The term LMIC is used to denote all low- and middle-income countries in the scope of the Index, except when analysing companies’ access strategies where the use of LMIC refers to lower-middle-income countries as per the World Bank income groups classification.

AbbVie Inc

Stock Exchange: New York Stock Exchange • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: 47,000

PERFORMANCE IN THE 2021 INDEX

17th place. AbbVie performs poorly in two of the three Technical Areas, with weak performance in access strategies and capacity building but a stronger performance in R&D and access planning for priority diseases. It also shows comparatively poor performance in responsible promotional practices and limited evidence in compliance controls.

Governance of Access: 17th place. AbbVie performs poorly in this area. The company does not have a clear access-to-medicine strategy with measurable objectives and a business rationale. It conducts internal and external audits but does not demonstrate other components of compliance controls looked for by the Index.

Research & Development: 12th place. AbbVie has an average performance in this area. Despite the lack of an access planning process during R&D or a post-trial access policy, the company has an average-sized priority R&D pipeline compared to peers with the majority of late-stage projects covered by an access plan.

Product Delivery: 17th place. AbbVie performs poorly in this area. Access strategies were identified for a few of its products. The company did not disclose, either publicly or to the Index, engagement in any inclusive business models. The company has entered into voluntary licence agreements for two compounds, enabling generic supply in 79 countries and issued a non-assert declaration for two other compounds. It engages in multiple health system strengthening initiatives, but evidence lacks on governance structures and sustainability.

OPPORTUNITIES FOR ABBVIE

Organise governance of access. AbbVie can establish an access strategy that is integrated within its corporate business strategy. Such strategy should apply to all therapeutic areas in which it operates with managerial and executive incentives linked to it. The governance can also include responsible business practices.

Increase product delivery building on its IP approach. AbbVie, with a voluntary licence for glecaprevir/pibrentasvir (Mavyret®) and a non-assert declaration for lopinavir/ritonavir (Aluvia®/Kaletra®), can increase the patient reach for these treatments. It can expand this licence to high-burden hepatitis C countries such as Brazil, China, India, Mexico, Thailand and Uzbekistan. For lopinavir/ritonavir it can publicly disclose the non-assert declaration.

Expand access planning to in-house R&D projects. AbbVie has access plans in place for R&D projects it develops in access-oriented partnerships for certain disease areas such as malaria. It can update the process to develop access plans for all R&D projects from phase II onwards, for all diseases. It can develop access plans for Mavyret® (recently approved for pediatric use in hepatitis C), elagolix (recently approved for treatment of pain associated with endometriosis) and ABT-165 (first-in-class therapeutic for patients with solid tumors).

CHANGE SINCE THE 2018 INDEX

- Issued a non-assert declaration for lopinavir/ritonavir (Aluvia®/Kaletra®).
- Signed a royalty-free voluntary licensing agreement via the Medicines Patent Pool (MPP) for glecaprevir/pibrentasvir, a pan-genotypic regimen for hepatitis C.
- Committed USD 5 million via the COVID-19 Community Resilience Fund directed towards 26 non-profit organisations to support healthcare workers and underserved communities.

All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. For the 2021 Index, AbbVie declined to submit data to the Access to Medicine Index.
SALES AND OPERATIONS

Business segments: Pharmaceutical products
Therapeutic areas: Immunology; Haematological oncology; Aesthetics; Neuroscience; Eye care; Women’s health; Virology
Product categories: Innovative medicines
M&A news: Completed acquisition of Allergan (aesthetics, neuroscience, eye care) in May 2020 for USD 63 billion; acquired Mavupharma (oncology) in 2019.

AbbVie’s products are sold in 77 out of 106 countries in scope. AbbVie has sales offices in 7 countries, sells via suppliers in 46 countries and via pooled procurement in 24 additional countries.

Net revenue by segment (2019) – USD
Pharmaceutical products 33,266 bn
Total 33,266 bn

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope
AbbVie has a total of 59 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 20 projects. The other 39 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (4 projects). Most of AbbVie’s priority projects are in the discovery stage. Of the projects targeting other diseases in scope, the focus is on oncology (34).
18 R&D projects are in late-stage development that target either a priority disease (8) or address a public health need in LMICs (10). Evidence of access planning was reported for 28% of these projects: 5 targeting a priority disease and none addressing a public health need in LMICs.

