Merck & Co, Inc

Stock Exchange: New York Stock Exchange • Ticker: MRK • HQ: Kenilworth, New Jersey, United States • Employees: 71,000

PERFORMANCE IN THE 2021 INDEX

15th place. Merck & Co, Inc (MSD) performs below average across all Technical Areas, with a weak performance in planning for access during R&D. There is a lack of evidence of access strategies and a poor performance in responsible promotional practices compared to peers.

Governance of Access: 14th place. MSD performs below average in this area. While having an access-to-medicine strategy with measurable objectives integrated within its overall corporate strategy, the company comparatively performs poorly in the area of responsible promotional practices.

Research & Development: 15th place. MSD performs below average in R&D. The company commits to registering trialled products, but does not have a process for access planning during R&D nor does it disclose any evidence of access plans for late-stage projects that address a public health need in LMICs.

Product Delivery: 16th place. MSD performs below average in this area. It has an access strategy for one product and only in upper-middle income countries. It is engaged in the development and implementation of one inclusive business model in Kenya and engages in some health system strengthening initiatives of which one meets all Good Practice Standards.

OPPORTUNITIES FOR MSD

Link incentive structures to access-to-medicine strategy. MSD has an access-to-medicine strategy, guided by its Access to Health Statement of Guiding Principles. Financial and non-financial incentives for senior executives, the CEO and in-country managers can be linked to it. Furthermore, it can review sales incentive structures for sales agents to adopt a balanced scorecard approach consistently, thus not solely promoting sales volume targets in countries in scope.

Expand access to patented medicines on EML. MSD agreed a licence for paediatric raltegravir (Srentess®); one generic company is manufacturing this product under this agreement. The company can further expand access in high-burden countries, by expanding registration and affordability. The company could prioritise increasing access to more on patent EML products, such as pembrolizumab (Keytruda®) and to further patented medicines considered for future inclusion, such as ertugliflozin (Steglatro®) for diabetes mellitus and doravirine (Pifeltro®) for HIV/AIDS.

Develop access planning process and access plans for all R&D projects. MSD can establish a formal access planning process and develop access plans for all clinical projects in Phase II and beyond, such as for gefapixant for endometriosis-related pain, tedizolid (Sivextro®) for S. pneumoniae and MK-8591 (islatravir) a pre-exposure prophylaxis (PrEP) to prevent HIV infection.

Improve transparency on access strategies at a product level. MSD can improve transparency on the access strategies it develops for marketed products, including information about how it reaches patients at the bottom of the income pyramid and a number of patients reached. Furthermore, it can disclose how it plans to reach patients in countries in scope with R&D projects in late-stage development.

CHANGE SINCE THE 2018 INDEX

- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Joined Bill and Melinda Gates Foundation on industry collaboration to address product development and delivery challenges related to COVID-19 and future pandemics.
- Pledged to ramp up HPV vaccine supply availability for Gavi-supported countries.
- As part of a broader refresh of its Access to Health Guiding Principles, the company set new KPIs on number of countries with affordability solutions initiated and number of patents filed in low-income countries (LICs)
- Entered into a non-exclusive voluntary licensing agreement with two generic medicine manufacturers for HIV/AIDS treatment doravirine in September 2020. The agreement covers 86 countries, including all sub-Saharan African countries.
- Collaborates with the Bill & Melinda Gates Foundation on the Phase 3 study investigating islatravir as an once-monthly oral pre-exposure prophylaxis (PrEP) treatment option for adolescent and adult women at high risk for acquiring HIV-1 infection in sub-Saharan Africa.

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, MSD declined to submit data to the Access to Medicine Index.

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.
SALES AND OPERATIONS

Business segments: Pharmaceuticals; Animal Health; Other Revenues
Therapeutic areas: Pharmaceuticals: Oncology; Vaccines; Hospital acute care; Immunology; Virology; Cardiovascular; Diabetes; Women’s health
Product categories: Innovative medicines; Vaccines; Animal health; Biosimilars
M&A news: In 2020 MSD acquired Themis, including the COVID-19 vaccine candidate, for USD 2.7 billion it acquired ArQule (oncology, rare diseases) and it acquired Oncoimmune (cancer, auto-immune diseases); acquired Immune Design (infectious diseases), Peloton Therapeutics (oncology), Tilos Therapeutics (oncology) and Calporta Therapeutics (neuroscience) in 2019.

MD products are sold in 81* out of 106 countries in scope. MSD has sales offices in 15 countries and sells products via suppliers or pooled procurement in 66* countries.

*In 2016, MSD reported sales in 81 countries.

