilities in Mauritania.

Johnson & Johnson, which ranks 3<sup>rd</sup>, scores well across multiple areas, in particular in building R&D capabilities, in activities outside the core pharmaceutical value chain, and in the key differentiating area of building pharmacovigilance capabilities.

Changes in the Index methodology from 2010 to 2012 make transparency around building pharmacovigilance capabilities a major differentiator for company performance in this Index and reflect a large

Figure 17 **Company Ranking Capability Advancement**



degree of movement in company rankings in this area since 2010. For example, low levels of pharmacovigilance capability building and low levels of disclosure in this area are central to Bristol-Myers Squibb, AstraZeneca and Eli Lilly falling in ranking. Johnson & Johnson, on the other hand, move from 8<sup>th</sup> place to 3<sup>rd</sup> largely due to the broad range of examples disclosed relating to building pharmacovigilance systems in multiple relevant countries.

**Most improved**

Outside the leaders group, Novo Nordisk has risen significantly in the rankings (from 16<sup>th</sup> to 4<sup>th</sup>), as a result of improved performance across many of the capability building areas. The company scores particularly well in the areas of QMS and GMP, in providing support to R&D and clinical trial capability building and for its contributions outside the core value chain. The Changing Diabetes in Children programme also involves a degree of innovation that increases the company's score.

Merck KGaA also rises (from 15<sup>th</sup> to 5<sup>th</sup>) on the back of its innovative Minilabs initiatives (outlined later in this chapter), as well as creditable performance in building QMS, GMP and R&D capabilities.

### Quality Management Systems & International Quality Standards

Substandard medicines can lead to treatment failure, increased sickness and drug resistance. As companies increasingly utilize manufacturing capacity in developing countries with potentially weak regulatory and safety systems, it is essential that local capacity in quality management is strengthened to ensure that safe and efficacious medicines are produced, reducing the risk of patient exposure to unwanted side effects of poor quality manufacturing. Typically this will take the forms of knowledge transfer and the presence and enforcement of quality-related standards and guidelines.

The highest-ranking companies (Bayer, GlaxoSmithKline, Gilead, Roche and Sanofi) provide support to country partners in the areas of meeting GMP and QMS standards. They set targets for quality standards from third-party manufacturers or in-house facilities in relevant

countries and provide training events, tools and long-term support for achieving those targets, conducting at least five training or similar activities since 2010. Novo Nordisk and Pfizer also rank highly in terms of commitment to this, but score lower on the corresponding performance measures.

Gilead shows a high level of commitment by making it a precondition of licences that licencees seek WHO prequalification or FDA tentative approval, thereby ensuring that manufacturing conforms to international levels of quality and safety.

Since 2010, eight companies (Bayer, Bristol-Myers Squibb, Gilead, Johnson & Johnson, Merck & Co., Merck KGaA, Pfizer and Sanofi) have increased their activities in this area. However, in many cases this is from a very low base of previous activity and in the case of Johnson & Johnson, Merck & Co., and Merck KGaA, these activities were limited to lower-middle-income countries and therefore exclude the poorest countries. Eli Lilly and AstraZeneca decreased their activities, with AstraZeneca now only making a broad commitment to advance capabilities in this area, making its level of commitment now similar to that of lower-ranking companies such as Astellas, Daiichi Sankyo, Eisai, Boehringer-Ingelheim and Takeda.

*GlaxoSmithKline, Sanofi, Bayer, Roche, Gilead have systems to support domestic manufacturers to meet quality standards.*

## Background

### What we examine

Effective and safe pharmaceutical R&D, manufacturing and distribution requires people who are well trained, have capabilities in a range of activities and who have access to financial, technological and organisational resources to complete their roles effectively.

In order for activities closely to match the needs of developing countries, to work in often challenging environments and to be able to respond to the needs of local populations, capabilities need to be built as far as possible within these environments. Investments in such capability advancements need to be long-term (over five years), sustainable and strategic, focussing on at least the following areas:

- Manufacturing safety and quality standards
- Research and development
- Supply chain integrity and efficiency
- Pharmacovigilance
- Health systems development, including in areas outside the standard pharmaceutical value chain

Increasingly it is being recognised that for initiatives to be effective over the long term they must:

- Be partnership-based
- Be in synergy with country priorities through engagement with national and local stakeholders
- Take a systemic as opposed to an ad hoc approach

Abbott and Astellas provided limited information about capacity building initiatives in QMS and GMP, showing that they conduct general auditing of their facilities but no knowledge or technology transfer to this end.

Among the Japanese companies, Eisai and Takeda are the only ones building capability in relevant countries, focussing their efforts in providing training in China (Takeda, Eisai), India and Indonesia (Eisai).

### Pharmacovigilance

Effective pharmacovigilance is essential for ensuring that medicines supplied following approval are safe, effective and of the intended quality. Companies can help develop national pharmacovigilance systems by taking a proactive approach to drug safety and post-marketing surveillance, engaging with local and international stakeholders, sharing best practice, and leveraging knowledge and resources to improve the effectiveness of national systems and resources. Strong information systems and communication channels must also be in place, reliably collecting pharmacovigilance data, regularly communicating with national and international regulatory authorities and enabling swift action to be taken if needed.

Overall, companies show an apparent lack

of willingness to engage in building national pharmacovigilance systems in developing countries. Only 3 companies (Johnson & Johnson, Novo Nordisk and Roche) score more highly than they did in 2010 in their commitment to support the implementation of pharmacovigilance systems in relevant countries. In terms of activities, 11 companies conduct their own pharmacovigilance activities but these are not geared towards building national capacities. While there may be some positive spillover effects from these efforts, real impact comes from initiatives with duration of five or more years, aligned to national strategies and in collaboration with local partners.

GlaxoSmithKline and Johnson & Johnson are the clear leaders in building pharmacovigilance systems in relevant countries, providing multiple long-term examples of engagement with national and local stakeholders and sponsoring and providing technical insight through training and consultancy. Their efforts show that it is possible for companies to systematically engage in national pharmacovigilance capacity building and strategically align this with market development. For example, GlaxoSmithKline plans to precede the introduction of its malaria vaccine in the developing world with activities to develop a robust national phar-

**3**  
**companies score higher than in 2010 on commitment to support the monitoring of drug side effects:**

- Johnson & Johnson
- Novo Nordisk
- Roche

- Be delivered within but also seek to enhance a partner country's ability to recognise, absorb and make effective the changes (it's 'absorptive capacity')

Essential activities for companies include:

- Engaging in local scientific research partnerships with public sector research institutes and/or universities with the aim of developing indigenous capacity in basic, applied or clinical research, including clinical trials
- Assisting local manufacturers and staff employed at in-house facilities operating in focus countries in building capabilities aimed at achieving international QMS and GMP quality standards
- Assisting governments, Health Ministries, procurement functions, logistics and

- distribution agencies and other parties to develop locally appropriate supply chain capabilities with the aim of improving affordability, accessibility and quality
- Supporting the development and/or implementation of national pharmacovigilance programmes
- Working on a needs basis to improve country health care systems

Some of these capabilities may be absent or only in an emerging phase in developing countries and the ability to advance these can be heavily reliant on company investment and on the provision of knowledge, training, know-how, technical materials and equipment, and technologies through licencing agreements and other inputs.

macovigilance programme in each country.

Besides the activities of these lead companies, there is little evidence of the industry taking a structured and strategic approach to building local pharmacovigilance capability. While local activities are certainly undertaken, the group of companies below GlaxoSmithKline and Johnson & Johnson (Sanofi, Roche and Merck KGaA) each have only one long-term pharmacovigilance capability building initiative across relevant countries. The three companies below this

(Merck & Co., Bayer and Novo Nordisk) carry out only ad hoc or short-term activities, with the remaining 12 companies reporting no pharmacovigilance capability building activities at all.

***Merck & Co. and Novartis lead in providing technological and financial support for multiple long-term research initiatives.***

In 2010, Abbott and AstraZeneca made commitments to build pharmacovigilance capabilities in relevant countries, but the activities they reported in the intervening period do not speak strongly to their having met their commitments.

Aside from the identified exceptions, overall it appears the industry is performing at a very low level with respect to pharmacovigilance capacity building.

**Research and Development Capacity**

Successful pharmaceutical innovation requires ongoing collaboration between many stakeholders (government, regulatory authorities, private and public research organisations, sources of funding, academia, health care delivery institutions, etc.), a deep understanding of the needs of patients and synergy with national development strategies. The ability of developing world stakeholders to be central to this pharmaceutical innovation process for developing products suitable for the poorest communities is crucial, and companies can focus on a range of activities to enable the development of local R&D capabilities in support of this aim.

In summary, companies can foster and support local scientific research partnerships with public sector research institutes and/or universities with the aim of developing indigenous capacity in basic, applied and clinical research, including clinical trials. Specific activities can also include:

- funding of research projects (grants, scholarships, prizes)
- provision of training workshops or materials
- sharing of know-how, technologies and best practices

Overall, since 2010 companies have marginally increased their efforts to foster research partnerships and support more academic institutions, with 12 companies engaging in more partnerships and training activities in relevant countries than in 2010.

Merck & Co. and Novartis are the leaders in this area, followed closely by GlaxoSmithKline and Johnson & Johnson, by being committed to providing support for multiple long-term research initiatives through technological and financial support. Merck & Co. has eight such initiatives, including one as part of EARNEST (Europe - Africa Research Network for Evaluation of Second-line Therapy), which builds clinical trial capacity in East Africa focussed on second-line treatments and HIV patient monitoring through CD4 counts. Novartis also has multiple initiatives ongoing, including being involved in a joint clinical research initiative since 2006 with Indonesia's Hasanuddin University and Eijkman Institute, to strengthen epidemiological and operational research surrounding neglected tropical diseases, including dengue and tuberculosis.

Gilead, Novo Nordisk, Sanofi and Boehringer-Ingelheim also have numerous initiatives to build capacity in relevant countries by training health care professionals, developing capacity in clinical trials, engaging in public-private partnerships, or developing local research capacities including among academics, but are distinguished from the leaders because their initiatives are not of more than five years duration.

It is encouraging that 18 of the companies do undertake some activities to build R&D capacities, but there is further to go, as half of those companies (Abbott, AstraZeneca, Bayer, Eli Lilly, Merck KGaA, Pfizer, Roche, Astellas, Eisai and Takeda) are only involved in between one and four initiatives, each of which lasts less than five years.

### Supply Chain

Supply chains are often weak in developing countries, with endemic susceptibility to drug diversion; poor demand forecasting; under-resourced storage facilities, leading to waste or theft; and weak management information systems, leading to stockouts and stock deterioration.

A particular problem is substandard, counterfeit or falsified medicines. These pose obvious risks to patients, and companies can help enhance the integrity of national supply chains by building drug testing capabilities in countries lacking these facilities. Merck KGaA's Minilabs, provided in collaboration with the Global Pharma Health Fund (GPHF), provides a good example, allowing for rapid field-based detection of potentially substandard medicines and currently covering 58 drug compounds, most of which are on the WHO Essential Medicines list. Takeda has also introduced a new quality assurance framework known as Good Distribution Practice, where the company performs analyses of seized drug samples, reports results and systematically engages with local, national and international stakeholders such as WHO and Interpol.

As with the other aspects of capability advancement, most companies make

relatively modest contributions to overall supply chain development, although there has been an improvement since 2010.

The leader in this area is Novartis, with multiple initiatives and partnerships in this area. Across multiple countries within the scope of the Index, for example, the Novartis Malaria Initiative's annual National Malaria Control Programme seminars bring supply chain and procurement specialists together to examine ways that the procurement and distribution of malaria treatments can be improved. The company's SMS For Life project, covered elsewhere in this report, is also at its heart a supply chain improvement project. As a third example, the company is actively engaged with the Egyptian Health Ministry across a range of capability improvement areas, including supply chain.

Novartis is followed by a group of Glaxo-SmithKline, Johnson & Johnson, Merck & Co., Novo Nordisk and Roche, each of which conducts a handful of activities in this area. However, the degree to which these activities are long term is variable. Johnson & Johnson and Novo Nordisk, for example, are involved in long-term activities (HIV/AIDS medicine supply chain management and Changing Diabetes in Children respectively)

## Strengthening local supply chain management



Johnson & Johnson has partnered with i+solutions to provide training in the Democratic Republic of Congo and South Africa to local workers involved in managing the HIV/AIDS

medicine supply chain. The training course, first developed in 2007, includes modules such as 'Monitoring & Evaluation of Antiretroviral Treatment Procurement & Supply

Management', for donor reporting and to identify weaknesses in the supply chain; and 'Supply & Warehouse Management for the First-level Health Facility'. Courses are available in

both English and French, in-person and on CD-ROM for those who cannot attend training courses.

but across the other companies the activities are typically ad hoc and short-term.

In terms of the remaining companies, Abbott, Gilead, Merck KGaA, Pfizer, Sanofi, Eisai and Boehringer-Ingelheim have conducted only one activity in the period of analysis. Meanwhile, Takeda, Daiichi Sankyo, Astellas, Eli Lilly, and Bristol-Myers Squibb show no activity at all in this area and, in fact, Bristol-Myers Squibb and Eli Lilly show less commitment to this work than in 2010 by not disclosing their activities. AstraZeneca no longer reports on providing relevant training in Least Developed Countries.

**Capability Advancement outside of the value chain**

Companies can enhance capabilities in a holistic manner, leveraging resources and knowledge in collaborations through committed, long-term

strategic approaches. Most companies engage in ad hoc, limited capability advancement activities, demonstrating the industry's splintered engagement in building health systems and ensuring quality medicine is available to patients. However, it is encouraging to see that 14 companies provide multiple examples of engaging with credible non-governmental organisations or provide funding where conflict of interest is fully absent.



Photo: Jon Rytter

Doctor examining in CDiC clinic, Ethiopia

Changing Diabetes in Children, launched by Novo Nordisk and later joined by Roche, demonstrates a comprehensive and sustainable approach that improves health outcomes and **strengthens health systems**.

GlaxoSmithKline engages in a number of these more holistic initiatives, including its African Malaria Partnership, together with AMREF, Save the Children, and the Planned Parenthood Federation of Nigeria. The project educates communities and trains community health volunteers to diagnose cases of severe malaria. This has led to training of approximately 800 community health workers and reached 20,000 children with Malaria treatment or treated bed nets.

Changing Diabetes in Children (CDiC) is another example. It is part of Novo Nordisk's World Diabetes Foundation and works with local partners and ministries of health to establish systems that can provide care and treatment for children with type 1 diabetes. Information systems and infrastructure have been strengthened, medicine and diagnostics supplied, and health care professionals and patients educated. This project is a marked example of a sustainable approach that improves health outcomes as well as strengthens health systems. ■

**Figure 18 Key Sub-themes**

Overall limited engagement in capability advancement, particularly pharmacovigilance. Value chain capacity building includes R&D, manufacturing and supply chain management.

- High
- Medium
- Low





# G Product Donations & Philanthropic Activities

## What matters

- Drug donations and philanthropic activities based on understanding of community needs, aligned with national health priorities and integrated with local environments and health practices
- Compliance with WHO Inter-Agency Guidelines for Medicine Donations, supported by a strong rationale, good internal processes, monitoring and reporting of outcomes
- Philanthropic activities supported by clear strategic rationale, with demonstrable sustainability and aligned with national health priorities

## Key trends

### Drug donations

An increasing move away from unfocussed multi-drug donations, driven by events or inventory, to targeted, needs-driven single-drug donations.

### Guideline compliance

High levels of commitment to WHO Inter-Agency Guidelines for Medicine Donation across almost all companies.

### Leaders' strategy

Among the leading companies, philanthropic activities built on a long-term view, highly integrated with national priorities and likely to deliver sustainable benefits.

## Company performance

### Leaders

- 1 GlaxoSmithKline
- 2 Sanofi
- 3 Johnson & Johnson

### Risers

- 1 Novo Nordisk
- 2 Merck KgaA
- 3 Eisai

### Fallers

- 1 AstraZeneca
- 2 Roche
- 3 Abbott

## Managing stock with SMS

Novartis' SMS for Life programme uses mobile phone text messaging to automatically keep health facilities that dispense anti-malarials and Novartis district managers who are responsible for medicine availability in their districts in regular touch with each other to manage stock levels. >76



Photo: Mark Tuschman for Novartis AG

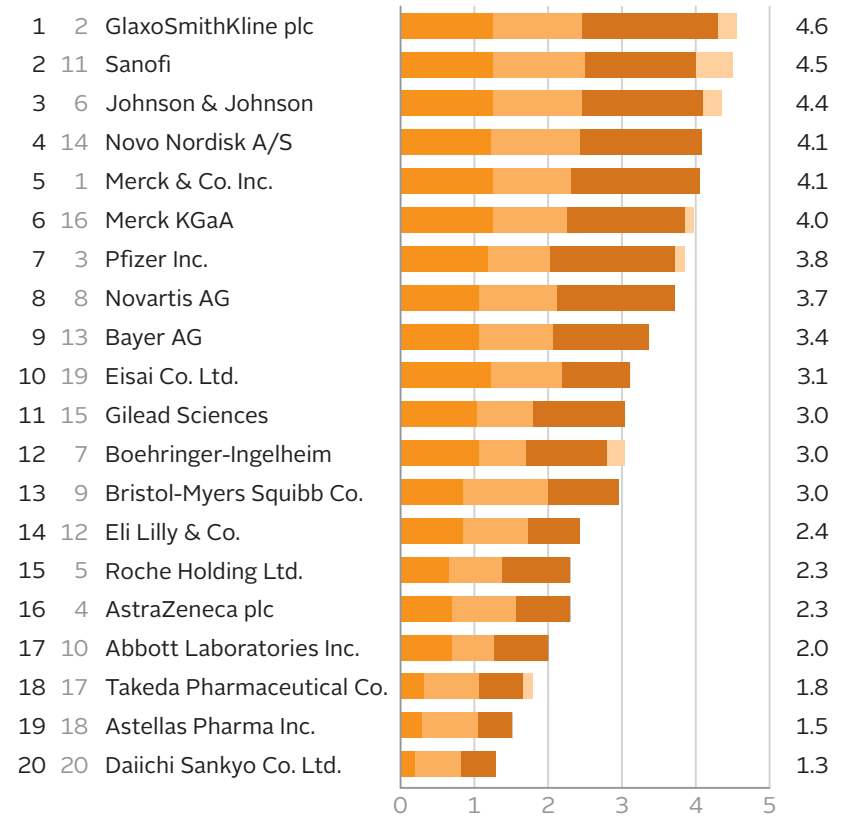


The level of activity in donations and philanthropy is high, with very substantial financial and non-financial resources being devoted to these activities. The highest-ranking companies are making good progress in directing these formidable resources to achieve the most positive outcomes, through increasingly needs-based initiatives that are aligned with national health priorities, well supported by good internal procedures and monitoring, and with reasonably high levels of transparency.

GlaxoSmithKline leads the area overall, with two single-drug donation programmes that involve substantial quantities and value of donated products and are well conducted, with good supporting processes and monitoring, rigorously selected external partners and, in one case, the use of WHO to validate the extent of need and the required response. Its philanthropic activities conducted directly and through ViiV Healthcare are also substantial and involve multiple initiatives across many relevant countries.

Sanofi follows closely in 2<sup>nd</sup> place, also with two single-drug donations well supported by processes and monitoring, but with a lower level of donation value. Through its Sanofi Espoir Foundation, the company also conducts philanthropic activities that set the benchmark for other companies, funding multiple long-term initiatives in close collaboration with national governments and national and international partners. These are aligned with national priorities and focussed on reducing health care inequalities over the long term while reducing disease burdens and improving health outcomes in the short term.

Figure 19 Company Ranking Product Donations & Philanthropic Activities



Johnson & Johnson, in 3<sup>rd</sup> place, also performs very well in this area, with extensive investment and good processes, but with one single-drug donation programme. It also has an extensive range of philanthropic activities.

Novo Nordisk (up 10 places) and Eisai (up nine places) rise primarily as a result of having introduced single-drug donation programmes since 2010. Both of these are discussed below. The rise of Merck KGaA (up 10 places) is primarily due to its disclosure of much more information than in 2010, which enabled a more complete assessment of its performance in this area.

For companies that have fallen in rank, AstraZeneca (down 12 places), Roche (down 11 places) and Abbott (down six places) fall significantly because they do not conduct single-drug donations and because they have not made significant progress in this area since 2010. They have therefore been overtaken by more active companies.

- Commitments
- Transparency
- Performance
- Innovation

### Product Donations

Overall, the majority of companies have improved, but some have fallen notably behind their peers. The improvement in some companies against the new criteria has been significant enough that three of the four leading companies in 2012 have not previously been in the leading group.

GlaxoSmithKline remains in the leading group, moving up one position since 2010 to lead, with a significant portfolio of drug donations. The company has two single-drug donation programmes for treating lymphatic filariasis and soil-transmitted helminths, and donated in excess of 500 million albendazole tablets in both 2010 and 2011 to relevant countries. It also has multi-drug donations supplying Combivir<sup>®</sup> and Epivir<sup>®</sup> on a not-for-profit basis via ViiV Healthcare. These donations are supported by a clear

policy and practice framework that involves maintaining close relationships with health authorities in potential target markets to establish need, and the use of the WHO to mediate and assess requests for donations. A rigorous partner selection approach seeks to ensure that target communities are reached effectively. Periodic auditing and documentation support this on an ongoing basis, and information about the outcomes of the programmes in place is available. Drug donations are carried out through these partners on behalf of the company itself and also through the Global Alliance to Eliminate lymphatic filariasis, a programme that also includes Johnson & Johnson, Merck & Co. and Eisai. The monetary value of GlaxoSmithKline's product donations is considerable, especially given that European companies do not enjoy the tax advantages afforded to US-based companies performing donations.

## Background

### What we examine

Needs-based product donations and sustainable philanthropic activities can have a positive impact on access and have for many years been conducted by the pharmaceutical industry. The quantity of such activities across all companies is significant and is to be welcomed. The question addressed by the Index is less whether it occurs or at what level, but whether the effectiveness of activities could be furthered by ensuring that they are genuinely needs-driven and are focussed on achieving long-term, sustainable improvements in access to health.

Regarding product donations, historically these have been multi-product and taken from available company stock, sometimes driven by an excess of inventory. Donations have been initiated by companies but also by governments and/or non-governmental agencies requesting help from companies during public health emergencies. Although a proportion of these donations have been useful in addressing developing world health issues, more often than not they are inappropriate<sup>15</sup> for a number of reasons, including that they may not be relevant for the emergency situation, may not be registered for use in the receiving country,

may ignore national distribution and warehousing practice and may incur high import taxes and storage overheads. They can also put additional burdens on local health systems by introducing unsorted, poorly labelled and expired/near-expiry products into the local environment.

As an alternative, some companies have conducted needs-based donation programmes, targeting specific diseases and geographical areas through single-drug donations, in several cases with a commitment to continue donation as long as there is need. These programmes, which typically have a defined strategy on the targeting, delivery and use of donated products and involve close collaboration with multiple partners including the WHO, governments and NGOs, are generally regarded as being more effective in achieving health outcomes than multi-drug inventory-driven programmes. This is in part because the donation addresses the known, specific need of a target community and is therefore likely to have a greater impact than a non-specific inventory-based approach with no clear outcome. Also, the close collaboration between local and international parties is more likely to lead

Sanofi, Johnson & Johnson and Novo Nordisk have risen in rank significantly, replacing Merck & Co., Pfizer and Roche in the leading group of companies in product donations. The emphasis on single-drug donations in the 2012 methodology partly accounts for their rise, in addition to their having improved their approach to product donations since 2010 enough to overtake the previous leading group.

Sanofi follows closely behind Glaxo-SmithKline, with two single-drug donation programmes covering three drugs for trypanosomiasis. It supports these with clear rationale, in line with WHO Inter-Agency Guidelines, and with monitoring, auditing and outcomes reporting. The company also demonstrates a holistic approach to some extent, in that logistical financial support is provided along with

the donation of pentamidine, which allows patients to be screened, treated and cured near to their homes, at an early, generally asymptomatic stage of disease.

Novo Nordisk, which rises 10 places to rank 4<sup>th</sup>, takes an integrated approach to donation in its Changing Diabetes in Children single-drug donation programme, started in 2010. Its donation of non-patented human insulin is conducted not in isolation, but supported by a company-provided programme of infrastructure, logistics and education enhancements. Monitoring and follow-up procedures seek to maximise the effectiveness for the target community, and the company is developing a sustainability plan to ensure that treatment in target communities will continue after the five-year term of the project. This sort of holistic approach emphasising capability building

## 3 out of the top 4 are new leaders:

- Sanofi
- Johnson & Johnson
- Novo Nordisk

to the selection of a medicine that is registered for use in the country, consistent with local treatment guidelines, with packaging adapted as required, and with time and training needed to ensure that local health care agencies have the skills to support the medicine. However, it should be noted that single-drug donations can also cause unforeseen issues in local environments by introducing multiple medicine supply chains. Companies should be mindful when conducting single-drug donations that they use existing routes of supply as far as possible.

Whatever the type of donation, WHO Inter-Agency Guidelines for Medicine Donations constitute the minimum standards for product donations and should always be followed. However, the top-performing companies will move their donation practices beyond this standard, for example by being part of a holistic approach to addressing health needs and strengthening health systems.

Since 2010, the Index has refined the criteria in this area to be more stringent in appraising the effectiveness of product donations. The focus is now primarily

on the commitment and performance of companies in delivering single-drug donations, which is consistent with the view that single-drug donations deliver more effective results. Also assessed is company compliance with WHO Inter-Agency Guidelines for Medicine Donations, the extent to which they are clear about the underlying rationale for the types/quantities/target communities of medicines included in their donation programmes and the extent to which they monitor and report outcomes of these donations.

The criteria covering philanthropy have also evolved since 2010. While the high historic level of company philanthropic activity is undoubtedly positive, it is unclear whether philanthropic initiatives have led to long-term, sustainable improvement in health outcomes aligned with national priorities. The scoring methodology has therefore been adapted to gauge performance in terms of the extent to which companies have a clear strategic rationale for their philanthropic activities (excluding drug donations), with sustainability at its heart, and the degree to which this aligns with national health priorities in the relevant country or countries.

and sustainability in addition to the drug donation provides an example of excellent practice in drug donation.

Johnson & Johnson too performs well, with a single-drug donation programme via Children without Worms (conducted in concert with GlaxoSmithKline), as well its multi-product donation activities to sell on a not-for profit basis or donate its Tiboazole<sup>®</sup> Miconazole MAT product for the treatment of oral thrush associated with HIV to Kenya's Mission for Essential Drug Supplies (MEDS). Its donation activities are conducted with a good set of supporting guidelines in line with WHO Inter-Agency Guidelines, clear follow-up procedures and a high level of transparency about drug types, volumes and destinations.

Other companies outside the lead group have also significantly improved their performance in product donations since 2010:

- Gilead has commenced a single-drug donation programme involving 450,000 vials of AmBisome<sup>®</sup> (amphotericin B liposomal) over five years for the treatment of visceral leishmaniasis. This is in addition to not-for-profit pricing arrangements in India.

- Eisai has entered into its first partnership with WHO in conjunction with the Bill & Melinda Gates Foundation and Sanofi to manufacture and donate diethylcarbamazine between 2013 and 2020 to treat lymphatic filariasis in developing countries. Periodic audits and follow-ups will assess the penetration of drugs in the communities targeted.

Companies lower down the rankings, however, continue to focus on multi-drug donations driven by external events and lacking a clear supporting rationale. It should be noted, however, that several companies are exploring working collaboratively with WHO and the UK Department of Health to combine multi-drug donations to assist in the long-term development of health systems and improve health outcomes in developing countries.

### Sustainable Philanthropy

Although the level of philanthropic activity is significant, companies could enhance the impact of much of that activity by adopting a more strategic, needs-based approach, aligned with national health priorities and oriented toward creating a legacy of sustainable long-term improvements in capabilities and patient health.

**1<sup>st</sup>**  
Eisai Co. Ltd. became the  
Japanese company  
to partner with WHO on  
**neglected tropical  
diseases.**

## Managing medicine supply with SMS

Novartis' SMS for Life programme enables SMS messaging between health facilities that dispense anti-malarials and Novartis district managers who are responsible for medicine availability in their districts. It was piloted in Tanzania, where an estimated 11 million people are infected with malaria each year and 220 people die from the disease each day. The messaging system sends a stock request message on Thursdays to the mobile phones of all

registered health facility workers, who then assess their inventory and respond via a free text message. If the system does not receive a reply by Friday, a reminder is sent. On Monday, information is collected to order

or redistribute medicine between sites as needed. At the beginning of the pilot, 26% of facilities had no anti-malarials; after the pilot this figure was reduced to less than 1%. Since April 2011, SMS

for Life has covered all 5,009 health facilities across Tanzania, and it now includes tuberculosis and leprosy medicines. It is currently being implemented in Kenya and Ghana.



