

RANK	SCORE
<b>18</b>	<b>2.15</b>
15 (2021)*	

# Merck & Co, Inc

Stock exchange: NYSE • Ticker: MRK • HQ: Rahway, New Jersey, US • Employees: ~68,000

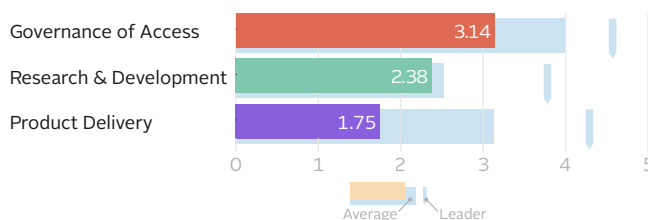
## PERFORMANCE IN THE 2022 INDEX

18<sup>th</sup> place. MSD performs below average in two of the three Technical Areas. In Governance of Access, there was no publicly-available evidence found of policies governing responsible promotional practices. In the Product Delivery Technical Area, it performs below average in its approach to equitable access strategies. Research & Development however, the company has strengthened its access planning framework and has access plans in place for several late-stage candidates in the pipeline.

**Governance of Access:** 20<sup>th</sup> place. MSD performs poorly in this area. It has an access-to-medicine strategy with measurable objectives integrated within its overall corporate strategy, but there is no evidence that sales incentives are decoupled from sales volume targets, nor is there evidence that senior management and in-country/regional managers are incentivised to perform on access-related goals. It also lacks evidence of a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

**Research & Development:** 11<sup>th</sup> place. MSD has an average performance in this area. The company now has a structured

How score was achieved



access planning framework in place, but evidence was not found that it applies this to all late-stage candidates. It has a small-sized priority pipeline but does participate in R&D capacity building.

**Product Delivery:** 19<sup>th</sup> place. MSD performs poorly in this area. One access strategy was identified for one product in an upper-middle income country. MSD has an average performance with regard to its participation in inclusive business models. The company engages in health systems strengthening and supply chain capacity building, but evidence of engagement in manufacturing capacity building was not found.

## OPPORTUNITIES FOR MERCK & CO

**Organise governance of access.** 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 this strategy. Furthermore, the company can decouple sales incentives for its sales agents from sales volume in countries in scope of the Index.

**Ensure all late-stage R&D projects have comprehensive access plans.** MSD has an R&D access planning process in place and project-specific access plans for 43% of its late-stage R&D projects. The company can apply this process to all late-stage R&D projects, including tedizolid (Sivextro®) for *S. pneumoniae*, islatravir (MK-8591) for the treatment of HIV infection and its chikungunya virus vaccine (V184).

**Expand access to patented medicines on the WHO Model List of Essential Medicines.** MSD has a non-exclusive voluntary license in place for paediatric raltegravir (Isentress®), for HIV, with one generic company already manufacturing it under this licence. The company can expand access to raltegravir in countries with a high disease burden by expanding registration and applying equitable pricing. The company can also expand access to products such as pembrolizumab (Keytruda®), which has multiple cancer indications, through equitable pricing strategies and/or non-exclusive voluntary licensing.

## CHANGES SINCE THE 2021 INDEX

- Entered into an agreement with UNICEF to supply up to 3 million courses of COVID-19 antiviral molnupiravir (Lagevrio®) to LMICs through the first half of 2022.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Licensed its COVID-19 antiviral molnupiravir (Lagevrio®) through the Medicines Patent Pool, covering 106 countries, 95 within the scope of the Index.
- Agreed with UNICEF to establish the world's first global Ebola vaccine stockpile of the Zaire ebolavirus vaccine (Ervebo®).
- Issued a USD 1 billion sustainability bond to support projects and partnerships that contribute to the advancement of the UN SDGs including access to healthcare and infectious disease research and development and to support initiatives that address access barriers and strengthen health systems.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources. For

the 2022 Index, MSD declined to submit data to the Access to Medicine Index. The term LMICs is used to denote all low- and middle-income countries in 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. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

\*In the 2021 Index, dense ranking was used. In the 2022 Index, standard competitive ranking is used. Therefore, a direct comparison with MSD's previous rank is not possible.

