PERFORMANCE IN THE 2021 INDEX

19th place. Bristol Myers Squibb is in the lower ranks across all Technical Areas, with weak performance, for example, in R&D in addition to a lack of evidence of access strategies. The company performs poorly in responsible promotional practices.

Governance of Access: 15th place. Bristol Myers Squibb performs below average in this area. While having an access-to-medicine strategy with measurable goals, the company performs poorly in the area of responsible promotional practices.

Research & Development: 16th place. Bristol Myers Squibb performs below average in R&D. The company commits to registering trialled products, but does not have a structured access planning process nor does it disclose evidence of access plans for late-stage projects that address a public health need in LMICs.

Product Delivery: 19th place. Bristol Myers Squibb performs poorly in this area. Access strategies were identified for a few of its products. The company does not disclose, either publicly or to the Index, mechanisms to ensure continuous supply. It is engaged in health system strengthening in China and sub-Saharan Africa but no initiatives aimed at building manufacturing or supply chain capacity were included for analysis.

OPPORTUNITIES FOR BRISTOL MYERS SQUIBB

Strengthen governance of access to medicine. Bristol Myers Squibb can integrate its access strategy within its corporate business strategy, thus ensuring that all therapeutic areas are covered. It can implement financial and non-financial incentives for its CEO and in-country managers, linked to the achievement of the strategy, similar to how some senior executives now have access-related incentives. Furthermore, it can review sales incentive structures to adopt a balanced scorecard approach consistently, thus not solely promoting sales volume targets in countries in scope of the Index.

Develop access planning process and access plans for all R&D projects. Bristol Myers Squibb can develop a formal access planning process and accordingly develop access plans for all projects in Phase II clinical development, especially for products addressing a public health need in low- and middle-income countries such as paediatric dasatinib (Sprycel®), nivolumab (Opdivo®) and pomalidomide (Pomalyst®) for multiple indications for cancer.

Strengthen post-trial access policy. Bristol Myers Squibb can strengthen its post-trial access policy to cover all patients who gain a clinical benefit from existing treatments, not just those with serious and/or life-threatening conditions. It can also commit to ensuring affordability of essential products following cessation of post-trial access.

Improve access to patented products on WHO EML. Bristol Myers Squibb has in total eight products on patent which are on the 2019 WHO Model List of Essential Medicines (WHO EML). The company can further prioritise expanding access to these products, such as dasatinib (Sprycel®), for imatinib-resistant chronic myeloid leukaemia and apixaban (Eliquis®) for ischaemic heart disease and management of stroke.

CHANGE SINCE THE 2018 INDEX

• Expanded collaborative agreement with the Max Foundation to provide dasatinib (Sprycel®) to reach 45% more cancer patients than the previous agreement and to support health system strengthening.
• Discontinued daclatasvir (Daklinza®) in countries where the product is no longer routinely used or when other options are available, and commits itself to not enforcing the patent for this product in these countries.
• Joined the COVID-19 Therapeutics Accelerator.
• Announced the termination of all R&D collaborations with product development partnerships on NTDs and AMR, while outlicensing part of its compound library to MMV and offering one-off donations to MMV and DNDi.
SALES AND OPERATIONS

Business segments: Biopharmaceuticals
Therapeutic areas: Oncology; Haematology; Immunology; Cardiovascular diseases; Fibrotic disease

Product categories: Innovative medicines


Bristol Myers Squibb’s products are sold in 13* out of 106 countries in scope. Bristol Myers Squibb has sales offices in 6 countries and sells products via suppliers or pooled procurement in 7* countries.

*In 2018, Bristol Myers Squibb reported sales in 13 countries.

Sales in countries in scope

Sales by geographic region

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

Bristol Myers Squibb has a total of 63 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 11 projects. The other 52 R&D projects target other diseases in scope. The projects targeting priority diseases are for neglected tropical diseases such as leishmaniasis, Chagas disease and onchocerciasis. Of the projects targeting other diseases in scope, the focus is on oncology (46 projects).

23 R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (21).* Evidence of access planning was in place for 8.70% of these projects: 2 targeting a priority disease but none addressing a public health need in LMICs.