Photo: Mark Tuschman for Novartis AG

Examples of activities conducted during the period of analysis by the best-performing companies in this area include:

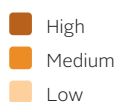
- When established in late 2010, the Sanofi Espoir Foundation set itself the goal of providing an appropriate framework and resource platform that would help advance access to medicine and reduce health care inequalities over the long term, in addition to responding immediately to humanitarian emergencies. The Foundation has made good progress, creating numerous collaborations with developing country governments, health authorities and national and international delivery partners. It requires all initiatives to act in partnership with local health authorities and in line with national plans and priorities to ensure that they are sustainable and appropriate for local environments and populations. In 2011 the Foundation committed €8.4 million (USD 10.7) to support 39 development aid projects of more than three years duration across 46 countries, including many relevant to the Index. These projects range in focus from treating cancer, preventing and treating diabetes, and diagnosing and supporting children with mental disabilities, to treating Buruli ulcers and creating a comprehensive approach to controlling Chagas disease, among numerous others of relevance to the poorest communities.
- The level of GlaxoSmithKline's investment in philanthropy is considerable. Its commitment in 2009 to re-invest 20% of profits from Least Developed Countries back into a variety of health infrastructure initiatives in those countries (approximately \$6 million in 2011) continues. In addition, grants and resource donations are made from other areas in the business. The company's ViiV Healthcare company (established and run in conjunction with Pfizer) has also committed to investments of £10 million (USD 15.8) in 117 projects across 21 countries, although this includes funding related to drug donations.
- Johnson & Johnson is involved in numerous philanthropic initiatives, the majority of which are aligned to national

and international health priorities and Millennium Development Goals (MDGs). The company's Neonatal Resuscitation Program in China, for example, supports MDG4 (reducing child mortality) by enabling nurses and midwives to resuscitate newborns suffering from birth asphyxia. The company reports that since the programme's inception, death due to this cause has fallen by 53% across a sample of 20 provinces. MDG4 and MDG5 (improving maternal health) are also supported by the company's initiative to reach more than 15 million new or expectant mothers across six developing countries, by sending them free mobile phone text messages regarding prenatal health, reminders of clinic appointments and information related to caring for their babies.

- As referred to above, Novo Nordisk's Changing Diabetes in Children initiative is notable because it combines drug donation with a holistic approach, including improvements to infrastructure, logistics and education enhancements to ensure that health outcomes and community benefits are maximised well beyond drug donation. ■

**Figure 20 Key Sub-themes**

Sustainable philanthropy increasing but need for more strategic single-drug donation programmes.



15 Pinheiro, C.P. 2008. Drug Donations: What Lies Beneath. Bulletin of the World Health Organization 86 (8): 580-1.



# Company Report Cards

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Each company report card highlights various key aspects of a company's 2012 Access to Medicine Index results.

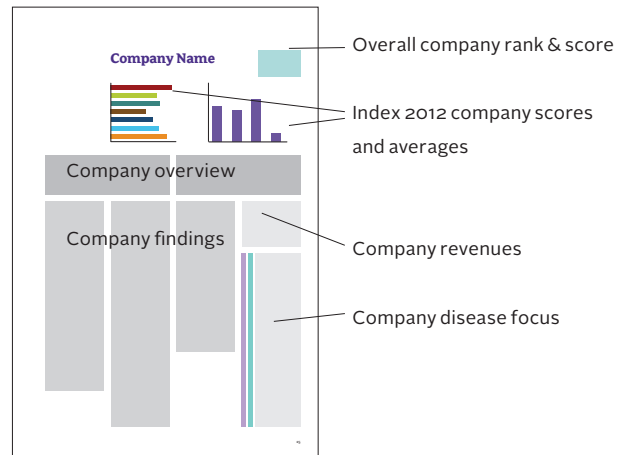
The 2012 Index reports on company activity in the period between June 2010 and June 2012, not including activities covered in the 2010 Index.

**Company scores**

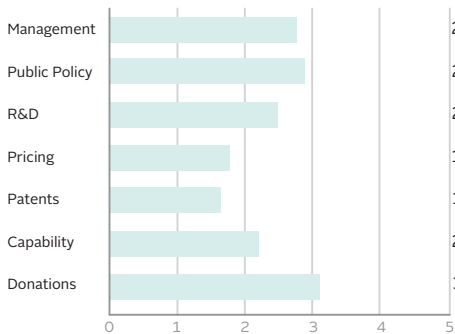
The report card graphs show a company's scores for each of the seven key areas of focus and four aspects of action measured by the 2012 Index. A company's overall score is a weighted combination of these scores. The graphs also compare a company's scores to the average 2012 scores of its Index peers.

**Disease focus**

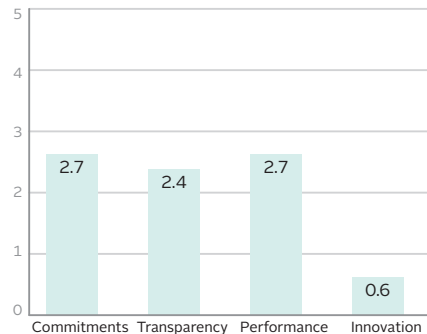
The disease table presents an overview of a company's products (as defined in the Appendix, p. 106) for the diseases covered by the 2012 Index. The table includes commercial products only and is not meant to represent all of a company's access to medicine initiatives or the range of diseases covered by these initiatives. 'Product' refers to an existing product in a company's portfolio as of the end of the reporting period (June 2012). 'Pipeline' denotes a product which was still being developed as of the end of the reporting period (June 2012). Some pipeline products may have been omitted due to non-disclosure agreements or other relevant legal contracts.



**Figure 21 Average 2012 scores of companies, key areas of focus**



**Figure 22 Average 2012 scores of companies, aspects of action**

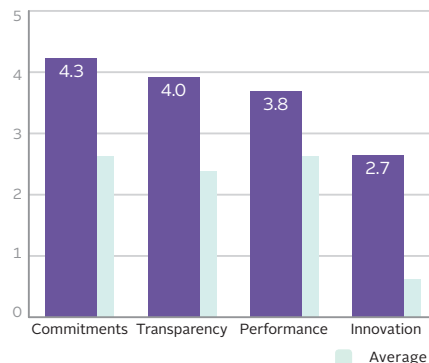
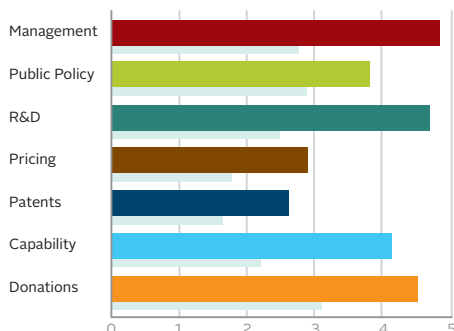




# GlaxoSmithKline plc

rank	score
<b>1</b>	<b>3.8</b>
1 (2010)	

## Score



## Company overview

GlaxoSmithKline is again at the head of the Index. It is the leader in general access to medicine management, research and development activity, capability advancement and drug donation and philanthropy. It makes its entire vaccine portfolio available to developing countries at an equitable price. It has a pro-access approach to patents and licencing. Although it has a code of conduct for ethical marketing that exceeds

the basic minimum standards, it is still not fully transparent about its product registration processes. It does not routinely undertake technology transfer, except for vaccines.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

## Leading practices

- New Developing Countries and Market Access Unit business model driven equally by commercial and social objectives in 50 emerging markets through partnerships, investment and philanthropy; reinvested approximately USD 6 million in 2011 from developing market profits, into capacity-building and philanthropic projects to strengthen the healthcare infrastructure in Least Developed Countries
- Open Innovation Strategy, aiming to stimulate research into diseases of the developing world; research scientists from around the world meet at its Tres Cantos campus to work on projects for the developing world, and in 2011 six projects were launched from this open lab
- Significant price reduction of most of patented products in Least Developed Countries; no patented drug will be priced more than 25% of price in United Kingdom
- Commitment to make no political contributions in developing countries
- Following the 2012 fine of USD 3 billion for misleading promo-

tion of a range of drugs including rosiglitazone (Avandia) for the period from January 1997 to 2004, commits to being fully transparent about all breaches of ethical marketing standards, and has set a relevant code of practice that exceeds IFPMA minimum standards

- Discloses clinical research results earlier than other companies, following completion of studies, rather than following approval or termination of the medicine

## Notable findings

- New business function as the single point of strategy and co-ordination of access to medicine as part of market access strategy, with board-level oversight, quantitative targets, performance evaluation and engagement with numerous relevant stakeholders; incentive scheme rewarding volume growth, encouraging managers to increase access initiatives
- Code of conducts in place for public lobbying, marketing and bribery and corruption, supported by monitoring and enforcement mechanisms applied to employees and third parties; transparent approach to policy positions on intellectual property and data

exclusivity

- Invests more than any other company in targeting relevant diseases; has a large portfolio of innovative and adaptive research and five instances of intellectual property sharing; engaged in multiple relevant collaborations with commitment that drugs produced as a result of these partnerships will be available to disease-endemic countries at an affordable price
- Implemented tiered pricing for large number of relevant diseases, and has introduced inter-country tiered pricing for 32 and intra-country tiered pricing for seven out of 33 of its products in several relevant countries
- Clear position statement outlining support for TRIPS flexibilities and does not enforce patents in Least Developed Countries; has issued 11 non-exclusive voluntary licences for antiretrovirals and, through the ViiV Healthcare Unit, commits to making entire antiretroviral portfolio available royalty-free to generic manufacturers; is in active negotiations with the Medicines Patent Pool

[continued on following page](#)

## Revenue

	2010	2011
Overall (bn USD)	44.0	44.1
US	33%	32%
Europe	32%	30%
Rest of World	35%	38%

## Disease focus

<span style="color: purple;">■</span>	Product
<span style="color: teal;">■</span>	Pipeline

- ■ Low respiratory infections
- ■ Diarrhoeal diseases
- ■ HIV/AIDS
- ■ Malaria
- ■ Tuberculosis
- ■ Pertussis
- ■ Measles
- ■ Meningitis
- ■ Tetanus
- ■ Unipolar depressive disorders
- ■ Ischaemic heart disease
- ■ Cerebrovascular disease
- ■ COPD
- ■ Diabetes mellitus
- ■ Asthma
- ■ Osteoarthritis
- ■ Cirrhosis of the liver
- ■ Nephritis and nephrosis
- ■ Epilepsy
- ■ Lymphatic filariasis
- ■ Soil transmd Helminthiasis
- ■ Leishmaniasis
- ■ Trypanosomiasis
- ■ Schistosomiasis
- ■ Trachoma
- ■ Dengue
- ■ Onchocerciasis
- ■ Leprosy
- ■ Chagas disease
- ■ Yaws
- ■ Fascioliasis
- ■ Buruli ulcer
- ■ Dracunculiasis
- ■ Neonatal infections
- ■ Maternal conditions

## GlaxoSmithKline plc (continued)

### Notable findings

*continued from previous page*

- Numerous capability advancement projects in research and development, including four local scientific research partnerships; has strengthened supply chain and quality management standards and is one among the few companies that work with local governments to improve pharmacovigilance
- Two single-drug donation programmes, with international public health organisations and government health departments, delivered by non-governmental organisations and rigorously selected third parties with a view to ensuring that donated products reach patients; number of sustainable philanthropic programmes

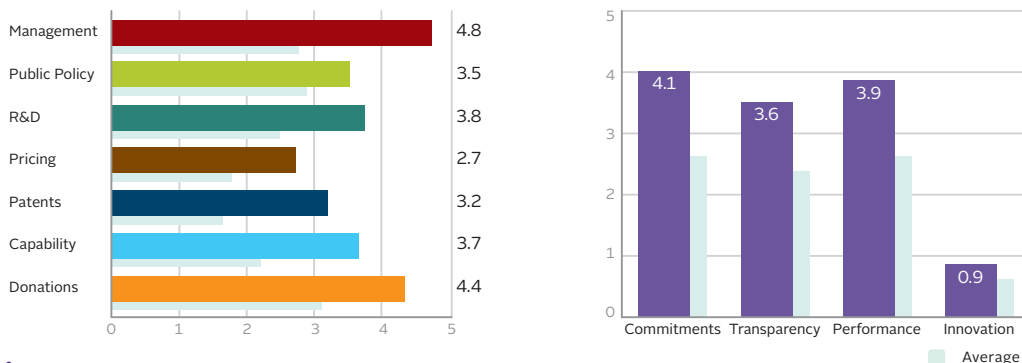
### Suggested areas for improvement

- Reveal more about marketing and promotional programmes
- Increase number of intellectual property sharing agreements
- Be more transparent about drug recalls
- Provide more details about the criteria for product registration in relevant countries and the status of marketing approvals for each relevant product
- Undertake technology transfer and use milestone-based agreements within non-exclusive voluntary licencing activity; participate in the Medicines Patent Pool

# Johnson & Johnson

rank	score
2 <sup>^</sup>	3.6
9 (2010)	

## Score



## Company overview

Johnson & Johnson has risen by seven places to 2<sup>nd</sup> position in this year's Index. It provides more details about its access policies and practices, and has improved its approach to access to medicine in key areas since 2010. It has established a new committee dedicated to managing its access strategy and the acquisition of Crucell has expanded its research and development portfolio. It has tiered pricing for all relevant

products, has issued non-exclusive voluntary licences, and publicly supports TRIPS flexibilities. It has made efforts to improve relevant capability advancement and has a large number of sustainable philanthropic activities. It declined to enter formal negotiations with the Medicines Patent Pool in December 2011 but discussions continue.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

## Leading practices

- Global strategy for access and affordability issues evidenced by Global Pharmaceutical Access Committee with board-level involvement
- Diverse and significant research and development pipeline targeted at relevant diseases, including neglected tropical diseases and communicable diseases
- Gives detailed information about its support of all TRIPS flexibilities, based on the Doha Declaration on TRIPS and public health
- Numerous long-term capability advancement and philanthropic projects in developing countries, including national pharmacovigilance programmes

## Notable findings

- Established committee to create global strategy for access and affordability issues, with board-level management; robust performance management system that rewards delivery of access initiatives and innovative business models; engagement with a variety of relevant stakeholders; provides information about policies and practices in annual and contributions reports

- Discloses more information about public policy and market influence activities, permits access to clinical trial data for its patented HIV/AIDS products through licencing agreements, and has codes of conduct and enforcement measures in place for ethical marketing and anti-bribery and corruption practices
- Increased share of pipeline dedicated to innovation in 13 relevant diseases and adaption of products for seven relevant diseases; engages in 11 public private partnerships; four instances of sharing intellectual property with research institutions and neglected disease drug discovery initiatives
- Inter- and intra-country pricing for all of its eight relevant products
- Issued non-exclusive voluntary licences for all three of its HIV/AIDS products and provides detailed information about policy position in support of TRIPS flexibilities
- Increased efforts to improve relevant local research and development, quality management, manufacturing and three national pharmacovigilance programmes in partnership with leading local institutions

- Single-drug donation programme for soil transmitted helminthiasis and sustainable philanthropy programmes focussed on maternal and child health

## Suggested areas for improvement

- Use stakeholder engagement opportunities to demonstrate greater thought leadership
- Give further details about lobbying activities specific to access in relevant countries
- Disclose more about contract partners for clinical trials
- Give more information about proportion of global revenue covered by tiered pricing
- Enter formal negotiations with the Medicines Patent Pool
- Introduce more single-drug donation programmes

## Revenue

	2010	2011
Overall (bn USD)	61.6	65.0
US	47.8%	44.5%
International	52.2%	55.5%

## Disease focus

<span style="color: #0070C0;">■</span>	Product
<span style="color: #00A651;">■</span>	Pipeline

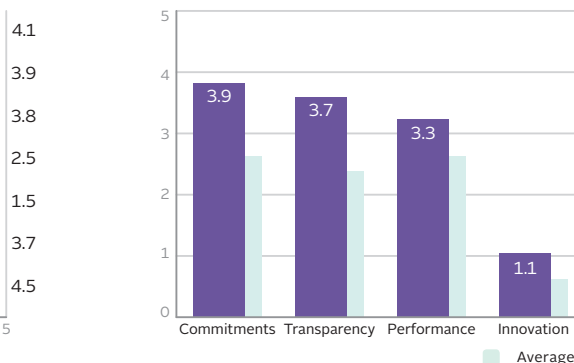
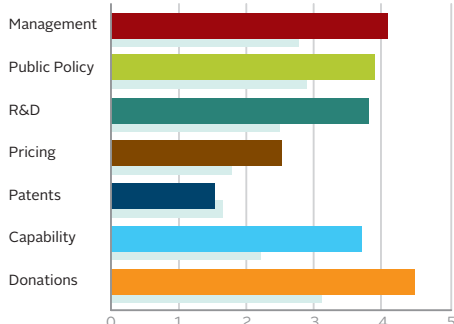
  

<span style="color: #0070C0;">■</span>	Low respiratory infections
<span style="color: #00A651;">■</span>	Diarrhoeal diseases
<span style="color: #0070C0;">■</span>	HIV/AIDS
<span style="color: #00A651;">■</span>	Malaria
<span style="color: #0070C0;">■</span>	Tuberculosis
<span style="color: #00A651;">■</span>	Pertussis
<span style="color: #0070C0;">■</span>	Measles
<span style="color: #00A651;">■</span>	Meningitis
<span style="color: #0070C0;">■</span>	Tetanus
<span style="color: #00A651;">■</span>	Unipolar depressive disorders
<span style="color: #0070C0;">■</span>	Ischaemic heart disease
<span style="color: #00A651;">■</span>	Cerebrovascular disease
<span style="color: #0070C0;">■</span>	COPD
<span style="color: #00A651;">■</span>	Diabetes mellitus
<span style="color: #0070C0;">■</span>	Asthma
<span style="color: #00A651;">■</span>	Osteoarthritis
<span style="color: #0070C0;">■</span>	Cirrhosis of the liver
<span style="color: #00A651;">■</span>	Nephritis and nephrosis
<span style="color: #0070C0;">■</span>	Epilepsy
<span style="color: #00A651;">■</span>	Lymphatic filariasis
<span style="color: #0070C0;">■</span>	Soil transmted Helminthiasis
<span style="color: #00A651;">■</span>	Leishmaniasis
<span style="color: #0070C0;">■</span>	Trypanosomiasis
<span style="color: #00A651;">■</span>	Schistosomiasis
<span style="color: #0070C0;">■</span>	Trachoma
<span style="color: #00A651;">■</span>	Dengue
<span style="color: #0070C0;">■</span>	Onchocerciasis
<span style="color: #00A651;">■</span>	Leprosy
<span style="color: #0070C0;">■</span>	Chagas disease
<span style="color: #00A651;">■</span>	Yaws
<span style="color: #0070C0;">■</span>	Fascioliasis
<span style="color: #00A651;">■</span>	Buruli ulcer
<span style="color: #0070C0;">■</span>	Dracunculiasis
<span style="color: #00A651;">■</span>	Neonatal infections
<span style="color: #0070C0;">■</span>	Maternal conditions

rank	score
3 <sup>▲</sup>	3.2
5 (2010)	

# Sanofi

## Score



## Company overview

Sanofi has moved up to 3<sup>rd</sup> position in the rankings this year because it has significantly improved its approach to access to medicine in several areas and it leads the field in the area of public policy. It has continued to invest in research and development, targeting relevant diseases, and has a broad range of molecules in its pipeline. The company has robust access management systems, inter- and intra-country tiered pricing,

works with local governments to improve capability advancement and has initiatives in both donations and sustainable philanthropy, with two single-drug donation programmes. It has not issued any non-exclusive voluntary licences, but commits to consider requests when needs arise.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

## Leading practices

- Established the Asia-Pacific Therapeutic Strategic Unit to support development of drugs with a positive cost/benefit ratio for the Asia-Pacific region, and also created a specific research and development unit focussing on communicable diseases, including multi-resistant bacterial infections, malaria, tuberculosis and neglected tropical diseases
- Advances capabilities in national pharmacovigilance in Africa in partnership with the Drugs for Neglected Diseases initiative and the Medicines for Malaria Venture for antimalarial FDC ASAQ Winthrop
- 15-year partnership with WHO to fight neglected tropical diseases extended to 2015; diseases include Buruli ulcer, human African trypanosomiasis, Chagas disease and leishmaniasis
- Strong public policy leadership: CEO co-chaired Gates-CEO Roundtable and the resulting Access and Affordable Working Group project led to a pilot programme in Ghana on differential pricing strategies

- structure, with board-level responsibility, internal incentive structure and performance management system with improved stakeholder engagement
- Commits to proactively fight bribery and corruption with enforced codes of conduct, gives more details about competition and marketing practices and public policy positions, including pricing, patents, donations, clinical trials and pharmacovigilance
- 15 innovative research and development molecules with a broad relevant disease scope, eight adaptive molecules for trypanosomiasis, leishmaniasis, tuberculosis, ischaemic heart disease, diabetes mellitus and pertussis, and numerous collaborations; four instances of sharing intellectual capital with research institutions and neglected disease drug discovery initiatives
- Inter-country tiered pricing for 28 and intra-country pricing for nine out of its 35 products in several relevant countries
- Provides more information about intellectual property and patent related positions, supports TRIPS flexibilities
- Engages in national pharmaco-

- vigilance programmes, works with stakeholders to improve research and development capacity, commits to build quality management systems and to assist local governments to build appropriate supply chain capabilities in many relevant countries
- Initiatives in both donations and philanthropy, including launch of Sanofi Espoir Foundation supporting 15 access-oriented projects and two single-drug donation programmes targeting trypanosomiasis

## Suggested areas for improvement

- Share clinical trial data with generics manufacturers before patents expire
- Provide more information about terms and conditions of research and development collaborations and the use of contract research organisations for clinical trials
- Give more details about reasons for and status of product registration in relevant countries and introduce packaging that differentiates between differently priced products to counter diversion
- Issue non-exclusive voluntary licences

## Revenue

	2010	2011
Overall (bn USD)	40.7	42.0
Western Europe	29.5%	27.3%
US	30.2%	29.8%
Emerging markets	29.5%	30.4%
Other	10.8%	12.5%

## Disease focus

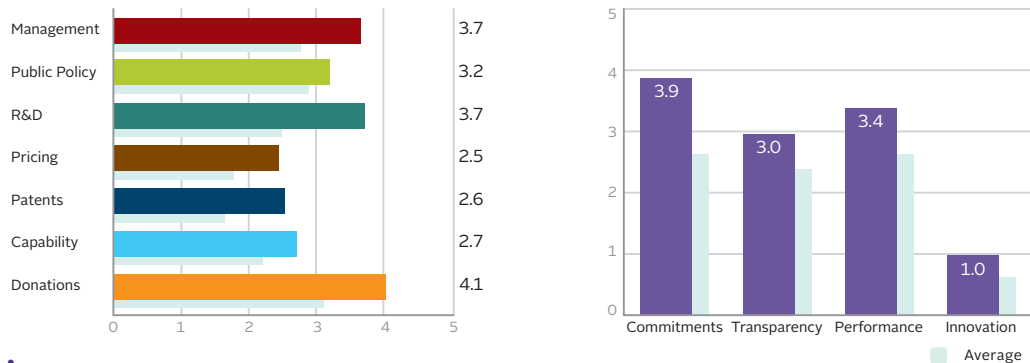
Legend: ■ Product, ■ Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
- Cerebrovascular disease
- COPD
- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmtd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

# Merck & Co. Inc.

rank	score
4 <sup>v</sup>	3.1
2 (2010)	

## Score



## Company overview

Merck & Co. has dropped two places in this year's Index. While its approach to some areas of access to medicine has advanced, it has been outpaced by other fast-rising companies that have made even more progress. It does not fully disclose details about some of its access activities, which has contributed to its fall to 4<sup>th</sup> position. It has a mature approach to access management. It has been innovative in its approach

to research and development and has multiple collaborations and instances of intellectual property sharing. It has introduced non-exclusive voluntary licences, has tiered pricing schemes and three long-standing single-drug donation programmes.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- The only company in the Index that is a member of the World Economic Forum's Partnering Against Corruption Initiative
- Engaged in a milestone-based technology transfer agreement as part of a non-exclusive voluntary licence for HIV/AIDS medicine Stocrin
- Merck for Mothers programme is a 10-year research and development collaboration with PATH, aimed at reducing maternal mortality globally, which will evaluate technologies in the prevention, diagnosis and treatment for haemorrhage, pre-eclampsia and family planning
- Publicly discloses the registration status of its HIV/AIDS medication, contraceptive products and its pneumonia vaccines
- Collaborating with the Reproductive Health Supplies Coalition and its partners to reach 100 million new users of modern contraception by 2015 through its Implanon access initiative

### Notable findings

- Mature access to medicine management systems, with performance evaluation, relevant targets and relevant stakeholder engagement
- Provides information about political contributions and public policy positions and commits to fight corruption through monitoring internal and third party activity
- Research and development for innovative and adaptive products, multiple collaborations and four instances of intellectual property sharing
- Well-established tiered pricing strategy for antiretroviral products, vaccines and women's health products in all countries in which they operate
- Issued a number of non-exclusive voluntary licences for its HIV/AIDS and diabetes products and declared that it will not assert its patent on the HIV/AIDS drug Stocrin in South Africa
- Three long-standing single-drug donation programmes: a pneumococcal vaccine, a programme for HIV/AIDS medication, and one for onchocerciasis (river blindness) and lymphatic filariasis (elephantiasis)

### Suggested areas for improvement

- Continue to improve internal incentive structures
- Work towards sharing clinical trial data with generics manufacturers before patents expire
- Provide more information about pre-clinical research and licencing arrangements for research collaborations
- Register products in more countries and be more transparent about drug recalls
- Give details of the terms and conditions for the non-exclusive voluntary licences issued and participate in the Medicines Patent Pool
- Stop lobbying relevant country governments such as Indonesia and Phillipines for stronger intellectual property protection and adopt a more pro-public health approach to the implementation of TRIPS by developing countries
- Strengthen national pharmacovigilance programmes

### Revenue

	2010	2011
Overall (bn USD)	45.9	48.0
US	42.7%	42.7%
Europe, Middle East and Africa	28.8%	28.7%
Japan	10.0%	10.0%
Other	18.5%	18.5%

### Disease focus

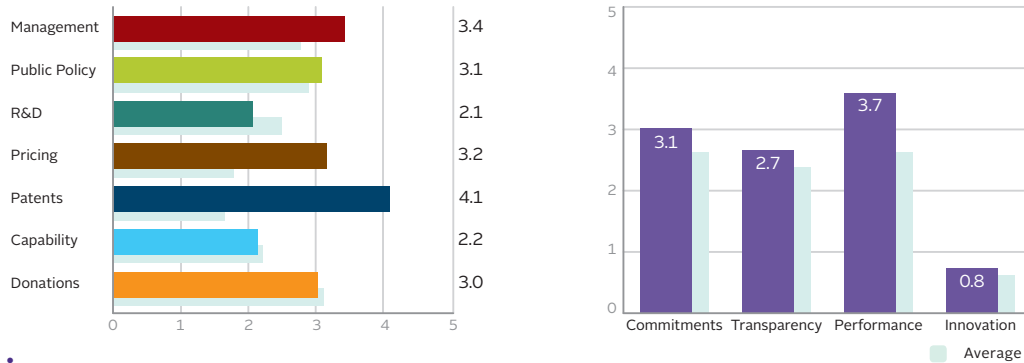
<span style="color: purple;">■</span>	Product
<span style="color: teal;">■</span>	Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
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- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

rank	score
5 <sup>th</sup>	3.0
4 (2010)	

# Gilead Sciences

## Score



## Company overview

Gilead still shows strong commitment in its approach to access to medicine, but has nonetheless fallen one place to 5<sup>th</sup> position in this year's Index, due to the fact that it is outperformed by peers in access management and research and development practices. It does not fully disclose details about its public policy and ethical marketing positions. Despite it being a relatively small company, it has constructive and proactive stakeholder engagement and it is the leader

among peers in terms of its pricing initiatives and patents and licencing approaches. Gilead is the first and the only company to date to join the Medicines Patent Pool. It has also implemented a single-drug donation programme.

