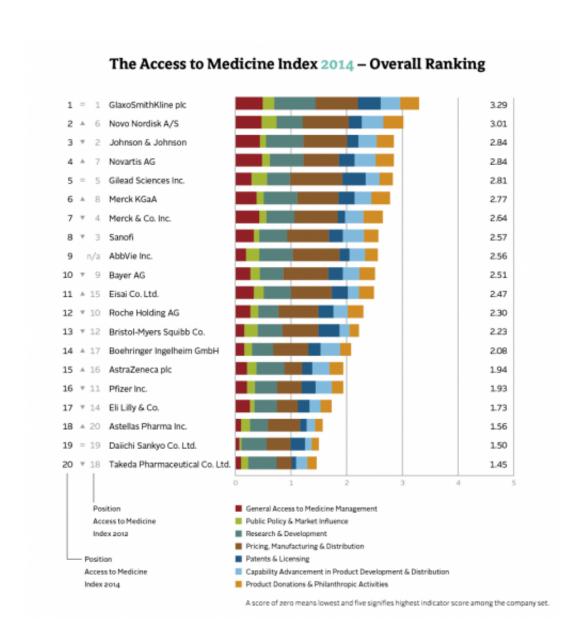


Pharmaceutical industry doing more to improve access to medicine in developing countries

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Access to Medicine Index 2014 - Overall Ranking

The world's leading pharmaceutical companies are doing more to improve access to medicine in developing countries, with a raft of new initiatives, scale-ups and innovations over the last two years. However, the industry struggles to perform well in some practices that matter, according to the 2014 Access to Medicine Index, published Monday.

GSK tops the Index for the fourth time. This is driven by robust performance across most areas, with several innovative practices. It has an innovative business model focused on Africa, a large relevant portfolio, a large share of its pipeline dedicated to relevant diseases, and numerous access-oriented intellectual property sharing partnerships.

Novo Nordisk has made the most progress, improving in five of the seven areas the Index focuses on. This has resulted in a remarkable leap from 6th to 2nd place, which is partly due to the fact that its access activities are well managed, integrated into its business strategy, and well targeted to local needs. It also applies access-oriented pricing strategies to diabetes products in all Least Developed Countries. Eisai has risen steadily with each Index, and ranks 11th, up four places from 15th in 2012.

Sanofi and Pfizer fell down the rankings most significantly, while Astellas, Daiichi Sankyo and Takeda remain at the bottom of the league.

"After sharpening what and how we measure, we are now able to draw a much clearer picture of the industry's strengths, weaknesses, progress and struggles, and what it takes to be a leader in access to medicine," said Wim Leereveld, founder and CEO of the Access to Medicine Index. "No company is in the top five in all areas we analyse, but the leaders



tend to perform well across most of them, even though they differ in their focus. Top performers innovate constantly, and usually have to innovate in several areas to maintain their position."

The Access to Medicine Index is an independent initiative that ranks the world's leading pharmaceutical companies according to what they are doing for the millions of people in <u>developing countries</u> who do not have reliable access to safe, effective and affordable medicines and vaccines. It is published every two years.

It scores companies on their performance, innovation, transparency and commitments across seven areas of activity considered key to improving access to medicine. The companies are graded on 95 factors covering these areas, including product research and development, to what extent they facilitate or resist efforts to create generic versions of their drugs, and how they approach pricing in developing countries. Lobbying activities, marketing ethics and product donations and other philanthropic activities are also evaluated.

"Companies that have the biggest market presence are not necessarily at the top of the Index. We found that four companies currently produce 50 percent of all the relevant products. Sanofi produces the most, followed by Novartis, GSK, then Pfizer. However, they are scattered across the Index," said Jayasree K. Iyer, Head of Research at the Access to Medicine Index. "This means that what defines where companies rank has less to do with how many relevant products they have, than with what they do with their products and expertise. We have found that this, in turn, tends to be closely linked to the importance given to access at the top of the company."

Lower respiratory infections, diabetes, cirrhosis of the liver (hepatitis), HIV/AIDS and malaria are getting the most attention from companies overall, while maternal and neonatal health conditions get relatively less



attention, Iyer said. She added that neglected tropical diseases are less neglected than they were two years ago, with a scaling up of donation programmes and a handful of new drug development projects, some in partnership with international organisations.