PORTFOLIO as selected for analysis by the Index

Bristol Myers Squibb has 23 medicines in scope, 18 of which are on patent. 52% of these medicines (12) are on WHO’s EML. The off-patent medicines target mainly non-communicable diseases (NCDs) such as schizophrenia, cardiovascular diseases and sickle cell disease. One off-patent medicine is antifungal. The on-patent medicines mainly target NCDs, such as cancer (9), schizophrenia and cardiovascular diseases. In addition, 4 products target HIV and 3 products target hepatitis B and C.

Access strategies were analysed for 14 products on the Bristol Myers Squibb’s portfolio – supranationally procured (4) or nationally procured HCP-administered (5) and self-administered products (5).

63 projects in the pipeline

23 products as selected for analysis by the Index*

Breakdown of projects*

Breakdown of products

*50 diseases and 211 product gaps in scope have been established as a 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.

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria.

‡Projects in the discovery phases and/or other drug development phases were not included in this breakdown.
Bristol Myers Squibb Co

**GOVERNANCE OF ACCESS**

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Has an access-to-medicine strategy with measurable objectives and a business rationale. Bristol Myers Squibb has an average performance. It has an access strategy linked to sustainability goals, including its hepatitis C virus (HCV) Developing World Strategy. The strategy covers some of the therapeutic areas in which the company is involved, including HCV in LMICs. The highest responsibility for access lies indirectly with the board, at the executive level with its World Access Council. Provides evidence of financial and non-financial access-related incentives at the executive level. Bristol Myers Squibb performs well. It incentivizes its senior executives to take action on access to medicine with financial and non-financial rewards. It does not disclose, however, whether in-country managers or the CEO are also incentivized toward access goals. Publicly discloses outcomes of a subset of its access-to-medicine activities. Bristol Myers Squibb performs well in transparency of access activities. It publicly discloses 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. Bristol Myers Squibb does not disclose that its sales agents are not solely incentivized on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers. Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bristol Myers Squibb performs below average, with evidence of some of the components looked for by the Index: audits (both internal and external and in all countries where it operates) and formal processes to ensure compliance with company standards by third parties. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment. Does not publicly support the Doha Declaration on TRIPS and Public Health. Bristol Myers Squibb does not publicly support any statement or action on the Doha Declaration on TRIPS and Public Health. There is no evidence of a policy to dissent from industry association positions.

**RESEARCH & DEVELOPMENT**

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No structured process for access planning reported. Bristol Myers Squibb does not have a structured process in place 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 peers, with access plans in place. Bristol Myers Squibb has 11 projects, including two late-stage candidates, in its pipeline that target a priority product gap. The company focuses on various priority areas, including leishmaniasis, Chagas disease and onchocerciasis. Evidence of an access plan accompanies both of Bristol Myers Squibb’s late-stage candidates targeting a priority product gap. These plans prioritize affordability and availability and are run in partnership with non-profit organisations (i.e. The Leprosy Institute Nepal and The Aurum Institute NPC). Many projects address a public health need in LMICs®. The company does not disclose evidence of access plans for late-stage projects. In this analysis, Bristol Myers Squibb has 21 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. Public policy to ensure post-trial access; commits itself to registering trialied products. Bristol Myers Squibb has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a life-threatening condition and no other therapeutic options. Once a product is approved, Bristol Myers Squibb commits itself to registering it in all countries where clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trials took place. No R&D capacity building initiatives included for evaluation. Bristol Myers Squibb has no initiatives included for analysis aimed at building R&D capacity in countries in scope of the Index. Companies could submit a maximum of five initiatives in this capacity building area. The company reported no information to the Index about building R&D capacity in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