Sales by segment (2019) – USD

<table>
<thead>
<tr>
<th>Segment</th>
<th>USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>41.751 bn</td>
</tr>
<tr>
<td>Animal Health</td>
<td>4.393 bn</td>
</tr>
<tr>
<td>Other revenues</td>
<td>0.696 bn</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>46.840 bn</strong></td>
</tr>
</tbody>
</table>

Sales by geographic region

<table>
<thead>
<tr>
<th>Region</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>177</td>
<td>177</td>
<td>177</td>
<td>177</td>
<td>177</td>
</tr>
<tr>
<td>International</td>
<td>108</td>
<td>108</td>
<td>108</td>
<td>108</td>
<td>108</td>
</tr>
<tr>
<td>USA</td>
<td>69</td>
<td>69</td>
<td>69</td>
<td>69</td>
<td>69</td>
</tr>
</tbody>
</table>

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope

MSD has a total of 52 R&D projects featuring a small-sized priority R&D pipeline compared to its peers: 13 projects. The other 39 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (5 projects) and lower respiratory tract infections (5). Of the projects targeting other diseases in scope, the focus is on oncology (34). 33 R&D projects are in late-stage development that target either a priority disease (9) or address a public health need in LMICs (24).* Evidence of access planning was reported in these sections for 3% of these projects: 1 targeting a priority disease, but none addressing a public health need in LMICs.

52 projects in the pipeline

<table>
<thead>
<tr>
<th>Communicable</th>
<th>Neglected tropical</th>
<th>Maternal and neonatal</th>
<th>Non-communicable</th>
<th>Multiple categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>36</td>
</tr>
</tbody>
</table>

Breakdown of projects**

The Merck & Co, Inc pipeline includes one of the two currently approved Ebola vaccines, Ervebo (RFSV-ZEBOV).

Breakdown of products

<table>
<thead>
<tr>
<th>Products</th>
<th>WHO EML</th>
<th>WHO EDL</th>
<th>Other</th>
<th><strong>Total</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines on patent</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>off patent</td>
<td>9</td>
<td>8</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Vaccines***</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other*</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

**Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

***Vaccines included in the analysis are both therapeutic and preventative.
† Other includes a vector control product. See Appendix I for definitions.
†† Product 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.
Merck & Co, Inc

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. MSD performs well here. It has an access strategy, guided by its Access to Health Statement of Guiding Principles, which covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, namely with the Public Policy and Responsibility Council reporting to the Executive Committee.

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

Publicly discloses outcomes of its access-to-medicine activities. MSD performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medicine activities, for example through its Corporate Social Responsibility report, and for its MSD for Mothers initiatives.

Performs comparatively poorly in responsible promotional practices. MSD does not disclose that its sales agents are not solely incentivised on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It has Guiding Principles for ethical business practices involving the medical and scientific community, but 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).

PUBLIC POLICY TO ENSURE POST-TRIAL ACCESS; COMMEMORATES THE 20 YEARS SINCE THE Doha Declaration on TRIPS and Public Health

Publicly supports the Doha Declaration on TRIPS and Public Health. MSD publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on its provisions. That is, it challenges the use of compulsory licensing, which it can respect only in very limited circumstances. There is no evidence of a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

No evidence found of structured process for access planning. MSD did not disclose to the index a structured process in place to develop access plans during R&D. The process is intended to be applied to some R&D projects for diseases in scope. MSD did not disclose 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 evidence of access plans for 11% of the late-stage candidates. MSD has 13 projects, including nine late-stage candidates in its pipeline, that target a priority product gap. The company focuses mostly on HIV/AIDS. Of MSD’s nine late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This plan for the newly registered Ebola vaccine Ervebo (rVSV-ZEBOV) includes WHO prequalification and registration in four African countries (DRC, Burundi, Ghana and Zambia). There are plans to make the product available at the lowest possible access price in Gavi-eligible countries.

Many projects address a public health need in LMICs*. The company did not disclose any access plans for the late-stage projects. In this analysis, MSD has 24 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 trialled products. MSD has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy is applied on a case-by-case basis. Once a product is approved, MSD 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 trial(s) took place.

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

PRODUCT DELIVERY

Public commitment not to enforce patents in countries in scope. MSD publicly pledges to neither file for nor enforce patents. This commitment applies in low-income countries.

Publicly discloses detailed information on patent status. Like most of its peers, MSD 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. Additionally, they self-disclosed US patent numbers for their whole US portfolio, vaccines and biologics.