Progress on several fronts

The industry has stepped up its efforts on several fronts. For instance, it is paying more attention to socioeconomic factors, such as people's ability to pay, increasingly tailoring prices within countries. Since 2012, the number of products in the pipeline appropriate for developing countries has grown by 47. More companies are experimenting with innovative access-oriented business models; three have introduced new models and three have expanded pilots. Companies are granting more licences to developing country companies to make and distribute generic versions of their medicines. Meanwhile, policies and activities to improve access to medicine continue to get better organised. All 20 companies now have some form of board-level representation for access-to-medicine issues, and the number of companies linking performance incentives to access to medicine has more than doubled since 2012.

Performance weak in two areas

However, progress is uneven across the areas of activity that matter, with the industry struggling to perform well in two important areas.

Firstly, nearly all companies (18) have been the subject of settlements or judgements regarding breaches in ethical marketing, bribery or corruption standards or competition laws in the last two years. During the period of analysis there were high-profile allegations of corrupt practices against several companies operating in China. The case against GSK, one of those companies, was settled after the period of analysis,



and therefore did not affect its score in the 2014 Index. Breaches captured in this Index range from paying or otherwise inappropriately incentivising doctors to prescribe their products, to collusions delaying market entry of generic medicines and misrepresenting the efficacy and safety of their products or those of their competitors. The Index's analysis reveals there is no direct correlation between a company's size, the breadth of its geographical footprint and its incidence of breaches, which indicates that breaches are not simply a cost of doing business. This evidence raises questions over the commitment and effectiveness of company governance of this area.

Secondly, companies remain conservative in their disclosure of where patents are active and when they will expire – information that is very useful to medicine procurers and generics manufacturers. Within the reporting period, no company independently and publicly disclosed patent statuses for products relevant to the Index.

Research and development analysis

Pharmaceutical company research and development (R&D) is a crucial element of enhancing access to medicine. The 2014 Index reveals how concentrated the relevant R&D is. Just five companies are developing 54% of the 327 products in the pipeline. All disease classes are being targeted, but more than half of the products under development target just five diseases: lower respiratory infections, diabetes, hepatitis, HIV/AIDS and malaria.

About 36% of the pipeline targets non-communicable diseases, which are becoming increasingly important in developing countries. Encouragingly, 83% of these have reached the stage of development where they are being tested on people, but plans to make them available are limited. Pricing strategies for them are also limited, and lag behind those for many communicable diseases.



More than half of the companies are developing "child-size" medicines, as liquids, chewable tablets, child-appropriate doses, or new formulations.

Research projects include an antifungal drug from Merck & Co. that is undergoing clinical trials to investigate whether it works for Chagas disease, a neglected tropical disease affecting South American countries; and GSK's development of a low-cost inhaler for asthma and COPD drugs for use in developing countries.

Since the 2012 Index, at least 30 products from the pipeline, for 11 diseases relevant to developing countries, have come to the market. These include:

- A new type of pill for multi-drug resistant tuberculosis that is the first new drug for the disease in 40 years. (Johnson & Johnson)
- A new once-a-day pill that is a complete HIV treatment. Gilead has issued licences allowing distribution of generic versions of the drug in 100 developing countries.
- A new child-dose HIV tablet (Johnson & Johnson) and approval for an existing HIV drug to be given to children (Bristol-Myers Squibb). Almost all children with HIV live in sub-Saharan Africa.
- A ground-breaking pill that can cure hepatitis C, which is a highburden disease in developing countries. The company has issued licences allowing distribution of <u>generic versions</u> of the drug in more than 91 developing countries. (Gilead)

"Our company report cards identify a tailored path for each <u>company</u> to follow in order to maximise its opportunities for improving access to medicine, based on its individual strengths and potential. They all address access issues in different ways, but our analysis shows that all companies can do more. Enhancing access to medicine is not the sole



responsibility of the pharmaceutical industry, but it is an important player," Leereveld said.

Provided by Access to Medicine Foundation

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