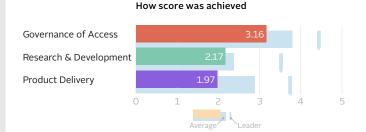
RANK	SCORE
16	2.21
18 (2022)	

# Merck & Co., Inc

Stock exchange: NYSE • Ticker: MRK • HQ: Rahway, New Jersey, US • Employees: 72,000

### **PERFORMANCE IN THE 2024 INDEX\***

**16**<sup>th</sup> **place**. MSD performs below average in all three Technical Areas. However, it has improved its performance in Governance of Access and Product Delivery, where it demonstrates Best Practice by sharing high-value intellectual property assets for tuberculosis and transferring technology for end-to-end manufacturing of vaccines.



## **OPPORTUNITIES FOR MSD**

Improve the quality and broaden the geographic reach of

access plans. MSD has access plans that predominantly focus on registering in countries where the company is conducting clinical trials. It can expand its plans, for example, by including equitable pricing and broadening the geographic coverage of these plans to focus on more low- and lower-middle-income countries. For example, it can enhance plans for clesrovimab – a preventative treatment for respiratory syncytial virus in infants which is currently in Phase III of clinical trials – beyond the seven countries in scope where it is conducting these trials.

Establish direct board-level responsibility for access to medicine. MSD places the highest responsibility for access with the Policy and ESG Council reporting to the Executive Committee. To further progress, MSD can ensure responsibility for access to medicine lies directly with the board. Expand manufacturing capacity building efforts for vaccines.

In 2022, MSD launched a technology transfer with Bio Farma to produce MSD's quadrivalent HPV vaccine locally in Indonesia. MSD can further expand these efforts to increase vaccine manufacturing for products prioritised for local production, such as Ebola vaccines, particularly in Africa.

Expand access strategies to key oncology products. MSD did not disclose access strategies for its cancer products in any country in scope. It can expand access by implementing equitable access strategies and/or engaging in voluntary licensing to enable generic supply in low- and middleincome countries; in particular, for its key immuno-oncology therapy pembrolizumab (Keytruda®), indicated for multiple cancer types and prioritised for licensing by public health organisations.

## **CHANGES SINCE THE 2022 INDEX**

- Entered a licensing agreement with the Gates Medical Research Institute (Gates MRI) for two pre-clinical antibacterial candidates in October 2022.
- 2022 marked 35 years of the Merck and Mectizan® donation programme, which began with the goal of eliminating onchocerciasis and later expanded to include lymphatic filariasis through the long-term donation of ivermectin (Mectizan®).
- Its HPV vaccines, Gardasil®4/Gardasil®9, were included in the Global HPV Consortium, which focuses on accelerating the prevention of HPV and eliminating cervical cancer.
- Newly entered a licensing and technology transfer agreement to have its four-valent HPV vaccine produced locally by Bio Farma in Indonesia. Merck also entered a technology transfer agreement with Chinese manufacturer Sinopharm to supply its COVID-19 treatment, molnupiravir, to the Chinese market in future.
- Signed an agreement with the faculty of medicine at Siriraj Hospital, Mahidol University, to establish a Clinical Site Partnership Project in Thailand.
- Announced that Merck for Mothers had reached more than 30 million women worldwide through its programmes supporting access to high-quality maternal care.
- Published its Sustainability Bond Allocation Report in 2023, where proceeds were used to fund projects and partnerships that contribute to the advancement of United Nations Sustainable Development Goals (SDGs), including access to health care and infectious disease research programmes. Merck Foundation committed USD 11mn over six years (2023 – 2028) to the University of New Mexico Health in support of its new initiative to bring high-quality care to an estimated 11mn people living with cancer in underserved communities throughout India, Indonesia, Malaysia and Vietnam.

\*For the 2024 iteration, MSD declined to submit data to the Access to Medicine Index.