### SALES AND OPERATIONS

**Business segments:** Animal health, pharmaceuticals and other segments.

**Therapeutic areas:** Cardiovascular, diabetes, hospital acute care, immunology, neuroscience, oncology and virology.

**Product categories:** Animal health, innovative medicines and vaccines.

**M&A news:** MSD acquired Acceleron Pharma Inc. in November 2021 for USD 11.5 billion.

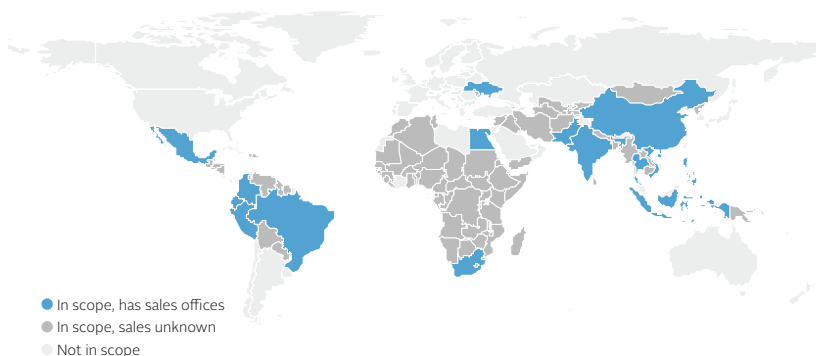
MSD's products are sold in 81\* out of 108 countries in scope of the Index. MSD has sales offices in 15 countries and sells via suppliers and/ or pooled procurement in 66\* countries.

\*In 2016, MSD reported sales in 81 countries.

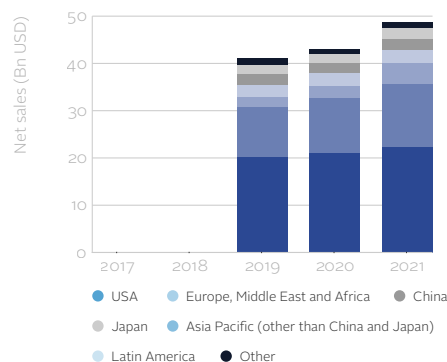
#### Net sales by segment (2020) – in USD

Animal health	4.70 bn
Pharmaceuticals	43.02 bn
Other segment sales	0.02 bn
<b>Total</b>	<b>47.75 bn</b>

#### Sales in countries in scope



#### Sales by geographic region



### SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

#### PIPELINE for diseases in scope

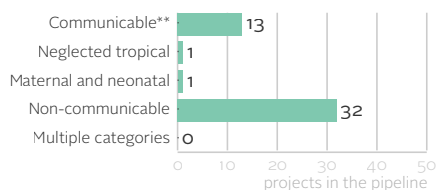
MSD has a total of 47 R&D projects in scope with 13 of these projects targeting priority diseases. The other 34 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (five projects). Of the projects targeting other diseases in scope, the focus is on oncology (29).

Twenty-eight R&D projects are in late-stage development that target either a priority disease (10) or address a public health need in LMICs (18)\*. Evidence of access planning was reported in these sections for 43% of these projects: three targeting a priority disease and nine addressing a public health need in LMICs.

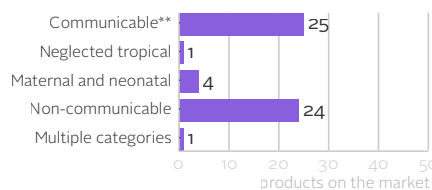
#### PORTFOLIO as selected for analysis by the Index

MSD has 37 medicines in scope, 23 of which are on patent, and 13 vaccines. 32% of the medicines (12) are on the WHO EML. In addition, the company markets one vector control product and four contraceptive methods and devices. The off-patent medicines target mainly non-communicable diseases (NCDs) (12) such as mental health (1) and cardiovascular diseases (4), cancer (2), asthma (2) and migraine (1); communicable diseases (CD) (3) such as HIV/AIDS, tuberculosis and hepatitis C. The on-patent medicines target CDs such as HIV/AIDS (5), hepatitis C (3), respiratory and other prioritised infections; and NCDs such as diabetes (6), cancer (3) and mental health (1). MSD's preventative vaccines (10) target CDs such as measles (2) and lower respiratory infections, and NCDs such as cancer (2). One vaccine is indicated for immunisation against HPV-related cervical cancer.