ABBVIE’S PORTFOLIO as selected for analysis by the Index
AbbVie has 15 medicines in scope, 9 of which are on patent. 60% of these medicines (9) are on WHO’s EML. The off-patent medicines target mainly non-communicable diseases such as hypertensive heart disease (3), while one other product targets endometriosis. The on-patent medicines mainly target HIV (2) and hepatitis C (3). In addition, two products are for oncology, one is for preterm birth complications and one other product targets endometriosis.
Access strategies were analysed for 11 products on AbbVie’s portfolio – supranationally procured (4) or nationally procured HCP-administered (4) and self-administered products (5).

Breakdown of projects*

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Projects in the pipeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable</td>
<td>11</td>
</tr>
<tr>
<td>Neglected tropical</td>
<td>0</td>
</tr>
<tr>
<td>Maternal and neonatal</td>
<td>0</td>
</tr>
<tr>
<td>Non-communicable</td>
<td>0</td>
</tr>
<tr>
<td>Multiple categories</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
</tr>
</tbody>
</table>

Breakdown of products

<table>
<thead>
<tr>
<th>Product Category</th>
<th>WHO EML</th>
<th>WHO EDL</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Vaccines</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

*50 diseases and 271 product gaps in scope have been established as priority by global health stakeholders. For other diseases/product gaps, 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.
**Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index.

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Access to Medicine Foundation
AbbVie Inc

GOVERNANCE OF ACCESS

Does not have a clear access-to-medicine strategy with measurable objectives. Unlike most of its peers, AbbVie does not have a clear strategy integrated within its overall corporate strategy. It has a general commitment to access to medicine. The highest responsibility for access lies directly with the board, with its Public Policy committee responsible for corporate responsibility aspects, including access.

Does not provide evidence of financial or non-financial access-related incentives at the managerial level. AbbVie performs relatively poorly here. It does not demonstrate evidence of having access-related incentives for senior executives or in-country managers.

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. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, for example through the IFPMA Global Health Progress platform.

Performs comparatively poorly in responsible promotional practices. AbbVie’s sales agents are solely incentivised on sales volume targets. The company does not disclose the level at which sales incentives are set. It does not publicly disclose information related to transfers of value to healthcare professionals in countries in scope (e.g., payments for attending events or promotional activities) unless required by local regulations, nor does it disclose a policy limiting such transfers.

RESEARCH & DEVELOPMENT

No structured process for access planning. In contrast, 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.

Average size priority R&D pipeline compared to peers, with access plans in place for 63% of the late-stage candidates. AbbVie has 20 projects, including eight late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including malaria, viral hepatitis (B and C), and coronaviral diseases. Of AbbVie’s eight late-stage candidates targeting a priority product gap, there is evidence of an access plan for five of them. These plans are applied through access-oriented partnerships with product development partnerships (PDPs) and focus on affordability and availability.

Some 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 ten 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 public health benefit for people living in LMICs*. Primarily, these projects concern clinical trials in countries in scope. Most target cancer.

No public disclosure of post-trial access policy. AbbVie does not have a publicly available policy for ensuring post-trial access to treatments for clinical trial participants, nor did it disclose such a policy to the Index.

One R&D capacity building initiative included for evaluation. AbbVie performs below average in this area, with one initiative included for evaluation. AbbVie’s initiative, providing scholarships to students attending the Asian University for Women (AUW), was identified for selection based on publicly available information and was also included in the 2018 Index. The initiative did not meet all Good Practice Standards, as no public information on a governance structure and clear goals and objectives could be identified.

PRODUCT DELIVERY

Lacks a public commitment on enforcing patents in countries in scope. AbbVie does not have a public policy that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, AbbVie publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Does not report newly shared IP assets with third-party researchers beyond existing agreements. AbbVie has existing agreements with, for example, product development partnerships like the Drugs for Neglected Diseases initiative (DNDi) and the TB Alliance. During the period of analysis, beyond the existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

Uses licensing and non-assert declarations to enable generic supply. The company has a non-exclusive voluntary licensing agreement in place for two compounds. Its licence for gliclazide/pibrentasvir (Mayyret®), a treatment for hepatitis C, encompasses 79 countries, including 52 middle-income countries in scope. Following the outbreak of the Covid-19 pandemic, it has issued a non-assert declaration for two compounds in scope, lopinavir/ritonavir (Aluvia®/Kaletra®), previously covered by a licence.

