PERFORMANCE IN THE 2022 INDEX

19th place. AbbVie is in the lower ranks across all Technical Areas. It engages in R&D for neglected tropical diseases but lacks access plans for R&D projects in the pipeline. It engages in non-exclusive voluntary licensing but has a comparatively poor performance in capacity building.

Governance of Access: 15th place. AbbVie performs below average in this area. It has an access-to-medicine strategy, but only has some compliance controls in place to mitigate the risk of non-compliance in countries in scope of the Index. It discloses the outcomes of only a subset of its access-to-medicine activities.

Research & Development: 20th place. AbbVie performs poorly in this area. AbbVie has a small-sized priority pipeline compared to its peers. The company does not have a framework in place for systematic access planning and does not have access plans for any of its late-stage pipeline candidates. It does not engage in R&D capacity building.

Product Delivery: 18th place. AbbVie performs poorly in this area. The company has an average performance in its approach to inclusive business models and supplying products through supranational procurers. However, its performance with regard to healthcare practitioner- and self-administered products is below average. The company engages in non-exclusive voluntary licencing for two compounds, enabling generic supply in 79 countries. AbbVie engages in health systems strengthening initiatives but doesn’t publicly disclose outcomes for most of these.

OPPORTUNITIES FOR ABBVIE

Develop access-related incentives for senior management. AbbVie has an access-to-medicine strategy, the Global Integrated Access Strategy (IAS), which serves as the foundation and starting point for regional (area level) and country (affiliates level) access strategies. Financial and non-financial incentives, oriented toward long-term goals, for the CEO and in-country managers can be linked to this strategy.

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. AbbVie can develop a formal access planning framework and accordingly apply access plans considering availability, affordability and sustainable supply for all its projects, no later than Phase II. For example, it can disclose access plans for flubentynol, an investigational treatment for river blindness being developed in collaboration with DNDi.

Expand access to its hepatitis C product, glecaprevir/pibrentasvir (Mavyret®), through equitable pricing and/or increased non-exclusive voluntary licensing. AbbVie can increase patient reach for glecaprevir/pibrentasvir, indicated for the treatment of chronic hepatitis C infection. It can expand its existing voluntary licence for this product to countries with a high burden of this disease such as the Republic of Moldova, Mongolia and Uzbekistan, or increase access by applying an equitable pricing strategy in these countries.

AbbVie can expand access to innovative medicines for cancer and women’s health products. The company can implement equitable access strategies and expand registration of products such as elagolix (Orilissa®) for endometriosis. AbbVie can file for registration in countries where the disease burden of endometriosis is the highest such as Algeria, Mongolia and Papua New Guinea.

CHANGES SINCE THE 2021 INDEX

• Established an ESG council to further strategic, enterprise-aligned delivery on AbbVie’s ESG Framework which includes global patient access and affordability as a key material driver.
• Newly established access strategy, the Global Integrated Strategy, covering all therapeutic areas.
• Developed an Executive Council on Neglected Diseases that coordinates across the company to contribute innovative technologies, diverse compounds for screening, and scientific expertise to partners to help address neglected tropical diseases.
• Announced a research collaboration with Scripps Research to develop antiviral treatments for COVID-19.

AbbVie Inc

Stock exchange: NYSE • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: ~50,000
SALES AND OPERATIONS

**Business segments:** Pharmaceutical sciences  
**Therapeutic areas:** Aesthetics, eye care, gastroenterology, immunology, neuroscience, oncology, virology, women’s health and other specialty areas.  
**Product categories:** Pharmaceuticals  
**M&A news:** AbbVie acquired Syndesi Therapeutics in March 2022 for USD 130 million upfront payment.

AbbVie’s products are sold in 81 out of 108 countries in scope of the Index. AbbVie has sales offices in 17 countries, and sells via suppliers and/or pooled procurement in an additional 64 countries.

Net revenue by segment (2021) – in USD

<table>
<thead>
<tr>
<th>Segment</th>
<th>Net revenue (Bn USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical sciences</td>
<td>56.20</td>
</tr>
<tr>
<td>Total</td>
<td>56.20</td>
</tr>
</tbody>
</table>

**Net revenue (Bn USD)**

<table>
<thead>
<tr>
<th>Year</th>
<th>International</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>40</td>
<td>10</td>
</tr>
<tr>
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<td>30</td>
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<td>20</td>
</tr>
<tr>
<td>2020</td>
<td>30</td>
<td>40</td>
</tr>
<tr>
<td>2021</td>
<td>40</td>
<td>50</td>
</tr>
</tbody>
</table>

**Sales in countries in scope**

**Sales by geographic region**

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

**PIPELINE** for diseases in scope

AbbVie has a total of 42 R&D projects in scope with six of these projects targeting a priority disease. The other 36 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (two projects). Of the projects targeting other diseases in scope, the focus is on oncology (31).

