

| RANK | SCORE |
|-----------|-------|
| 15▼ | 2.03 |
| 13 (2016) | |

Bristol-Myers Squibb Co.

Stock Exchange: New York Stock Exchange • Ticker: BMY • HQ: New York City, New York, United States • Employees: 23,700

PERFORMANCE

Falls from 13th place in 2016, to 15th. It continues to show strong performance in its approach to the pro-access management of IP, but its processes for access planning in R&D are weak. Its equitable pricing approach is average.

Management: Rises 2 places to 13th. The company does not assign responsibility for access at the board level (only executive level), but improves with commitments to measure impact.

Compliance: Rises 9 places to 7th. Prohibits political financial contributions outside of the US, and discloses financial support to patients' organisations.

R&D: Rises 3 places to 17th. Remains in last quartile. No clear process for access planning during development, and none of its late-stage projects have plans for access.

Pricing: Falls 4 places to 16th. Fails to commit clearly to the rapid registration of products, with an average performance in equitable pricing.

Patents: Falls 1 place to 4th. A continued strong approach to licensing maintains its performance, and newly discloses patent statuses via Pat-INFORMED.

Capacity: Falls 2 places to 18th. A focus on health systems strengthening, however, no included initiatives meet all good practice standards.

Donations: Rises 4 places to 10th. Newly included donation programme focused on chronic myeloid leukaemia, in partnership with the Max Foundation.

OPPORTUNITIES

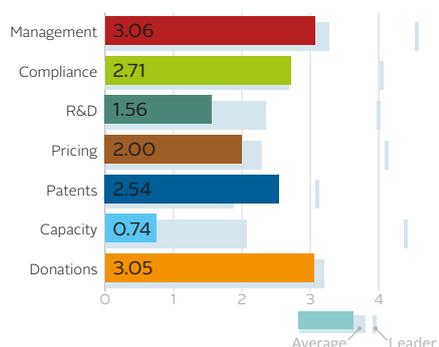
Develop a process to establish more access plans for R&D. Bristol-Myers Squibb can develop a clear approach to establishing access plans for R&D projects during development that takes into account the specific considerations necessary for each project, especially for its late-stage projects. Currently, none of its projects have access provisions in place.

Expand use of equitable pricing. Dasatinib (Sprycel®) for the treatment of leukaemia is an on-patent first-line product on the WHO EML that has no equitable pricing strategies in place. Applying equitable pricing strategies to this product, to countries where disease burden is high, would help increase affordability for those most in need: for example, Brazil, Indonesia, Pakistan, Afghanistan, Bangladesh and Nigeria.

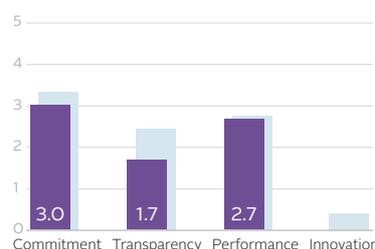
Review incentives for sales agents. Bristol-Myers Squibb can improve its commitment to ensure responsible sales practices by decoupling sales incentives from sales targets. Removing the emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

Expand access by engaging in voluntary licensing. Bristol-Myers Squibb can expand access for more products against high-burden diseases (outside of HIV/AIDS) by utilising voluntary licensing to increase generic supply. Possible products could include dasatinib (Sprycel®), listed on the 2017 WHO Model List of Essential Medicines (WHO EML) for imatinib-resistant chronic myeloid leukaemia, as well as apixaban (Eliquis®) for ischaemic heart disease and management of stroke and other blood clots.

Performance by technical area



Performance by strategic pillar



CHANGE SINCE 2016

- Joined Access Accelerated with multiple initiatives such as its Secure the Future programmes focused on NCDs. It has also committed to measure impact and share results publicly via Access Observatory.
- Takes affordability and some socioeconomic factors into account for all intra-country equitable pricing strategies.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Expanded its non-exclusive voluntary licence for Atazanavir (Reyataz®) indicated for HIV to include 12 new countries, eight of which are middle-income countries within the scope of the Index.
- Moved a substantial portion of its R&D projects along the pipeline.
- Committed to \$50 million over five years to support the Global HOPE initiative, which aims to train approximately 4,800 healthcare workers to provide quality paediatric cancer care.