#### 47 projects in the pipeline



#### 55 products as selected for analysis by the Index†



#### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	3	3	5	2	0	13
Addresses needs of LMICs*			0	8	5	5	0	18
Other projects in scope			0	14	1	1	0	16

#### Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	21			23
off patent	10	4			14
Vaccines	12	1			13
Contraceptives	2	2			4
Diagnostics			0		0
Other†				1	1

\*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. \*\*Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. \*\*\*Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. ‡Other includes vector control products.

# Merck & Co, Inc

## GOVERNANCE OF ACCESS

RANK 20

SCORE 3.14

**Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy.** MSD performs strongly. 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.** Merck's performance is below average. The company 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 of the Index. It facilitates accountability and transpar-

ency by consistently sharing the outcomes of its MSD for Mothers initiatives in a centralised manner directly on its website.

**Performs comparatively poorly in responsible promotional practices.** MSD does not disclose whether 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 and discloses information related to transfers of values to healthcare professionals in countries in scope of the Index in accordance with law and local regulations and association guidance (e.g. payments for attending events or promotional activities).

**Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.** MSD performs relatively poorly, demonstrating evidence of some components looked for by the Index: audits (both internal and external, covering

third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of fraud-specific risk assessment, country risk-based assessment, or a continuous system to monitor activities. No breaches in countries in scope of the Index were publicly found in the period of analysis.

**Publicly supports the Doha Declaration on TRIPS and Public Health.** MSD publicly shares support of the Doha Declaration on TRIPS and Public Health but expresses reservations on its provisions. That is, it challenges compulsory licensing, stating it should only be used in very limited circumstances. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, MSD, like all other member companies in scope of the Index, is by default connected to this activity.

## RESEARCH & DEVELOPMENT

RANK 11

SCORE 2.38

**Access planning processes encompass all projects in the pipeline.** The company reported no information to the Index about its access planning processes. However, evidence of this was identified in the public domain. MSD has a structured process to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope of the Index. In general, MSD begins developing access plans for R&D projects in Phase II of clinical development.

**A small-sized priority R&D pipeline compared to peers, with evidence of access plans for 30% (3/10) of the late-stage candidates.** MSD has 13 projects, including ten late-stage candidates in its pipeline, that target a priority product gap. These projects focus mostly on HIV/AIDS. Of MSD's ten late-stage candidates targeting a priority product gap, three have evidence of an access plan in place. The company did not participate in the Access to Medicine Index data submission. However, evidence of access plans for three projects was found in the public domain.

For example, MSD agreed a non-exclusive voluntary licensing agreement with the Medicines Patient Pool for its COVID-19 antiviral molnupiravir (MK-4482 and EIDD-2801) before it received emergency regulatory authorisation.

**Many projects address a public health need in LMICs\*, with 50% (9/18) of late-stage projects supported by access plans.** In this analysis, MSD has 18 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 of the Index or are first-in-class projects. Most target cancer. The company did not participate in the Access to Medicine Index data submission. However, MSD has a policy whereby once a product is approved, it commits to registering it in all countries where clinical trials for the product have taken place. Therefore, commitments to

register in countries in scope apply to nine of these projects.

**Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.** However, MSD does disclose fully disaggregated R&D investment data to Policy Cures Research.

**One R&D capacity building initiative included for analysis meets all Good Practice Standards.** MSD's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. The company did not participate in the Access to Medicine Index data submission. However, based on information in the public domain, one initiative could be included for analysis. In this initiative, MSD partners with Seeding Labs to improve access to laboratory equipment for the scientific community in LMICs.