[A full company profile is available on \[www.accesstomedicineindex.org\]\(http://www.accesstomedicineindex.org\)](#)

### Leading practices

- Sole participant in this Index in the Medicines Patent Pool for HIV/AIDS medications, considered to be the best hope for ensuring sustained access to new first-line treatments for the disease that may be able to counter rising resistance to existing antiretroviral drugs
- Proactive stakeholder engagement to generate thought leadership, for example partnership with the Wilton Park group to organise a high-level dialogue on financing continued scale-up of HIV treatment
- Provides details about inter-country equitable pricing strategy, with a status report available online for its HIV/AIDS medicines

### Notable findings

- Board-level ownership of access to medicine initiatives, with time-bound quantitative and qualitative targets and relevant stakeholder engagement
- Inter-country tiered pricing for its two HIV/AIDS products in a majority of relevant countries, with full public disclosure of all pricing-related information
- Licencing strategy for HIV/AIDS drugs considered best practice: respects TRIPS flexibilities, has issued non-exclusive voluntary licences, joined the Medicines Patent Pool in 2011
- Provides information about non-exclusive voluntary licences issued and the patent status of HIV/AIDS medications Viread and Truvada
- As part of non-exclusive voluntary licencing strategy, extended commitment to waive royalty payments on paediatric products developed and sold by its licencing partners
- New single-drug donation programme for visceral leishmaniasis

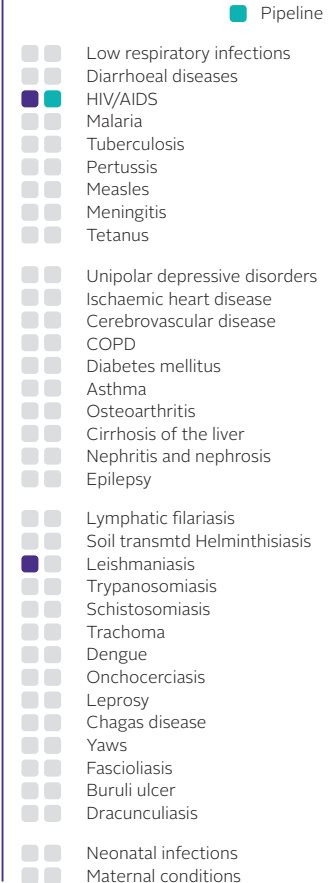
### Suggested areas for improvement

- Provide more details about incentives rewarded to senior management for access initiatives
- Give information about lobbying activities, marketing and promotional programmes, competition policies
- Conduct research and development into relevant diseases, increase number of partnerships and intellectual property sharing agreements
- Expand equitable pricing practices to include more relevant products and implement intra-country tiered pricing
- Increase efforts to develop locally appropriate supply chain capabilities and introduce pharmacovigilance programme

### Revenue

	2010	2011
Overall (bn USD)	7.9	8.4
US	53.2%	55.0%
France	6.5%	7.0%
UK	5.7%	6.2%
Spain	5.7%	5.9%
Italy	4.3%	4.7%
Germany	3.5%	4.4%
Switzerland	5.8%	2.1%
Rest of the world	15.3%	14.7%

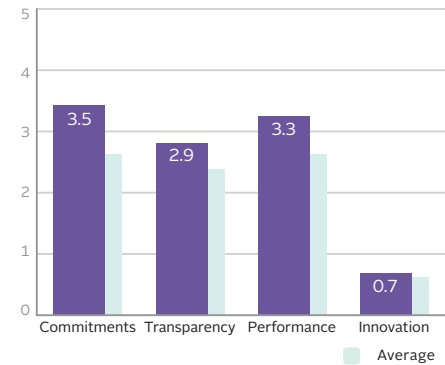
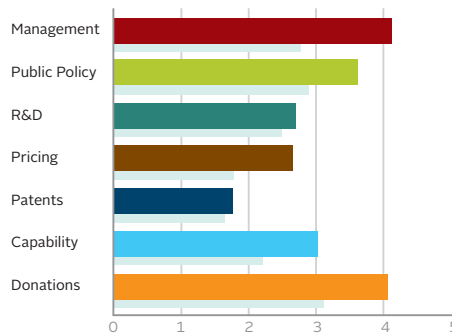
### Disease focus



# Novo Nordisk A/S

rank	score
6 <sup>▲</sup>	3.0
8 (2010)	

## Score



## Company overview

Novo Nordisk has risen by two places in the ranking to 6<sup>th</sup> position by providing more information about its access activities, and having a more access-oriented approach to public policy, patents and philanthropy. It is the only company in the Index that commits to not seeking data exclusivity and has issued non-exclusive voluntary licences on genetic technology.

The company has equitable pricing initiatives for its diabetes medicines and has numerous capability advancement and philanthropic programmes in many relevant countries, including a single-drug donation programme in Sub-Saharan Africa.

A full company profile is available on [www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Leader in commitment to not seeking data exclusivity, and waives patent rights in more than 97% of relevant countries
- Tiered pricing schemes for insulin greater than any differential disclosed by peers
- One of the largest pipelines dedicated to diabetes products for both innovative and adaptive research and development
- Monitoring of stakeholder engagement with global tracker

### Notable findings

- Has strong board management, target setting and performance management in place and has also implemented a stakeholder tracking tool
- Is the only company that commits to share clinical trial data with generics manufacturers before patents expire, and shows a greater focus on fighting corruption and bribery
- Significant proportion of innovative and adaptive research and development pipeline dedicated to diabetes products, two instances of intellectual property sharing, and issues non-exclusive voluntary licences on genetic technology for

use as research tools and diagnostic agents

- Intra- and inter-country tiered pricing for three diabetes products, offers insulin at a differential price in all 48 Least Developed Countries with a significant price reduction, and increased number of product registrations in relevant countries
- Supports TRIPS flexibilities and commits not to file patents in Least Developed Countries, applies for patent protection in only three of the 103 relevant countries - India, China and South Africa – and provides more information about patents and licencing activity
- Commitment to capability advancement in research and development through public private partnerships with China and support for pharmacovigilance programmes
- New single-drug donation programme in Sub-Saharan Africa combined with a programme of education and equipment donation is part of long-standing philanthropic programme; transparent about donation activity

### Suggested areas for improvement

- Be more transparent about lobbying activities in relevant countries
- Give further details about the terms and conditions of research and development collaborations
- Develop distinct packaging to prevent product diversion
- Issue non-exclusive voluntary licences for patented products

### Revenue

	2010	2011
Overall (bn USD)	10.4	11.4
North America	38.9%	40.1%
Europe, Middle East and Africa	30.7%	28.9%
International	13.7%	14.1%
Japan & Korea	9.3%	9.4%
Region China	7.4%	7.5%

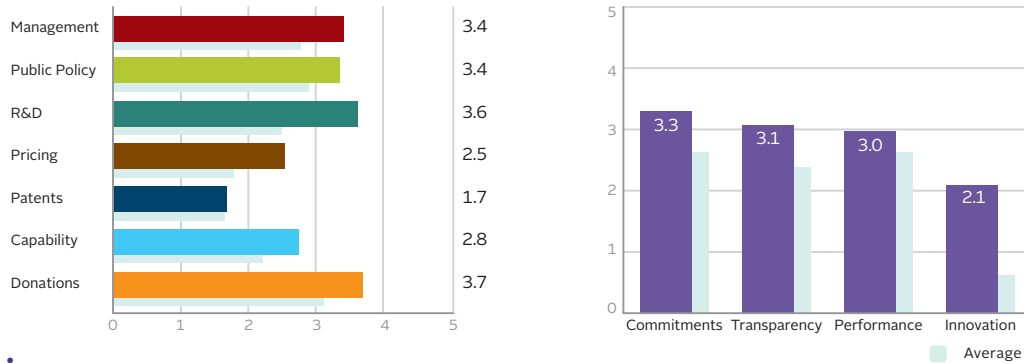
### Disease focus

	Product	Pipeline
Low respiratory infections		
Diarrhoeal diseases		
HIV/AIDS		
Malaria		
Tuberculosis		
Pertussis		
Measles		
Meningitis		
Tetanus		
Unipolar depressive disorders		
Ischaemic heart disease		
Cerebrovascular disease		
COPD		
Diabetes mellitus	■	■
Asthma		
Osteoarthritis		
Cirrhosis of the liver		
Nephritis and nephrosis		
Epilepsy		
Lymphatic filariasis		
Soil transmd Helminthiasis		
Leishmaniasis		
Trypanosomiasis		
Schistosomiasis		
Trachoma		
Dengue		
Onchocerciasis		
Leprosy		
Chagas disease		
Yaws		
Fascioliasis		
Buruli ulcer		
Dracunculiasis		
Neonatal infections		
Maternal conditions		

rank	score
<b>7<sup>th</sup></b>	<b>2.9</b>
3 (2010)	

# Novartis AG

## Score



## Company overview

Novartis has slipped four places to 7<sup>th</sup> position in this year's Index. This is largely because while other fast-rising companies have made advances in many activities, its approach to access to medicine, although somewhat improved, has not progressed as far. The company is an innovator in public policy and pricing and has a strong research and development portfolio targeting a large number of relevant diseases.

It has a robust access management system and three established single-drug donation programmes. However, it does not have a pro-access approach to patents and licencing – it has not issued any non-exclusive voluntary licences and does not support patent pools for pharmaceuticals.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

## Leading practices

- Innovative in public policy and marketing for its third party auditing and enforcement mechanisms
- Implemented the Novartis Arogya Parivar programme, a sustainable for-profit initiative that has combined access to medicine and the provision of healthcare services for the lowest socio-economic strata in rural areas of India to address locally prevalent diseases
- SMS for Life partnership works to strengthen supply and distribution chains by eliminating stock-outs of anti-malaria drugs in Africa

- malaria, tuberculosis, leishmaniasis, diabetes mellitus and diarrhoeal diseases treatments
- Innovative inter- and intra-country tiered pricing mechanisms for the majority of product portfolio in a large amount of countries; innovative supply chain management programmes
- Supports TRIPS flexibilities, does not file for any patents in Least Developed Countries
- Works to improve capability advancement in research and development, quality management and manufacturing
- Three long-standing single-drug donations for fascioliasis, tuberculosis and leprosy

## Notable findings

- Maturing approach to access management, with relevant management structures, performance management systems and stakeholder engagement
- Monitors third party ethical marketing behaviour, enforces internal anti-bribery policies and conducts spot-checks on suppliers
- Innovative and adaptive research and development for a number of relevant diseases and collaborations with a variety of other organisations; four instances of intellectual property sharing for

## Suggested areas for improvement

- Introduce a centralised management system for access initiatives
- Provide more information about lobbying and political contributions, and share clinical trial data with generics manufacturers before patents expire
- Give further details about terms and conditions of research and development partnerships
- Introduce policy guiding the timeline for registration of products
- Issue non-exclusive voluntary licences and engage with the Medicines Patent Pool
- Increase efforts to strengthen national pharmacovigilance programmes

## Revenue

	2010	2011
Overall (bn USD)	50.6	58.6
Other	42%	45%
US	31%	33%
Germany	8%	7%
Switzerland	1%	1%
Japan	8%	9%
France	5%	5%

## Disease focus

■ Product  
■ Pipeline

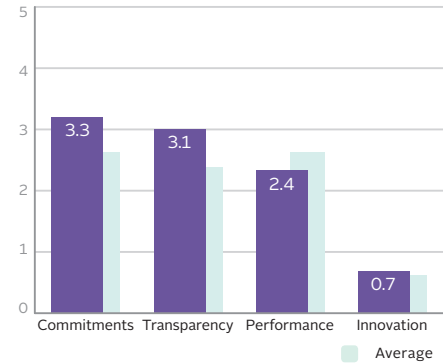
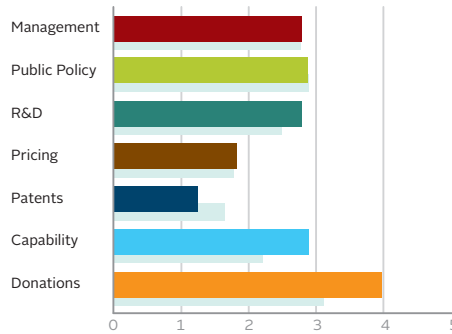
- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
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- COPD
- Diabetes mellitus
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- Soil transmtd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions



# Merck KGaA

rank	score
8 <sup>▲</sup>	2.5
17 (2010)	

## Score



## Company overview

Merck KGaA has risen nine places to 8<sup>th</sup> position in this year's Index, largely because it has provided more information about its tiered pricing, management strategy and single-drug donation programmes. It conducts innovative research and development for a drug to treat schistosomiasis and, relative to its size, has a high level of intellectual property sharing. It has a robust approach to anti-counterfeiting with a number of long-term initiatives aimed at preventing counter-

feit drugs entering the supply chain. It has not issued any non-exclusive voluntary licences and does not give specific details about its position regarding TRIPS. It is not fully transparent about some of its ethical marketing practices, research and development collaborations, drug recalls or multi-drug donation programmes.

A full company profile is available on [www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Assurance of supply chain integrity through Mobile Authentication System, which allows for rapid detection of counterfeit drugs in the field; co-operation with governments and third parties
- Engaged in implementing and developing good pharmacovigilance practices in northwest Africa, in partnership with national centres; collaborated with the Tunisian drug regulatory authority to align the country's regulations to EU guidelines on pharmacovigilance

### Notable findings

- Introduced access to medicine charter with board-level responsibility, stakeholder engagement reflects initiatives for product donation and research and development targeting neglected tropical diseases, and provides detailed information about access strategy and policies
- Transparent about lobbying and public policy positions, monitored and enforced codes of conduct for ethical marketing for employees and third parties

- Innovative research and development for paediatric version of Praziquantel to treat schistosomiasis, and adapting this drug and anti-diabetic medication Glucophage; five collaborations for relevant diseases and two instances of intellectual property sharing
- Inter-country tiered pricing for some of its products in a number of relevant countries
- Respects TRIPS flexibilities, no longer files patents in Least Developed Countries and will not seek to enforce any existing patents
- Supports manufacturing plants in Pakistan, India and Indonesia to develop quality systems, provides training for supply chain to reinforce anti-counterfeiting measures in Africa, the Americas and China, and is engaged in national pharmacovigilance programme in northwest Africa
- Gives detailed information about long standing single-drug donation programme in collaboration with WHO for elimination of schistosomiasis in Sub-Saharan Africa, and about other philanthropic activities

### Suggested areas for improvement

- Develop access to medicine management systems and internal incentives programmes
- Provide more information about disciplinary action for ethical marketing codes of conduct violations and share clinical trial data with generics manufacturers before patents expire
- Increase investment into in-house innovative research and development and give further details about collaborations, which contract research organisations are used for research, and drug recalls
- Introduce intra-country tiered pricing and monitor prices charged by sales agents and third parties
- Give more details about policy stance for TRIPS<sup>+</sup> and issue non-exclusive voluntary licences
- Increase efforts to improve capability advancement in research and development
- Provide more information about type, destination and volume of multi-drug donation programmes

### Revenue

	2010	2011
Overall (bn USD)	11.7	12.9
North America	19%	18%
Europe	49%	40%
Asia/Africa/Australasia	17%	30%
Latin America	15%	12%

### Disease focus

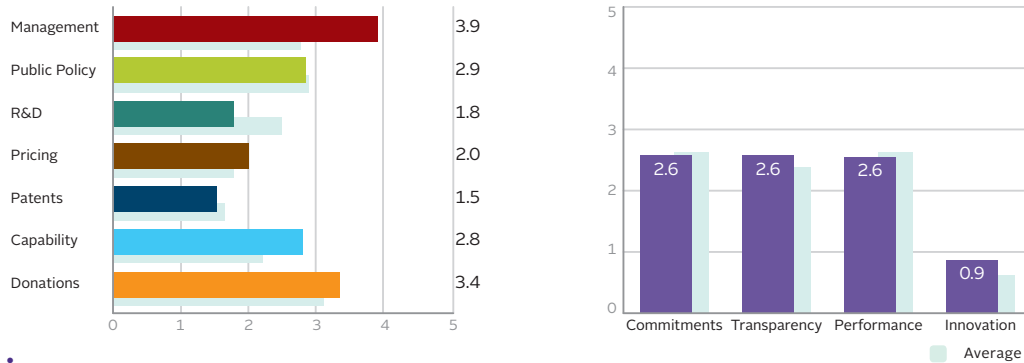
<span style="color: purple;">■</span>	Product
<span style="color: teal;">■</span>	Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
- Cerebrovascular disease
- COPD
- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

rank	score
9 <sup>▲</sup>	2.4
14 (2010)	

# Bayer AG

## Score



## Company overview

Bayer has risen by five places since 2010 to rank 9<sup>th</sup> in this Index, mainly due to its improved approach to managing access to medicine, its tiered pricing practices and three single-drug donation programmes. The company's access approach is focussed on its contraceptives portfolio. Research and development for relevant diseases is conducted mainly through collaborations; the company has no relevant innovative

molecules in its pipeline. Despite having a more transparent approach to intellectual property than previously, it has not granted any non-exclusive voluntary licences and its overall stance is not pro-access.

[A full company profile is available on \[www.accesstomedicineindex.org\]\(http://www.accesstomedicineindex.org\)](#)

### Leading practices

- Intra-country differential pricing model along four market segments implemented for the contraceptive Microgynon<sup>®</sup>, using four separate distribution channels, differentiated branding and packaging to prevent product diversion
- Helps to improve safety reporting requirements in the Association of Southeast Asian Nations countries, in collaboration with the WHO Uppsala Monitoring Centre

### Notable findings

- Senior management responsibility and accountability, quantitative and qualitative targets in place, greater transparency about approach and initiatives through annual sustainability report, relevant stakeholder engagement
- Adaptive research and development for products such as Moxifloxacin for tuberculosis, and a paediatric version of Nifutimox for Chagas disease
- Tiered pricing programmes for the contraceptive Microgynon<sup>®</sup>
- Provides more information about position regarding TRIPS flexibilities and stance on patenting activity in Least Developed Countries
- Improved capability advancement programmes for quality management and manufacturing standards and supports pharmacovigilance programmes on an ad hoc basis
- Long standing single-drug donation programmes to combat Chagas disease and different strains of human African trypanosomiasis, and more disclosure about programme outcomes

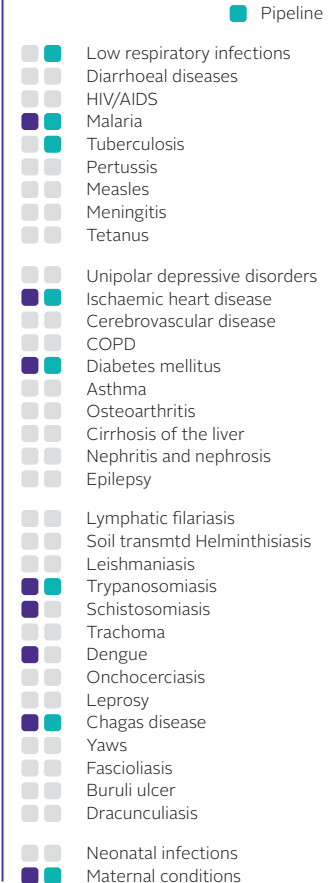
### Suggested areas for improvement

- Provide more details about internal breaches and resultant disciplinary action, marketing and promotional programmes, and about position regarding sharing clinical trial data with generics manufacturers before patents expire
- Invest more in innovative research and development for relevant diseases, and be more transparent about the terms and conditions of intellectual property sharing for relevant collaborations; provide evidence of conducting due diligence prior to using contract research organisations and of their codes of conduct
- Introduce tiered pricing for more products in portfolio, particularly for the Mirena contraceptive coil
- Issue non-exclusive voluntary licences and be more transparent about position regarding TRIPS<sup>+</sup>
- Improve capability advancement for supply chain management and more sustainable pharmacovigilance programmes
- Be more transparent about sustainable philanthropic programmes

### Revenue

	2010	2011
<b>Bayer Group</b>		
Overall (bn USD)	46.9	45.3
<b>Bayer Health Care</b>		
Overall (bn USD)	20.9	21.2
Europe	37.7%	37.1%
North America	27.6%	25.4%
Asia/Pacific	19.3%	21.3%
Latin America/Africa/Middle East	15.4%	16.2%

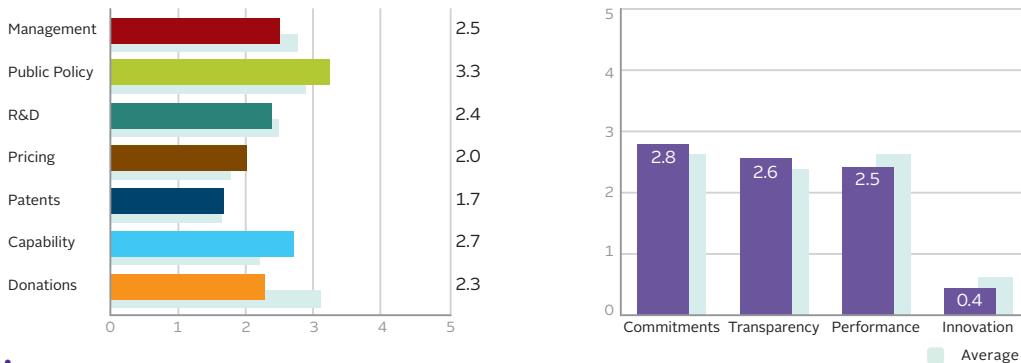
### Disease focus



# Roche Holding Ltd.

rank	score
10 <sup>v</sup>	2.3
6 (2010)	

## Score



## Company overview

Roche falls four places in this year's Index to 10<sup>th</sup> position. Roche has advanced to a lesser degree than other companies in most of its access to medicine activities and it gives few details about its access activity. It has numerous adaptive molecules in its R&D pipeline but has no relevant innovative molecules this Index period. It has an increased focus on equitable pricing this year. Although the company does not

have any non-exclusive voluntary licences, it commits to consider them if approached within the 12 countries where it applies patents. It has sustainable philanthropy programmes particularly for cancer, but has no single-drug donation schemes. It is in active negotiations with the Medicines Patent Pool.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Provides information about advocacy stances on important access issues, including clinical trial conduct in developing countries, pricing, donations, counterfeiting, patenting practices and its working relationship with government officials and patient groups in relevant countries – it is unique in providing clarity across so many issues
- Expansion of the AIDS Technology Transfer Initiative established in 2006, to the area of manufacturing biologics in India

### Notable findings

- Direct board responsibility for access management with quantitative and qualitative targets to implement access strategy
- Public policy positions support several access issues, including product donations and clinical trial conduct, and does not enforce patents in 91 out of the 103 relevant countries
- Ten adaptive molecules in the research and development pipeline targeting a number of relevant diseases
- Shares intellectual property, particularly for malaria
- Inter-country tiered pricing scheme for six medicines including HIV/AIDS, tuberculosis and diabetes treatments, and new intra-country tiered pricing for diabetes diagnostics; tiered pricing covers significant share of market in relevant countries
- Greater effort to build capabilities of healthcare workers to assess the efficacy of HIV treatment in resource-limited countries; one pharmacovigilance initiative partnership with the Chinese government

### Suggested areas for improvement

- Give more details about performance management system to support targets for access initiatives
- Provide more information about marketing and promotional programmes and share clinical trial data with generics manufacturers before patents expire
- Increase number of innovative molecules in research and development pipeline and number of relevant partnerships, and provide details about terms and conditions of collaborations
- Roll out tiered pricing programmes to other relevant countries
- Issue non-exclusive voluntary licences and commit to support TRIPS flexibilities, and progress negotiations with the Medicines Patent Pool towards conclusion
- Increase capability advancement efforts, especially in research and development and pharmacovigilance
- Introduce one or more single-drug donation programmes

### Revenue

	2010	2011
Overall (bn USD)	49.7	44.5
Europe	29%	28%
US	35%	34%
Japan	10%	10%
International	26%	28%

### Disease focus

<span style="color: purple;">■</span>	Product
<span style="color: teal;">■</span>	Pipeline

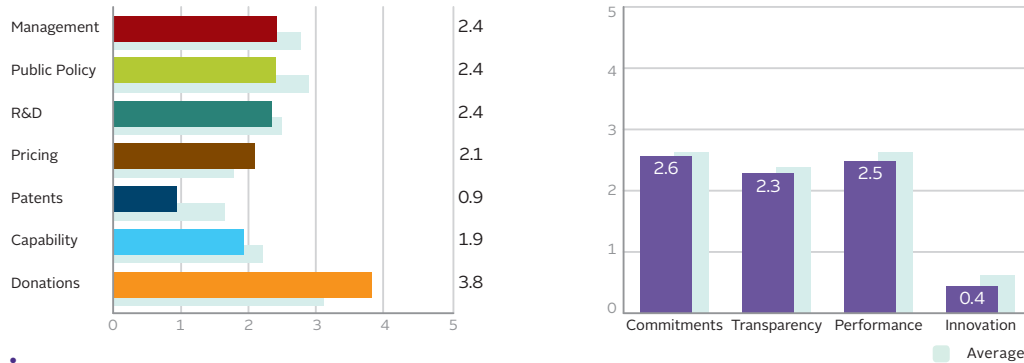
  

<span style="color: purple;">■</span>	Low respiratory infections
<span style="color: teal;">■</span>	Diarrhoeal diseases
<span style="color: purple;">■</span>	HIV/AIDS
<span style="color: teal;">■</span>	Malaria
<span style="color: purple;">■</span>	Tuberculosis
<span style="color: teal;">■</span>	Pertussis
<span style="color: purple;">■</span>	Measles
<span style="color: teal;">■</span>	Meningitis
<span style="color: purple;">■</span>	Tetanus
<span style="color: teal;">■</span>	Unipolar depressive disorders
<span style="color: purple;">■</span>	Ischaemic heart disease
<span style="color: teal;">■</span>	Cerebrovascular disease
<span style="color: purple;">■</span>	COPD
<span style="color: teal;">■</span>	Diabetes mellitus
<span style="color: purple;">■</span>	Asthma
<span style="color: teal;">■</span>	Osteoarthritis
<span style="color: purple;">■</span>	Cirrhosis of the liver
<span style="color: teal;">■</span>	Nephritis and nephrosis
<span style="color: purple;">■</span>	Epilepsy
<span style="color: teal;">■</span>	Lymphatic filariasis
<span style="color: purple;">■</span>	Soil transmtd Helminthiasis
<span style="color: teal;">■</span>	Leishmaniasis
<span style="color: purple;">■</span>	Trypanosomiasis
<span style="color: teal;">■</span>	Schistosomiasis
<span style="color: purple;">■</span>	Trachoma
<span style="color: teal;">■</span>	Dengue
<span style="color: purple;">■</span>	Onchocerciasis
<span style="color: teal;">■</span>	Leprosy
<span style="color: purple;">■</span>	Chagas disease
<span style="color: teal;">■</span>	Yaws
<span style="color: purple;">■</span>	Fascioliasis
<span style="color: teal;">■</span>	Buruli ulcer
<span style="color: purple;">■</span>	Dracunculiasis
<span style="color: teal;">■</span>	Neonatal infections
<span style="color: purple;">■</span>	Maternal conditions

rank	score
<b>11</b>	<b>2.2</b>
11 (2010)	

# Pfizer Inc.

## Score



## Company overview

Pfizer's rank is unchanged since 2010 at 11<sup>th</sup> place, and although it has improved in a range of activities, scoring measures are more stringent this year and there is greater competition from peers. It is more transparent about its access to medicine management structures and has improved its approach to fighting bribery and corruption. The company's research and development programme focusses on innovative research, conducted through external collaborations. It has equitable pricing programmes, two single-drug donation programmes and an established sustainable approach to

philanthropy. It does not have a robust access management system and is not transparent about clinical trials. Its approach to patents and licencing is not pro-access. In 1996, a breach in its clinical trial conduct for the meningitis antibiotic Trovan<sup>®</sup> resulted in a lawsuit and in 2011 the company began to pay final compensation to claimants.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Supports the Infectious Diseases Institute in Uganda – a centre of excellence for prevention, treatment, training and research that strengthens regional capacity in HIV/AIDS, malaria and tuberculosis
- Global Health Fellows programme aims to set systems in place to reduce supply interruptions, commodity losses and distribution costs in a number of developing countries

research and development, supply chain management and manufacturing

- Eight sustainable philanthropic programmes, including smoking cessation, prevention of malaria facility in Kenya, and long-standing single-drug donation programmes for trachoma and HIV/AIDS

### Suggested areas for improvement

- Ensure board-level ownership of access initiatives supported by senior management and a structured performance management system and improve stakeholder engagement
- Provide more information about lobbying and marketing practices and improve monitoring and enforcement measures of anti-corruption codes of conduct, and agree to sharing clinical trial data with generics manufacturers before patents expire
- Increase investments into in-house innovative research and development and be more transparent about use of contract

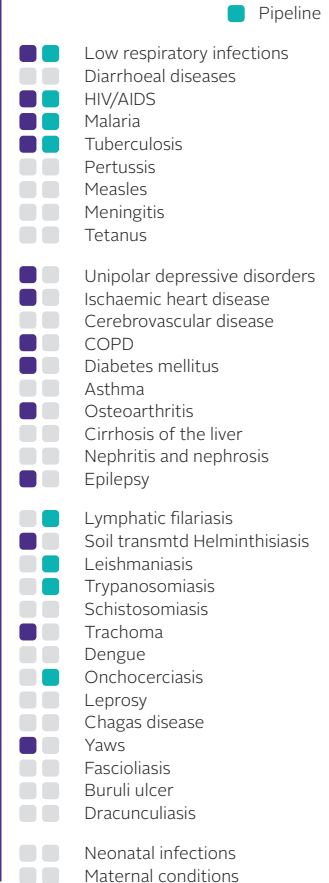
research organisations, clinical trial registrations and results

- Give more details about quality management, drug recall policies and procedures and the decision making process for product registration
- Be more transparent about position on TRIPS flexibilities, issue non-exclusive voluntary licences and participate in the Medicines Patent Pool
- Implement national pharmacovigilance programmes
- Provide details about the value of drug donations

### Revenue

	2010	2011
Overall (bn USD)	67.8	67.4
US	43%	40%
Developed Europe	24.4%	24.2%
Developed rest of the world	15.0%	16.4%
Emerging markets	17.6%	19.4%

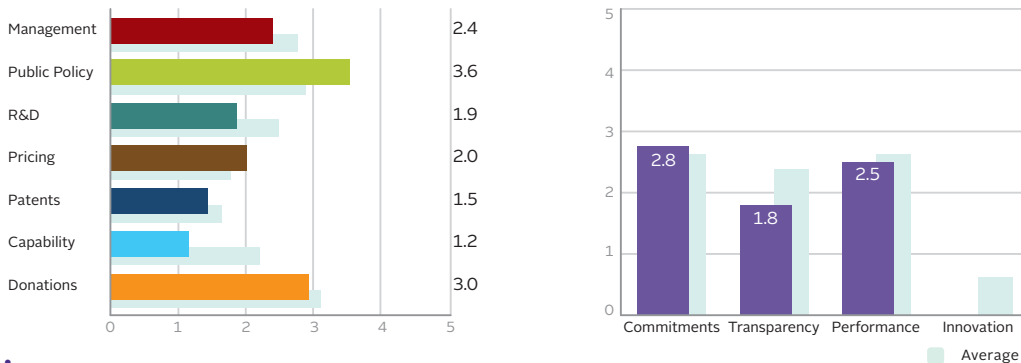
### Disease focus



# Bristol-Myers Squibb Co.

rank	score
12 <sup>▲</sup>	2.1
15 (2010)	

## Score



## Company overview

Bristol-Myers Squibb has risen by three places to 12<sup>th</sup> position in this year's Index. Its performance improved in various areas, including public policy and research & development, with new molecules in its pipeline as a result. However, performance in several areas, including patents and licencing, capability advancement and drug donation is average or below average compared to its peers. Tiered pricing schemes are in place but it is difficult to determine their impact

because the company does not disclose enough details to evaluate them. It is in active negotiations with the Medicines Patent Pool. The company's access to medicine focus is on HIV/AIDS and diabetes and is conducted mainly through its corporate philanthropy programme.