PIPELINE for diseases and countries in scope

Comparatively small pipeline: 25 R&D projects (all medicines) for diseases in scope.

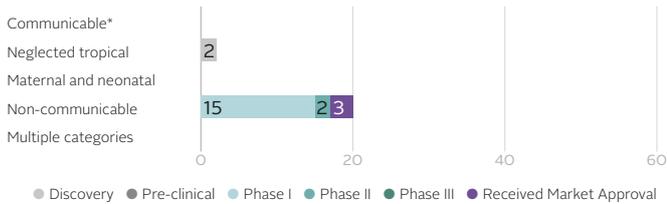
Clinical candidates: 18, including a factor XIa inhibitor for ischaemic heart disease and lirilumab for the treatment of multiple cancer types.

Regulatory approvals: 5, for additional indications for nivolumab (Opdivo®) in the treatment of five different cancers in scope.

R&D focus: non-communicable diseases (cancer).

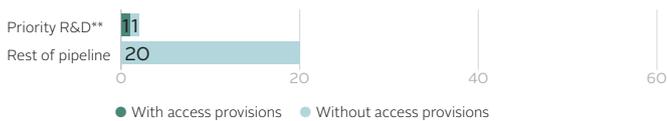
Access provisions: for 1 project, with provisions incorporated in partnership with the Drugs for Neglected Diseases initiative (DNDi).

Projects in the pipeline: 22



Bristol-Myers Squibb has the highest portion of projects progressing through the clinical pipeline. This pipeline is almost entirely comprised of projects targeting cancer with two projects for neglected tropical diseases.

Projects for R&D priority targets with access provisions: 1



Of Bristol-Myers Squibb's 25 R&D projects, one is supported by access provisions: a screening partnership with DNDi for Chagas disease, leishmaniasis and human African trypanosomiasis. None of its eight late-stage projects have provisions.

PORTFOLIO for diseases and countries in scope

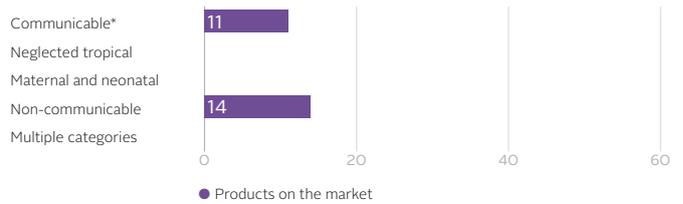
Comparatively small portfolio: 25 products (all medicines) for diseases in scope.

Portfolio focus: non-communicable diseases (cancer and ischaemic heart disease) and communicable diseases (HIV/AIDS).

Essential medicines: 68% of Bristol-Myers Squibb's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

First-line treatments: 68% of Bristol-Myers Squibb's medicines have first-line indications for diseases in scope.

Products on the market: 25



Bristol-Myers Squibb's portfolio includes products such as nivolumab (Opdivo®), which has been approved for several different cancer types, and the antipsychotic agent aripiprazole (Abilify®).

Essential medicines with first-line indications: 15



76% of Bristol-Myers Squibb's medicines are listed on the WHO EML and/or as first-line treatments: e.g., daclatasvir (Daklinza™), efavirenz (Sustiva®) and aztreonam (Azactam®).

BUSINESS CONTEXT

One business unit: Biopharmaceuticals, with four main therapeutic areas (oncology; immunology; cardiovascular diseases; and fibrotic diseases).

