

RANK	SCORE
17▼	1.88
9 (2016)	

AbbVie Inc.

Stock Exchange: New York Stock Exchange • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: 29,000

PERFORMANCE

Falls from 9th to 17th place. AbbVie* continues to lack evidence of a clear access-to-medicine strategy, despite having key products in scope for the treatment of hepatitis C.

Management: Rises 2 places to 15th, but remains in the last quartile with no evidence of an access-to-medicine strategy, and no public intention to measure impact.

Compliance: Falls 9 places to 17th for failing to disclose how company associates are held accountable, and does not report several expected components of an internal control framework.

R&D: Falls 6 places to 12th as it lacks a public policy for post-trial access, and has access plans in place for a comparatively small proportion of late-stage projects.

Pricing: Falls 8 to places 18th for failing to disclose data concerning volume of sales and price disclosures.

Patents: Holds 8th place. Has licensed key HIV products through the MPP, and publicly discloses patent statuses via Pat-INFORMED.

Capacity: Falls 4 places to 16th, with limited information on its activity in capacity building.

Donations: Falls 4 places to 13th. Despite having four structured programmes, these reach a comparatively small number of countries.

OPPORTUNITIES

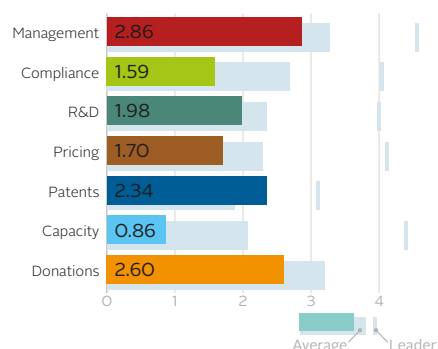
Establish an overarching access strategy. AbbVie can consolidate its access approaches into an overall strategy and clearly align it with its corporate strategy.

Expand process to establish more access plans for R&D projects. While AbbVie has a process in place to establish access provisions for R&D projects during development, it appears to cover R&D projects for only a subset of the diseases in scope. Further, it does not have a clear timeline in place to develop these provisions as early as possible. By refining its process to include the consideration of all projects for diseases in scope and to establish access plans earlier in the development process, AbbVie can ensure that products are available to more patients as soon as possible following market approval.

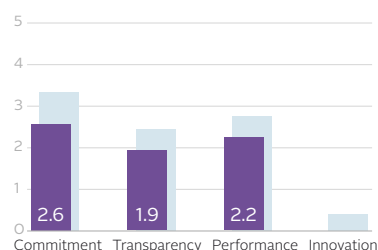
Strengthen internal controls against non-compliance. AbbVie can incorporate additional processes to mitigate the risk of non-compliance with ethical standards. For example, it can establish formal processes that hold third-parties accountable to the companies' standards. It can develop fraud-specific risk assessments, processes for continuous monitoring of compliance and procedures to segregate duties. The company can also expand its auditing mechanism to incorporate both internal and external resources, and apply these standards to third parties that it engages with in countries in scope.

Expand access further by maximising effectiveness of licensing approach. In order to improve availability of the essential medicines which AbbVie has agreed voluntary licences for (glecaprevir/pibrentasvir [Mavyret™] and lopinavir/ritonavir [Aluvia®/ Kaletra®]), AbbVie can: boost the geographic scope of these licences further, incorporating further countries with a high prevalence of HIV/AIDS and hepatitis C. AbbVie can also maximise the effectiveness of its licensing approach to access by reviewing future generic company activity in countries within the scope of agreed licences where AbbVie itself does not have sales. In cases where generic company activity remains absent/ limited, AbbVie can consider proactively registering and pricing equitably within these countries to facilitate competition and access, or by identifying mechanisms within licences to incentivise generic market entry.