[A full company profile is available on \[www.accessstomedicineindex.org\]\(http://www.accessstomedicineindex.org\)](#)

### Leading practices

- Initiative with WHO through BMS Foundation to develop community-based care of tuberculosis, including HIV/AIDS co-infection, in five African countries
- HIV Global Access Programme in 60 countries, working in various partnerships, aiming to improve access to medicine for people with HIV/AIDS, particularly in Sub-Saharan Africa

### Notable findings

- Board-level oversight of access to medicine initiatives
- Explicit and enforced codes of conduct in ethical marketing and anti-corruption
- Patents not enforced for HIV/AIDS medicines in Sub-Saharan Africa
- Expanded research and development pipeline targeted at HIV/AIDS and diabetes
- Inter-country tiered pricing for seven of the company's 12 HIV/AIDS products in 65 of 77 relevant countries in which it operates
- Philanthropic programme providing care and support for communities affected by HIV/AIDS in Africa

### Suggested areas for improvement

- Introduce measurable targets for access to medicine initiatives in management system and a clear, structured reporting system
- Invest more into research and development of relevant diseases, increase number of partnerships conducive to access and provide more information about collaborations and licencing agreements
- Give details about which countries benefit from tiered pricing schemes, and the pricing reduction between tiers, as well as objectives, targets and milestones
- Provide more information about non-exclusive voluntary licences and approach to TRIPS flexibilities and commit to participate in the Medicines Patent Pool
- Build capability advancement in research and development, supply chain management and pharmacovigilance
- Introduce one or more single-drug donation programmes

### Revenue

	2010	2011
Overall (bn USD)	19.5	21.2
US	65%	65%
Europe	18%	17%
Emerging markets	4%	4%
Japan, Asia		
Pacific & Canada	8%	9%
Latin America, Africa and Middle East	4%	4%
Other	0.6%	0.4%

### Disease focus

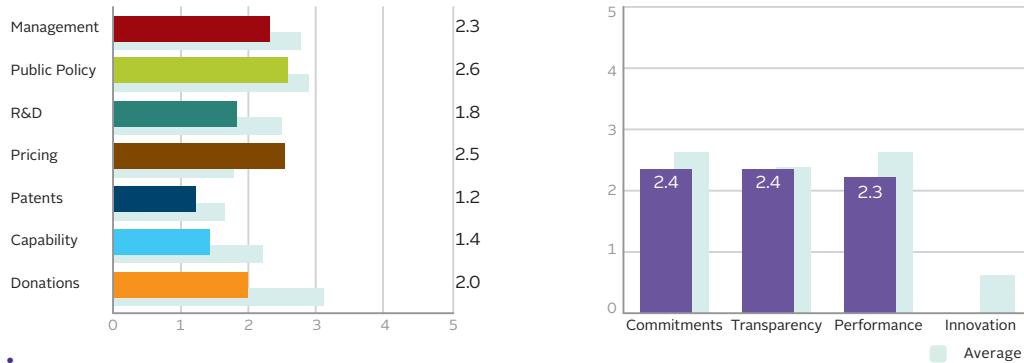
<span style="color: purple;">■</span>	Product
<span style="color: teal;">■</span>	Pipeline

- ■ Low respiratory infections
- ■ Diarrhoeal diseases
- ■ HIV/AIDS
- ■ Malaria
- ■ Tuberculosis
- ■ Pertussis
- ■ Measles
- ■ Meningitis
- ■ Tetanus
- ■ Unipolar depressive disorders
- ■ Ischaemic heart disease
- ■ Cerebrovascular disease
- ■ COPD
- ■ Diabetes mellitus
- ■ Asthma
- ■ Osteoarthritis
- ■ Cirrhosis of the liver
- ■ Nephritis and nephrosis
- ■ Epilepsy
- ■ Lymphatic filariasis
- ■ Soil transmtd Helminthiasis
- ■ Leishmaniasis
- ■ Trypanosomiasis
- ■ Schistosomiasis
- ■ Trachoma
- ■ Dengue
- ■ Onchocerciasis
- ■ Leprosy
- ■ Chagas disease
- ■ Yaws
- ■ Fascioliasis
- ■ Buruli ulcer
- ■ Dracunculiasis
- ■ Neonatal infections
- ■ Maternal conditions

rank score  
**13<sup>▼</sup> 2.0**  
 10 (2010)

# Abbott Laboratories Inc.

## Score



## Company overview

Abbott's fall by three places in this year's Index can be explained in part by the fact that it has not made advances in some of the areas that are considered vital for improving access to medicine. For example, it has not introduced non-exclusive voluntary licences, nor does it participate in the Medicines Patent Pool and it has no single-drug donation programmes. It has a tiered pricing scheme but that is limited to one of its HIV/AIDS medicines. It has a number of research and development collaborations and shares intellectual

property, but has no in-house innovative or adaptive research for relevant diseases. The company states that it favours market-based solutions for access challenges.

[A full company profile is available on www.accessmedicineindex.org](http://www.accessmedicineindex.org)

## Leading practices

- No leading practice identified for this company.

## Notable findings

- Acquired Solvay Pharmaceuticals and the Healthcare Solutions division of Piramal Healthcare Ltd., as part of expansion into emerging markets with branded generics
- Increased number of research and development partnerships, working with Drugs for Neglected Diseases initiative, Medicines for Malaria Venture and the TB Alliance, and engages in intellectual property sharing
- Tiered pricing strategy in place for HIV/AIDS medicine Aluvia in a large number of countries
- Increased number of capacity-building programmes related to research and development, including a diagnostic and treatment service in Western Kenya and a public-private partnership with the Tanzanian government to address healthcare needs in the country

## Suggested areas for improvement

- Strengthen board-level visibility and management of access to medicine, and broaden the base of staff to be measured and incentivised
- Be more transparent about lobbying and public policy position, and share clinical trial data with generics manufacturers before patents expire
- Introduce in-house innovative and adaptive research and development, giving details about related investments and partnerships and the use of contract research organisations in clinical trials
- Extend tiered pricing scheme to more products in portfolio
- Issue non-exclusive voluntary licences, participate in the Medicines Patent Pool and build on improvements in transparency around TRIPS
- Improve capability advancement in manufacturing, quality management standards, supply chains and pharmacovigilance
- Implement one or more relevant single-drug donation programmes

## Revenue

	2010	2011
Overall (bn USD)	35.2	38.9
US	49.1%	47.0%
Japan	4.2%	5.2%
Germany	4.7%	4.8%
The Netherlands	5.9%	5.9%
Italy	3.7%	3.8%
Canada	3.1%	2.9%
France	3.3%	3.1%
Spain	3.1%	3.2%
United Kingdom	2.5%	2.5%
Other	20.4%	21.6%

## Disease focus

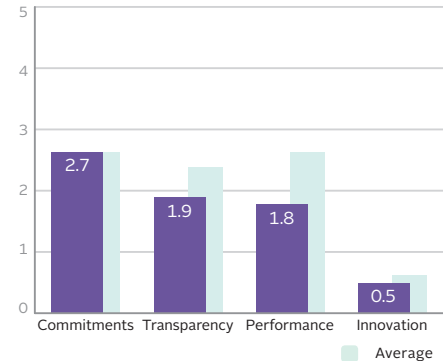
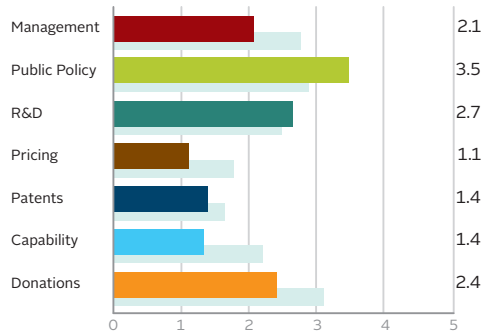
Legend: ■ Product, ■ Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
- Cerebrovascular disease
- COPD
- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmtd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

# Eli Lilly & Co.

rank	score
14 <sup>▼</sup>	2.0
13 (2010)	

## Score



## Company overview

Eli Lilly has fallen one place in the Index this year to 14<sup>th</sup> position. While it has made some advances in its approach to access to medicine, it has not progressed as far as peers in most activities. The company does not provide full details about access initiatives. It has not issued any non-exclusive voluntary licences, and does not explicitly support TRIPS

flexibilities. However, it has made improvements in general management, in research and development, particularly regarding intellectual property sharing, in public policy, where it discloses more information, and it has single-drug donation programmes.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Open Drug Discovery programme makes the company's drug discovery and development process accessible to researchers who can register their research molecules online
- Developed a more sustainable business focus for its access strategies by evolving an emerging markets business unit comprised of more than 70 countries, the majority of which are relevant countries
- USD 30 million invested into a non-communicable diseases healthcare infrastructure partnership to research new comprehensive approaches to treatment

### Notable findings

- Improved governance and management structure to support access to medicine approach, including extensive stakeholder engagement
- Comprehensive disclosure of US and European advocacy and lobbying activity
- Codes of conduct in place to ensure ethical marketing and anti-corruption practices
- Conducts research on relevant diseases, such as diabetes and unipolar depressive disorder, and provides evidence of one adaptive molecule for unipolar depressive disorder
- Three instances of intellectual property sharing for research into drugs for tuberculosis and malaria
- Inter- and intra-country tiered pricing for insulin
- States that it has single-drug donation programme for tuberculosis and diabetes

### Suggested areas for improvement

- Implement specific performance management system and incentive structure, provide more information about stakeholder engagement outcomes
- Be more transparent about marketing and promotional activities and competition-related policies, including which countries and which specific clinical trial data is shared with generics manufacturers before patent expiry
- Increase number of research and development partnerships for relevant diseases
- Expand scale and scope of tiered pricing programme to other products in portfolio and provide information about price reduction between tiers
- Disclose policy position regarding TRIPS and the Doha Declaration, issue non-exclusive voluntary licences
- Introduce capability advancement directed at research and development, supply chain management and pharmacovigilance
- Provide more information about single-drug donation programmes

### Revenue

	2010	2011
Overall (bn USD)	23.6	24.3
US	56%	53%
Europe	22%	22%
Japan	7%	9%
Other foreign countries	15%	16%

### Disease focus

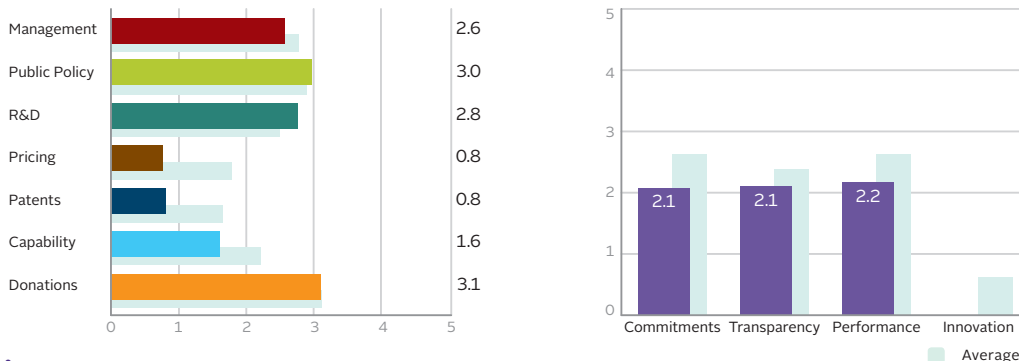
<span style="color: purple;">■</span>	Product
<span style="color: teal;">■</span>	Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
- Cerebrovascular disease
- COPD
- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

rank	score
15 <sup>▲</sup>	1.9
16 (2010)	

# Eisai Co. Ltd.

## Score



## Company overview

Eisai has risen by one place since the 2010 Index. It has made progress in various areas, including access to medicine management, drug donations, philanthropy, research and development collaborations and intellectual property sharing. Despite Eisai's small size, its efforts to implement some access initiatives are on a par with those of larger companies.

However, even though the company has made steps to improve its access approach, it has been outperformed by peers. It has not introduced relevant tiered pricing or non-exclusive voluntary licences.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- No leading practice identified for this company.

### Notable findings

- Improved in all aspects of access to medicine management, including dedicated board-level oversight, monitoring of initiatives and relevant stakeholder engagement
- Shares relevant clinical trial data with generics manufacturers before patent expiry in Least Developed Countries, although previously offered this in all relevant countries except Bangladesh
- Monitored codes of conduct in place for lobbying, ethical marketing, anti-bribery and anti-corruption
- Increased focus on relevant innovative and adaptive research and development, collaborations and evidence of three instances of intellectual property sharing for neglected tropical diseases
- Affordable pricing programmes for epilepsy and unipolar depressive disorder products in India
- Globally implements quality management standards in line with WHO Good Manufacturing Practices
- Committed to a single-drug donation programme with WHO for lymphatic filiarisis, beginning in 2013

### Suggested areas for improvement

- Provide more information about annual targets and performance monitoring for access initiatives
- Give more details about lobbying and marketing practices and scale and scope of enforcement systems
- Establish research and development collaborations using socially responsible licencing agreements
- Apply principals of current tiered pricing programme for breast cancer drug to products for diseases relevant to the Index
- Issue non-exclusive voluntary licences, give more information about patent and product registration status
- Develop and expand capability advancement for quality management systems and supply chain management, and improve pharmacovigilance efforts

### Revenue

	2010	2011
Overall (bn USD)	7.9	8.1
Japan	47.8%	60.1%
US	40.5%	25.4%
Europe	7.1%	8.7%
Others (Asia, Latin America)	4.6%	5.8%

### Disease focus

Legend: ■ Product, ■ Pipeline

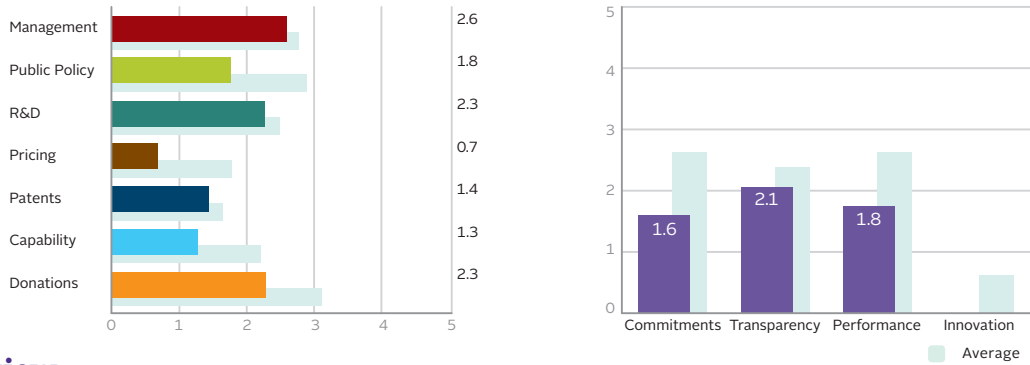
- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
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- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions



# AstraZeneca plc

rank	score
16 <sup>v</sup>	1.6
7 (2010)	

## Score



## Company overview

AstraZeneca's decline in the Index from 7<sup>th</sup> to 16<sup>th</sup> place is largely due to the fact that it has not made many advances in its access to medicine approach since 2010. It is not engaged in important access activities such as non-exclusive voluntary licences, relevant single-drug donation and tiered pricing. Furthermore, it maintains a stance on intellectual prop-

erty that is not considered conducive to access. Its research and development portfolio is limited, with no new relevant investments or initiatives since 2010. Compared to its peers, AstraZeneca performs below average in patents and licencing, equitable pricing and capability advancement.

A full company profile is available on [www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- AstraZeneca remains invested in several long-term health infrastructure projects in relevant countries, including three key programmes with AMREF, British Red Cross, Red Crescent and Plan International

### Notable findings

- Senior management involvement in access to medicine initiatives and regular engagement with stakeholders
- Expanded operations in developing countries - establishment of manufacturing plants in China and Algeria
- Enforces policies to ensure ethical marketing practices upheld by employees and third parties
- Carries out in-house research focussed on several diseases covered by the Index, including tuberculosis and COPD
- More activities focussed on building research capacity: support to Peking University for a Clinical Pharmacology Unit, participation in the More Medicines for Tuberculosis consortium, and participation in the Medicines for Malaria Venture
- New philanthropic programme which aims to support improved health and lifestyle choices for adolescents in India and Zambia

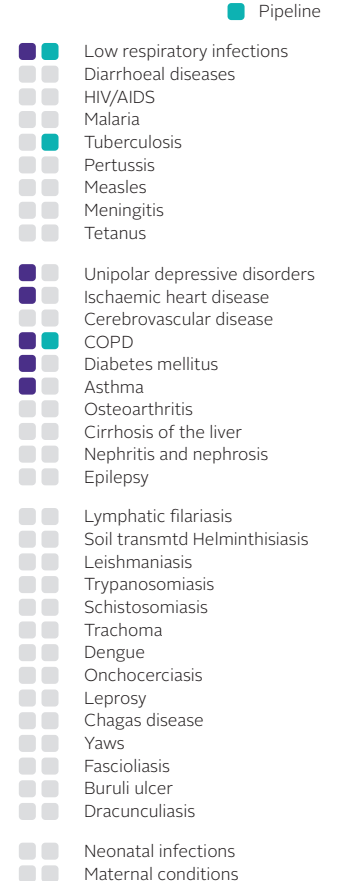
### Suggested areas for improvement

- Implement an incentive structure to reward access-oriented initiatives
- Provide more information about lobbying and share clinical trial data with generics manufacturers before patents expire
- Invest more into relevant research and development, increase number of relevant partnerships and be more transparent about the licencing details of collaborations
- Introduce tiered pricing programmes
- Adopt a more pro-access approach to intellectual property by issuing non-exclusive voluntary licences and supporting TRIPS flexibilities
- Increase capability advancement across the board, particularly in pharmacovigilance
- Build on existing single-drug donation programme for breast cancer, which is not a disease covered by the Index, by introducing more programmes for relevant diseases

### Revenue

	2010	2011
Overall (bn USD)	33.3	33.6
UK	3.1%	2.6%
Rest of Europe	28.0%	26.5%
Americas	50.0%	49.1%
Asia, Africa & Australasia	18.9%	21.8%

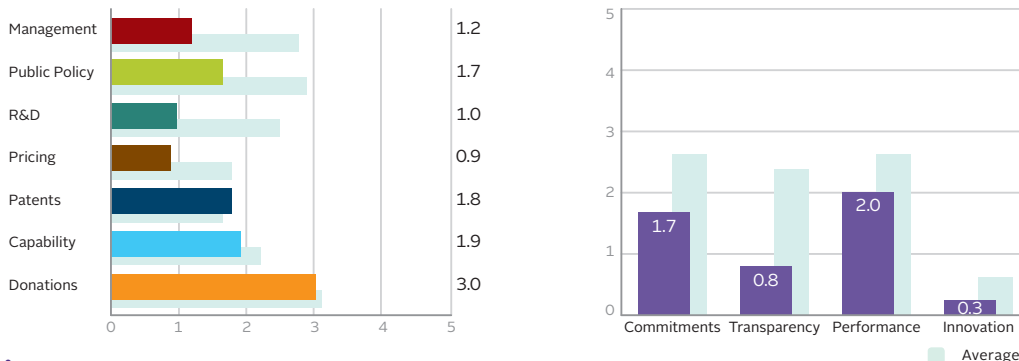
### Disease focus



rank	score
<b>17<sup>v</sup></b>	<b>1.5</b>
12 (2010)	

# Boehringer-Ingelheim

## Score



## Company overview

Boehringer-Ingelheim is a privately held company and discloses little information to the Index about much of its access to medicine activity. This has a significant effect on its ranking in the Index this year, and it drops five places to 17<sup>th</sup>. The company focusses its access initiatives on HIV/AIDS with tiered pricing, an access-oriented approach to patents and licencing and philanthropic initiatives for this disease. It has

added more relevant diseases to its research and development pipeline since 2010. It is in active negotiations with the Medicines Patent Pool. Overall however, it fares poorly against more stringent scoring measures and the fact that other companies are more transparent about their activities.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Diverse access initiatives for its antiretrovirals, such as non-assert declarations and tiered pricing programmes, with a not-for-profit price in Least Developed Countries and a reduced price in middle income countries
- Sustainable health programme, Making More Health, launched in collaboration with the Ashoka Foundation - an India-based non-governmental organisation - to support social entrepreneurs to advance sustainable health solutions across developing countries

### Notable findings

- Expanded research and development pipeline for relevant diseases such as asthma, cerebrovascular disease, diabetes mellitus and malaria
- Inter-country tiered pricing for antiretrovirals in 56 out of the 58 countries in which the company operates
- Refrains from asserting rights over a larger number of patents (up from 6 to 14) for antiretroviral medication and respects TRIPS flexibilities

### Suggested areas for improvement

- Implement robust performance management system to support access to medicine approach and set and disclose tangible targets and provide more information about resources invested, progress and outcomes of access initiatives
- Widen scope of access initiatives beyond HIV/AIDS to other disease areas
- Give greater detail about practices in lobbying and marketing, commit to enforced codes of conduct for ethical marketing and anti-corruption
- Increase number of innovative and adaptive research and development molecules for communicable diseases and establish collaborations that are conducive to access
- Provide more information about equitable pricing practices
- Commit to participating in the Medicines Patent Pool
- Introduce capability advancement programmes relevant to product development and distribution, and improve pharmacovigilance efforts

### Revenue

	2010	2011
Overall (bn USD)	15.5	16.2
Europe	32%	31%
Americas	45%	46%
Asia, Australasia and Africa	23%	23%

### Disease focus

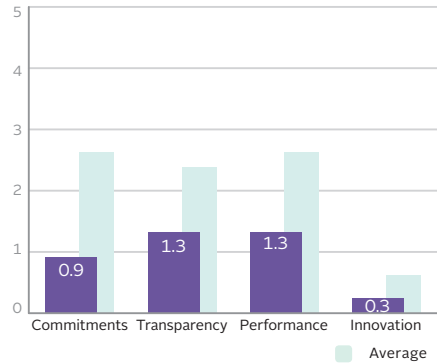
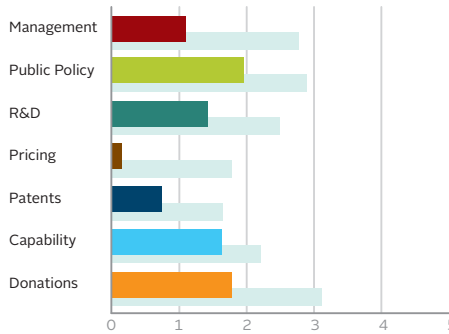
Legend: ■ Product, ■ Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
- Cerebrovascular disease
- COPD
- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

# Takeda Pharmaceutical Co.

rank	score
<b>18</b>	<b>1.1</b>
18 (2010)	

## Score



## Company overview

Takeda remains in 18<sup>th</sup> position in this year's Index because it has a nascent and primarily philanthropic approach to access to medicine initiatives. It has made some improvements in its research and development pipeline and its philanthropic activity and, with the acquisition of a generics manufacturer, operates in a larger number of relevant countries. However, the company does not have dedicated management for access issues, does not collaborate on research and develop-

ment or share intellectual property, has not implemented tiered pricing schemes, does not have a pro-access approach to patents and licencing, makes little effort to improve capability advancement and has no single-drug donation programmes.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- Endowment programme with Global Fund to Fight AIDS, Tuberculosis and Malaria which aims to support and strengthen the capacity of healthcare workers in Nigeria, Senegal and Tanzania

### Notable findings

- Acquired generics manufacturer Nycomed, increasing its presence in relevant markets, and expanded its vaccine division including work on a polio virus vaccine
- Increased share of research and development pipeline for relevant diseases, added two new molecules for unipolar depressive disorder; adaptive research to look at the effects of tropical climates on its products
- Improved anti-counterfeiting programme
- Greater focus on philanthropic activities aligned with Millenium Development Goals including improving child health and prevention of HIV/AIDS

### Suggested areas for improvement

- Incorporate access initiatives into business model with board-level responsibility, measurable targets, and performance management system, and improve stakeholder engagement
- Be more transparent about lobbying and marketing practices, share clinical trial data with gener-

- ics manufacturers before patents expire and commit to fight bribery and corruption
- Initiate collaborative research and development relationships and commit to share intellectual property
- Introduce tiered pricing programmes, monitor third party pricing practices and be more transparent about product registration status
- Issue non-exclusive voluntary licences. Provide more information about attitude towards TRIPS flexibilities and the Doha declaration and product patent status in Least Developed Countries
- Work with local organisations to improve capability advancement in research and development and pharmacovigilance
- Introduce one or more single-drug donation programmes

### Revenue

	2010	2011
Overall (bn USD)	17.1	18.4
Japan	50.8%	48.6%
Americas (incl. US and Latin America)	35.0%	30.8%
Europe	12.2%	17.5%
Asia	2.0%	3.2%

### Disease focus

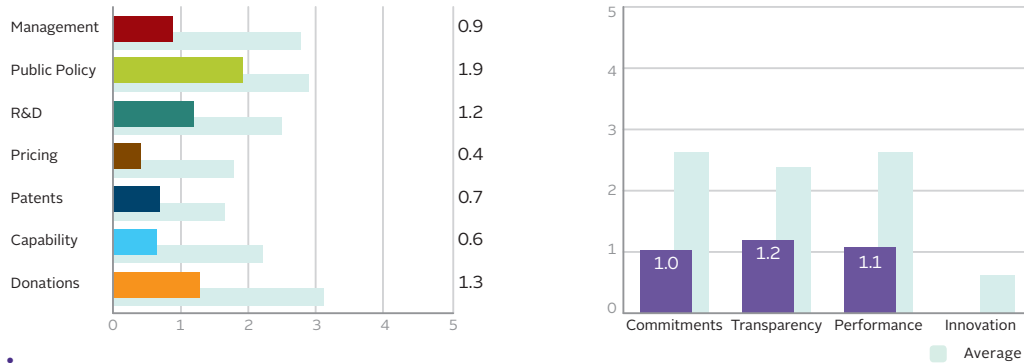
Legend: ■ Product, ■ Pipeline

- Low respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Tuberculosis
- Pertussis
- Measles
- Meningitis
- Tetanus
- Unipolar depressive disorders
- Ischaemic heart disease
- Cerebrovascular disease
- COPD
- Diabetes mellitus
- Asthma
- Osteoarthritis
- Cirrhosis of the liver
- Nephritis and nephrosis
- Epilepsy
- Lymphatic filariasis
- Soil transmtd Helminthiasis
- Leishmaniasis
- Trypanosomiasis
- Schistosomiasis
- Trachoma
- Dengue
- Onchocerciasis
- Leprosy
- Chagas disease
- Yaws
- Fascioliasis
- Buruli ulcer
- Dracunculiasis
- Neonatal infections
- Maternal conditions

rank score  
**19<sup>▲</sup> 0.9**  
 20 (2010)

# Daiichi Sankyo Co. Ltd.

## Score



## Company overview

Daiichi Sankyo has risen one place in the Index this year to 19<sup>th</sup> position. Most of the company's access to medicine activity is centred on product donation and philanthropy, with a focus on maternal and child health. It has added new products in its research and development portfolio. It does not disclose information about much of its access activity

and, while it has introduced equitable pricing programmes for some of its products, it has released very few details about them.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

### Leading practices

- No leading practice identified for this company.