Nine R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (7). Evidence of access planning was not reported for any of these projects.

**PORTFOLIO** as selected for analysis by the Index

AbbVie has 19 medicines in scope, 14 of which are on patent and two contraceptive methods. 37% of the medicines (7) are on the WHO EML. The off-patent medicines target mainly non-communicable diseases (NCDs) such as hypertensive heart disease (2), cancer (1) and endometriosis (1). Furthermore, there is one off-patent medicine for preterm birth complications. The on-patent medicines mainly target NCDs, such as mental health conditions (5) and cancer (2) and communicable diseases such as HIV/AIDS (2), and hepatitis C (2). In addition, one product is for endometriosis, one for migraine and other products target preterm birth complications.

**42 projects in the pipeline**

- Communicable**: 4
- Neglected tropical: 2
- Maternal and neonatal: 36
- Non-communicable: 0
- Multiple categories: 0

**21 products as selected for analysis by the Index**

- Communicable**: 4
- Neglected tropical: 0
- Maternal and neonatal: 2
- Non-communicable: 13
- Multiple categories: 2

**Breakdown of projects**

- Targets established R&D priorities: 6
- Addresses needs of LMICs*: 15
- Other projects in scope: 21

**Breakdown of products**

- Medicines on patent: 11
- Off patent: 4
- Vaccines: 0
- Contraceptives: 1
- Diagnostics: 0
- Other*: 0

*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 technical lifecycle and projects that follow a different development cycle (e.g. diagnostics).**

*Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.

*Other includes vector control products.
AbbVie Inc

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. AbbVie performs strongly. It has an access strategy, the Global Integrated Access Strategy (IAS), which serves as the foundation and starting point for product specific strategies at the regional (area) and country (affiliate) level. The IAS covers all of the therapeutic areas in which the company is involved, including Immunology and Oncology and Specialty. The highest responsibility for access lies directly with the board, with its Public Policy committee responsible for corporate responsibility aspects, including access.

Provides evidence of financial access-related incentives at the executive level. AbbVie performs average in this area. It demonstrates evidence of having access-related incentives for senior executives under its key material driver of Patient Affordability and Accessibility within its ESG framework.

Publicly discloses outcomes of a subset of its access-to-medicine activities. AbbVie performs well in transparency regarding access activities. It discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. For example, the company publicly shares how it contributes to the achievement of the UN SDG3 targets. It shares the outcomes of its access-to-medicine activities for only a subset of initiatives, although it does so in a centralised manner within its ESG Action Report.

Performs above average in responsible promotional practices. AbbVie’s sales agents are not incentivised solely on sales volume targets. It does not publicly disclose information related to transfers of values to healthcare professionals (HCPs) in countries in scope of the Index (e.g. payments for attending events or promotional activities) unless required by local regulations, nor does it disclose a policy limiting such transfers, but it does have global, international, and local policies for engaging with HCPs.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. AbbVie has an average performance, demonstrating evidence of some components looked for by the Index: audits (both internal and external) and formal processes to ensure third-party compliance with company standards. However, AbbVie does not disclose to the Index whether there is fraud-specific risk assessment done in countries in scope of the Index. Additionally, there is no evidence of a continuous monitoring system of activities or country-based assessments. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health. AbbVie does not publicly share any support of the Doha Declaration on TRIPS and Public Health. There is evidence of industry association lobbying on IP 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, AbbVie, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

No structured process for access planning reported. AbbVie does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to its peers. AbbVie has six projects, including two late-stage candidates in its pipeline that target a priority product gap. The priority pipeline focuses on various diseases, including HIV/AIDS, onchocerciasis and tuberculosis. AbbVie did not disclose evidence of access plans for any late-stage projects.

Many projects address a public health need in LMICs. The company does not disclose evidence of access plans for any of the late-stage projects. In this analysis, AbbVie has seven late-stage R&D projects 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 benefit for people living in LMICs. Primarily, these projects are first-in-class molecules. Most target cancer. AbbVie did not disclose evidence of access plans for any of the late-stage projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, AbbVie does disclose fully disaggregated R&D investment data to Policy Cures Research.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. AbbVie’s performance is below average in this area.