**PRODUCT DELIVERY**

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Lacks a public commitment not to enforce patents in countries in scope. Bristol Myers Squibb 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, Bristol Myers Squibb discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction. In addition to the older assets, Bristol Myers Squibb newly shared one IP asset with third-party researchers developing products for diseases in scope during the period of analysis. During the period of analysis Bristol Myers Squibb has newly shared one IP asset with third-party researchers developing products for diseases in scope. It shares this asset with the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. The asset shared is molecule libraries. The new agreement is in addition to previously agreed IP sharing agreement with the Drugs for Neglected Diseases initiative (DNDi). Uses licensing to enable generic supply. Bristol Myers Squibb has non-exclusive voluntary licensing agreements in place for two compounds (for the diseases in scope). Its broadest licence, for azithromycin sulfate (Reyotab®), encompasses 96 countries, including 68 middle-income countries in scope. The company announced in March 2020 that the marketing authorisations for dacomitinib (Daklinza®) will be withdrawn or will be allowed to lapse in countries where the product is no longer routinely prescribed or where there are other therapeutic options available. Following the withdrawal/lapse of the marketing authorisation in each country, the patents will be allowed to lapse. In the interim period between the withdrawal/lapse of a market-
ing authorisation and the patent expiry, the company will not enforce its patents for daclatasvir in the country. This means that 17 more countries in scope (including Egypt, Arab Rep. and Moldova), not included in the licence territory will soon be able to procure from generic companies.

Filed to register some new products in the majority of high burden countries. Bristol Myers Squibb has filed 10% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, apixaban (Eliquis®) for stroke has been filed for registration/registered in six high burden countries in scope.

Has access strategies for some supranationally procured products in scope for this analysis. Bristol Myers Squibb performs below average in securing access for products procured supranationally. For one of the four products assessed in this category, evidence was publicly available that demonstrated strategies both in countries eligible for supply from such procurers and also in at least one non-eligible country. For example, the company applies equitable strategies, makes donations and has licences for the viral hepatitis medicine daclatasvir (Daklinza®) outside the Global Fund procurement. For the remaining products it usually lacks evidence of equitable pricing strategies in non-eligible countries and evidence of patient reach.

No evidence of access strategies for any of its health-care practitioner-administered products in scope of this analysis. Bristol Myers Squibb has not disclosed, either publicly or to the Index, access strategies for any of the products assessed by the Index in this category.

Has few access strategies for its self-administered products for some countries in scope of this analysis. Bristol Myers Squibb performs poorly in this area. For three out of the five products assessed, weak evidence of access strategies which consider ability to pay and affordability was publicly disclosed. The company makes efforts to reach additional patients through inter-country pricing strategies and donations. For example, in Paraguay and Cambodia, it uses donations to increase access to dasatinib (Sprycel®), an oncology medicine. Information which demonstrates patient reach through these approaches is not available.

No manufacturing capacity building initiatives included for evaluation. Bristol Myers Squibb has no initiatives included for analysis aimed at building manufacturing capacity in countries in scope of the Index. 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. Bristol Myers Squibb has no supply chain capacity building initiatives included for analysis. 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.

Three health system strengthening initiatives meet all Good Practice Standards. Bristol Myers Squibb performs above average in this indicator, with four health system strengthening initiatives that were included in analysis. 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. Three initiatives meet all Good Practice Standards, having a clear governance structure and long-term aims in place. The company’s initiatives were identified on the basis of publicly available data. Examples include:

- Delivering Hope®, raising awareness on hepatitis B and C, informing health policy and building health worker capacity to address these diseases and promote prevention in India and China, reaching 700,000 people.
- Secure the Future®, implementing over 250 programmes in 22 countries in Africa since 1999, including a sustainable model for HIV care in partnership with UNAIDS, WHO and the Baylor International Pediatric AIDS Initiative (BIPAI), treating over 1 million children in Botswana, Lesotho, eSwatini, Uganda and Tanzania.

Has not engaged in the development and implementation of inclusive business models. Compared to its peers, Bristol Myers Squibb 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.

Few mechanisms identified to improve supply chain efficiency in countries in scope of the Index. Bristol Myers Squibb performs less well than other companies in this area, disclosing limited information publicly on the steps it takes to ensure the continuous supply of its medicine in countries in scope of the Index. In 2018, the company reported having a demand planning system in place. No additional information on ensuring continuous supply was identified publicly by the Index.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended timeframe. Bristol Myers Squibb does not disclose publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities.

Donates in response to an expressed need and monitors delivery to end user. Bristol Myers Squibb previously reported that it ensures ad hoc donations are carried out in response to an expressed need. Moreover, it monitors the delivery until the end user; however it is unclear whether this is defined as the patient.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Bristol Myers Squibb is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Max Access Solution programme where it donates dasatinib (Sprycel®) for leukaemia to 15 countries since 2017.