Boehringer Ingelheim

PERFORMANCE IN THE 2022 INDEX

13th place. Boehringer Ingelheim is a middle-performing company. The company has an average performance in Governance of Access and Research and Development but performs below average in Product Delivery. Boehringer Ingelheim has improved its R&D access planning framework but does not publicly disclose the patent status of its products via Pat-INFORMED.

Governance of Access: 12th place. Boehringer Ingelheim has an average performance in this area. It has a clear access-to-medicine strategy and discloses outcomes of its access-to-medicine activities, but it lacks a continuous system to monitor activities as part of its compliance framework for countries in scope of the Index.

Research & Development: 12th place. Boehringer Ingelheim has an average performance in this area. It has introduced a structured access planning framework and applies this to all late-stage pipeline candidates. However, the company has a small-sized priority pipeline and has an average performance in R&D capacity building.

Product Delivery: 14th place. Boehringer Ingelheim has a below average performance in this area. The company has access strategies for all its products but lacks examples in low-income countries. It builds capacity in supply chains, manufacturing and health systems, though some initiatives lack evidence of certain quality standards such as public disclosure of outcomes. The company shares intellectual property assets with third party researchers but does not publicly disclose the patent status of its products via Pat-INFORMED.

OPPORTUNITIES FOR BOEHRINGER INGELHEIM

Improve the quality of access plans for late-stage R&D projects. Boehringer Ingelheim has introduced a new policy to systematically plan for access before Phase II of clinical development and has plans in place for all late-stage candidates analysed. For non-communicable diseases the company’s access plans focus mostly on registration in countries in scope of the Index. For example, for projects such as iclperin (BI 429809) for schizophrenia and BI 459506 for diabetes, Boehringer Ingelheim can include more access components such as equitable pricing and licensing in its plans.

Improve transparency of the patent status of its products. Boehringer Ingelheim publicly commits to not file for or enforce patents in 61 countries within the scope of the Index, including all Least Developed Countries and low-income countries and a subset of lower-middle income countries and upper-middle income countries. The company can disclose detailed patent information publicly, either on its website or via Pat-INFORMED, including for its biological products.

Improve access to products on the WHO Model List of Essential Medicines (EML). Boehringer Ingelheim engages in equitable pricing for some of its products. The company has seven products on the WHO EML. The company can further expand access to these products, such as dabigatran (Pradaxa®), for prevention of stroke, and afatinib dimaleate (Giotrif®/Gilotrif®), for lung cancer, via equitable pricing in LICs. Boehringer Ingelheim can engage in non-exclusive voluntary licencing for patented medicines for type 2 diabetes mellitus, such as empagliflozin (Jardiance®).

CHANGES SINCE THE 2021 INDEX

- Newly demonstrates access-related incentives for senior-level executives.
- Created a Vulnerability Framework with input from different organisations to ensure that its access-to-medicine strategies are reaching all vulnerable populations.
- Newly demonstrates evidence that sales incentives are decoupled from sales volume targets.
- Improved access planning during R&D by broadening its framework and implementing it to its entire pipeline, as well as ensuring that all access planning begins in pre-clinical development.
- Established an office in Kenya to serve some of the most vulnerable communities in sub-Saharan Africa and exploring equitable access initiatives in the region.
- Committed (together with Boehringer Ingelheim Stiftung) EUR 150 million into antibiotic R&D of which EUR 40 million is already invested in the Antimicrobial Resistance (AMR) Action Fund, joint venture Aurobac and invested in five biotech companies.
- Created the investment vehicle Boehringer Ingelheim Social Engagement, endowed with EUR 50 million to provide financing for impact to social businesses in vulnerable communities, as an extension of Making More Health.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.
SALES AND OPERATIONS


Therapeutic areas: Cardiometabolic diseases, cancer immunology, central nervous system diseases, immunology, oncology and respiratory diseases.

Product categories: Animal health, biosimilars and innovative medicines.

M&A news: Boehringer Ingelheim signed an option to acquire Trutino Biosciences in June 2022.

Boehringer Ingelheim’s products are sold in 71 out of 108 countries in scope of the Index. Boehringer Ingelheim has sales offices in 17 countries, and sells via suppliers and/or pooled procurement in an additional 54 countries.