Performance by technical area



Performance by strategic pillar



CHANGE SINCE 2016

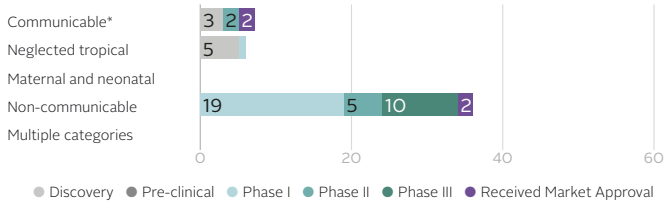
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Received FDA approval for the pangenotypic viral hepatitis C treatment glecaprevir/pibrentasvir (Mavyret™) in August 2017; it is the third pangenotypic treatment to market but the first eight-week treatment.
- Joined the Drugs for Neglected Diseases initiative's NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis through compound library sharing.
- Partnered with the Philippines Society of Newborn Medicine to reduce the prevalence of respiratory distress syndrome (RDS).
- Partnered with the Medicines Patent Pool in fall of 2018 to provide a non-exclusive voluntary licence for glecaprevir/pibrentasvir (Mavyret™), increasing access to the important 8 week treatment for hepatitis C by enabling generic production of the pangenotypic medicine.

*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. In 2018, AbbVie Inc. declined to submit data to the Access to Medicine Index.

PIPELINE for diseases and countries in scope

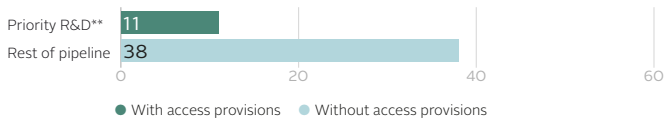
Mid-sized pipeline: 49 R&D projects (all medicines) for diseases in scope.
Clinical candidates: 37, including two Phase II clinical candidates that are part of two potential single-exposure cures for malaria.
Regulatory approvals: 4, including glecaprevir/pibrentasvir (Mavyret™) for the treatment of hepatitis C virus (pangenotypic).
R&D focus: medicines: non-communicable diseases (cancer), communicable diseases (malaria) and neglected tropical diseases (Chagas disease and leishmaniasis).
Access provisions: for 11 projects, all applied through access-oriented partnerships.

Projects in the pipeline: 49



The bulk of AbbVie's neglected tropical diseases projects are in the discovery stage with the notable exception of its Phase I tylosin analogue macrofilaricides (TylAMac™), a potential therapy for filariatic diseases developed in collaboration with the Drugs for Neglected Diseases initiative (DNDi).

Projects for R&D priority targets with access provisions: 11

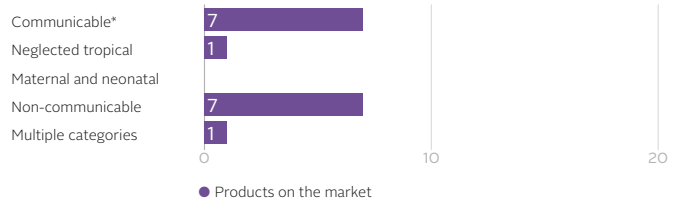


Of AbbVie's 49 R&D projects, 11 are supported by access provisions: e.g., two malaria projects include equitable pricing and registration strategies. Two of its 21 late-stage projects have provisions.

PORTFOLIO for diseases and countries in scope

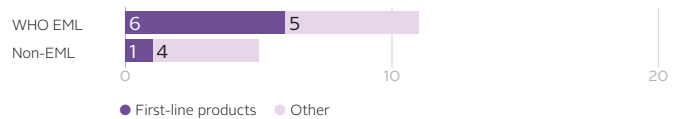
Comparatively small portfolio: 16 products (all medicines) for diseases in scope.
Portfolio focus: medicines: non-communicable diseases (hypertensive heart disease and epilepsy) and communicable diseases (viral hepatitis C).
Essential medicines: 69% of AbbVie's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).
First-line treatments: 44% of AbbVie's medicines have first-line indications for diseases in scope.

Products on the market: 16



AbbVie's portfolio includes products such as palivizumab (Synagis®) for the prevention of respiratory syncytial virus (RSV) in high-risk paediatric patients and an oral powder formulation of ritonavir (Norvir®) to treat HIV/AIDS in children.

Essential medicines with first-line indications: 6



75% of AbbVie's medicines are listed on the WHO EML and/or as first-line treatments: e.g., lopinavir/ritonavir (Kaletra®) for HIV/AIDS and beractant (Survanta®) for neonatal respiratory distress syndrome.

BUSINESS CONTEXT

One business unit: Pharmaceuticals, with four main therapeutic areas (immunology, oncology, virology and neuroscience).