### Notable findings

- Acquisition of Ranbaxy, a generics manufacturer with a view to incorporating access programmes into a hybrid business model
- New commitment to develop drugs for communicable and inflammatory diseases
- Improved product portfolio, adding products for six relevant disease areas: nephritis, cirrhosis of the liver, meningitis, ischaemic heart disease, trachoma and maternal health conditions
- Implementation of inter- and intra-country tiered pricing programmes: inter-country tiered pricing for four of 17 relevant products and intra-country tiered pricing for nine out of its 17 relevant products
- Philanthropic initiatives in India, Cameroon and Tanzania focussing on maternal and child health

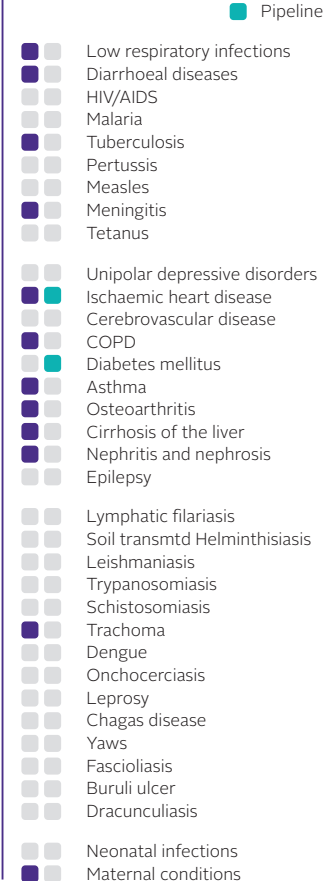
### Suggested areas for improvement

- Develop access to medicine strategy and install dedicated management system
- Be more transparent about lobbying and marketing practices, enforce codes of conduct and anti-corruption standards and share data clinical trial data with generics manufacturers before patents expire
- Increase number of relevant research and development partnerships and give more information about contract partners for clinical trials
- Disclose more information about tiered pricing programmes
- Issue non-exclusive voluntary licences, commit to respect TRIPS flexibilities and reveal more information about patent and product registration status
- Introduce capacity-building programmes and increase pharmacovigilance efforts
- Introduce one or more single-drug donation programmes

### Revenue

	2010	2011
Overall (bn USD)	12.2	11.8
Japan	65.0%	64.2%
North America	23.2%	23.2%
Europe	8.4%	8.8%
Other regions	3.4%	3.8%

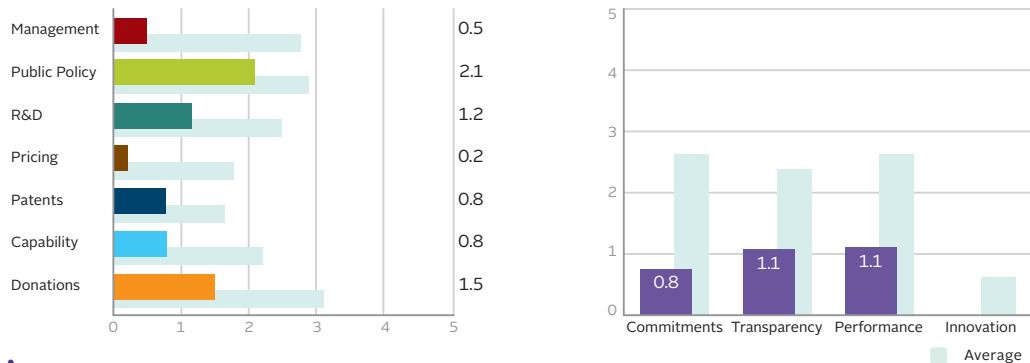
### Disease focus



# Astellas Pharma Inc.

rank	score
<b>20<sup>v</sup></b>	<b>0.9</b>
19 (2010)	

## Score



## Company overview

Astellas has fallen one place in the Index this year to 20<sup>th</sup> position. The company focusses on diseases not covered by the Index, and its access to medicine activity is mainly centred on product donation and philanthropy. It is not involved in non-exclusive voluntary licencing or tiered pricing and does not fully support TRIPS flexibilities, all of which are key

measures in the Index. In addition, it does not have a management structure dedicated to access initiatives, and discloses little information about its lobbying and marketing activities. However, it has made small steps towards improving investments in relevant research and development.

[A full company profile is available on www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)

## Leading practices

- No leading practice identified for this company.

## Notable Findings

- New research and development collaboration with Drugs for Neglected Diseases initiative for three neglected tropical diseases; and a public-private partnership with TI Pharma, Merck KGaA and the Swiss TPH to develop paediatric form of Praziquantel to treat schistosomiasis
- Does not file patents in Least Developed Countries for three of its four relevant drugs
- Contributes to the WHO Research and Training in Tropical Diseases fellowship programme, supports local drug discovery research in Malaysia
- Donated 15,000 mosquito nets in Tanzania and birth centres in Indonesia; has various programmes to improve maternal health, infant mortality rates, and to fight HIV/AIDS, malaria and other diseases

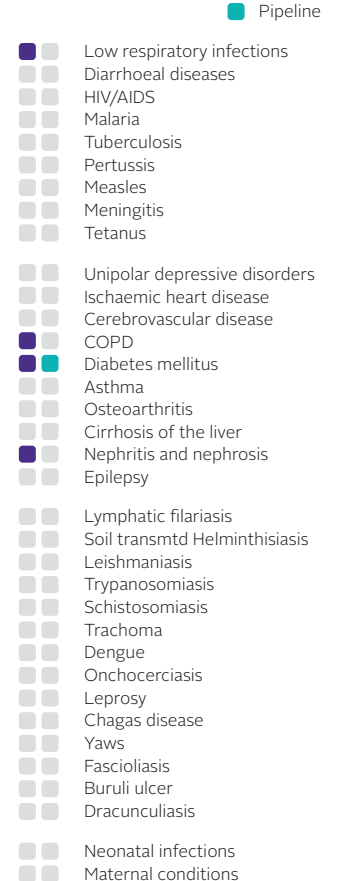
## Suggested areas for improvement

- Ensure executive management of access initiatives, supported by targets and performance management practices, and improve stakeholder engagement
- Give more information about lobbying and marketing activities and share clinical trial data with generics manufacturers before patents expire
- Dedicate greater share of pipeline to innovative research and development and engage in intellectual property sharing
- Introduce relevant tiered pricing programmes
- Issue non-exclusive voluntary licences and refrain from asserting patent rights for any relevant drug in Least Developed Countries, and commit to fully supporting TRIPS flexibilities
- Improve capability advancement in supply chain management and in pharmacovigilance
- Implement one or more single-drug donation programmes

## Revenue

	2010	2011
Overall (bn USD)	11.9	11.8
Japan	57.0%	57.6%
Americas	19.6%	18.9%
Europe	19.9%	19.8%
Asia a.o. regions	3.5%	3.7%

## Disease focus





# Appendix

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## **Methodology Report 2012**

### **Stakeholder Review - May 2012**

The Methodology Report 2012 is a separate, comprehensive report detailing what and how we measure. It details the review and refinement of the indicators, a process which involved a thorough technical feedback process. In this appendix, the essential components are provided.

## Methodology Scopes

### 1 Company Scope

Index 2012 covers the same 20 originator companies included in Index 2010. Selection of the companies is based on market capitalisation, including only pharmaceutical operations, and the relevance of product portfolios to the Index Diseases (as defined by 'Disease Scope'). One unlisted company, Boehringer Ingelheim, is still included since it meets the size and portfolio relevance criteria used by the Index team in company selection. Maintaining the 2010 list of originator companies covered by the Index will enable comparability and trend analyses over time.

Generic companies were not captured in the Index 2012, following stakeholder feedback consultations in 2011. The Access to Medicine Foundation is conducting additional research to determine if and how the generic business model should be included and ranked.

Table 1 **Index Company Scope**

	Ticker	Company	Country	Market Cap*
1	JNJ-N	Johnson & Johnson	USA	179.09
2	PFE-N	Pfizer Inc.	USA	166.35
3	NOVN-VX	Novartis AG	CHE	137.73
4	ROG-VX	Roche Holdings Ltd.	USA	117.13
5	MRK-N	Merck & Co. Inc.	USA	114.91
6	GSK-LN	GlaxoSmithKline plc	GBR	113.53
7	SAN-FR	Sanofi	FRA	98.99
8	ABT-N	Abbott Laboratories Inc.	USA	87.53
9	NOVO'B-KO	Novo Nordisk A/S	DNK	64.29
10	AZN-LN	AstraZeneca plc	GBR	61.44
11	BMJ-N	Bristol-Myers Squibb Co.	USA	59.72
12	BAY-FF	Bayer AG	DEU	52.98
13	LLY-N	Eli Lilly & Co.	USA	48.11
14	4502-TO	Takeda Pharmaceutical Co.	JPN	34.55
15	GILD-O	Gilead Sciences	USA	30.74
16	MRK-FF	Merck KGaA	DEU	21.72
17	4503-TO	Astellas Pharma Inc.	JPN	18.72
18	4568-TO	Daiichi Sankyo Co. Ltd.	JPN	13.91
19	4523-TO	Eisai Co. Ltd.	JPN	11.75
20	Not Publicly Listed	Boehringer-Ingelheim	Not Publicly Listed	

\* Market Cap as of December 31<sup>st</sup>, 2011 (billion USD)



## 2 Geographical Scope

Index 2012 focusses on the Low-income and Lower-middle-income Countries (LIC and LMICs) based on World Bank classifications. The World Bank classification is a widely used economic ranking. To capture certain exceptional countries that show high inequality within the country, the HDI is used in addition to the World Bank classifications. These coun-

tries are considered more economically advanced overall by the World Bank, but show wide disparities in human development and well-being (according to the HDI 2011).

Table 2 Index Countries

Country	Classification	Country	Classification	Country	Classification
<b>East Asia &amp; Pacific</b>		<b>Middle East &amp; North Africa</b>		Madagascar	LIC
Cambodia	LIC	Algeria	MHDC	Malawi	LIC
China	MHDC	Djibouti	LMIC	Mali	LIC
Fiji	LMIC	Egypt, Arab Rep.	LMIC	Mauritania	LMIC
Indonesia	LMIC	Iraq	LMIC	Mozambique	LIC
Kiribati	LMIC	Jordan	MHDC	Namibia	MHDC
Korea, Dem. Rep.	LIC	Morocco	LMIC	Niger	LIC
Lao PDR	LMIC	Syrian Arab Rep.	LMIC	Nigeria	LMIC
Marshall Islands	LMIC	West Bank and Gaza	LMIC	Rwanda	LIC
Micronesia, Fed. Sts.	LMIC	Yemen, Rep.	LMIC	São Tomé and Príncipe	LMIC
Mongolia	LMIC			Senegal	LMIC
Myanmar	LIC	<b>South Asia</b>		Sierra Leone	LIC
Papua New Guinea	LMIC	Afghanistan	LIC	Somalia	LIC
Philippines	LMIC	Bangladesh	LIC	South Africa	MHDC
Samoa	LMIC	Bhutan	LMIC	Sudan	LMIC
Solomon Islands	LMIC	India	LMIC	Swaziland	LMIC
Thailand	MHDC	Maldives	MHDC	Tanzania	LIC
Timor-Leste	LMIC	Nepal	LIC	Togo	LIC
Tonga	LMIC	Pakistan	LMIC	Uganda	LIC
Tuvalu	LMIC	Sri Lanka	LMIC	Zambia	LMIC
Vanuatu	LMIC			Zimbabwe	LIC
Vietnam	LMIC	<b>Sub-Saharan Africa</b>			
		Angola	LMIC	<b>Countries included in Index 2010, excluded in Index 2012</b>	
<b>Europe &amp; Central Asia</b>		Benin	LIC	Tunesia	
Armenia	LMIC	Botswana	MHDC	Azerbaijan	
Georgia	LMIC	Burkina Faso	LIC	Iran	
Kosovo	LMIC	Burundi	LIC	LIC: Low-income Country	
Kyrgyz Rep.	LIC	Cameroon	LMIC	World Bank income	
Moldova	LMIC	Cape Verde	LMIC	classification	
Tajikistan	LIC	Central African Rep.	LIC	LMIC: Lower-middle-income	
Turkmenistan	LMIC	Chad	LIC	Country World Bank	
Ukraine	LMIC	Comoros	LIC	income classification	
Uzbekistan	LMIC	Congo, Dem. Rep.	LIC	MHDC: Medium Human Develop-	
		Congo, Rep.	LMIC	ment Country UN Human	
<b>Latin America &amp; Caribbean</b>		Côte d'Ivoire	LMIC	Development Index	
Belize	LMIC	Equatorial Guinea	High Income		
Bolivia	LMIC	Eritrea	LIC	<b>18 New countries</b>	
Dominican Rep.	MHDC	Ethiopia	LIC	3 Countries out of the scope	
El Salvador	LMIC	Gabon	MHDC		
Guatemala	LMIC	Gambia, The	LIC		
Guyana	LMIC	Ghana	LMIC		
Haiti	LIC	Guinea	LIC		
Honduras	LMIC	Guinea-Bissau	LIC		
Nicaragua	LMIC	Kenya	LIC		
Paraguay	LMIC	Lesotho	LMIC		
Suriname	MHDC	Liberia	LIC		

### 3 Disease Scope

The Priority Diseases covered by the Index 2012 are largely consistent with the Index 2010. To ensure the best possible comparability between pharmaceutical companies, discounted, non age-weighted WHO DALY data are used. In total, 10 communicable diseases, 10 non-communicable diseases, 14 neglected tropical

diseases, are included based on their DALY ranking. A new category was added to the scope that includes maternal health and neonatal infections. They form a significant global health concern, which is reflected in the Millennium Development Goals.

Table 3 **Index Disease Scope**

Communicable Diseases		Non-Communicable Diseases		Neglected Tropical Diseases	
Low respiratory infections	93.383	Unipolar depressive disorders	45.873	Lymphatic filariasis	6.361
Diarrhoeal diseases	72.627	Ischaemic heart disease	41.469	Soil transmitted Helminthiasis (Intestinal nematode infections)	4.045
HIV/AIDS	60.505	Cerebrovascular disease	34.147	Leishmaniasis	1.960
Malaria	37.625	Chronic obstructive pulmonary disorder	24.138	Trypanosomiasis	1.743
Tuberculosis	33.145	Diabetes mellitus	12.866	Schistosomiasis	1.628
Pertussis	31.693	Asthma	12.503	Trachoma	1.306
Measles	15.914	Osteoarthritis	10.304	Dengue	638
Meningitis	11.366	Cirrhosis of the liver	9.204	Onchocerciasis	480
Lymphatic filariasis	6.361	Nephritis and nephrosis	7.655	Leprosy	180
Tetanus	5.406	Epilepsy	6.428	Chagas disease	88
				Yaws*	–
				Fascioliasis*	–
				Buruli ulcer*	–
				Dracunculiasis* (Guinea worm)	–
<b>Maternal Health and Neonatal Infections</b>					
Neonatal infections and other conditions		212.380			
Maternal conditions		39.216			

\* Neglected Tropical Diseases as classified by WHO, but for which have not been captured in the GDB Report 2008.

### 4 Product Type Scope

The product type scope for Index 2012 is necessarily broad to capture the wide-ranging product types available to support prevention, diagnosis and treatment of Index Diseases in the Index Countries. Drawing closely from the definitions provided by the G-Finder 2011 Summary of R&D (Annex 1), the scope is as follows, as in 2010:

#### Medicines

All medicines used to treat directly the target pathogen or diseases process regardless of formulation. Those medicines used only for symptomatic relief are not included.

#### Therapeutic vaccines

Investigational vaccines specifically intended to treat infection.

#### Preventive vaccines

Investigational vaccines specifically intended to prevent infection; including vaccine design, preclinical and clinical development and other activities essential for successful vaccine development and uptake.

#### Diagnostics

Diagnostic tests for use in resource-limited settings (cheaper, faster, more reliable, ease of use in the field).

#### Microbicides

Topical microbicides specifically intended to prevent HIV.

#### Vector control products

- *Pesticides*  
Only includes chemical pesticides intended for global public health use and which specifically aim to inhibit and kill vectors associated with transmitting relevant Index Diseases.
- *Biological control products*  
Only includes research and development of innovative biological control interventions that specifically aim to kill or control vectors associated with transmitting relevant Index Diseases.
- *Vaccines targeting animal reservoirs*  
Only includes research and development of veterinary vaccines specifically designed to prevent animal to human transmission of neglected diseases.

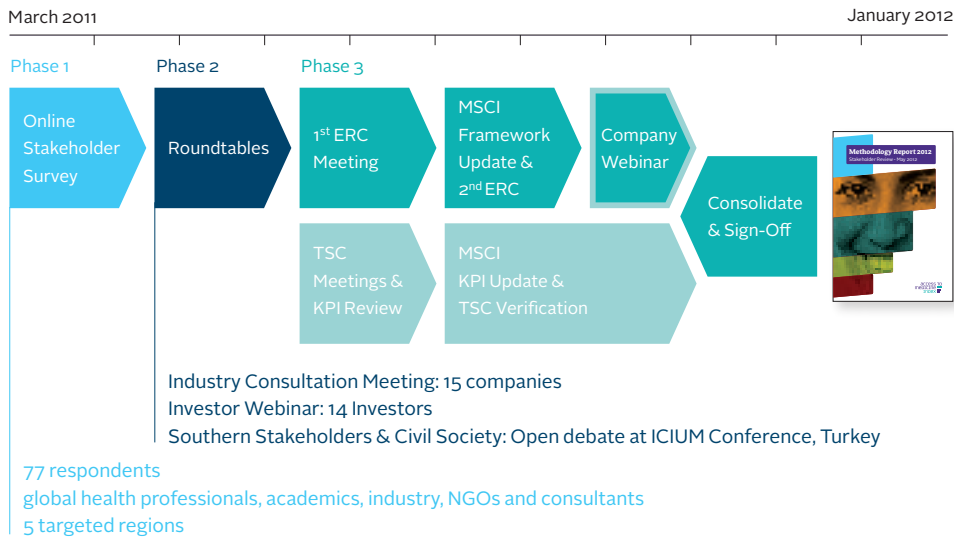
#### Platform technologies

- Adjuvants and immunomodulators
- Delivery technologies and devices
- General diagnostic platforms

Note: This category has strict limitations which aim to identify only those R&D activities directed specifically at ID's or to meet IC-needs. Further details of how this is determined can be found in the G-Finder Report 2011.

# Stakeholder Engagement 2012

Figure 23 Stakeholder Engagement : Process of Input



### Stakeholder Consultation

The 2012 methodology was developed vis-à-vis a multi-stakeholder approach, which guided refinements and enhancements to the 2010 Index methodology. The goals of the stakeholder engagement process were three-fold:

- to adjust the methodology to reflect changing global health care priorities,
- to refine and improve the methodology based on lessons learned from past Indices and
- to evaluate company policies and performance to better reflect the access to medicine realities on the ground.

This approach included three phases of consultations. The **online stakeholder survey** represented the launch of external feedback. This detailed online questionnaire survey was publicly available and brought in the feedback from diverse stakeholder groups, including global health professionals, academics, industry, NGOs, and consultants. The second phase involved high level consultations with several **stakeholder groups**, including industry, investors, southern stakeholders and civil society. The third phase encompassed a **methodology review process** guided by political and technical representation that was separated into the Expert Review Committee (ERC) and the Technical Subcommittees (TSC).

### The Expert Review Committee

The Expert Review Committee (ERC) is made up of individuals from a variety of stakeholder groups, all active in some capacity on the access to medicines agenda. The committee has reviewed the methodology for Index 2012 on two separate occasions in July and October 2011, ensuring verification of the outputs from the Technical Subcommittee (TSC) process.

Convened in 2009, the mandate of the ERC is purely advisory in nature, with the objective of providing strategic guidance, recommendations and advice to the Access to Medicine Index team on the scope, structure, content and methodology of the third Access to Medicine Index assessment. The ERC members' involvement is intended to ensure different viewpoints are taken into consideration in establishing the latest Access to Medicine Index methodology, and is intended to further build on the preceding consultation exercises that have taken place.

Table 4 Expert Review Committee

Chair	Sophia Tickell, Meteos
Government	Charles Clift, Centre on Global Health Security at Chatham House
Multi-lateral Organisations	Richard Laing, World Health Organization
Investors	My-Linh Ngo, Henderson Global Investors
Industry	Eduardo Pisani, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
NGOs	Tim Reed, Health Action International (HAI)
Academia	Dennis Ross-Degnan, Harvard Medical School
Government	Sakthivel Selvaraj, Public Health Foundation of India
Generics Industry	Dilip Shah, International Generic Pharmaceutical Alliance (IGPA)

### Technical Subcommittees

The Technical Subcommittee process was a new addition in 2012, leveraging the expertise of global health professionals, academics and consultants representing Technical Area expertise. The TSC members were consulted individually and as a group addressing key indicators across the Technical Areas of the Access to Medicine Index. They provided detailed feedback on the Index 2012 indicator refinement process, taking the methodology to a new level of precision and refinement of our key performance

indicators. An overview of the outcomes of the TSC process is provided in Methodology Report 2012.

Note: Government representatives, academics and global health organisations have been indicated as the stakeholders groups that were comparatively underrepresented in the online survey. The Technical Subcommittee review is a key highlight of academic and civil society consultation that has greatly improved the Index 2012 methodology refinement process.

**Table 5 Technical Subcommittee Contributors**

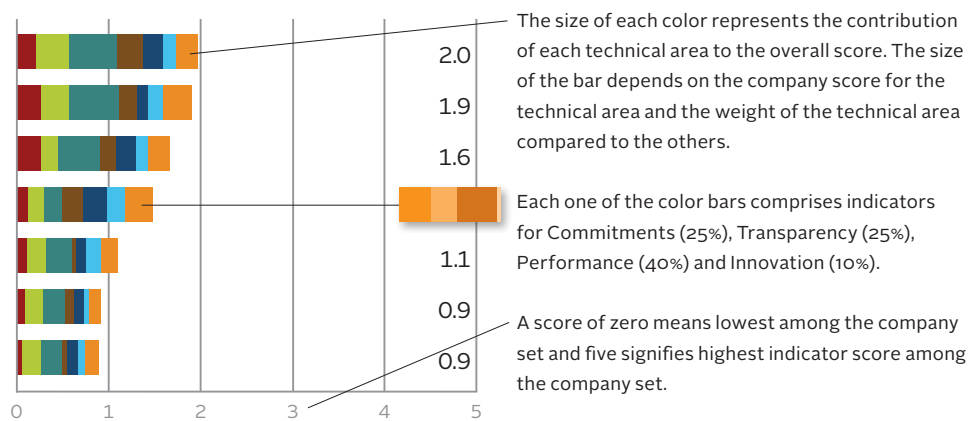
Pricing, manufacturing and distribution	Margaret Ewen, Health Action International, Netherlands Alan Staple, Clinton Health Action Initiative, USA Prashant Yadav, University of Michigan, USA
Intellectual property and competition	Kevin Outterson, University of Boston, USA Chan Park, Medicine Patent Pool, USA Warren Kaplan, University of Boston, USA Peter Beyer, World Health Organization, Switzerland
Research and development	Dr. Javier Guzman, Policy Cures, UK Dr. Paul Wilson, Columbia University, USA
Promotions, marketing and anti-corruption	Michelle Forzley, Global Public Health Attorney, USA John Chalker, Management Sciences for Health Center for Pharmaceutical Management, UK Jillian Kohler, University of Toronto, Canada

The Access to Medicine Index team remains ultimately responsible for decisions on the final methodology associated with reporting material, and the findings of the Access to Medicine Index. Following collection of the stakeholder feedback through the aforementioned process, the methodology was updated by the Access to Medicine Foundation.

#### **Other Sources of Feedback**

In addition to the above primary routes for obtaining stakeholder feedback, the Access to Medicine Foundation remains open to feedback from other entities willing to provide comments and suggestions. Maintaining openness through engaging and building partnerships with all the stakeholder groups is crucial to the long-term success, legitimacy and impact of the Index. It should be pointed out that no single feedback mechanism has disproportionately affected the Index methodology. Rather, the output of the survey, in depth consultations and other feedback processes were studied by the Expert Review Committee. We maximized our efforts to ensure that all the stakeholders receive equal representation in the stakeholder engagement process.

## Ranking and Scoring Process



### Summary of the scoring process ATM Index 2012

- Quantitative indicators, such as the number of molecules relevant to the Index Diseases (IDs) in companies' R&D pipelines are adjusted based on the total size of the pipeline, total revenues or other relevant figures representing company size. Consistent with the relative ranking approach of the Access to Medicine Index, the adjusted numbers are then leveraged for scoring from zero to five, to account for company size.
  - There are three experimental indicators in Index 2012. Some quantitative indicators, such as number of molecules moving through the R&D life cycle (Indicator C.III.5), the companies' trends in sales in the Index Countries (Indicator A.III.3), and the pricing differential between highest and lowest tiers (Indicator D.III.2) faced data quality issues. In these cases many companies did not disclose the data, or disclosed it in such a way that it was not comparable either with the other companies or across different years. These indicators were marked as 'experimental' and after refinement of the indicators, and more consistent company disclosure in the next iterations of the Index, these indicators will be used for the ranking process.
  - To avoid distortion of the weighting system, for the three performance indicators which were changed to experimental after the weights were assigned, neutral scores were used. Please refer to point 5.
  - When an indicator is not applicable to a single or a set of companies, unless stated otherwise in the scoring guidelines, neutral scoring is used. For example, when a company has no single-drug donation programs, it gets a lower score in commitments for the indicator related to single-drug donation programmes. However, for the transparency indicator related to disclosure of single-drug donation decisions, and the performance indicators related to value and outcomes of single-drug donation programmes, a neutral score is used, as the company has already been penalized.
  - Unless stated otherwise in the scoring guidelines, neutral scoring was carried out for different Technical Areas using one of three approaches, depending on the quality of the data. For cases where data was reliable and robust in the relevant strategic pillar of the indicator which was to be neutrally scored, and no other relevant indicators exist in other strategic pillars of that TA, neutral scoring comprised a weighted average of all the indicator scores for the company within the strategic pillar of that technical area (excluding the indicator(s) which receive a neutral score). For the single-drug donations transparency indicator example, this would be the weighted average of the other two indicators scored under Transparency in Product Donations and Philanthropic Activities, excluding the indicator which received a neutral score.
- For cases where other indicators within the Technical Area could be used as a proxy to capture the sub-topic that we could not calculate within the specific indicator for technical reasons, a weighted average of the relevant indicators was used (for Indicator D.III.2, for example). For cases where no other strategic pillars' indicators within the technical area captured the sub-topic or if they did, data was not robust, and neither was strategic pillar the indicator belonged to, the average of the entire Technical Area's score was used, not including the indicator(s) under question (for Indicator D.III.3, for example).
- Scoring was carried out based on data from a wide range of information sources including companies themselves, independent reports, databases from the World Health Organization (WHO) and other multilateral organisations, as well as news databases, such as Lexis Nexis and MSCI's Impact Monitor.
  - The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process beginning with scoring by the company analyst based on the data collection period, followed by verification by the analyst in charge of each technical area. Finally, the senior analyst, along with each analyst on the team, engaged in

an extensive quantitative and qualitative check of each indicator for each company. The project management (PM) team engaged in spot-checking and scoring verification with the senior analyst to ensure consistency.

8. A statistical analysis has been carried out on the final scores to check for significant correlations between different indicators and the distribution

of each indicator. Based on the analysis of every single indicator, adjustments were made to some indicators' scoring guidelines to ensure maximum variability. In addition, some indicators with high correlation were marked for possible removal in the next iterations of the Index.

## Limitations of the Methodology

### Study Limitations

Limitations exist in every study of this design. Major limitations specific to this study are discussed here. These and other methodological limitations will be reviewed for Index 2014, as part of the multi-stakeholder Methodology Review process.

### Data Comparability

The outputs analysed in this study and the findings generated relate only to the geographical, disease, product and company scope determined by the Executive Review Committee (ERC). The Index team invested significant time in ensuring the greatest possible consistency between the 2010 data and the 2012 data, to allow for longitudinal analysis. Comparability was not always possible and where an indicator was dependent on comparison with 2010 data, trend analysis was not possible.

In general, all products, diseases, countries and access initiatives are treated equally in the study, although it is recognised they are not equal. For example, in the R&D area, all compounds are treated equally. The scoring guidelines attempt to deal with this in many cases by adding in a quality aspect, but currently it is difficult to capture both the quality aspect and the variations of scale between initiatives. In the future, weights could be adjusted by disease burden.

### Data Collection

To ease data collection and ensure it was stored in a more accessible way, a purpose-built data platform was created. This added some benefits and some challenges, the latter of which was sometimes reported to have delayed or limited data collection and submission. This may have resulted in lost points for companies. Researchers tried to mitigate this by following up with clarification questions and a fact check of the Company Profiles.

### Indicator Reliability

Despite best efforts to devise indicators that can adequately reflect access issues, verification processes identified certain major differences between the data that was collected in relation to activities observed in the field. Tiered pricing programmes were initially analyzed for the geographic reach that they had and the relevance

of their disease coverage – and for the degree of price lowering for the poorest markets - but failed to include the quantity of products to which tiered pricing is applied. This led to some overvaluing of company initiatives which were global but for only one or two products, and a subsequent overhaul of pricing-related indicators to ensure the correct variables were included in the analysis – geographic scope, product scope, and disease scope.

### Measuring Outcomes and Impacts

The study as currently designed is not intended to measure the direct impact of companies' access initiatives on patients. Alternative measures have been used as proxies for patient access, some of which have been more successful than others. For example, measures for appraising the outputs of tiered pricing schemes in the 2012 indicators attempted to provide proxies for patient affordability and access outcomes/impacts. However the data submitted was not comparable and the relevant indicator was therefore not used. This is partly because not all companies disclose the extent of their price reductions, but also because across companies that do disclose, there is little commonality in the way that pricing tiers are constructed and the reference points used to calculate price reductions. It is therefore not possible to compare schemes on a like for like basis in order to assess who is delivering affordability. Furthermore, companies who engage in affordable pricing initiatives other than tiered pricing receive no credit. Other equitable pricing schemes should be captured by the scope of the Index in 2014.