Net sales by segment (2021) – in EUR

<table>
<thead>
<tr>
<th>Segment</th>
<th>Net Sales (bn EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human pharmaceutical</td>
<td>15.29</td>
</tr>
<tr>
<td>Animal health</td>
<td>4.30</td>
</tr>
<tr>
<td>Biopharmaceutical contract</td>
<td>0.92</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>0.03</td>
</tr>
<tr>
<td>Other</td>
<td>0.08</td>
</tr>
<tr>
<td>Total</td>
<td>20.62</td>
</tr>
</tbody>
</table>

Sales by geographic region

<table>
<thead>
<tr>
<th>Region</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>40</td>
<td>38</td>
<td>38</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Americas</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Asia/Africa/Australia</td>
<td>40</td>
<td>38</td>
<td>38</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Boehringer Ingelheim has a total of 35 R&D projects in scope with two of these projects targeting priority diseases. Thirty-three R&D projects target other diseases in scope. Of the projects targeting other diseases, the focus is on oncology (19), kidney diseases (6), neurology (3), COPD (2), diabetes (1) and heart disease (1). Eight R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (7). Evidence of access planning was in place for 100% of these projects.

PORTFOLIO as selected for analysis by the Index

Boehringer Ingelheim has 20 medicines in scope, 15 of which are on patent. 60% of these medicines (11) are on the WHO EML. In addition, the company markets one vector control product. The off-patent medicines target mainly non-communicable diseases (NCDs) such as chronic obstructive pulmonary disease and asthma (2), ischaemic heart disease and stroke (2) and diabetes mellitus (1). The on-patent medicines also target the same NCDs as well as hypertensive heart disease (3) and cancer (1).

Breakdown of projects

<table>
<thead>
<tr>
<th>Phase</th>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration/Approval</th>
<th>Other***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targets established R&amp;D priorities</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Addresses needs of LMICs*</td>
<td>9</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Other projects in scope</td>
<td>16</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>17</td>
<td></td>
</tr>
</tbody>
</table>

Breakdown of products

<table>
<thead>
<tr>
<th>Medicine Category</th>
<th>WHO EML</th>
<th>Non-EML</th>
<th>WHO EDL</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines on patent</td>
<td>7</td>
<td>8</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines off patent</td>
<td>4</td>
<td>1</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Vaccines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraceptives</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in the clinical phase of development were included for this analysis.

**Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.

***Other includes projects that have a different development cycle (e.g. diagnostics).

†Other includes vector control products.
Boehringer Ingelheim

**GOVERNANCE OF ACCESS**

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Boehringer Ingelheim performs strongly. It has an Access to Healthcare Approach, part of its “Sustainable Development – For Generations” framework, which includes both human and animal health. The strategy covers all therapeutic areas in which the company is involved, namely non-communicable diseases (NCDs). The highest responsibility for access lies directly with the board.

Provides evidence of financial or non-financial access-related incentives at the executive level. Boehringer Ingelheim performs above average. It demonstrates evidence of access-related incentives for senior executives and in-country managers.

Publicly discloses outcomes of its access-to-medicine activities. Boehringer Ingelheim performs above average in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the index. It shares the outcomes of its access-to-medicine activities in a centralized manner directly on its website and within its annual report.

Performs above average in responsible promotional practices. Boehringer Ingelheim’s sales agents are not solely incentivized on sales volume targets. However, the company sets incentives based on sales targets at the individual level for agents. It publicly discloses information related to transfers of values to healthcare professionals in countries in scope of the index (e.g., payments for attending events or promotional activities) according to law and industry association and has global and local policies governing such transfers to ensure compliance with the applicable regulations.

Has compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Boehringer Ingelheim demonstrates evidence of the following components assessed by the Index: fraud-specific risk assessment, audits (both internal and external) covering third parties and in all countries where it operates, country risk-based assessments and formal processes to ensure third-party compliance with company standards. It does not, however, demonstrate adequate evidence of a continuous system to monitor activities. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Boehringer Ingelheim publicly shares support of the Doha Declaration on TRIPS and Public Health. It views the Declaration as a mechanism offering more juridical certainty to countries which may intend to use the system. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Boehringer Ingelheim, like all other member companies in scope of the index, is by default connected to this activity.