## Merck & Co, Inc

### SALES AND OPERATIONS

Therapeutic areas: Cardio-metabolic diseases, immunology, infectious diseases, neuroscience, oncology, vaccines

Product categories: Animal health, innovative medicines, vaccines

M&A news: In 2023 MSD acquired Imago BioSciences Inc. for USD 1.35bn; Prometheus Biosciences Inc. for

#### Sales in countries in scope

In scope, has sales offices
In scope, no sales

Not in scope

USD 10.8bn; and Caraway Therapeutics Inc. for USD 610mn USD. In 2024, it acquired Harpoon Therapeutics Inc. for USD 650mn. MSD's Animal Health Division acquired Vence for an undisclosed amount and Elanco's Aqua Business for USD 1.3bn USD in 2022 and 2024, respectively. In 2024, MSD acquired Abceutics, Inc. for USD 208mn.

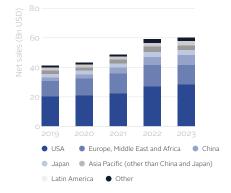
MSD's products are sold in  $81^*$  out of 113 countries in scope of the Index. MSD has sales offices in 15 countries and sells

via suppliers and/ or pooled procurement in 66\* countries.

### Net sales by segment (2023) – in USD

Animal health	5.63 bn
Pharmaceuticals	53.58 bn
Other segment sales	0.91 bn
Total	60.12 bn

#### Sales by geographic region



## SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

#### **PIPELINE** for diseases in scope

MSD has 36 R&D projects in scope, 5 of which target priority diseases, focusing on HIV/AIDS (3), RSV (1) and malaria (1). The remaining 31 projects target other diseases in scope, including cancer (23) and cardiovascular diseases (3). Of the 36 R&D projects, 35 are in late-stage development, with evidence of access planning for 69% (24/35) of these.

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

MSD has 55 products in scope, including 37 medicines and 13 vaccines; 28 of these products are listed on the WHO EML. Most of the products are on patent (30). Its medicines mostly target non-communicable diseases, such as diabetes (7), cardiovascular diseases (5) and cancer (4). Its medicines for communicable diseases include HIV (5) and hepatitis C (3), and it has a medicine that is indicated for both cancer and hepatitis (B and C). It has 1 vector control product for rabies and 4 contraceptive methods and devices. MSD's vaccines include 2 for measles, 2 for lower respiratory infections, and 2 HPV vaccines for prevention of cervical cancer.

## 55 products in the portfolio

Breakdown of products

off patent

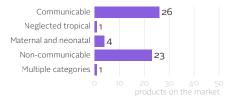
Medicines on patent

Vaccines

Contraceptives

Diagnostics

Other



WHO EMI

9 4

19

1

Non-EML WHO EDI

Other Total

24

13

13

4

o

1 1

## 36 projects in the pipeline



### Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	0	0	1	1	2	0	1	0	5
with access plan				0	2	0	1		3
Other projects in scope			0	22	7	0	2	0	31
with access plan				12	7	0	2		21

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

## Merck & Co, Inc

### **GOVERNANCE OF ACCESS**

#### NK 18 SCORE 3.16

**18<sup>th</sup> place.** MSD performs poorly in this Technical Area. The company has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy. However, the highest responsibility for access to medicine lies indirectly, rather than directly, with MSD's Board. Additionally, it does not disclose sufficient evidence of having a robust set of controls to mitigate the risk of non-compliant or corrupt activities in countries in scope. Further, the company does not publicly express any support for the Doha Declaration on TRIPS and Public Health.

The highest responsibility for access lies indirectly with the Board, namely with the Policy and ESG Council reporting to the Executive Committee. MSD has access-related incentives for its CEO, senior executives and in-country managers. In 2023, the company added new sustainability metrics to its company scorecard, linking a percentage of employee compensation to key sustainability goals, including Access

Comprehensive access-to-medicine strategy integrated within the overall corporate

to Health.

strategy. Its strategy, guided by its Access to Health Statement of Guiding Principles, covers all therapeutic areas in which the company is involved. MSD publicly discloses its commitments to access to medicine, along with companyspecific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regularly in its Impact Report. Shows comparatively poor commitment to responsible business practices. There is

evidence that MSD sets individual-level targets for sales agents, but it does not disclose, publicly or otherwise, if incentives are solely based on sales volume. Additionally, MSD does not provide evidence, publicly or otherwise, of having a global policy that commits to ensuring ethical interactions with healthcare professionals. Further, it only publicly discloses information on transfers of value to healthcare professionals in countries in scope if required by law or local regulation.