M&A news: 2016 acquisition of Padlock Therapeutics, a biotechnology company specialising in autoimmune diseases. 2017 acquisition of IFM Therapeutics, a biopharmaceutical com-

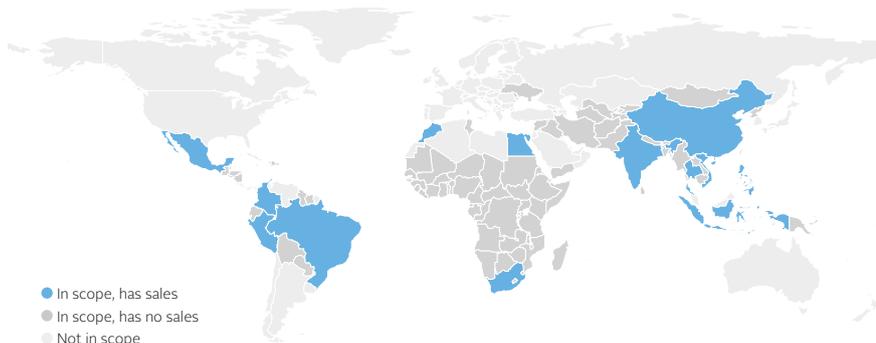
pany specialising in immunotherapy for cancer and inflammatory diseases.

Presence in emerging markets: In 2018, Bristol-Myers Squibb reports sales in 13 countries in scope; 24 less than in the 2016 Index. It reports that around 20% of its sales in 2017 came from regions outside of Europe and the USA.

Revenue by segment (2017) - USD

| | |
|---------------------|-----------|
| Medicines (product) | 20,776 MN |
| Total | 20,776 MN |

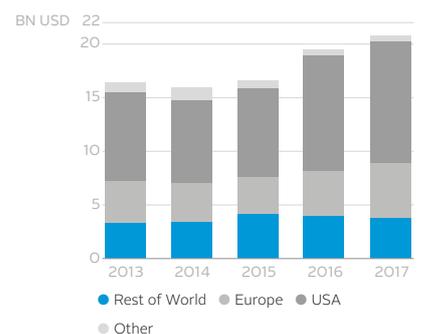
Sales in countries in scope



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



Bristol-Myers Squibb Co.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 13 SCORE 3.06

Has an access-to-medicine strategy with executive-level responsibility. Bristol-Myers Squibb has an access-to-medicine strategy with a business rationale. The strategy includes measures such as equitable pricing, licensing, philanthropy and capacity building. The highest level of responsibility for access sits with its Worldwide Access Council, at the executive level.

Financial and non-financial access-related incentives to reward employees. Bristol-Myers Squibb performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include awards for performance and public recognition by senior company leaders in internal meetings and through internal social media for objectives reached.

One of 16 companies working on impact measurement. Bristol-Myers Squibb measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, targets, objectives and performance information. For its HIV and hepatitis C medicines that are available in countries in scope, the company reports tracking the number of patients benefiting from its medicines. Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

Discloses who it engages with, incorporates local perspectives into strategies. Bristol-Myers Squibb publicly discloses which stakeholder groups it engages with on access issues, but does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE

RANK 7 SCORE 2.71

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Bristol-Myers Squibb has a code of conduct relating to ethical marketing and anti-corruption and provides biannual com-

pliance training for employees and third parties. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Bristol-Myers Squibb's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an internal auditing department for the whole company, involving both internal and external resources and applying to all third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

Above average transparency regarding access-related practices. Bristol-Myers Squibb publicly discloses its policy positions on access-related topics (e.g., its policy committing to provide appropriate patient access to medicines). It is one of the few companies in scope to have a policy that prohibits political financial contributions outside the USA. The company publicly discloses its membership of patient organisations, including the financial support it provides. It discloses policies for responsible engagement within its Principles of Integrity. It does not publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT

RANK 17 SCORE 1.56

PROJECTS: 25 IN CLINICAL DEVELOPMENT: 18

Publicly commits to R&D to meet public health needs. Bristol-Myers Squibb 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 linked to sources 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. Bristol-Myers Squibb has one of the smallest pipelines in the Index with 25 projects. For diseases in scope where priorities exist, Bristol-Myers Squibb is active in two projects; both of these target priority R&D gaps.