### Transparency and availability of data

A further limitation was the lack of available and/or reliable data, particularly in the pricing and R&D areas, as well in relation to outcomes and impacts. Companies are often unwilling to disclose this data, or do so only partially or in a mode that is idiosyncratic to the company's own reporting systems and therefore inconsistent and incomparable with others. Occasionally, where sensitive data can be analyzed, results cannot be published due to public disclosure legal constraints. This has been a significant obstacle in finding and reporting a reliable trend and a meaningful relationship in the pricing area, in particular, and also in the area of research and development.

### Statistical Issues

In the indicator review process, a major objective was to reduce by around 10% the number of indicators used in the analysis. Rather than lose measures for important components of access, companies' activities that were double-counted due to overlap between the commitments and performance pillar sections were removed. Statistically speaking, not having all topics included under all strategic pillars distorted the scores somewhat. This, in turn, led to a case in the Capability Advancement Technical Area where scoring was skewed significantly. In this case, as pharmacovigilance is the only transparency indicator this Index (compared to last Index when there were three transparency indicators), winning or losing 25% of the technical area became possible based on disclosure of pharmacovigilance activity. The companies who have no national pharmacovigilance fare poorly and those which did improved. This explains the ranking change in this area, and the disproportional increase of the importance of pharmacovigilance in the Index.

### Disease Scope

The criteria for the Index's disease scope focusses on disease burden, determined by Daily Adjusted Life Years (DALYs) as stated by the WHO Global Burden of Disease 2004 and according to the WHO's ICD-10 codes. Decided during a thorough Methodology Review, which emphasized continuity from 2010 wherever possible, and ratified by the ERC, this disease scope was somewhat fixed during the period of analysis. To maintain consistency with Index 2010, 10 disease classes were kept in each category, unless there was a very clear and strong body of evidence speaking to an urgent need to amend the disease scope. Consequently, maternal health and neonatal infections were added as a new disease category to the scope of this Index. However, medicine for viral hepatitis, another public health concern, were not included because the disease is not necessarily the primary cause of terminal liver cirrhosis, which is the condition that is within the Index Disease scope.

### Company scope and accounting for different business models

Generic companies were excluded in the Index 2012 study. Even though our published Methodology Review 2012 said that we 'actively encourage disclosure of all access to medicines related activities across the companies' different business units', many originator companies understood this to mean that data about their generic operations should be excluded. Therefore, access initiatives conducted by these operations - often located in the MHDCs - were not included in the study. For Index 2014, global accounting definitions will be applied to determine which generic operations are to be considered within the scope of analysis. Companies will be explicitly encouraged to submit data about the generic arms that are fully integrated into the parent company, and to exclude those that are other stages of merger and acquisition.

### Treatment of Breaches

In 2010, breaches anywhere in the world were counted against companies. In 2012, only breaches in Index Countries counted quantitatively. As performance in the Public Policy area is determined by lack of breaches - and these are potentially hard to determine - this treated companies relatively generously in terms of scoring. A limitation of this approach is that - with fewer regulatory and enforcement resources available to protect the public interest - many breaches in developing countries are harder to detect than those in developed countries. Equally, out of court settlements may be even more prevalent in developing countries, making transparency around these cases difficult to achieve. This approach may miss some potentially deeper problems within company practices and to address this, for 2014 the approach will be reviewed and a 'red flag' system may be integrated into the scoring mechanism, allowing for negative weighting for any egregious controversy, no matter what it is for or where it is has taken place.

## Indicators and Scoring Guidelines

The Scoring Guidelines are, in the main but with some exceptions, scaled according to current industry practice as shown in the spectrum of evidence provided (i.e. a score of 5 represents the best that the companies are currently doing, and a score of 0 or 1 represents the least they are currently doing).

### A General Access to Medicine Management

#### A.I Commitment 25%

**A.I.1 40%** The company has a governance system that includes direct board-level responsibility and accountability for its access to medicine initiatives for the Index Countries.

- 5 The company has board-level representation and an executive committee or an executive role (such as VP).
- 2.5 The company has a board-level process and representation and a director.
- 1 The company has board-level representation but no director or executive.
- 0 No representation in the company's senior governance bodies.

**A.I.2 30%** The company commits to work with relevant stakeholders including universities, patient groups, local governments, employees, local and international NGOs and peers with the aim of improving access to medicines.

- 5 The company has a strategy and platform for outreach to >10 relevant stakeholder groups for 3 relevant initiatives.
- 4 The company has a strategy and platform for outreach to relevant stakeholder groups for 3 relevant initiatives.
- 2.5 The company has a strategy and platform for outreach to relevant stakeholder groups for 2 relevant initiatives.
- 1 The company has a strategy and platform for outreach to relevant stakeholder groups for a relevant initiative.
- 0 The company has no relevant stakeholder engagement.

**A.I.3 30%** The company commits to the development of internal incentive structures to reward effective delivery of initiatives that improves access to medicines in Index Countries.

- 5 The company provides evidence of plans to develop within the next 12 months

an HR/performance management strategy and policy with supporting processes providing clear financial and non-financial incentives for performance relating to corporate social responsibility for relevant issues.

- 2.5 The company provides evidence of incorporating some incentives aimed at improving access through its business activities.
- 1 The company has a general approach towards employee incentives, such as spot rewards for exceptional employees or incentives that apply to all employees and not just senior management.
- 0 No evidence found in relation to the above.

#### A.II Transparency (25%)

**A.II.1 50%** The company reports on its access to medicine policies and practices and discloses its overall rationale for its access to medicine activities.

- 5 The company publishes a publicly available annual report (on its website) on its related policies/activities; short/long term rationale, objectives and outputs (as part of annual report or separate) AND resources (Financial/HR/IP) which is issued not later than one year from the end of the fiscal year under coverage.
- 2.5 The company publishes an annual report on its related policies/activities and long term objectives but no information on short term targets or performance OR resources committed which is issued not later than one year from the end of the fiscal year under coverage.
- 1 The company's annual reporting is issued more than 1 year from the end of the fiscal year under coverage.
- 0 The company does not include the above information in its annual reporting.



**A.II.2** The company discloses quantitative and qualitative performance measures and targets for its access to medicine practices related to the Index Countries.

**50%**

- 5 The company discloses measurable annual performance targets related to all its relevant initiatives, including number of products to achieve marketing approvals; number of long-term research and product development collaborations; specific price targets for relevant products.
- 4 The company discloses measurable annual performance targets.
- 2.5 The company discloses long-term objectives for its relevant initiatives.
- 0 The company discloses no targets for its relevant initiatives that can be tied into the business cycle.

**A.III Performance (40%)**

**A.III.1** The company has a management system including quantitative targets to implement and monitor its Access to Medicine strategy in the Index Countries.

**40%**

- 5 The company has a centralized performance management system that uses quantitative and qualitative measures to collect data and appraise performance across its global operations.
- 2.5 The company has an evaluation/ performance management system for access to medicine but it is not centralized or comprehensive.
- 1 The company has qualitative and quantitative targets for its Access to Medicine strategy but no specific performance management system.
- 0 The company does not have quantitative and qualitative targets.

**A.III.2** Senior management participates in public debate and engages with the different stakeholder groups with the goal of dialogue and knowledge sharing aimed at improved access to products for the Index Diseases in the Index Countries (measured through sponsoring and participating in relevant conferences, workshops, etc.).

**25%**

- 5 The company hosts or plays a significant role to disseminate knowledge (agenda development role/organising committee/lead sponsor) in >15 reputable\* conferences/symposia.
- 4 The company engages in 5-15 of the above.
- 2.5 The company engages in 2-5 of the above.
- 1 There is no evidence of more than 1 of the above.
- 0 The company does not provide evidence of the above.

*\*'Reputable' events are considered to be those which heavily involve organisations such as governments, major international agencies, regulatory bodies, foundations, academia, PPPs/PDPs and NGOs.*

**A.III.3** Trends in the company's sales in the LIC and LMIC markets compared to sales in the rest of the world during the past five years.

**10%**

Companies scored a 5, 2.5 or 0 based on a sliding scale.  
Due to the absence of reliable data for this indicator all companies were scored neutrally.

**A.III.4** The company has internal incentive structures to reward effective delivery of initiatives that improves access to medicine in the Index Countries for the Index Diseases.

**25%**

- 5 The company has an HR/performance management strategy and active policy and related processes providing clear financial and non-financial incentives for relevant performance of senior management and directors.
- 2.5 The company has a broad HR/performance management strategy providing clear financial and non-financial incentives for relevant performance and there is evidence that this is active (company has supporting processes).
- 0 The company does not provide any evidence that it provides incentives for relevant performance.

**A.IV Innovation (25%)**

**A.IV.1** The company has adopted innovative (unique in the sector) approaches to General Access to Medicine Management including governance, management systems and stakeholder engagement.

**100%**

- 5 The company has adopted innovative (unique in the sector) approaches to general access to medicine management, including governance, management systems, financial and non-financial incentive schemes, and stakeholder engagement and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has adopted innovative (unique in the sector) approaches to general access to medicine management, including governance, management systems, financial and non-financial incentive schemes, and stakeholder engagement but does NOT disclose progress or resources inputs.
- 0 No innovative initiatives discovered for the company in this area.

## B Public Policy & Market Influence

### B.1 Commitment 25%

**B.1.1** The company commits to transparency in its lobbying activities and the positions it seeks to promote where it has an impact on access to medicine in the Index Countries. **30%**

- 5 The company commits to transparency with regard to its lobbying activities, including its public policy positions and political contributions.
- 4 The company commits to transparency in relevant lobbying activities yet not in its political contributions.
- 2.5 The company commits to transparency with regard to its public policy positions via formal policy statements on relevant issues or commits to only a general statement.
- o The company makes no commitments with regard to transparency in its lobbying activities.

**B.1.2** The company commits to endorse and support competition and to refrain from anti-competitive practices or pursue arrangements with generic manufacturers that might delay their market entry in the pharmaceutical markets in the Index Countries for products related to the Index Diseases. **30%**

- 5 The company publicly discloses its commitment related to competition with its peers (both originator and generics) which endorses competition and commits not to adopt practices that hamper competition (e.g., arrangements with competitors for delayed entry to the market, etc.).
- 2.5 The company discloses to the Index its commitment related to competition with its peers (both originator and generics) which endorses competition and commits not to adopt practices that hamper competition.
- o The company does not make any policy statements in this area.

**B.1.3** The company refrains from pursuing data exclusivity for products related to the Index Diseases in the Index Countries. **20%**

- 5 The company systematically commits not to pursue data exclusivity for all relevant products.
- 4 The company commits not to pursue data exclusivity for specific conditions and/or diseases.
- o The company makes no policy statement on data exclusivity or has a negative stance on data exclusivity.

**B.1.4** The company commits to enforce a code of conduct regarding ethical marketing practices for all sales agents and local third party\* distributors and contractors consistent with its own internal standards. **10%**

- 5 The company has processes in place to monitor marketing practices and enforce ethical marketing codes of practice by all its sales agents in the relevant countries which includes auditing of the agents' practices.
- 2.5 The company has specific ethical marketing codes of practice for all its sales agents in the relevant countries, but no auditing (monitoring or enforcement) mechanisms.
- o The company makes no provisions with regards to the marketing behaviour of the local sales agents.

*\* Third parties include local distributors (including sales agents, wholesalers, clinics and pharmacies, faith based hospitals, pharmacy retail units/chains, private health facilities, transport providers), customs services providers, CROs, public affairs, PR, events companies or marketing contractors (and other third party contractors such as QMS consultants).*

**B.1.5** The company commits to proactively engage in fighting corruption through its internal anti-bribery and anti-corruption codes of conduct, external commitments and memberships. **10%**

- 5 The company has all of the following:
  - a) is a member of the World Economic Forum's Partnering Against Corruption Initiative (PACI),
  - b) is a signatory to UN Global Compact,
  - c) has a code of conduct that addresses anti-corruption, and,
  - d) has internal and/or external auditing of its code specifically related to its ethical practices (financial auditing does not count).
- 4 The company has internal and/or external auditing of its ethics codes and has 2 out of 3 of the above.
- 2.5 The company has no internal and/ or external auditing but has 2 out of 3 of the above.
- 1 The company has no internal and/ or external auditing but has 1 out of 3 of the above.
- o The company makes none of the above commitments.

**B.II Transparency (25%)**

**B.II.1** The company discloses the positions it seeks through its advocacy activities related to access to medicines in, or with potential impact on, the Index Countries.

- 15%**
- 5 The company has comprehensive public policy disclosure on all major access related issues, such as counterfeiting, clinical trial conduct, pharmacovigilance, pricing, and product donations in at least half of all relevant countries.
  - 2.5 The company discloses some of the above relevant positions that it seeks in at least half of the relevant countries.
  - o The company makes no disclosure regarding the public policy positions.

**B.II.2** The company discloses any potential governance conflict of interests and/or interest groups or institutions it financially supports, through which it might advocate its public policy positions at regional, national or international levels where relevant to access to medicine in the Index Countries.

- 15%**
- 5 The company makes detailed transaction level disclosure on lobbying payments to different stakeholders with specific Index country reporting.
  - 4 The company makes detailed transaction level disclosure on lobbying payments to different stakeholders but no specific Index country reporting.
  - 2.5 The company has partial disclosure in this area, supplying aggregate figures only.
  - o The company makes no disclosure in this area.

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

- 10%**
- 5 The company publicly discloses all the board seats and memberships that it holds in relevant third party institutions in the relevant countries including organisations operating in the relevant countries.
  - 4 The company discloses all memberships that it holds in relevant third party institutions in relevant countries including organisations operating in the relevant countries.
  - 2.5 The company makes partial public disclosure of its relevant memberships.
  - o The company makes no disclosure in this area.

**B.II.4** The company discloses policies related to competition in areas such as data exclusivity, patent extensions or other arrangements with generic manufacturers that might delay their market entry for Index products in the Index Countries.

- 5 The company clearly articulates its stance in the following areas: patent extension in relevant countries (ever greening), arrangements with generics companies which might delay their market entry, data exclusivity, TRIPS<sup>+</sup> (and any major components), and compulsory licencing.

1-4 The company makes disclosure of public policy positions on any of the above 5 areas; each one has one score.

- o The company makes no disclosure in this area.

**B.II.5** The company discloses detailed information regarding its marketing and promotional programmes in the Index Countries, such as payments to or promotional activities directed at physicians or other key health care professionals or opinion leaders.

- 20%**
- 5 The company discloses detailed information related to drug promotion in areas such as payments to physicians and methods for incentivising health care providers, pharmacies etc. in the relevant countries.
  - 2.5 The company discloses its approach without regularly disclosing exact contribution figures and performance information in this area (including aggregate data but no details).
  - o The company makes no disclosure in this area.

**B.II.6** The company voluntarily discloses all information regarding its breaches of internal and internationally recognised codes of conduct for ethical marketing, bribery and/or corruption in Index Countries in the last five years and also litigations related to marketing practices in the Index Countries.

- 10%**
- 5 The company discloses detailed, current information (i.e. location, time, year) in these areas in its annual report including cases having taken place in the relevant countries in relation to breaches of the following codes of conduct: IFPMA Ethical Marketing Guidelines, DHHS Code of Conduct, PhRMA Code of Conduct; FPIA codes of conduct and UNGC; WHO ethical criteria and relevant anti corruption codes such as PACI and the UN Global Compact.
  - 4 The company discloses minimal information on breaches (i.e. location, time, year).
  - 2.5 The company discloses only aggregate numbers related to its breaches or litigations as part of its annual report.
  - o The company makes no disclosure in this area.

**B.III Performance (40%)****B.III.1 The company has been in breach of any national or international codes of conduct in relation to lobbying, ethical marketing and/ or bribery and corruption.****45%**

- 5 The company has not been the subject of any cases.
- 4 The company has only been the subject of one unconcluded litigation or regulatory proceeding.
- 3 The company has been the subject of several unconcluded litigations or regulatory proceedings.
- 2 The company has been the subject of one litigation with negative ruling/ settlement with payment or regulatory proceeding with a fine.
- 0 The company has been the subject of several litigations with negative rulings/ settlement with payment or numerous regulatory proceedings with fines.

For companies with operations in <5 Index Countries the applicable scores are:

- 3 The company has not been the subject of any cases.
- 2.5 The company has only been the subject of one unconcluded litigation or regulatory proceeding.
- 1 The company has been the subject of one litigation with negative ruling/ settlement with payment or regulatory proceeding with a fine.
- 0 The company has been the subject of more than one litigation with negative rulings/settlement with payment or a few regulatory proceedings with fines.

**B.III.2 Is there evidence\* of the company's anti-competitive behaviour\*\* in the Index Countries based on fines or litigation records during the past five years?****45%**

- 5 The company has not been the subject of any cases.
- 4 The company has only been the subject of one unconcluded litigation or regulatory proceeding.
- 3 The company has been the subject of several unconcluded litigations or regulatory proceedings.
- 2 The company has been the subject of one litigation with negative ruling/ settlement with payment or regulatory proceeding with a fine.
- 0 The company has been the subject of several litigations with negative rulings/ settlement with payment or numerous regulatory proceedings with fines.

For companies with operations in <5 Index Countries the applicable scores are:

- 3 The company has not been the subject of any cases.
  - 2.5 The company has only been the subject of one unconcluded litigation or regulatory proceeding.
  - 1 The company has been the subject of one litigation with negative ruling/ settlement with payment or regulatory proceeding with a fine.
  - 0 The company has been the subject of more than one litigation with negative rulings/settlement with payment or a few regulatory proceedings with fines.
- \* evidence to refer to fines or reports/ controversies.*  
*\*\* excluding all IP anticompetitive practices.*

**B.III.3 The company has taken disciplinary action against third parties\* or employees who violate its code of conduct for ethical marketing or lobbying and anti-corruption.****10%**

**Part b (qualitative no scoring) - The company has established stringent enforcement mechanisms for disciplinary action against third parties or employees which violate its codes of conduct for ethical marketing or lobbying and anti-corruption.**

- 5 The company has clearly defined enforcement processes and disciplinary measures, and disciplinary action is taken for lobbying/corruption and/or marketing violations, with disclosure of such actions.
- 2.5 The company has clearly defined enforcement processes and disciplinary measures, but no evidence or disclosure of specific disciplinary action(s) taken for lobbying/corruption and/or marketing violations.
- 1 There is no evidence of defined enforcement of disciplinary mechanisms and/ or the codes of conduct do not apply to third parties.
- 0 The company has abrogated its own internal whistleblower policies in accordance with internal and/or internationally recognised codes of conduct; and has not taken disciplinary actions appropriately and/or retaliated against an employee for the whistle blowing action.

*\* Third parties are defined as follows: Sales Agents, Distributors (e.g. wholesalers, pharmace reatil units/chains, private health facilities, transport providers) or customs services providers, CROs, public affairs, PR, events companies or marketing contractors and other third party contractors such as QMS consultants.*

**B.IV Innovation (25%)**

- B.IV.1** The company has adopted an innovative (unique in the sector), sustainable approach to improving ethical and efficient business performance and interactions in Index Countries in areas such as marketing, lobbying, anti-corruption, and pro-competition.
- 100%**
- 5 The company has adopted innovative (unique in the sector) approaches to promoting ethical, pro-competitive and anti-corrupt behaviours in relation to relevant products in relevant countries, including incentive programmes

- for employees and third parties, and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has adopted innovative (unique in the sector) approaches to promoting ethical, pro-competitive and anti-corrupt behaviours in relation to relevant products in relevant countries but does not disclose progress or resources inputs.
- o No innovative initiatives discovered for the company in this area.

## C Research & Development

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**C.1 Commitment 25%**

- C.1.1** The company commits to carry out research focussing on the development of both innovative and new remedies for the Index Diseases and adaptive new formulations of its existing products for the Index Diseases with the goal of improving access to medicine in the Index Countries.
- 40%**
- 5 The company makes a specific strategic commitment in multiple relevant disease areas to invest in innovative and adaptive research and development for relevant diseases with specific implementation objectives in this area.
- 4 The company makes the same specific commitment as above but without specific implementation objectives.
- 2.5 The company commits to innovative or adaptive R&D for relevant diseases in general or specific mention of only one disease area.
- 1 The company makes a general commitment in this area without including future time bound objectives or specific mention of innovative research.
- o The company makes no commitments in this area.

- 2.5 The company makes only a broad commitment to post-trial access (without specific details of how access will be assured by employees or CROs) or does so through its stated compliance with the Declaration of Helsinki and the UN Guiding Principles for Business and Human Rights and any of the following good practice guidelines or protocols: the The Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials of UNAIDS, the Nuffield Council on Bioethics, The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Steering Committee on Bioethics (CDBI) of the Council of Europe (CoE): Additional Protocol to the Convention on Human Rights and Biomedicine, The European Group on Ethics in Science and New Technologies (EGE): Opinion Nr 17 on the ethical aspects of clinical research in developing countries, published in Jan 2003.
- o The company makes no commitments in this area.

- C.1.2** The company commits to provide products for free to the clinical trial participants in Index Countries (i.e. post-trial access), at minimum consistent with codes such as the Helsinki Code for Clinical Trials.
- 15%**

- 5 The company has a specific, detailed approach to post-trial access for trials conducted by employees and CROs in relevant countries which assures patient benefits in a large variety of different circumstances.
- 4 The company has the above but does not assure patient benefits in all likely circumstances.

- C.1.3** The company commits to ensuring equitable access to products successfully developed through R&D partnerships.
- 15%**

- 5 The company systematically applies principles of socially responsible and humanitarian licencing in the relevant countries in relation to the intellectual property generated in public private partnerships and PDPs for relevant diseases (i.e. either waives all rights over the IP generated or explicitly encourages affordable, timely and high quality supply to relevant populations).
- 2.5 The company systematically applies principles of socially responsible and

humanitarian licencing in relation to the intellectual property generated in public private partnerships and PDPs for a subset of relevant diseases in only a subset of the relevant countries.

- o The company makes no commitments in this area.

**C.I.4** **30%** **The company commits to ensuring that partner CROs uphold ethical standards when conducting clinical trials in Index Countries, at minimum consistent with codes such as the Helsinki Code for Clinical Trials.**

- 5 The company provides evidence that it conducts due diligence in relation to ethical conduct when selecting CROs, applies codes of conduct consistent with those applied to employees, at minimum consistent with the Declaration of Helsinki, and has in place procedures for monitoring performance and taking disciplinary action for any violations.
- 2.5 The company provides evidence of doing all of the above but does not have clear procedures for monitoring and enforcement.
- o The company makes no commitments in this area.

**C.II** **Transparency (25%)**

**C.II.1** **30%** **The company discloses the resources dedicated to its research and development activities conducted in-house and/or in collaboration for Index Diseases suitable the Index Countries.**

- 5 The company discloses (a minimum of) 2 of the following 3: the amount of capital investments, financial resources or human resources it dedicates to all the relevant diseases for which it carries out R&D or engages in research collaborations on a periodic basis (in-house only).
- 4 The company discloses (a minimum of) 1 of the following 3: the amount of capital investments, financial resources or human resources dedicated to research or research collaborations to a majority of the disease areas in which the company is active.
- 3 The company discloses 1 of the following 3: the amount of capital investments, financial resources or human resources dedicated to 1 or more specific research initiatives or research collaborations or company discloses at the level of 5 score on an engagement basis only.
- 2 The company discloses at the level of 4 score on an engagement basis only.
- 1 The company discloses at the level of 3 score on an engagement basis only.
- o The company makes no disclosure in this area.

**C.II.2** **30%** **The company discloses the licencing details pertaining to its research collaborations related to the Index Diseases (with regard to Intellectual Property rights, access provisions etc.).**

- 5 The company publicly discloses the existence and mandate of all relevant collaborations plus licencing details in relation to the duration of engagements, company's obligations, delivery milestones, march-in clauses and IP rights (such as supply channels, territory, disease scope, pricing, delivery timescales, royalties or other payment structures).
- 4 The company carries out a full public disclosure of the existence and mandate of the majority of its relevant collaborations plus partial licencing details relating to at least one of its collaborations.
- 3 The company publicly discloses the existence and mandate of most of its relevant collaborations or provides examples of its licencing details.
- 2 The company discloses licencing details at 4 or 5 level on an engagement basis only.
- 1 The company discloses licencing details at the level of 3 only on an engagement basis only.
- o The company makes no disclosure in this area.

**C.II.3** **10%** **The company discloses its research pipeline related to both in-house research and collaborations targeting Index Diseases (where disclosure is not legally required).**

- 5 The company publicly discloses its a) research and development pipeline (phase 1, 2 and 3), for all products, with diseases/indications specified) plus b) areas of basic/pre-clinical activity for all relevant diseases and products related to its in-house and c) collaborative research.
- 4 The company publicly discloses two of the above three elements of its R&D pipeline.
- 3 The company publicly discloses one of the above three elements of its R&D pipeline.
- 2.5 The company discloses one of the above three levels of detail regarding its research pipeline for relevant diseases, at the disease category level.
- 2 The company makes complete disclosure (of the three defined elements of its R&D pipeline) on an engagement basis only.
- 1 The company makes partial disclosure (1 or 2 of the above three elements of its R&D pipeline) on an engagement basis only.
- o The company makes no disclosure in this area.

*The company with receive a 2.5 score if there is no relevant information to disclose.*

- C.II.4** The company discloses information about the result of all of its clinical trials conducted in Index Countries regardless of the outcome and whether the trial was conducted in-house or through a third-party (i.e. CRO).  
**15%**
- 5 The company publicly discloses all relevant country-conducted clinical trials (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: Initial trial registration and result disclosure within one year.
  - 4 The company publicly discloses the same to a similar (or slightly lower) standard than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: initial trial registration and result disclosure, however not within one year.
  - 2.5 The company either publicly discloses relevant country-conducted clinical trial information to a lower standard, or does not disclose relevant information as defined above.
  - 1 The company discloses relevant clinical trial information (as described above) on an engagement basis only.
  - 0 The company makes no disclosure on either issue detailed above.

- C.II.5** The company discloses information about contract partners for clinical trials (i.e. CROs) in Index Countries.  
**15%**
- 5 The company publicly discloses comprehensive company details in relation to all CROs conducting clinical trials in relevant countries (discloses name of CROs and names of relevant countries where the trials are been conducted).
  - 4 The company publicly discloses names of CROs only.
  - 2.5 The company discloses some data on an engagement basis.
  - 0 The company makes no disclosure in this area.

### C.III Performance (40%)

- C.III.1** Portion of financial R&D investments dedicated to Index Diseases out of the company's total R&D expenditures.  
**15%**
- 5 The company has provided the data of investments disaggregated at the product level and the company has a significant proportion of investment in multiple disease areas.
  - 4 The company has provided the aggregated data of investments and the company has a significant proportion of investment in multiple disease areas.
  - 3 The company has provided the data of investments disaggregated at the

- product level and investment in one or two relevant disease areas only.
- 2 The company has provided the aggregated data of investments and investment in one or two relevant disease areas only. 1.5 If the company has not provided any investment figures across its portfolio but we have discovered examples of investments for the relevant diseases R&D areas.
- 0 The company has no relevant R&D investments.

*Based on G-Finder Methodology\* and adjusted for the total company R&D investments.*

### C.III.2 Share of research pipeline reflecting 'new molecules' for Index Diseases including in-house and collaborative research. **20%**

- For companies that have multiple Index disease focus.
- 5 Share of pipeline is >10% dedicated to new molecules for relevant diseases.
  - 4 Share of pipeline has 5-10% dedicated to relevant diseases.
  - 3 Share of pipeline has <5 % dedicated to relevant diseases or more than 50% with only one or two relevant disease focus.
  - 2 The company has not provided any molecules in its pipeline for relevant diseases but we have discovered examples of such molecules through research of publicly available information.
  - 0 The company has no molecules/activity with respect to R&D for relevant diseases.

For companies that have only one or two Index disease focus:

- 5 Share of pipeline is >50% dedicated to new molecules for relevant diseases.
- 4 Share of pipeline has 25-50% dedicated to relevant diseases.
- 3 Share of pipeline has <25% dedicated to relevant diseases or more than 50% with only one or two relevant disease focus.
- 2 The company has not provided any molecules in its pipeline for relevant diseases but we have discovered examples of such molecules through research of publicly available information.
- 0 The company has no molecules/activity with respect to R&D for relevant diseases.

### C.III.3 Share of research pipeline and products registered reflecting 'adapted molecules or new technologies' specific to an Index Disease and an unmet need in an Index Country, including in-house and collaborative research. **20%**

- For companies that have multiple Index disease focus:
- 5 Share of pipeline is >10% dedicated to adapted molecules for relevant diseases.

- 4 Share of pipeline has 5-10% dedicated to relevant diseases.
- 3 Share of pipeline has <5 % dedicated to relevant diseases or more than 50% with only one or two relevant disease focus.
- 2 The company has not provided any molecules in its pipeline for relevant diseases but we have discovered examples of such molecules through research of publicly available information.
- 0 The company has no molecules/activity with respect to R&D for relevant diseases.

For companies that have only one or two Index disease focus:

- 5 Share of pipeline is >50% dedicated to adapted molecules for relevant diseases.
- 4 Share of pipeline has 25-50% dedicated to relevant diseases.
- 3 Share of pipeline has <25% dedicated to relevant diseases or more than 50% with only one or two relevant disease focus.
- 2 The company has not provided any molecules in its pipeline for relevant diseases but we have discovered examples of such molecules through research of publicly available information.
- 0 The company has no molecules/activity with respect to R&D for relevant diseases.