In addition to the older assets, MSD newly shared one IP asset with third-party researchers. During the period of analysis MSD has newly shared one IP assets with third-party researchers developing products for diseases in scope. It shares this asset with the research institute Seattle Children’s research Institute, via the WIPO Research collaboration. The asset shared includes performing assay and share advice about drug target structure for schistosomiasis. The new agreement is in addition to previously agreed IP sharing agreements with the research institute Butantan in Brazil.
Uses licensing to enable generic supply, MSD has a non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence for its paediatric formulation of raltegravir (Sintetix®) encompasses 89 countries including 61 middle-income countries in scope. It has not issued any non-assert declarations for products in scope. Outside period of analysis, the company entered into a non-exclusive voluntary licensing agreement with two generic medicine manufacturers for HIV/AIDS treatment doravirine in September 2020. The agreement covers 26 countries, including all sub-Saharan African countries.

No evidence of new products in scope filed for registration in the majority of high burden countries. MSD did not disclose evidence of filing for any of its ten assessed products in more than half of the relevant top to high burden countries in scope (disease-specific subset of countries with the highest burden of disease). However, WHO prequalified the Ebola Zaire vaccine, Live (Ervebo®), in November 2019. It facilitated the registration of the vaccine in several African countries such as the Democratic Republic of Congo, Burundi, Ghana and Zambia. The company has also publicly disclosed the registration status for other products on their website.

Has access strategies for some supranationally procured products in scope of this analysis. MSD has an average performance in securing access for products procured supranationally. For four of the five products assessed in this category, examples of strategies both in countries eligible for supply from such procurers and in at least one non-eligible country were found publicly. For example, the company offers the same terms for the HPV vaccine Gardasil® in GAVI transitioning countries as it does in GAVI-eligible countries. Information which demonstrates patient reach through these approaches is not available.

No evidence of access strategies for any of its health-care practitioner-administered products in scope of this analysis. MSD has not disclosed, either publicly or to the Index, access strategies for any of the five products assessed by the Index in this category. The products are oncology treatments, antibiotics and a product targeting ischaemic heart disease.

Limited available evidence on access strategies for its self-administered products for countries in scope of the analysis. MSD performs poorly in this area. Examples of access strategies considering affordability in UMICs was found publicly for one out of the five products assessed. The company makes efforts to reach additional patients through the use of both inter- and intra-country pricing strategy. For example, in UMICs MSD offers discounts for contraceptives to organisations that serve women of all income levels, like Planned Parenthood affiliates. However, there was no public information about the reach of such initiatives or examples in LMICs and LICs.

No manufacturing capacity building initiatives included for evaluation. MSD 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 manufacturing capacity building in countries in scope of the Index. No initiatives were identified for selection based on publicly available information.

Three supply chain capacity building initiative meet all Good Practice Standards. MSD performs above average in this indicator, with three supply chain capacity building initiatives included for analysis and meeting all Good Practice Standards. MSD’s initiatives were identified for selection based on publicly available information. For example, MSD’s Informed Push Model (IPM-SPL) implements an innovative supply chain model aimed at eliminating stockouts of contraceptives at health facilities in Senegal, which was recognised as a Best Practice in the 2018 Index.

One health system strengthening initiative meets all Good Practice Standards. MSD performs above average in this indicator, with four health system strengthening initiatives included for analysis: 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. MSD’s initiatives were identified for selection based on publicly available information. One initiative, MSD for Mothers, meets all Good Practice Standards, demonstrating a good governance structure and long-term aims. For the other four initiatives, such information could not be found publicly.

Has engaged in the development and implementation of new inclusive business models. MSD performs above average when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope of the Index. It has developed a model focused on maternal health: MonCare.

Few mechanisms identified to improve supply chain efficiency in countries in scope of the Index. MSD performs less well than other companies in this area, disclosing little information publicly on the steps it takes to ensure the continuous supply of its medicine in countries in scope of the Index. Few strategies were identified based on publicly available information, including the use of dual API sourcing for some of its supply nodes and markets.

Does not disclose a policy for reporting substandard and falsified (SF) medicines in countries in scope within the recommended timeframe. MSD does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities. It has a public policy on tackling counterfeit products.

Donates in response to an expressed need and monitors delivery to end user. MSD publicly reports 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.

Publicly commits itself to the achievement of elimination, eradication or control goals in its structured donation programmes for NTDs. Two structured donation programmes for NTDs were included for analysis where elimination, eradication or control goals are possible. In one programme, MSD publicly commits itself to eliminating onchocerciasis (since 1987) and lymphatic filariasis (from 1998 to 2020) by donating ivermectin (Mectizan®) in 27 countries.