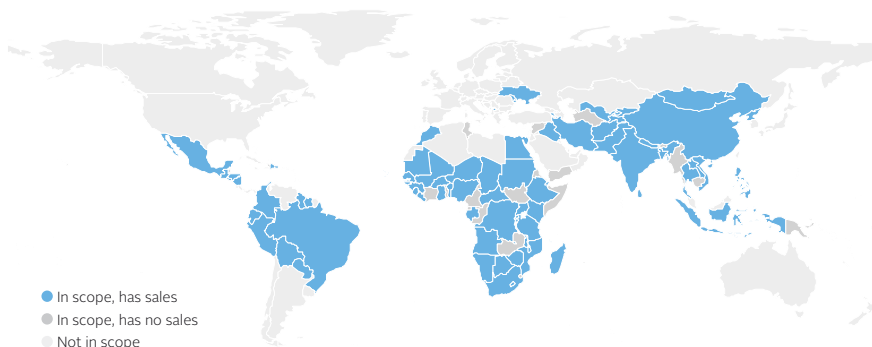
M&A news: 2016 acquisition of Stemcentrx, specialising in developing oncology medicines targeting small cell lung cancer and other solid tumours.

Presence in emerging markets: In 2016, AbbVie reported sales in 81 countries in scope. Data for 2018 not available.

Revenue by segment (2017) - USD

Pharmaceutical products	28,216 MN
Total	28,216 MN

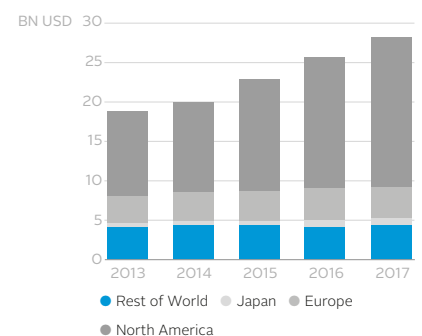
Sales in countries in scope



Statistics relate only to diseases and countries in scope.

*Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.
 **See Appendix IV for definition.

Revenue by geographic region



AbbVie Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 15 SCORE 2.86

Lacks overarching access-to-medicine strategy; responsibility for access lies at board-level. AbbVie does not have an overarching access-to-medicine strategy, but shows evidence of some activities guided by access-related goals. For example, it conducts research to develop new medicines for neglected diseases, supported by its Executive Council on Neglected Tropical Diseases and its corporate responsibility commitments to access to medicine. The highest level of responsibility for access sits with a board-level committee.

Financial access-related incentives in place for employees. AbbVie has financial incentives in place to motivate employees to perform on access-related issues. These incentives include awards based on access efforts.

Measures and monitors outcomes and progress; not impact. AbbVie measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its Foundation's partnership with Direct Relief International, AbbVie reports having established a data management and order tracking system to ensure effective monitoring of its HIV testing programmes in Least Developed Countries. However, it does not report measuring the impact of its initiatives.

Stakeholder engagement: incorporates local perspectives into strategies. AbbVie publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, or its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 17 SCORE 1.59

Does not report processes for ensuring third-party compliance with standards. AbbVie has a code of conduct relating to ethical marketing and anti-corruption. It provides regular compliance training for employees. The company performs relatively poorly when it comes to enforcing compliance measures and non-sales incen-

tives. It does not provide evidence of having formal processes in place to ensure compliance with standards by third parties. Further, its incentives for sales agents are based solely on sales targets.

Internal control framework lacks Index criteria. AbbVie's internal control framework for ensuring compliance meets one of the criteria looked for by the Index. This is an auditing and review mechanism, however, it does not report that this mechanism involves both internal and external resources, nor that it applies to all third parties in countries where AbbVie operates. The company does not report conducting fraud-specific risk assessments, nor does it demonstrate evidence of having a monitoring system in place to track compliance, or having procedures to segregate duties to ensure decisions are checked by another party.

Below average transparency regarding access-related practices. AbbVie does not publicly disclose policy positions that impact access to medicine. Neither does it disclose political contributions in countries in scope. AbbVie publicly discloses its financial support and membership of relevant organisations for access. It does not, however, publish its policies for responsible engagement. Neither does it publicly disclose its policy approach to payments made to health-care professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 12 SCORE 1.98

PROJECTS: 49 IN CLINICAL DEVELOPMENT: 37

Publicly commits to R&D to meet public health needs. AbbVie has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on external guidance including the United Nations Sustainable Development Goals. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. AbbVie has a mid-sized pipeline in the Index with 49 projects. For diseases in scope where priorities exist, AbbVie is active in 13 projects; 11 of these target priority R&D gaps.