**C.III.4 Research and product development partnerships in which the company has been involved, with the aim of developing products or new formulations for Index Diseases specifically targeting Index Countries' needs (adjusted for the number of the molecules in the company's research pipeline).**

- 10%**
- 5 The company has been involved in >12 relevant product development collaborations during the survey period.
  - 4 The company has been involved in 9-12 relevant product development collaborations active during the survey period.
  - 3 The company has been involved in 5-9 relevant product development collaborations active during the survey period.
  - 2 The company has been involved in 3-5 relevant product development collaborations active during the survey period.
  - 1 The company has been involved in 1-3 relevant product development collaborations active during the survey period.
  - 0 The company has no active relevant product development collaborations during the survey period.

**C.III.5 Number of candidates relating to Index Diseases moving through research and development life cycle from early research phases to more advanced phases.**

An experimental indicator, as original guidelines suggested comparing Index 2010 data with Index 2012 data to

determine the number of molecules that progressed to different stages in each company's pipeline, as a percentage of the company's actual relevant disease R&D pipeline. Data collected for this indicator was, however, not comparable to 2010 data and scoring in this way was not possible. All companies scored neutrally.

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

- 5%**
- 5 All licences in relation to the company's relevant research collaborations are socially responsible.
  - 4 Most (>75%) licences in relation to the company's relevant research collaborations are socially responsible.
  - 2.5 >50% of the company's licences in relation to the company's relevant research collaborations are socially responsible.
  - 1 <50% of the company's licences in relation to the company's relevant research collaborations are socially responsible.
  - 0 The company has no socially responsible licencing.

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

- 5%**
- 5 The company has not been the subject of any cases.
  - 4 The company has only been the subject of one or two legal cases without rulings or the recipient of a couple of regulatory notices.
  - 3 The company has been the subject of several cases (without a ruling) or regulatory notices issued to company.
  - 2 The company has been the subject of several legal cases (with negative rulings) or regulatory notices but no major precedent setting cases.
  - 1 The company has been the subject of at least one significant legal case (with negative ruling) or regulatory notices related to its clinical trial conduct, in the relevant countries during the last 5 years.
  - 0 The company has been the subject of several significant cases and at least one major case with a negative ruling.

For companies with operations in less than 5 countries the applicable scores are:

- 5 The company has not been the subject of any cases.
- 4 The company has only been the subject of one or two legal cases without rulings or the recipient of a couple of regulatory notices.



- 3 The company has only been the subject of a single legal case and /or regulatory notice.
- 2 The company has been the subject of a several legal cases (with negative rulings) and regulatory notices.
- 1 The company has been the subject at least one significant legal case (with negative ruling).
- 0 The company has been the subject of several significant cases and at least one major case with a negative ruling.

*For companies with no operations in the relevant countries the score will be zero. 'Major' is defined as possibility to set a precedent.*

*For each of the following scores it is assumed: the case was with respect to its clinical trial conduct, the case occurred in a relevant country, it occurred in the last 5 years and it was brought against the company itself or one of its third-parties for whom it was legally responsible.*

**C.III.8** The company provides evidence of sharing its intellectual capital (e.g., molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g. WIPO Re: search, CDD, OSDD) that develop products for Index Diseases on terms most conducive to access for the Index Countries.

- 15%**
- 0-5 Total number of instances of company providing third-party access to its relevant disease-related intellectual property during the survey period divided by total company revenue in 2010 and 2011. This number was scaled across all companies to achieve a revenue-standardized score. Companies who engaged in intellectual capital sharing received a score between 2.5 and 5. Companies who did not provide any evidence of sharing received a 0.

**C.III.9** The company provides evidence about the steps it takes to ensure that partner CROs uphold ethical standards when conducting clinical trials in Index Countries, at minimum consistent with codes such as the Helsinki Code for Clinical Trials.

- 5%**
- 5 The company provides evidence that it audits and monitors CROs in relation to compliance with ethical behaviour guidelines AND, where relevant, applies processes for disciplinary action for any violations of guidelines/codes of practice.
  - 2.5 The company provides evidence as above although does not provide evidence that it applies processes for disciplinary action for any violations of guidelines/ codes of practice.
  - 0 The company provides no evidence of monitoring or enforcement of ethical behaviours of CROs.

**C.IV Innovation (25%)**

**C.IV.1** The company has adopted innovative (unique in the sector), sustainable or open business models to further the global R&D agenda for the development of products for Index Diseases.

- 100%**
- 5 The company has adopted innovative (unique in the sector) R&D approaches or business models, including open approaches to IP, for relevant diseases (excluding new molecules for non-communicable Infectious Diseases) with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.
  - 2.5 The company has adopted innovative (unique in the sector) R&D approaches or business models, including open approaches to IP, for relevant diseases (excluding new molecules for non-communicable Infectious Diseases) but does NOT disclose progress or resources inputs.
  - 0 No innovative initiatives discovered for the company in this area.

## D Manufacturing and Distribution

### D.1 Commitment 25%

#### D.1.1 The company commits to implement inter-country tiered pricing models for the products related to the Index Diseases in the Index Countries to ensure affordability. 30%

- 5 The company applies inter-country tiered pricing models to all its products and all the relevant countries where it operates.
- 4 The company applies inter-country tiered pricing models for a large number of relevant countries and for a large proportion of its relevant country portfolio.
- 3 The company applies inter-country tiered pricing models to a large number of relevant countries for at least one of its relevant country products.
- 2 The company applies inter-country tiered pricing models to at least one product and a small number of countries.
- 1 The company expresses a general commitment to implement inter-country tiered pricing.
  - o The company makes no inter-country tiered pricing commitments.

#### D.1.2 The company commits to implement intra-country tiered pricing models for the products related to the Index Diseases in the Index Countries to ensure affordability. 15%

- 5 The company applies intra-country tiered pricing models to all its products and all the relevant countries where it operates.
- 4 The company applies intra-country tiered pricing models for a large number of relevant countries and for a large proportion of its relevant country portfolio.
- 3 The company applies intra-country tiered pricing models to a large number of relevant countries for at least one of its relevant country products.
- 2 The company applies intra-country tiered pricing models to at least one product and a small number of countries.
- 1 The company expresses a general commitment to implement intra-country tiered pricing.
  - o The company makes no intra-country tiered pricing commitments.

#### D.1.3 The company adopts clear policies to control the pricing practices of its local sales agents with the aim of improving affordability and accessibility of the products. 20%

- 5 The company has a pricing monitoring process including training and audit mechanisms for its sales agents (third party distributors) for all relevant products and relevant countries.
- 4 The company has a pricing monitoring process including training or audit mechanisms for its sales agents (third

party distributors) for some relevant products and relevant countries.

- 2.5 The company has general pricing guidelines for its sales agents.
  - o The company has no policies or practices aimed at controlling the pricing of its local sales agents.

#### D.1.4 The company has in place the policies, procedures and resource needed to carry out effective drug recalls (product and packaging) in the Index Countries where it operates. 10%

- 5 The company provides evidence of compliance with WHO GMP guidelines for drug recalls (written procedures describing the action to be taken, including the need to consider a recall in the case of a complaint concerning a possible product defect; processes for an investigation and evaluation of a complaint; and appropriate follow-up action, possibly including product recall; storage of recalled products; periodic evaluation of recall processes) in all relevant countries where its products are available and to commits to make its best efforts to achieve highest possible standards.
- 2.5 The company provides evidence of compliance with WHO GMP guidelines for drug recalls (as noted above) in some of the relevant countries where it makes its products available and to commit to make its best efforts to achieve highest possible standards.
  - o The company makes no commitment in this area.

#### D.1.5 The company commits to needs-based (facilitation of rational use) brochure and packaging adaptation for its products destined for Index Countries (at least equal to local regulatory requirements). 10%

- 5 The company discloses that its product brochures and packaging information is consistent with that approved by the country's drug regulatory authority for the majority of the relevant diseases and relevant countries where its products are sold.
- 2.5 The company discloses that its product brochures and packaging information is consistent with that approved by the country's drug regulatory authority for a sub-set (or one) of the relevant diseases and relevant countries where its products are sold.
  - o The company makes no disclosure in this area.

**D.I.6** The company commits to file for marketing approval or product registration of its products for the Index Diseases in the Index Countries in need.

**15%**

- 5 The company has specific targets to register all products for relevant diseases in all of Sub-Saharan Africa and all other Low-Income Countries and Low and Middle Income Countries within 12 months of market launch.
- 2.5 The company has committed to register a sub-set of its products for relevant diseases in all of Sub-Saharan Africa, Low-Income Countries and Low and Middle Income Countries but has not committed to a timeframe.
- o The company makes no commitment to register its products for the relevant diseases in the relevant countries.

## **D.II Transparency (25%)**

**D.II.1** The company discloses the percentage of its global revenues covered under equitable/tiered pricing programmes.

**25%**

- 5 The company publicly discloses the proportion of its global revenues covered by tiered pricing programmes.
- 3.5 The company publicly discloses a subset of the above information, such as country categories and distribution channels.
- 2.5 The company provides engagement-based disclosure of the proportion of global revenues covered by tiered pricing programmes.
- o The company makes no disclosure in this area.

*If a company does not have tiered pricing programmes it receives a neutral score.*

**D.II.2** For products relating to the Index Diseases in the Index Countries, the company discloses its average prices in the lowest tiers and average prices in the highest tiers OR the percentage reduction from the average prices in the highest tier to the average prices in the lowest tier.

**35%**

- 5 The company discloses the average price reductions between the highest and lowest pricing tiers for all its products for which it has a tiered pricing programme.
- 3.5 The company discloses a subset of the above information such as a price relative to a reference price for the lowest tier.
- 2.5 The company provides engagement-based disclosure of the average price reductions between highest and lowest tiers for which it has a tiered pricing programme.
- o The company makes no disclosure in this area.

*If a company does not have tiered pricing programmes it receives a neutral score.*

**D.II.3** The company discloses its decision process regarding registration (marketing approval) and also the status of marketing approvals for each product related to Index Diseases in the Index Countries.

**20%**

- 5 The company publicly discloses the criteria used in its decision making process for obtaining marketing approval and the registration status of all its products for the relevant diseases in all the relevant countries.
- 4 The company publicly discloses the criteria and partial information about the registration status of its products for relevant diseases.
- 3 The company publicly discloses the criteria or partial information about the registration status of its products for relevant diseases.
- 2 The company discloses the criteria used in its decision-making process for obtaining marketing approval and the registration status of all its products for the relevant diseases in all the relevant countries through engagement.
- 1 The company discloses partial information through engagement.
- o The company makes no disclosure in this area.

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

**10%**

- 5 The company gives full details of its Quality Management System (QMS) publicly and is ICH Q10 compliant.
- 4 The company gives details of its QMS publicly but to a level less than 5.
- 2.5 The company gives partial details of its QMS on engagement.
- o The company does not provide any details on its QMS.

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

**10%**

- 5 The company publicly discloses the date, location and the reason for drug recalls it has been involved in an integrated accessible way.
- 3.5 The company publicly discloses the mentioned data in aggregate format only.
- 2.5 The company discloses the detailed information on an engagement basis.
- 1 The company discloses aggregated information on an engagement basis.
- o No disclosure with regard to product recalls and the underlying product side effects.

*If a company does not have drug recalls it receives a neutral score.*

**D.III Performance (40%)****D.III.1 Do the company's equitable/tiered pricing programmes for products relating to Index Diseases cover all or a significant percentage of Index Countries? 20%**

- 5 > 75% of the company's market is covered by tiered pricing programmes for >75% products related to relevant diseases and countries.
- 2.5 50-75% of the company's market is covered by tiered pricing programmes for >75% of products OR >75% of the company's market is covered by tiered pricing programmes for 50-75% of products.
- 2 50-75% of the company's market is covered by tiered pricing programmes for 50-75% of products.
- 1 <50% of the company's market is covered by tiered pricing programmes for >50% of products or > 50% of the company's market is covered by tiered pricing programmes for <50% of products.
- o None of the company's global market is covered by tiered pricing programmes for products related to relevant diseases and countries.

*Companies with no tiered pricing programme receive a neutral score.*

**D.III.2 The difference in average price of products for Index Diseases in Index Countries in the lowest tier vs. the average price of products for Index Diseases in the highest tier (globally) is significantly lower than the average price in the highest tier (such that the differential is beneficial for access) OR the percentage reduction between the average prices in the highest tier to the average prices in the lowest tier is significant (such that the differential is beneficial for access). 20%**

- 5 The difference between the average price of products in the lowest tier and the average price in the highest tier is >75%.
- 2.5 The difference between these average price points is 50-75%.
- o The difference between these average price points is <50% OR the company has not disclosed its tiers.

*If a company does not have tiered pricing it receives a neutral score.*

Experimental indicator, all companies given a proxy score based on the other relevant tiered pricing indicators in the Pricing Technical Area, due to incomplete and incomparable data.

**D.III.3 Has the company attempted to register (obtain marketing approval for) its products for Index Diseases in the Index Countries in need? 15%**

- 5 On average, the company has registered the majority of its products (relative to company portfolio size) in the majority of relevant countries.

- 4 On average, the company has either registered the majority of its products in some relevant countries or has registered some of its products in the majority of relevant countries.
- 3 On average, the company has registered at least half of its products in at least half of the relevant countries.
- 2.5 On average, the company has either registered at least half of its products in a few relevant countries or has registered a few of its products in at least half of the relevant countries.
- 2 On average, the company has registered less than half of its products in less than half of relevant countries.
- 1 No registration disclosure or no registration-related controversies.
- o Registration efforts achieved less than the above or there were controversies found related to registration indicating the company's behaviour in this area as barrier to access.

Indicator scored neutrally for all companies due to incomplete and incomparable data.

**D.III.4 Have drug recalls occurred due to product or packaging quality issues in the Index Countries for products produced by the company, its licencees or other manufacturing partners during the past five years? 20%**

- 5 No company or licensee/manufacturing partner product recalls related to quality issues during the past 5 years in the relevant countries.
- 2.5 No cases of company drug recalls found but cases of licensee/manufacturing partner drug recall due to quality issues in the relevant countries were discovered - or drug recalls due to packaging issues, not due to quality issues.
- 1 The company makes no disclosure in this area.
- o Drug recall related to quality issues with company produced products in the relevant countries occurred during the past 5 years.

**D.III.5 The company files for WHO Prequalification list, tentative approval of US Food and Drug Administration, European Medicines Agency or other stringent regulatory authority approval for its eligible products for the Index Diseases. 10%**

- 5 The company has applied for any of the mentioned processes for all its products qualifying for these processes.
- 2.5 The company has applied for any of the mentioned processes for some of its qualifying products - or the company has no eligible products covered by the mentioned processes.
- o The company has not filed for any of the mentioned processes.

**D.III.6** Do products for Index Diseases, destined for Index Countries, for which tiered pricing is used, have special packaging or other distinct markers to prevent product diversion?\*

15%

- 5 >50% of products in portfolio on WHO Essential Drugs List are tagged or packaged differently.
- 2.5 >50% in portfolio not on WHO EDL are tagged or packaged differently.
- o The company does not have special tagging or packaging.

\* Reflecting a needs-driven approach, for Index 2012 priority was given for anti-diversionary differential packaging for tiered priced products on the WHO Essential Medicines List (EML).

**D.IV Innovation (25%)**

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

50%

- 5 The company has adopted innovative (unique in the sector) business models related to pricing for drugs for the relevant diseases in the relevant countries which can result in more affordability or accessibility of such medications.

- 2.5 The company has adopted innovative (unique in the sector) business models related to pricing for drugs for the relevant diseases in the relevant countries but NO progress or inputs disclosed.
- o No innovative initiatives discovered for the company in this area.

**D.IV.2** The company has introduced innovative approaches (unique in the sector) to manufacturing and distribution of products for the Index Diseases which may help with sustainable delivery of such products for the Index Diseases in the Index Countries.

50%

- 5 The company has adopted innovative (unique in the sector) business models related to increasing research capacity for the relevant diseases and countries. Only innovative projects for which either progress or human or financial resources are disclosed should be taken into consideration.
- 2.5 The company has adopted innovative (unique in the sector) business models related to increasing research capacity for the relevant diseases and countries but NO progress or inputs disclosed.
- o No innovative initiatives discovered for the company in this area.

## E Patents and Licencing

**E.1 Commitment 25%**

**E.1.1** The company commits to not filing for patents related to its products for the Index Diseases in LDCs.

15%

- 5 The company makes a general commitment not to patent, to abandon any existing patents or issue non-assert declarations on any IP AND to publish information concerning existing patents relating to products for relevant diseases in any Least Developed Country through direct or indirect means.
- 2.5 The company makes a general commitment not to patent, to abandon any existing patents or issue non-assert declarations on any IP AND publish information concerning existing patents relating to products for relevant diseases in certain regions (such as Sub-Saharan Africa) OR for a sub-set of its products.
- o The company makes no commitments in this area.

**E.1.2** The company commits to respect the right of the Index Countries to use the TRIPS flexibilities in-line with the Doha Declaration on

25%

the TRIPS Agreement and Public Health in the Index Countries.

- 5 The company dissents from the Special 301 Watch List, stating that it respects the countries' right to use the different TRIPS flexibilities provided in the Doha Declaration on TRIPS and Public Health (e.g., compulsory licences, parallel importation) either through a public policy statement or engagement.
- 4 General commitment to the Doha Declaration on TRIPS and Public Health with explicit mention to commit to respect at least one of the flexibilities above.
- 2.5 General commitment to the Doha Declaration on TRIPS and Public Health yet no mention of TRIPS flexibilities or explicit commitment in this area through either of the above-mentioned channels.
- 1 The company makes no statement on TRIPS.
- o The company makes a general policy statement against the use of part or all the TRIPS flexibilities by the qualifying relevant countries, makes a statement in support of the Special 301 Watch List or

makes no commitment to relevant countries' right to use the TRIPS flexibilities.

**E.1.3** The company commits to engage in non-exclusive voluntary licencing (NEVL) or use humanitarian use exemption (HUE) and binding non-assert clauses for exclusive voluntary licencing (EVL) where NEVL haven't been obtainable under principles of humanitarian/socially responsible licencing.

**30%**

- 5 The company has in place a policy to engage in non-exclusive voluntary licencing that is socially responsible for relevant products with qualified manufacturers where third party production is deemed conducive to increased affordability and accessibility or to use humanitarian use licence (HUL) and binding non-assert clauses for exclusive voluntary licencing (EVL) where NEVL haven't been obtainable under principles of humanitarian/ socially responsible licencing, demonstrating constructive engagement of its legal/IP team on such matters.
- 4 The company has in place a policy to consider non-exclusive, voluntary licencing with socially responsible terms, where appropriate, or humanitarian use licencing, or binding non-assert declarations, demonstrating that such tools have been considered by its legal/IP team where relevant.
- 3 The company has in place a policy to consider voluntary licencing or the above-mentioned tools for a sub-set of its products but does not mention non-exclusive nature and not for all products.
- 2.5 The company does not have in place a policy to carry out voluntary licencing but has tiered pricing for relevant products in relevant countries or they consider it as an option where it is appropriate.
- o The company makes no commitments regarding non-exclusive socially responsible licencing and has no tiered pricing in place for relevant pharmaceutical products.

**E.1.4** The company commits to engage in technology transfer related to the manufacturing, testing, storage and handling of products for Index Diseases (or APIs) through use of appropriate milestones.

**30%**

- 5 The company has in place a policy, or provides evidence that it has active licences with provisions, to transfer technical know-how related to the manufacturing, testing, storage and handling of relevant products (or APIs) through use of appropriate milestones.
- 2.5 The company makes a general public statement emphasising its commitment to the transfer of relevant technical know-how.

- 1 The company commits to provide technical know-how relating to the manufacturing, testing, storage and handling of relevant products upon request.
- o The company makes no policies or public statements or other demonstrated forms of commitment.

**E.II Transparency (25%)**

**E.II.1** The company discloses its explicit support of usage of TRIPS flexibilities based on the Doha Declaration on TRIPS and public health.

**25%**

- 5 The company discloses explicit support for Doha Declaration and usage of TRIPS flexibilities in relation to relevant countries.
- 4 The company discloses explicit support for the Doha Declaration and three to four TRIPS flexibilities.
- 3 The company discloses explicit support for two TRIPS flexibilities.
- 2 The company discloses explicit support for one TRIPS flexibility.
- o The company makes no disclosure of support for the Doha Declaration.

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

**45%**

- 5 The company publicly discloses the patent status for all patents for all relevant products.
- 2.5 The company publicly discloses the patent status for some relevant products.
- o The company makes no disclosure about patent status.

**E.II.3** The company discloses detailed information about the voluntary licencing activities it is engaged in and its binding non-assert clauses for products related to the Index Diseases for the Index Countries (such as licence duration, licence territory, technology transfer etc.).

**30%**

- 5 The company fully discloses complete information regarding the terms of its voluntary licences per relevant drug, the name/location of the licensee, the exclusive/non-exclusive nature of the licence, licence duration, territory, scope/application, milestones, royalty terms, pricing clauses and any humanitarian use exemption clauses and production information (supply units).
- 4 The company discloses partial information on the above-mentioned items for a subset of its licensees and products but no production information.
- 2.5 The company discloses partial information on an engagement basis on voluntary licencing but no production information.
- o The company makes no disclosure in this area.

**E.III Performance (40%)**

**E.III.1 20%** Does the company actively engage in non-exclusive voluntary licencing and/or use legally binding non-assert declarations/ clauses for the Index Countries for its products related to the Index Diseases?

- 5 The company has issued non-exclusive voluntary licencees and/or non-assert declarations to >10 generic manufacturers for three or more relevant disease products.
- 4 The company has issued non-exclusive voluntary licencees and/or non-assert declarations to >10 to generic manufacturers for two relevant disease products.
- 3 The company has issued non-exclusive, voluntary licencees and/or non-assert declarations to >5 generic companies for one product.
- 2.5 The company has no product that is a candidate for licencing (no patented products) OR the company has a score of greater than 2.5 on pricing indicators.
- 1.5 The company has not provided detailed information on non-exclusive voluntary licencing but evidence has been discovered of non-exclusive, voluntary licencing activity.
- o The company has not granted voluntary licencees for any of its products.

**E.III.2 20%** Does the company have technology transfer agreements in place as part of its licence agreements and milestones/deliverables related to technology transfer and transfer of technical know-how in its licencing activities?

- 5 The company has technology transfer agreements in place and the milestones within it related to technology transfer and transfer of technical know-how are fulfilled.
- 2.5 The company has technology transfer agreements in place but has no disclosure around fulfilment of milestones.
- o The company does not have technology transfer agreements in place.

**E.III.3 20%** The company supports patent pools such as The Medicines Patent Pool for development of New/adaptive remedies for the Index Diseases in the Index Countries.

- 5 The company has completed a licence agreement with the Medicines Patent Pool (MPP) covering ALL relevant countries.
- 4 The company has completed a licence agreement with the MPP covering at least 90% of People Living with HIV (PLHIV) in the relevant countries.
- 3 The company has completed a licence agreement with the MPP covering at least 85% PLHIV in relevant countries.
- 2 The company has entered into formal negotiations with the MPP.
- o The company is not in formal negotiations with the MPP.

*Neutral score for a company that has no relevant products for inclusion into the Patent Pool.*

**E.III.4 20%** Is there evidence that the company actively lobbies national or regional government public health authorities or other companies and their trade associations, either directly or through third parties, for TRIPS<sup>+</sup> measures (e.g. data exclusivity etc.)?

- 5 There is no evidence that the company has engaged in lobbying activities for any aspect of TRIPS + measures.
- 2.5 There is at least one incident where the company has lobbied for TRIPS + measures.
- o The company has three or more instances of lobbying for TRIPS<sup>+</sup>.

**E.III.5 20%** Is there evidence that the company employs an IP strategy that is conducive to access to affordable products for Index Diseases in the Index Countries (e.g. actively engage in pro-competitive approaches such as legally binding NADs and/or avoids anti-competitive practices such as evergreening, thickening, protection of research tools etc.)?

- 5 The company provides evidence of using non-assert clauses in third party licencing agreements; socially responsible licencing agreements; and humanitarian use exemptions, where relevant AND no evidence is found that the company is involved in anti-competitive practices in relation to access to medicines\*.
- 2.5 No evidence is found that the company is involved in any anti-competitive practices that restrict access to medicines, including any of those included above.
- 1 The company has been involved in anti-competitive practices included above but does pro-access terms in its licencing agreements (including non-assert clauses and/or socially responsible licencing clauses).
- o The company has been involved in anti-competitive practices listed above and does not implement non-assert declarations or employ socially responsible licencing approaches.

*\*including patenting in Least Developed Countries; evergreening of products for relevant diseases to protect new applications for use that extend their patented life; creating patent thickets to deter R&D in certain technological areas related to relevant diseases; extending patent application dates (to prevent public disclosure); pay-for-delay; anti generic campaigns; using patent challenge clauses in licencees; interventions at regulatory agencies to delay generic registrations; advocacy tactics to undermine public confidence in generic products and acting against usage of TRIPS flexibilities by the relevant countries based on the Doha Declaration on TRIPS and Public Health.*

**E.IV Innovation (25%)**

**E.IV.1 100%** The company has engaged in innovative (unique in the sector), sustainable programmes aimed at decreasing the impact of the exclusivity conferred by patent protection that could result in increased affordability and accessibility of medicines to individuals with financial barriers to access (e.g., adopted innovative socially responsible licencing practices aiming at increased effectiveness of its licencing programmes).

- 5 The company has adopted innovative, sustainable programmes aimed at decreasing the impact of the exclusivity conferred by patent protection that could result in increased affordability and accessibility of medicines

to individuals with financial barriers to access (e.g., adopted innovative socially responsible licencing practices aiming at increased effectiveness of its licencing programmes) and supports this with evidence of progress and/or human or financial resources invested.

- 2.5 The company has adopted innovative, sustainable programmes aimed at decreasing the impact of the exclusivity conferred by patent protection that could result in increased affordability and accessibility of medicines to individuals with financial barriers to access - but does NOT disclose progress or resources inputs.
  - o No innovative initiatives discovered for the company in this area.

## F Capability Advancement in Product Development and Distribution

**F.I Commitment 25%**

**F.I.1 25%** The company commits to assist Index Country manufacturers and local staff employed at in-house facilities operating in Index Countries in building quality management systems aimed at achieving international quality standards\*.

- 5 The company demands quality standards from its third party manufacturers or in-house facilities in Low Income Countries and commits to provide them with the training and tools needed to maintain drug quality consistent with international standards AND implements milestones for the development of QMS capacity in Lower-middle-income countries.
- 4 The company commits to all of the above except only in respect of the Lower-middle-income countries.
- 3 The company either provides quality training & tools as listed above or has specific quality management requirements as listed above in its third party manufacturer or in-house facilities.
- 2 The company makes a broad commitment.
- o The company makes no such commitment.

\*Such as, FDA, EMA, WHO GMP or exually recognised national certifications.

**F.I.2 25%** The company commits to engage in local scientific research partnerships with public sector research institutes and/or universities with the aim of developing indigenous capacity in basic, applied or clinical research, including clinical trials, in Index Countries.

- 5 The company commits to and is found to have > 5 examples of relevant country PPPs and/or academic/public sector collaborations and/or clinical research programmes, focussed on generating local research capacity in multiple relevant countries OR a few (between 2-4) examples of significant, repeated exercises aimed at increasing the local research capacity in relevant countries.
- 4 The company commits to and has at least one major, significant, repeated exercise, OR a few (between 2-4) examples of PPPs and/or academic collaborations and/or clinical research programmes aimed at increasing the local research capacity in relevant countries.
- 2.5 At least one, single example of a research collaboration in the relevant countries which is not repeated.
  - o The company does not engage in activities in this area.

**F.I.3 25%** The company commits to assist Index Country governments (e.g. MoH/procurement, logistics and distribution agencies) and other distributors to develop, locally appropriate supply chain capabilities with the aim of improving affordability, accessibility and quality of the delivered Index Disease products.

- 5 Several examples of long-term engagements (5+ years) with relevant country governments or distributors in the following areas that can help prevent drug diversion, stockouts or counterfeiting in the relevant countries: Distribution & Logistics (expiration, stockouts,



- theft, mark-ups, counterfeiting); Information gaps (Information flow in/out of the warehouse inventory systems; Demand forecasting/smoothing for supply efficiency); Business System design (industry attachments; project/business management systems); Drug regulation/batch/shipment control and Physical facilities.
- 2.5 The company commits to limited activities, as listed above.
- o The company makes no disclosure in this area.

**F.I.4** **The company commits to support the development and/or implementation of national pharmacovigilance programmes in the Index Countries.**  
**25%**

- 5 The company commits to and is found to have > 2 examples of engagement with local stakeholders to support and establish national pharmacovigilance systems in a large number of relevant countries, including disclosure of detailed mechanisms OR human or financial inputs (including training, consultancies, secondments; inputs to development of national programme).
- 4 The company commits to and is found to have one or two examples of engagement with local stakeholders to support and establish national pharmacovigilance systems in a large number of relevant countries, including disclosure of detailed mechanisms OR human or financial inputs as above.
- 2.5 The company has provided evidence such as a detailed approach towards supporting national pharmacovigilance programmes OR resources as above in at least one relevant country.
- 1 The company has provided evidence of internal pharmacovigilance in one or more relevant country.
- o The company does not engage in pharmacovigilance in relevant countries.