Has a set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. MSD performs moderately in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards. However, it does not disclose sufficient evidence, publicly or to the Index, of fraud-specific risk assessments and region or country risk-based assessments in countries in scope. MSD has an ethical decision-making framework for employees. No breaches in countries in scope were found in the period of analysis.

## MSD does not publicly share any support for the Doha Declaration on TRIPS and Public

**Health.** It has a publicly available policy statement on intellectual property, but it does not align with principles embodied in the Declaration. Further, MSD states that compulsory licensing may hinder equitable access.

Fulfils some criteria across 2 processes for measuring and reporting patient reach. For

MSD's process for its innovative portfolio, which covers some of its products in scope of the Index, information on country coverage was unavailable but the metrics, assumptions and limitations are publicly available. The resulting patient reach numbers are published regularly and demonstrate improvements. The process also has a measurable patient reach goal but no associated health outcomes goal was identified.

#### **RESEARCH & DEVELOPMEN**

RANK 12 SCORE 2.17

**12<sup>th</sup> place.** MSD has a below-average performance in this Technical Area. The company has a public access planning framework in place from Phase II onwards but did not disclose access plans for all late-stage candidates. Its access plans comprise of commitments to register in countries where it conducts clinical trials. It has a small-sized priority pipeline, which has declined in size and does not publicly disclose disaggregated R&D investment data, but it does participate in R&D capacity building.

Structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects in scope, no later than Phase II. The company makes a public commitment addressing its systematic approach to access planning for LMICs.

Small-sized priority R&D pipeline, compared to peers, with access plans in place for 75% (3/4) of the late-stage candidates. Priority R&D pipeline of 5 projects, including 4 late-stage projects that target a priority gap. The company focuses on various priority areas, including HIV/AIDS and malaria. Of MSD's 4 late-stage candidates targeting a priority product gap, 3 (75%) have evidence of an access plan in place, including registration preparation and inclusion of special populations in clinical trials.

Large-sized pipeline, compared to peers, addressing other diseases in scope, with 68% (21/31) of late-stage projects covered by access plans. The company has 31 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. The projects mainly target cancer and cardiovascular diseases. MSD provides evidence of access plans for 21 of its 31 late-stage projects, including registration preparation and the inclusion of special populations in clinical trials. MSD does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, it does disclose anonymised disaggregated R&D investment data to Impact Global Health (formerly Policy Cures Research).

One of the two R&D capacity building initiatives included for analysis meets all Good Practice Standards (GPS). In this initiative, MSD provides equipment to Seeding Labs. In turn, the organisation provides this equipment to research institutions in LMICs.

## Merck & Co, Inc

## PRODUCT DELIVERY

#### NK 17 SCORE 1.97

**17<sup>th</sup> place.** MSD performs poorly in this Technical Area. The company did not report any national access strategies for its products. However, it engages in supranational agreements to supply four of its products. For two products, the company also engages in non-exclusive voluntary licensing. It shows evidence of two new technology transfers, improving its performance in manufacturing capacity building. It engages in some supply chain capacity building and health system strengthening initiatives, but few meet all Good Practice Standards.

MSD did not disclose registration data to the Index. However, evidence in the public domain indicates that it has utilised WHO Prequalification to facilitate registration for multiple products.