**RESEARCH & DEVELOPMENT**

Access planning processes encompass all projects in the pipeline. Boehringer Ingelheim has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. Boehringer Ingelheim begins developing access plans for R&D projects before Phase II of clinical development.

A small-sized priority R&D pipeline compared to peers. Boehringer Ingelheim has two projects, including one late-stage candidate in its pipeline that target a priority product gap. This project is supported by an access plan.

Many projects address a public health need in LMICs,* with 100% (7/7) of late-stage candidates covered by access plans. In this analysis, Boehringer Ingelheim has seven projects in late-stage development, that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope of the Index and/or are first-in-class molecules. The projects mainly focus on cancer and kidney diseases. Boehringer Ingelheim provides evidence of access plans for all seven late-stage projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Boehringer Ingelheim does not disclose disaggregated R&D investment data to global health organisations.

One R&D capacity building initiative included for analysis meets all Good Practice Standards. Boehringer Ingelheim’s performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. Boehringer Ingelheim’s Research Beyond Borders (RBB) initiative enables 30 research collaborations with universities and research organisations in countries in scope of the Index to advance drug discovery in areas of high unmet medical need.

**PRODUCT DELIVERY**

Public commitment not to enforce patents in countries in scope. Boehringer Ingelheim publicly commits to not file for or enforce patents. This commitment applies to 61 countries within the scope of the Index, of which all Least Developed Countries and LICs in scope of the Index and a subset of LMICs and UMICs.

Does not publicly disclose information on patent statuses on their website. Unlike all its peers, Boehringer Ingelheim does not disclose the patent status of its products for diseases in scope of the Index on their website nor in Pat-INFORMED.

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*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.
Boehringer Ingelheim has entered into collaboration with a public-private partnership. For example, the Pakistan-Rabies-Free Campaign is a health systems strengthening initiative done in collaboration with the Indus Hospital in Karachi that aims to involve communities in mass rabies vaccination campaigns and ultimately reduce the incidence of rabies in Pakistan. This initiative meets all GPS.

Two of the four health systems strengthening initiatives included meet all Good Practice Standards. Boehringer Ingelheim’s performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all GPS than what is average for this indicator. For example, the Pakistan-Rabies-Free Campaign is a health systems strengthening initiative done in collaboration with the Indus Hospital in Karachi that aims to involve communities in mass rabies vaccination campaigns and ultimately reduce the incidence of rabies in Pakistan. This initiative meets all GPS.

Has engaged in scaling up three and pilot- ing two inclusive business models. Boehringer Ingelheim performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Healthy Entrepreneurs social start-up trains over 8,000 entrepreneurs to enable them to sell healthcare products in remote villages and reaches more than 10 million individuals on a yearly basis.

Boehringer Ingelheim’s performance is above average in the use of third-party researchers. Boehringer Ingelheim engages in three new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company also has existing agreements of this nature in place that were established before the current Index cycle.

No use of licensing agreements. Boehringer Ingelheim does not engage in voluntary licensing for products in scope of the Index.

Includes evidence of new products in scope. Boehringer Ingelheim did not disclose evidence of filing for registration any new products. Among old products, its most widely filed product, emagliflozin (Jardiance®), mainly used in individuals with type 2 diabetes, has been filed for registration in 37 countries in scope of the Index, three among the highest disease burden (Guyana, Sri Lanka and Mexico). Uganda and Yemen are the low-income countries where Boehringer Ingelheim has registered its products analysed under this indicator.

Has access strategies for its supranationally procured product in scope for this analysis. Boehringer Ingelheim has an average performance in securing access for its product procured supranationally. Boehringer Ingelheim supplies its rabies vaccine (Rabisin®), through PAHO, and it shared evidence of access strategies in countries not eligible to benefit from such procurement. The company provides evidence of an increase in animal vaccinations reach over the last two years.