*Emphasis here is on national pharmacovigilance programmes (vs. global programmes).*

**F.II** **Transparency (25%)**

**F.II.1** **The company discloses details of its capability advancement activities related to the development and/or implementation of national pharmacovigilance programmes in the Index Countries.**  
**100%**

- 5 The company publicly discloses information about the financial OR technical OR human resources dedicated to its in-house activities and collaborations aimed at improving national pharmacovigilance systems in the relevant countries.
- 3.5 The company discloses on engagement information about the financial OR technical OR human resources dedicated to

- its in-house activities and collaborations aimed at improving pharmacovigilance systems in the relevant countries.
- 2.5 The company discloses its approach in relevant countries but no disclosure related to human or financial resources.
- 1 The company discloses information about its internal pharmacovigilance in relevant countries.
- o The company makes no disclosure in this area.

*Emphasis here is on national pharmacovigilance programmes (vs. global programmes).*

**F.III** **Performance (40%)**

**F.III.1** **Is there evidence that the company assists local Index Country manufacturers or in-house manufacturing facilities to achieve international good manufacturing standards\* in the Index Countries?**  
**20%**

- 5 The company has conducted >5 training workshops or consultancies and/or technology transfers across relevant countries and geographies with the aim of achieving compliance with WHO GMP or equivalent internal standards including in Lower Income Countries.
- 4 The company has provided 1-4 training workshops or consultancies and/or technology transfers in at least one relevant country with the aim of achieving compliance with WHO GMP or equivalent internal standards in Lower-Income Countries or Lower-Middle-Income Countries.
- 2.5 There is evidence of at least one example of technology transfer or training in at least one relevant country aimed at achieving compliance with WHO GMP or equivalent internal standards.
- o The company does not carry out activities in this area.

*\* Such as FDA, EMA or the WHO GMP or equally recognised national certifications.*

**F.III.2** **Is there evidence that the company participates in local partnerships with public sector research institutes or universities in the Index Countries with the aim of increasing local capacity for health research (including clinical trials capacity) and product development?**  
**20%**

- 5 The company has >5 long-term (>5 years) engagements in active capacity building initiatives with local research institutions such as building clinical trials capacity\* or other research capacities\*\* PLUS funding initiatives such as sponsorships.
- 4 The company is engaged in 5-10 of the above-mentioned initiatives (<5 years) with the aim of transferring research capacity to relevant country organisations.

- 2.5 The company commits to support at least one example of academic research OR commits to participate in local PPPs OR commits to clinical research programmes aimed at transferring research capacity to relevant countries through one of outlined measures.
- o The company makes no commitment in this area.

*\*e.g. training in data management, ethical review board conduct/management, software provision.*

*\*\*e.g. transferring hardware and know-how through training, conferences, exchanges, secondments, co-authorship of papers.*

**F.III.3** The company is engaged in programmes/partnerships with Index Country governments (e.g. MoH/procurement, logistics and distribution agencies) and other distributors to develop, locally appropriate supply chain capabilities with the aim of improving affordability, accessibility and quality of the delivered Index Disease products.

- 20%**
- 5 The company is engaged in >5 programmes/partnerships with relevant governments and other distributors to develop locally appropriate supply chain capabilities\* OR at least one long-term (>5 years) collaboration in relevant countries to achieve the same.
- 4 The company is engaged in 2-4 programmes/partnerships with relevant governments to achieve the same.
- 2.5 The company is engaged in at least one programme/partnership with relevant governments to achieve the same.
- o The company does not engage in these activities.

*\* Supply chain capabilities include efforts to prevent drug diversion, deterioration, stock-outs or counterfeiting and improve overall forecasting and procurement management.*

**F.III.4** The company is actively engaged in developing and implementing national pharmacovigilance-related programmes in the Index Countries.

- 20%**
- 5 The company is engaged in >2 active long-term engagements (>5 years) with leading institutions in country\* to build pharmacovigilance capacity according to a national/regional plan, with the aim of improving the effectiveness of pharmacovigilance systems in a large number of relevant countries where it operates.
- 4 The company is engaged in two active long-term engagements as listed above.
- 3 The company is engaged in one active long-term engagements as listed above.
- 2 The company is engaged in ad hoc activities (e.g. providing resources and infrastructure and materials) to support the implementation of pharmacovigilance systems with no specific mention

of alignment with national/regional capacity building plans, for only specific disease areas or product or a sub-set of countries.

- o The company is not engaged in supporting pharmacovigilance-related systems in relevant countries.

*\*Leading institutions may include: national pharmacovigilance committee, health and drug regulatory authorities, local pharmaceutical representatives, health services and decision making agencies.*

**F.III.5** The company carries out other initiatives (where there is no conflict of interest) with potential for improving capacity of Index Country organisations to address access to medicine in those countries.

- 20%**
- 5 The company has several examples of evidence of activities involving reputable international organisations\* and/or contributing money to a fund run by reputable organisations that run programmes that build other capacities outside the pharmaceutical value chain where conflict of interest is fully absent.
- 2.5 The company has one example of evidence of the above.
- o The company provides no examples of activities in this area.
- \* For example, the WHO, leading INGOs, or local leading NGOs.*

**F.IV Innovation (25%)**

**F.IV.1** The company has introduced innovative (unique in the sector) approaches to working with the Index Country organisations to improve the quality and accessibility of the products for Index Diseases.

- 50%**
- 5 The company has adopted innovative (unique in the sector) approaches to local capacity advancements in quality and supply chain management (including securing pharmaceutical supply-chain, demand forecasting, pharmacovigilance, and local quality management) with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has adopted innovative (unique in the sector ) approaches to local capacity advancements in quality and supply chain management (including activities described above) but does NOT disclose progress or resources inputs.
- o No innovative initiatives discovered for the company in this area.

**F.IV.2** The company has introduced innovative (unique in the sector) approaches to working with the Index Country organisations which help improve the local research and product development capacity and other capacities for the Index Diseases.

- 5 The company has adopted innovative (unique in the sector) approaches to long-term local capacity advancements in research and product development (including technology commercialisation/knowledge transfer and clinical trials research and management) with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has adopted innovative (unique in the sector) approaches to local capacity advancements in research and product development (including technology commercialisation/knowledge transfer and clinical trials research and management) but does NOT disclose progress or resources inputs.
  - o No innovative initiatives discovered for the company in this area.

## G Drug Donations and Philanthropic Activities

### G.1 Commitment 25%

#### G.1.1 10% The company commits to comply with the World Health Organization Inter-Agency Guidelines for Drug Donations in the Index Countries for all its drug donation activities.

- 5 The company has a donation policy and makes a commitment to respect the WHO inter-agency Guidelines for Drug Donations in all its donations activities OR to ALL of its core components:
  - a) meeting local needs (maximum benefit for the recipients),
  - b) participatory approach (respecting the wishes of the recipient),
  - c) optimised drug donation quality (no double standard in quality) and
  - d) effective communication between donor and recipient\* and is a member of Partnership for Quality Medical Donations (PQMD).
- 4 The company makes a general commitment to respect the WHO inter-agency Guidelines for Drug Donations in all its donations activities OR to ALL of its core components above but are NOT a member of PQMD.
- 2.5 The company's commitment in this area is partial or conditional or based on an internal code equivalent to the WHO Guidelines for Drug Donations containing at least three of the four areas outlined above.
  - o The company has not committed to respect the WHO Guidelines for Drug Donations recommendations.

\* WHO Guidelines for Drug Donations Revised 1999 WHO/EDM/P AR/99.4.

#### G.1.2 30% The company commits to ensuring that donated products are administered to patients in the Index Countries.

- 5 The company has stringent regular monitoring processes or reporting to ensure that the product donations which are donated directly or through intermediaries reach the targeted communities in need based on standards set out in the

WHO Interagency Guidelines for Drug Donations.

- 2.5 The company has a guideline for its donations programmes and donation management intermediaries but does not regularly monitor performance and certify the donations activities carried out on its behalf.
  - o The company makes no commitments in this area.

#### G.1.3 30% The company commits to and explains its rationale for investing in health infrastructure-related philanthropic projects (outside of the standard value chain) in the Index Countries and their relevance to long term sustainable access to medicines in Index Countries.

- 5 The company has a sustainable, long term approach to supporting health care infrastructure/capacity advancement in the relevant countries, set out in a specific statement of its strategic approach, which has linkage to national health system/research/pharmacovigilance development plans, aimed at improved drug delivery and use.
- 2.5 The company discloses only a general statement in this area without providing details on the areas of its strategic focus or rationale for infrastructure building or objectives.
  - o The company's philanthropic activities are not focussed on bringing about sustainable, long-term change in the target relevant countries.

\* WHO Guidelines for Drug Donations Revised 1999 WHO/EDM/P AR/99.4.

#### G.1.4 30% The company commits to delivering single-drug donation programmes, in line with WHO Inter-Agency Guidelines for Drug Donations.

- 5 The company commits to single-drug donation programmes AND commits to follow the WHO Interagency Code on Drug Donations or all of the following conditions:\*

- a) meeting local needs (maximum benefit for the recipients),
  - b) participatory approach (respecting the wishes of the recipient),
  - c) optimised drug donation quality (no double standard in quality) and
  - d) effective communication between donor and recipient.
- 2.5 The company commits to single-drug donation programmes but does not declare that this is the preferred mode of making drug donations.
- o No evidence of any commitment to single-drug donation programmes.

## **G.II Transparency (25%)**

### **G.II.1 40%** The company discloses the process and criteria for deciding the drug types and destinations for its drug donation programmes in the Index Countries.

- 5 The company publicly discloses details with regard to how it plans the drug types and volumes for ALL of its single-drug-donations programmes carried out directly by the company or through intermediaries in the relevant countries for the relevant diseases.
- 2.5 The company discloses partial information on the drug types and volume of its single-drug donations.
- o The company did not provide information nor disclosed upon engagement.

*Companies that have no single-drug donation programmes receive a neutral score.*

### **G.II.2 40%** The company discloses detailed information about the type, volume and destination of products that are part of its multi-drug donation programmes donated in the Index Countries.

- 5 The company publicly discloses the type, volume and destination (organisation or country).
- 4 The company publicly discloses two of three of the items above.
- 3 The company publicly discloses one of three of the items above.
- 2.5 The company does not have a donations programme.
- 2 The company discloses the equivalent of score 5 on engagement basis only.
- 1 The company discloses the equivalent of score 3 or 4 on engagement basis only.
- o The company makes no disclosure in this area.

### **G.II.3 20%** The company discloses the amount of resources dedicated to and achievements resulting from its philanthropic activities in the Index Countries.

- 5 The company discloses the financial and/or human resources and/or the output or progress for each of its philanthropic projects (e.g. improved allocation of public resources; improved capabilities

in sector including numbers of qualified personnel to complete tasks; improved hardware to enable tasks to be undertaken).

- 4 The company discloses the financial and/or human resources and/or the output for some of its philanthropic projects.
- 2.5 The company discloses the information at the aggregate level.
  - o The company makes no disclosure in this area.

## **G.III Performance (40%)**

### **G.III.1 25%** For the companies' single-drug donation programmes, what were the outcomes or impacts of these programmes during the reporting period?

- 5 The company discloses the impacts of outputs of each of its single-drug donation programmes (e.g. number of patients reached who otherwise would not have been; improved allocation of government resources; improved patient outcomes such as prevention of epidemic outbreak).
- 4 The company discloses the impacts/ outputs for some of its single-drug donation programmes.
- 2.5 The company discloses the above information but at the aggregate level.
  - o The company makes no disclosure in this area.

*Companies that do not have single-drug donation programmes receive a neutral score.*

### **G.III.2 25%** The value of donated products which were donated based on targeted, needs-based strategic donations programmes to the Index Countries during the period of analysis (single-drug donations adjusted for the company size).

Divide value of single-drug donations during Index period by company total revenue 2010 & 2011. Revenue-standardized number is scaled and scored.

*Companies that don't have any single-drug donation programmes receive a neutral score.*

### **G.III.3 25%** The scale and scope of donated products to the Index Countries during the period of analysis.

- 5 The company has 3 or more strategic long-term donation programmes.
- 3.5 The company has 2 strategic long-term donation programmes.
- 2.5 The company has 1 single-drug donation programme.
  - 1 The company has multi-drug donation programmes only, without targeting known social needs.
  - o The company makes no drug donation programmes.

**G.III.4** There is evidence that the company's philanthropic activities (excluding drug donation programmes) are aligned with and support implementation of national health system development plans and stated health priorities in the Index Countries.

**25%**

- 5 The company provides evidence that >10 company philanthropic initiatives are explicitly linked to national health/pharmaceutical/vaccine development plans.
- 3.5 The company provides evidence of 5-10 company philanthropic initiatives as above.
- 2 The company provides evidence of 3-5 initiatives as above.
- 1 The company provides evidence of 1-2 initiatives as above.
- o The company provides no evidence that philanthropic initiatives are related to national development plans.

#### **G.IV Innovation (25%)**

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

**50%**

- 5 The company has adopted innovative (unique in the sector) approaches to managing drug donations with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has adopted innovative (unique in the sector) approaches to managing drug donations but does NOT disclose progress or resources inputs.
- o The company has no innovative initiatives discovered in this area.

**G.IV.2** The company has introduced innovative (unique in the sector) approaches to philanthropic programmes to make it more sustainable and linked to better health outcomes in the Index Countries which may result in sustainable health improvements.

**50%**

- 5 The company has adopted innovative (unique in the sector) approaches to philanthropic programmes in relevant countries which may result in sustainable health improvements and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has adopted innovative (unique in the sector) approaches to philanthropic programmes in relevant countries which may result in sustainable health improvements but does NOT disclose progress or resources inputs.
- o The company has no innovative initiatives discovered in this area.

## Abridged Summary of Academic and Technical Sources in the Methodology Development and Data Analysis of Index 2012

### ■ General Documents

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- WHO, 1999. Guidelines for Drug Donations (2<sup>nd</sup> Edition). Geneva: World Health Organization. Available: [http://www.searo.who.int/LinkFiles/Prevention\\_and\\_Control\\_Guidelines\\_Drug\\_Donations.pdf](http://www.searo.who.int/LinkFiles/Prevention_and_Control_Guidelines_Drug_Donations.pdf)
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### ■ General Access to Medicine Management

- Abraham, J., 2002. The Pharmaceutical Industry as a Political Player. *Lancet* 360, 1498-502.
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## Definitions

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### Active Licencee

An 'active licencee' is defined as a licencee under which production is happening or the licencee is planning to start production in the near future, in contrast to a 'dormant licencee.' Active voluntary licencing includes only full licencing of the final product for manufacturing by the licencee. Multiple 'active' voluntary licences should be in place for the drug to be counted without global or regional marketing exclusivity for the licencee. An active licencee is a licencee under which production is happening or the licencee is actively progressing towards production.

### Adaptive Research

Research involving the development of new formulations of existing compounds aimed at adapting those compounds to possess specific environmental (heat-resistant formulations), social (fixed-dose combinations) or demographic (paediatric formulations) characteristics.

### Bolar

A Bolar provision allows generic manufacturers to use the technology of a patented medicine in order to assist in marketing or regulatory approval processes.

### Candidates

The number of molecules or compounds in a company's R&D pipeline.

### CD4 count

CD4 count refers to the number of CD4/Tcells in the blood, which protect against infections. These cells are targeted by the HIV virus and their destruction leads to the immunodeficiency response of AIDS. Therefore, it is a parameter to measure the progression of HIV/AIDS.

### Clinical Trial Phases

- Phase I: In these studies a study medicine is investigated in a small group of healthy volunteers. This phase is to determine the safety profile of the medicine and how it is metabolized and excreted.
- Phase II: In these initial studies a study medicine is investigated in a larger group of patients with a focus on efficacy and safety.
- Phase III: During this phase the study medicine's efficacy and safety is studied in different populations. Different doses are tested and its efficacy and safety are compared to other therapeutic agents. When favourable results are demonstrated in this phase, regulatory approval for marketing can be obtained.
- Phase IV: These are studies that are conducted after market approval. Typically, they investigate safety, efficacy, or optimal use in a large population.

### Collaborative Research

Research done jointly by a number of parties including academic researchers, governments and pharmaceutical companies and/or in public-private partnerships.

### Company Size

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

### Compound/Molecule Libraries

These libraries are collections of molecules/compounds used to explore complex disease pathways and to assist in the characterization of disease targets.

### Compulsory Licence

Government allows a third party to produce a patented product or use a patented process without the consent of the patent owner.

### Country Classifications

Countries are classified based on the UN Human Development Index, UN Department of Economic and Social Affairs classification and on the income level categories according to the World Bank. The relevant categories are:

- Least Developed Countries (LDC) – UN DESA
- Low-income countries (LIC) – World Bank
- Lower-middle-income country (LMIC) – World Bank
- Medium human development countries (MHDC) – UN Human Development Index
- High-income countries (HIC) – World Bank

### DALY (Disability Adjusted Life Years)

WHO definition: 'The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.'

### Data Exclusivity

Data exclusivity refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications.

### Declaration of Helsinki

The Declaration of Helsinki was initially adopted in 1964 as a reaction to the lack of a general accepted code of conduct for human research. It is a code of conduct for physicians to guarantee ethical clinical trial conduct. Essential principles revolve around respect for the individual and the right to make self-determined informed decisions.

**Differential Pricing**

Adapting drug prices to the purchasing power of consumers in different geographical or socioeconomic segments. Differential pricing improves affordability of medicines in low income settings, and is therefore a form of equitable pricing.

**Doha Declaration**

The Doha declaration on the TRIPS Agreement was issued to prevent possible constraints the agreement would put on access to medicine. It enables governments to protect public health by two tasks. First, it provides a solution when countries have difficulties issuing a compulsory licence. Second, Least-Developed Countries do not have to apply provisions on pharmaceutical patents until 2016.

**Drug Diversion**

Channeling lower-priced drugs from developing countries into developed markets or from lower income segments to high-income segments within a country.

**Drug Recall**

A drug is removed from the market because it is found to be either defective or potentially harmful. This is done either by the drug manufacturers or by the drug regulatory authority.

**Evergreening of Drugs**

Extension of a patent(s) on a branded drug through obtaining IP protection on new applications or fields of use. Typically, it is a metabolite or other very close chemical relative or a reformulation of a highly profitable, branded drug.

**Exclusive Voluntary Licencing**

Authorization given voluntarily by the patent holder to a single generic company on an exclusive basis, allowing the production of the patented article as if it were a generic.

**Exhaustion of IPR**

Limit of Intellectual Property Rights under which, a product protected by an IP rights once marketed by the company or by others with company consent, the IP rights of commercial exploitation over this given product can no longer be exercised by the company as they are 'exhausted'.

**G-Finder References for Disease Scope**

G-FINDER only includes infectious diseases that follow three criteria:

- Disproportionally affect the developing world
- There is a need for new products (i.e. there is no existing product OR improved or additional products are needed)
- There is market failure (i.e. there is insufficient commercial market to attract R&D by private industry)

**Generics Manufacturing**

In this document, Generics Manufacturing refers to manufacturing of pharmaceutical products by a company, which does not hold the patent for the product (produced under voluntary licence or based on TRIPS flexibilities etc.), or to a product whose patent has expired.

**Generics**

The term *Generics* is defined as;

- a) products where the key patent has expired and/or;
- b) the product is produced under licence. For example, the term 'generic' products refers to products for which a company is carrying out in-licence manufacturing of an on-patent product. The Index does not aim to capture innovative molecules licenced at the pre-clinical and clinical stages of development; therefore, this definition of 'generics' applies only to in-licence manufacturing of final (post-phase III) products.

**Humanitarian Licence Reservation/Humanitarian Use Exemption**

A provision in a licence agreement by a licensor to reserve in advance the possibility of granting rights to third parties to achieve social and access outcomes for people in need.

**In-house Research**

Research done by a company internally to discover new drugs.

**Innovative Research**

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

**Inter-Country\* Tiered Pricing**

Differential pricing between countries, where drugs in low- and middle-income countries are systematically priced lower than in developed countries. This improves affordability for lower-income countries.

**Intra-Country\* Tiered Pricing**

Differential pricing within an Index country based on the different socioeconomic segments. Intra-country tiered pricing can be better suited to countries in emerging markets with an expanding middle class. This method of pricing increases access to medicines for the lower socioeconomic segments.

\* The term 'country' in 'intra' and 'inter' is used as a general term to define any differential pricing policies that a company has implemented in the Index countries that varies between countries and within countries (taking into account access barriers). All Index countries where a product is used to treat Index diseases will come into this category.

**Long-Term**

A project, commitment, engagement or plan is considered long-term when it is over 5 years.

**Multi-Drug Donations**

Donations for which there is no clear, defined strategy. This may include a company donating a range of medicines based on stock availability, which may or may not be based on the explicit needs of a country.

**NDA (New Drug Application)**

An NDA contains all the preclinical and clinical information obtained during the testing phase.

**Non-Assert Declaration**

A legally-binding commitment by a rights holder not to enforce certain patents in a defined group of countries. Allows a generic version of a patent-protected article to be produced in a resource-limited setting.

**Non-Exclusive Licencing**

Non-Exclusive Licencing of the intellectual property of a final product to another organisation for manufacturing, distribution and sales of that product in the licence territory, without provision of exclusivity to that organisation.

**Non-Exclusive Voluntary Licencing**

Authorization given voluntarily by the patent holder to generic companies on a non-exclusive basis, allowing more than one company to produce the patented article as if it were a generic.

**Originator Company**

A company whose revenues are mostly from sales of patented products and focusses on research and development, aimed at developing new pharmaceutical products.

**Outside the Value Chain**

Activities beyond the scope of the company's normal operations and distribution channels.

**Parallel Import**

Unauthorized imports of a patented or trademarked product from a country where it is already marketed.

**Patent**

An intellectual property right providing an inventor with a legal monopoly right to prevent others from making, using, or selling the new invention for a defined period of time, subject to a number of exceptions.

**Patent Pool**

Portfolio of patents and other relevant intellectual property rights held by various actors made available on a non-exclusive basis to third parties, (e.g. generic manufacturers) against the payment of royalties.

**Period of Analysis**

The period of analysis of Index 2012 includes the full 2010 and 2011 fiscal years.

**Pharmacovigilance**

Defined by the World Health Organization (WHO) as the 'science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.'

**Prequalification of Medicines by WHO**

A service provided by WHO to assess the quality, safety and efficacy of medicinal products in order to accelerate introduction of successful candidates into use.

**Pro-Access**

Pro-access seeks to ensure access through provisions that address public health needs. A pro-access licence will have explicit terms embedded within it that ensure timely drug development and market registration, safe and acceptable products delivered to populations who need them, and a price that is affordable to those people and commercial imperatives will be balanced against patient needs.

**Products**

Products, technologies or commodities, which are described in the product type scope: medicines, therapeutic vaccines, preventive vaccines, diagnostics, microbicides, vector control products, and platform technologies.

**Revenue**

The total sales revenues generated over the past five years (2007-2011). It is the 'top line' or 'gross income' figure from which costs are subtracted to determine net income.

**Single-drug Donations**

Donations for which a defined strategy exists as to the type, volume, and destination of donated products. Single-drug donations are based on long-term, targeted donation programmes based on country needs.

**Socially Responsible Licencing [SRL]**

A licencing concept that involves various principles or provisions (such as territorial scope, pricing and milestones for delivery) in licencing agreements aiming to achieve certain social outcomes such as access to, and affordability of, crucial technologies for people in need.

**Spurious/Falsely-labeled/Falsified/Counterfeit (SFFC) medicines**

Drugs that are deliberately mislabeled which include the products with wrong ingredients, insufficient ingredient or fake packaging.

**Strategic Pillar**

As part of the Index's analytical framework, the indicators under each Technical Area are broken down into four Strategic Pillars - Commitments, Transparency, Performance and Innovation.

**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.

**Technical Area**

As part of the Index's analytical framework, the seven major Technical Areas under which the companies are analysed in Index 2012 are: General Access to Medicine Management, Public Policy & Market Influence, Research & Development, Pricing, Manufacturing & Distribution, Patents & Licencing, Capability Advancement in Product Development & Distribution, and Product Donations & Philanthropic Activities.

**Technology Transfer**

Technology transfer refers to any process by which any party gains access to another's technical information and successfully learns and absorbs it into its research, development or manufacturing process.

**Treatment**

First line treatment: Refers to standard therapeutic agents that are first choice for treatment. This choice is based on favourable clinical results in a large population. Second-line treatment: When efficacy of first-line therapy is low or when it induces too many side effects, additional therapeutic agents may be added to treatment or substitute first-line therapy.

**Trade-Related Aspects of Intellectual Property Rights (TRIPS)**

The TRIPS agreement was issued to protect intellectual property rights around the world under international rules. The WTO's TRIPS Agreement covers five broad issues:

- How basic principles of the trading system and other international intellectual property agreements should be applied
- How to give adequate protection to intellectual property rights
- How countries should enforce those rights adequately in their own territories
- How to settle disputes on intellectual property between members of the WTO
- Special transitional arrangements during the period when the new system is being introduced.

**TRIPS + (or TRIPS Plus)**

In addition to the restrictions in patents laws in the TRIPS agreement, TRIP Plus provisions refer to measures contained in multilateral, regional, plurilateral or national intellectual rules and practices that protect IP rights beyond the minimum standards set out in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and may hinder Index Country governments from acting in the public interest. This covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions under the TRIPS Agreement.

## Acronyms

AIDS	Acquired Immuno Deficiency Syndrome	LHDC	Low Human Development Country [UN]
AMREF	African Medical and Research Foundation	LIC	Low Income Country [WB]
API	Active Pharmaceutical Ingredient	LMIC	Lower Middle Income Country [WB]
ATM	Access to Medicine	MDG	Millennium Development Goal
CDBI	Steering Committee on Bioethics (Council of Europe)	MHDC	Medium Human Development Country
CDD	Collaborative Drug Discovery	MIC	Middle-Income Country
CDiC	Changing Diabetes in Children	MMV	Medicines for Malaria Venture
CIOMS	Council for International Organizations of Medical Sciences	MoH	Ministry of Health
COB	Cobicistat	MPP	Medicines Patent Pool
COPD	Chronic Obstructive Pulmonary Disorder	NAD	Non-Assert Declaration
CRO	Contract Research Organization	NCD	Non-Communicable Disease
CSR	Corporate Social Responsibility	NCE	New Chemical Entities
DALY	Disability Adjusted Life Years	NDRA	National Drug Regulatory Authority
DC	Developing Country	NEVL	Non-Exclusive Voluntary Licencing
DD	Drug Donation	NGO	Non-Governmental Organization
DFID	Department for International Development (UK Government)	NTD	Neglected Tropical Diseases
DHHS	Department of Health and Human Services (USA Government)	ODA	Official Development Assistance
DNDi	Drugs for Neglected Diseases initiative	OSDD	Open Source Drug Discovery
EARNEST	Europe-Africa Research Network for Evaluation of Second-line Therapy	PACI	Partnering Against Corruption Initiative
EML	Essential Medicines List	PDP	Product Development Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations	PLHIV	People Living with HIV
EGE	European Group on Ethics in Science and New Technologies	POINT	Pool for Open Innovation against Neglected Tropical Diseases
EMA	European Medicines Agency	PPP	Public-Private Partnership
ERC	Expert Review Committee	PQMD	Partnership for Quality Medical Donations
EVG	Elvitegravir	PhRMA	The Pharmaceutical Research and Manufacturers of America
EVL	Exclusive Voluntary Licencing	R&D	Research and Development
FCPA	Foreign Corrupt Practices Act (USA)	QMS	Quality Management System
FDA	Food and Drug Administration (USA)	RBM	Roll Back Malaria
FDC	Fixed Dose Combination	SEC	Securities and Exchange Commission
FTC	Emtricitabine	TA	Technical Area
GAVI	Global Alliance for Vaccines and Immunization	TB	Tuberculosis
GBD	Global Burden of Disease	TDF	Tenofovir
GMP	Good Manufacturing Practices (WHO)	TRIPS	Trade-related Aspects of Intellectual Property Rights
GPHF	Global Pharma Health Fund	TSC	Technical Subcommittee
GPP	Good Participatory Practice (Guidelines for Biomedical HIV Prevention Trials of UNAIDS)	UN	United Nations
HDI	Human Development Index	UNAIDS	Joint United Nations Programme on HIV/AIDS
HIC	High-Income Country	UNGC	United Nations Global Compact
HIV	Human Immunodeficiency Virus	UNDP	United Nations Development Programme
HUE	Humanitarian Use Exemption	UNFPA	United Nations Population Fund
HUL	Humanitarian Use Licencing	UNWTO	United Nations World Trade Organizations
ICB	Industry Classification Benchmark	VL	Voluntary Licence
ICH Q10	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Quality Guidelines	WB	World Bank
ICCR	Interfaith Center on Corporate Responsibility	WHO	World Health Organization
IC	Index Country	WIPO	World Intellectual Property Organization
ID	Index Disease	WTO	World Trade Organization
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations		
INGO	International Non-Governmental Organization		
IP	Intellectual Property		
LDC	Least Developed Country [UN]		

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\*As of June 30, 2011, based on eVestment, Lipper and Bloomberg data.

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