Supplies 4 products through supranational

**agreements.** MSD supplies 2 of its products, indicated for HIV and COVID-19, via different procurers, including The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), UNICEF and the US President's Emergency Plan for AIDS Relief (PEPFAR). In addition to supranational agreements, MSD has non-exclusive voluntary licensing agreements for these products to enable generic supply. The company supplies its HPV vaccine Gardasil®4 via Gavi, the Vaccine Alliance. The fourth product, its Ebola virus vaccine (Ervebo®), is supplied through UNICEF, which has created a stockpile of 500,000 doses for outbreak response.

No evidence of access strategies for its healthcare practitioner (HCP)-administered products. MSD has not disclosed, either publicly or to the Index, access strategies for any of the 5 products assessed by the Index in this category. The products selected include oncology medicines, antibiotics and a 9-valent HPV vaccine.

No evidence of access strategies for its selfadministered products. MSD has not disclosed, either publicly or to the Index, access strategies for any of the 4 products assessed by the Index in this category. The products are indicated for diabetes and HIV.

MSD publicly commits not to file for or enforce patents for all products in all LICs in scope.

Publicly discloses product patent status for countries in scope. Like most peers, MSD publicly discloses patent information for small molecules in scope via the Pat-INFORMED database, including information such as filing date, grant number, grant date and jurisdiction. Additionally, on its website, MSD discloses patent numbers for countries in scope for some of its products.

MSD has 2 non-exclusive voluntary licensing agreements to enable generic supply. One of the licensing agreements is for raltegravir for paediatric use, indicated for HIV, which covers 89 countries in scope and was issued in 2015. The other licence is for molnupiravir, indicated for the treatment of COVID-19, and includes 98 countries in scope and was issued in 2021.

Neither of the 3 manufacturing capacity building initiatives included for analysis meet all GPS. In 1 initiative, MSD is transferring technology

to manufacture the HPV vaccine (NusaGard) to Bio Farma. The goal of the transfer is to allow Bio Farma to produce the full product from API to finished product for supply in Indonesia.

Two of the three supply chain capacity building initiatives included for analysis meet all GPS. For example, MSD is part of the Reproductive Health Supplies Coalition's Global Family Planning Visibility and Analytics Network (GFP-VAN). GFP-VAN collects data from multiple sources, allowing procurers of reproductive health supplies to have visibility across the supply chain and prevent stockouts.

One of the three health system strengthening initiatives included for analysis meets all GPS. MSD for Mothers is MSD's global initiative to prevent maternal deaths through maternity care and contraception. As of 2024, the initiative reached more than 30mn women through a range of programmes focused on improving the quality of maternity care.

MSD newly engaged in 1 IP-sharing agreement with a drug discovery initiative to accelerate drug development. In this agreement, the company has granted Gates Medical Research Institute an exclusive global licence for MK-7762 and MK-3854 to support clinical and non-clinical research to discover new affordable treatment regimens for TB. MSD also remains engaged in an existing agreement.

Fulfils all criteria for ad hoc donations. MSD has public policies and supply processes to carry out ad hoc donations rapidly in response to expressed need, with delivery monitored to ensure donations reach patients. Additionally, the company publicly commits to adhering to the most recent WHO Guidelines for Medicine Donations.

MSD publicly commits to continuing long-term donation programmes to support the elimination of onchocerciasis, lymphatic filariasis and rabies. One of its programmes is active in 27 countries in scope, with the company pledging to donate ivermectin (Mectizan®) for as long as necessary until onchocerciasis and lymphatic filariasis are eliminated.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, MSD engages in technology transfer and supply chain capacity building. However, it does not disclose information about other mechanisms such as communication with relevant stakeholders about issues that may affect the supply chain and managing a buffer stock of relevant, finished products.

MSD does not disclose, publicly or to the Index, evidence of a policy for reporting substandard and falsified medicines in countries in scope to national or local regulatory 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.

No evidence of inclusive business models that meet inclusion criteria. However, MSD engages in initiatives that address access needs of neglected populations. The company is partnering with mPharma on their model in Nigeria and Ghana to expand access to testing for human papillomavirus (HPV) and increase access to HPV vaccinations. MSD and mPharma developed new financing options that aim to limit costs of vaccination.