Filed to register some new products in the majority of high burden countries. AbbVie has filed 12% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, lopinavir/ritonavir (Aluvia®/Kaletra®) for HIV/AIDS has been filed for registration/registered in eight high burden countries in scope, including Malawi, Namibia and Zambia.

Has access strategies for its supranationally procured products in scope for this analysis. AbbVie performs below average in securing access for products procured supranationally. For the two products assessed in this category, the Index drew on public information about strategies both in countries eligible for supply from such procurers and at least one country not eligible for such supply. For example, the company has equitable pricing strategies

† Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiative goals align with or support institutional goals; measures outcomes; has long term aims/aims for sustainability.

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and a licence for lopinavir/ritonavir (Aluvia®/Kaletra®) for non-eligible Global Fund countries. Information demonstrating patient reach through these approaches is not available.

Has access strategies for only one healthcare-practitioner-administered product in scope of this analysis. AbbVie performs poorly in this area. Examples of access strategies which consider affordability in LMICs and LICs are publicly available for one of the four products assessed. It makes efforts to reach additional patients through donations. AbbVie donated 2,500 vials of beractant (Survanta®) for the prevention of respiratory distress syndrome in premature newborns in Kosovo and 500 vials in India. However, no information was publicly available about access strategies and patient reach for the other three products.

Has few access strategies for self-administered products for some countries in scope of this analysis. AbbVie performs poorly in this area. Examples of access strategies which consider affordability in LMICs and LICs are publicly available for one of the five products assessed. It makes efforts to reach additional patients through equitable pricing strategies and licensing. For example, in LMICs and LICs in Africa, AbbVie has inter-country pricing strategies. However, no information was publicly available about the reach of such initiatives, and examples of access strategies for three out of five products.

No manufacturing capacity building initiatives included for evaluation. AbbVie has no initiatives included for analysis aimed at building manufacturing capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building manufacturing capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

No supply chain capacity building initiatives included for evaluation. AbbVie has no initiatives included for analysis aimed at building supply chain capacity. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building supply chain capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

Five health system strengthening initiatives included for evaluation. AbbVie performs below average in this area. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index. Five initiatives that met all criteria for inclusion were found based on publicly available information: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, and (plan to) measure outcomes. However, no information on governance structure and long-term sustainability could be identified. For example, since 2000 AbbVie partners with Baylor College of Medicine International Pediatric AIDS Initiative (BIPAI) to support the Kamuzu Central Hospital (KCH) in Malawi, reportedly reducing childhood cancer and blood disorder deaths from 90% at the start of the programme to 50%.

Has not engaged in the development and implementation of inclusive business models. Compared to peers, AbbVie performs relatively poorly when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid (which may include vulnerable populations) in countries in scope, with a long-term horizon. No initiatives were disclosed to the Index and no initiatives were found following a review of publicly available data.

Multiple mechanisms identified to ensure continuous supply in countries in scope of the Index. AbbVie performs well in this area, taking multiple steps to ensure the continuous supply of its medicines in countries in scope of the Index. The company reported to have a supply chain planning program in place, more details of which are under confidentiality.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope. AbbVie previously demonstrated evidence of reporting SF medicines to relevant regulatory authorities and WHO Rapid Alert, on a case-by-case basis. It does not disclose, publicly or to the Index, evidence that it requires reporting to occur within the timeframe of 10 days looked for by the Index, nor does it distinguish time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to an expressed need and monitors delivery to end user. AbbVie has a public policy in place to ensure ad hoc donations are carried out in response to an expressed need and it monitors the delivery until the end user.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. AbbVie is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it 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 since 2013 and 2015 through Americares and Direct Relief, respectively.

§ Supranationally procured means procured through international organisations such as GAVI, UNICEF, the Global Fund.