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Has an average performance in ensuring continuous supply of medicines in LMICs. Boehringer Ingelheim is involved in supply chain capacity building initiatives in LMICs. The company also has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, manages a buffer stock of relevant products and is involved in technology transfer initiatives. The company works with multiple active pharmaceutical ingredient suppliers for some products and otherwise keeps buffer stocks to mitigate supply risks.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Boehringer Ingelheim has a policy for reporting SF medicines to national regulatory authorities within seven days. It discloses to the Index, but not publicly, whether it has quicker reporting time frames for cases that only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Boehringer Ingelheim has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Boehringer Ingelheim is publicly committed to supporting the goal of zero human dog-mediated rabies deaths by 2030: it includes donating the rabies vaccine (Rabisin®) in six countries in scope of the Index.
PERFORMANCE IN THE 2022 INDEX

15th place. Bristol Myers Squibb performs below average in two of three Technical Areas. The company has performed below average for access strategies, yet it performs strongly in health systems strengthening. It has improved in access planning in R&D but has a small-sized priority pipeline.

Governance of Access: 14th place. Bristol Myers Squibb has an average performance in this area. It has an access-to-medicine strategy integrated within the overall corporate strategy. It provides evidence of financial and non-financial access-related incentives at the executive level but does not disclose whether in-country managers or the CEO are also incentivised toward access goals.

Research & Development: 17th place. Bristol Myers Squibb performs poorly in this area. The company has a structured access planning process in place, but it does not apply this to all late-stage candidates. The company has an average performance in R&D capacity building.

Product Delivery: 15th place. Bristol Myers Squibb has a below average performance in this area. The company has strengthened its performance in manufacturing capacity building by participating in technology transfers, yet its performance in equitable access strategies is below average for certain products. It engages in high quality health systems strengthening initiatives but lacks involvement in supply chain capacity building. The company has non-exclusive voluntary licensing agreements in place for two compounds to enable generic supply in LMICs.

OPPORTUNITIES FOR BRISTOL MYERS SQUIBB

Develop access-related incentives for senior management. Bristol Myers Squibb has an access strategy linked to sustainability goals, which includes all therapeutic areas in which the company is involved. Financial and non-financial incentives for the CEO and in-country managers can be tied to the achievement of the sustainability goals under their access strategy. The incentives can also be oriented toward long-term goals.

Ensure all late-stage R&D projects have comprehensive access plans. Bristol Myers Squibb can develop access plans for all projects from Phase II of clinical development. The company has plans in place for 73% of late-stage projects. These plans primarily consist of commitments to registering products in countries where clinical trials for that product have been conducted. Access plans for nivolumab (Opdivo®) and pomalidomide (Pomalyst®), indicated for multiple cancer types, can also include additional access components such as equitable pricing.

Improve access to on-patent cancer drugs on WHO Model List of Essential Medicines (EML). Bristol Myers Squibb has four on-patent products on the WHO EML, including dasatinib (Sprycel®), a product indicated for imatinib-resistant chronic myeloid leukaemia. The company provides access to dasatinib in at least one upper-middle income country via an equitable pricing strategy and to low-income countries and lower-middle income countries via the Max Foundation donation programme. Bristol Myers Squibb can expand access to the product via registration, equitable pricing and non-exclusive voluntary licensing agreements in more countries, especially those where the burden of disease is the highest, such as Afghanistan, Haiti and Ethiopia.

CHANGES SINCE THE 2021 INDEX

- Launched the first ever Global Access Report, which highlights Bristol Myers Squibb’s efforts and progress towards advancing access to healthcare and health equity globally.
- Newly demonstrates evidence that sales agent incentives are decoupled from sales volume targets.
- Introduced a structured framework to include access planning in all its pipeline projects.
- Started a new capacity building initiative with multiple partners to support sustainable and effective administration of innovative therapies for the treatment of cancer in LMICs.
- Newly licensed the >4000-member library to Medicines for Malaria Venture (MMV) in addition to donating USD 1 million to support the missions of both MMV and Drugs for Neglected Diseases initiative (DNDi).
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.
- Acquired a global exclusive license to develop, manufacture and commercialise Rockefeller’s novel monoclonal antibody duo treatment against COVID-19.