\*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, 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.

## PRODUCT DELIVERY

RANK 19

SCORE 1.75

**Public commitment not to enforce patents in countries in scope.** MSD publicly pledges to neither file for nor enforce patents. This commitment applies in LICs.

**Publicly discloses information on patent status.** Like most of its peers, MSD discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. MSD discloses patent information such as filing date, grant number, grant date and jurisdiction. Additionally, it discloses US patent numbers for its entire US portfolio of vaccines and biologics.

**Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers.** MSD does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

**Uses licensing to enable generic supply.** MSD has a non-exclusive voluntary licensing agreement in place for two compounds (for diseases in scope). Its licence for its paediatric formulation of raltegravir (Isentress®), indicated for HIV/AIDS, encompasses 89 countries within the scope of the Index including 59 middle income countries. MSD also has a licence for its COVID-19 antiviral, molnupiravir (Lagevrio®), agreed with 27 sublicensees, covering 95 countries relevant to the Index including 68 middle income countries.

**No evidence of filing for registration new products in any country in scope on average.** MSD did not disclose evidence of filing for registration any of its analysed products.

**Has access strategies for all its supranationally procured products in scope of this analysis.** MSD performs below average in securing access for products procured supranationally. For all of the three 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 has a tiered pricing policy for vaccines, including the pneumococcal vaccine polyvalent (23-valent) (Pneumovax®23). Information regarding patient reach was not found in the public domain.

**Has an access strategy for its healthcare practitioner-administered products in scope of this analysis.** MSD performs below average in securing access for healthcare practitioner-administered products. Evidence of an access strategy that considers some affordability factors was found in China for pembrolizumab (Keytruda®), an oncology product. No evidence of access strategies for the remaining products were found in the public domain, nor was evidence regarding patient reach, either publicly or to the Index. The products are an oncology treatment, antibiotics and a product targeting ischaemic heart disease.

**No evidence of access strategies for any of its self-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 diabetes treatments, a product targeting asthma and one targeting migraine.

**No manufacturing capacity building initiatives included for analysis.** There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. MSD's performance is below average in this area.

**Both supply chain capacity building initiatives included for analysis meet all Good Practice Standards.** MSD's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average but an average number of initiatives meet all Good Practice Standards (GPS) for this indicator. For example, MSD is a member of the Neglected Tropical Disease (NTD) Supply Chain Forum which provides a common platform for all partners to come together and explore options to manage the NTD drug supply chain.

**One of the two health systems strengthening initiatives included meets all Good Practice Standards.** MSD's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. For example, MSD for Mothers is a USD 650 million global initiative, contributing the company's scientific and business expertise and financial resources to address preventable maternal deaths through supporting quality maternity care and access to modern contraception. This initiative meets all GPS.

**Has engaged in scaling up two inclusive business models but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria.** MSD performs average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. In Kenya, MSD is supporting the expansion of M-TIBA to include maternal health services through Mom Care, a new platform that links patients, providers and payers to improve the financing and delivery of maternity care.

**Performs below average in terms of ensuring continuous supply of medicines in LMICs.** MSD shows evidence of its involvement in supply chain capacity building initiatives and transfers technology with third-party manufacturers in LMICs. However, there is no evidence that the company works with relevant stakeholders to communicate issues that may affect the supply chain, maintains a network of several active pharmaceutical ingredient suppliers, nor manages a buffer stock of relevant products.

**Does not disclose a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index.** MSD does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities. However, it publicly discloses having a global Product Integrity Strategy on tackling counterfeit products, and reports that it responds in alignment with local regulatory requirements.

**Donates in response to expressed need and monitors delivery.** MSD has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

**Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria.** In one programme, for over 15 years MSD has publicly committed to supporting the elimination of onchocerciasis and lymphatic filariasis by donating ivermectin (Mectizan®) in 27 countries in scope of the Index until goals are achieved.