PRODUCT DELIVERY

No public commitment not to enforce patents in countries in scope. AbbVie does not have a public policy that sets out its approach to filing for or enforcing patents in LMICs.

Publicly discloses information on patent status. Like most of its peers, AbbVie publicly discloses the patent statuses for small molecules in scope of the Index. AbbVie discloses patent information such as grant number and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. AbbVie does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

*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.
Uses licensing and non-assert declarations to enable generic supply. AbbVie has non-exclusive voluntary licensing agreements in place for two compounds. Its licence for glecaprevir/pibrentasvir (Mayret®), a treatment for hepatitis C, encompasses 79 countries within the scope of the Index, including 54 middle income countries.

Filed to register new products in one country in scope on average. AbbVie did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among new products, glecaprevir/pibrentasvir (Mayret®), for viral hepatitis C, has been filed in two countries within the scope of the Index. Among old products with the same indication, its most widely filed is omibitasvir/paritaprevir/ritonavir/daclatasvir (Viekira®), filed in 13 countries relevant to the Index, including high burden countries such as Republic of Moldova and Ukraine. None of AbbVie’s products considered for analysis are filed for registration in LICs.

Has access strategies for its supranationally procured products in scope. AbbVie performs above average in securing access for products procured supranationally. For the two products assessed in this category, lopinavir/ritonavir (Aluvia®/ Kaletra) and ritonavir (Norvir®), AbbVie has procurement agreements with the Global Fund. The price agreed is disclosed and publicly available. The company applies pricing strategies that consider relevant payers’ ability to pay in Algeria, a non-eligible Global Fund country, and it provides evidence of patient reach for both the products.

Has access strategies for only one health-care practitioner administered product in scope of this analysis. AbbVie has a below average performance in this area. For one of the three products assessed, the company provides evidence of access strategies in UMIC and LIC country examples. It makes efforts to reach additional patients through donations and has initiatives to strengthen the healthcare systems. For example, AbbVie applies a cost-plus pricing strategy for beractant (Survanta®) in Uganda that is aligned across sub-Saharan Africa. The company provides education through expert training and peer-to-peer mentorship, as well as through a call-to-action stakeholder’s meeting to elevate neonatology to treat neonates at three key Ugandan hospitals. Patient reach is not available.

Has few access strategies for self-administered products for some countries in scope of this analysis. AbbVie has a below average performance in this area. For one of the three products assessed, evidence of an access strategy in countries of all assessed income levels (UMIC, LMIC, LIC) was found publicly. For example, the non-exclusive voluntary license with the Medicines Patent Pool (MPP) for glecaprevir/pibrentasvir (Mayret®) is still active. Patient reach evidence is not disclosed.

No manufacturing capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. AbbVie’s performance is below average in this area.

No supply chain capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. AbbVie’s performance is below average in this area.

None of the five health systems strengthening initiatives included meets all Good Practice Standards. AbbVie’s performance is below average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In the Partnership with Baylor College of Medicine International Pediatric AIDS Initiative (BIPAI), AbbVie aims to reduce mortality, increase adherence and decrease rate of patients lost to follow up among children and families affected by HIV/AIDS in Romania and Malawi. This initiative meets all GPS.

Has engaged in scaling up one inclusive business model (IBM) but has not shown evidence of its involvement in piloting any new IBMs that meet all inclusion criteria. AbbVie performs average in the use of IBMs aimed at meeting the access needs of populations at the base of the income pyramid (including other under-served populations) in LMICs. The Access to Care Program facilitates the availability of the company’s HIV medications in LMICs in addition to providing continuous medical education in 15 African countries to increase treatment capacity, knowledge and clinical skills.

Shows average performance in terms of ensuring continuous supply of medicines in LMICs. AbbVie 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 works with several active pharmaceutical ingredient suppliers. However, there is no evidence that the company transfers technology to local manufacturers or is involved in supply chain capacity building initiatives that meet inclusion criteria for evaluation.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope of the Index. AbbVie demonstrates evidence of reporting SF medicines to relevant regulatory authorities and the WHO, on a case-by-case basis. It does not disclose evidence, publicly or to the Index, that it requires reporting to occur within the timeframe of ten days looked for by the Index, nor does it provide evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. AbbVie has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows some evidence of monitoring the delivery of donations.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis. However, AbbVie is engaged in other structured donation programmes such as the programme whereby it has been donating beractant (Survanta®) for infant respiratory distress syndrome to six countries in scope of the Index since 2015 through Direct Relief.