No clear process to consider access during development. Bristol-Myers Squibb does not have a clear process in place to develop access plans during R&D. Instead, Bristol-Myers Squibb considers access on a case-by-case basis. In general, Bristol-Myers Squibb develops access plans for R&D projects late in the development process and close to submission for market approval. To date, Bristol-Myers Squibb does not have any project-specific access provisions in place for its eight late-stage R&D projects. Five of these projects were approved during the period of analysis.

Public policy to ensure post-trial access; commits to registering trialed products. Bristol-Myers Squibb has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Bristol-Myers Squibb commits to registering it in all countries where clinical trials for the product have taken place.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 16 SCORE 2.00

PRODUCTS: 25

COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 5

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

Some new products in scope filed for registration in the majority of priority countries. Bristol-Myers Squibb has filed 10% 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 registration information for any of its products.

20% of products have equitable pricing strategies targeting priority countries. Bristol-Myers

Squibb's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 20% of its products for diseases in scope. These strategies apply to an average of 65% of priority countries. Most of these strategies apply inter-country pricing; these take into account an average of three socioeconomic factors. Bristol-Myers Squibb also applies an equitable pricing strategy to one further product informed by a public health rationale.

Globally consistent recall guidelines for countries in scope but no processes to track products. Bristol-Myers Squibb 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 4 SCORE 2.54

Publicly discloses detailed information on patent statuses. Like most of its peers, Bristol-Myers Squibb 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. Bristol-Myers Squibb has non-exclusive voluntary licensing agreements in place for two compounds (for diseases in scope). Its broadest licence, for atazanavir sulfate (Reyataz®), encompasses 97 countries including 66 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. Bristol-Myers Squibb reported existing agreements with product development partnerships such as the Drugs for Neglected Diseases initiative (DNDi). 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. Bristol-Myers Squibb 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 18 SCORE 0.74

Eight initiatives included for evaluation. Bristol-Myers Squibb has eight capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners.

Companies could submit a maximum of 25 initiatives across all areas for assessment; Bristol-Myers Squibb submitted 22.

Focused on strengthening health systems. Bristol-Myers Squibb has initiatives that meet inclusion criteria in three areas of capacity building: manufacturing, R&D, and health system strengthening. Most of these initiatives are focused on health system strengthening in the disease areas of HIV/AIDS, viral hepatitis (B and C) and cancer.

Most initiatives meet most good practice standards. None of Bristol-Myers Squibb's included initiatives meet all the good practice standards looked for by the Index. While its health system strengthening projects have good governance structures in place, some initiatives fall short on setting clear, measurable goals and objectives.

Does not provide evidence of reporting substandard or falsified medicines to relevant authorities. Bristol-Myers Squibb has a policy for the prevention and handling of counterfeit medicines. However, it does not provide evidence that it systematically reports cases of substandard or falsified medicines to relevant authorities and/or WHO Rapid Alert.

PRODUCT DONATIONS

RANK 10 SCORE 3.05

STRUCTURED DONATION PROGRAMMES: 1

Responds to emergencies and humanitarian crises and tracks delivery. Bristol-Myers Squibb 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, PQMD), and it works, for example, with Americares and Direct Relief to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Bristol-Myers Squibb's ongoing donation programme is focused on cancer. The programme is carried out in partnership with the the Max Foundation and has been ongoing since 2016. The company's cancer programme for chronic myeloid leukemia supplies dasatinib (Sprycel®) in 15 countries. In 2017, Bristol-Myers Squibb reports to have reached 118 patients. During the period of analysis Bristol-Myers Squibb also donated products for the treatment of hepatitis C in a demonstration project with several partners.

Ensures long-term access through transition planning. Bristol-Myers Squibb has transition plans in place for its dasatinib (Sprycel®) donation programme, to ensure ongoing access for patients once the programme ends. It commits

to contractually agree to continue providing the product to patients once the programme has ended, as long as patients meet certain eligibility criteria (e.g., recommendation from physician, there are no other means available to access the product, etc.).

BEST & INNOVATIVE PRACTICES

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