Access provisions in place for 10% (2/21) of late-stage candidates. AbbVie has a general process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for

neglected tropical diseases and tuberculosis. Information is publicly available on project-specific access provisions for two of AbbVie's late-stage R&D projects. Both projects are being conducted in partnership with the Medicines for Malaria Venture (MMV).

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, and it does not provide an internal policy that can be evaluated.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 18 SCORE 1.70

PRODUCTS: 16

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 4

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. AbbVie does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implementing inter-country equitable pricing strategies for a minority of its products for diseases in scope. This does not explicitly apply to future products. Its public commitments also apply to intra-country equitable pricing strategies, albeit to only some of its products.

A third of new products in scope filed for registration in the majority of priority countries. AbbVie has filed 33% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share the registration status for any of its products.

25% of products have equitable pricing strategies targeting priority countries. AbbVie's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 25% of its products for diseases in scope. These strategies apply to an average of 76% of the relevant priority countries and take an average of three socio-economic factor into account.

Globally consistent recall guidelines for countries in scope but no processes to track products. AbbVie has guidelines for drug recalls that apply to all countries in scope. It does not

demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

PATENTS & LICENSING

RANK 8 SCORE 2.34

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

Uses licensing to enable generic supply. AbbVie has non-exclusive voluntary licensing agreements in place for two compounds (for diseases in scope). Its broadest licence, for paediatric lopinavir/ritonavir (LPV/r) (Aluvia®/ Kaletra®), encompasses 93 countries, including 62 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Does not report newly sharing IP assets with 3rd-party researchers beyond existing agreements. AbbVie reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi) and the Medicines for Malaria Venture (MMV). During the period of analysis, beyond existing agreements, the company reports no instances where it newly shares IP assets with third-party researchers developing products for diseases in scope.

No public commitment not to enforce patents in countries in scope. AbbVie does not have a public policy available that sets out its approach to filing for or enforcing patents in low- and middle-income countries.

CAPACITY BUILDING

RANK 16 SCORE 0.86

One initiative included for evaluation. AbbVie has one capacity building initiative that was included for analysis by the Index: i.e., the initiative demonstrably addresses a specific local need and involves local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment. AbbVie's initiatives were identified for selection based on publicly available information.

Initiative aimed at building local R&D capacity. AbbVie has one initiative which meets inclusion criteria in R&D capacity building. It provides scholarships for students to study science at The Asian University for Women in Bangladesh. AbbVie does not publicly disclose initiatives which meet inclusion criteria in any of the other areas of capacity building.

Limited publicly available data on initiatives.

AbbVie's included initiative meets the criteria for inclusion, but no additional good practice standards looked for by the Index. The company reported no information to the Index about its R&D capacity building initiative, and publicly available information is limited.

Timely approach to confirming and reporting substandard or falsified medicines. AbbVie provides evidence that it systematically confirms suspected cases of substandard or falsified medicines and then reports confirmed cases to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days for each, confirmation and reporting).

PRODUCT DONATIONS

RANK 13 SCORE 2.60

STRUCTURED DONATION PROGRAMMES: 4

Responds to emergencies, humanitarian crises and tracks delivery. AbbVie donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in response to the 2017 Mexico earthquake. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works with independent organisations, such as Americares, to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Four donation programmes covering diseases and countries in scope. AbbVie's programmes are focused on communicable and non-communicable diseases. All four programmes are carried out in partnership with independent partners. Its programme for respiratory distress in newborns supplies the treatment beractant (Survanta®) in four countries and has been ongoing since 2015. Meenakshi Medical Mission Hospital in India reports that beractant (Survanta®) has already helped to treat over 400 infants and preterm babies a year.

Ensures long-term access through transition planning. AbbVie has transition plans in place for one of its programmes to ensure ongoing access for patients once the programme ends. It commits to continuing this programme and fulfilling local product needs as identified by its partner Americares.

BEST & INNOVATIVE PRACTICES

No best or innovative practices were identified for this company in this Index.