RANK	SCORE
7	3.27
5 (2022)	

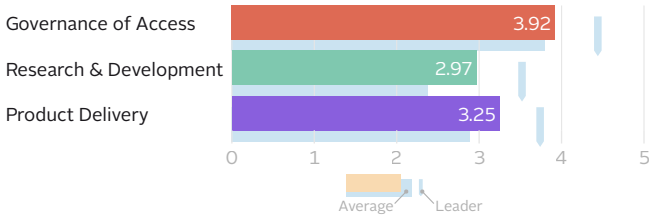
Merck KGaA

Stock exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 62,908

PERFORMANCE IN THE 2024 INDEX

7th place. Merck ranks in the top ten and performs above average in all three Technical Areas. It commits to continue its long-term donation programme to support the elimination of schistosomiasis. In Research & Development, it has access plans in place for all of its projects.

How score was achieved



OPPORTUNITIES FOR MERCK

Improve the quality and broaden the geographic reach of access plans for cancer projects. Merck has access plans in place for all late-stage R&D candidates. Currently, its access plans for oncology projects focus on registration preparation in an average of six countries in scope. The company can expand its plans, for example, by including equitable pricing and/or licensing and broadening the geographic coverage of these plans to focus on more low- and lower-middle income countries.

Support local availability through its supply chain model and report outcomes. In 2023 Merck launched its 'Go-to-Market' model which aims to address distribution of the company's products in 21 African countries through building regional stocks and conducting supply chain knowledge transfer. Merck can build manufacturing capacity in these countries by engaging, for example, in technology transfer initiatives with local manufacturers and offering technical or financial support. The company can also provide detailed reporting on outcome measurements and the sustainability of its model.

Expand access to innovative oncology products. Merck has access strategies in place for most of its innovative oncology medicines, but these are limited in geographic reach. It can increase access to key cancer medicines, such as tepotinib (Tepmetko®), indicated for lung cancer, and avelumab (Bavencio®), indicated for bladder cancer, through increasing registration and/or engaging in equitable access strategies.

CHANGES SINCE THE 2022 INDEX

- Since 2022, Merck's access-to-medicine strategy now covers all therapeutic areas the company is involved in.
- Opened a EUR 20mn distribution centre in Brazil to serve its customers in the region.
- Received a positive scientific opinion for arpraziquantel from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). EMA assessed arpraziquantel under the EU-M4all procedure for high-priority medicines intended for use in countries outside the EU.
- Arpraziquantel was added to the World Health Organization (WHO)'s List of Prequalified Medicines.
- In 2023, Merck launched its 'Go-to-Market' model, which aims to address distribution of the company's products in 21 African countries through building regional stocks and supply chain knowledge transfer.
- Expanded its collaboration with Biocartis, improving patient access to RAS biomarker testing in the Middle East and North Africa region.

Merck KGaA

SALES AND OPERATIONS

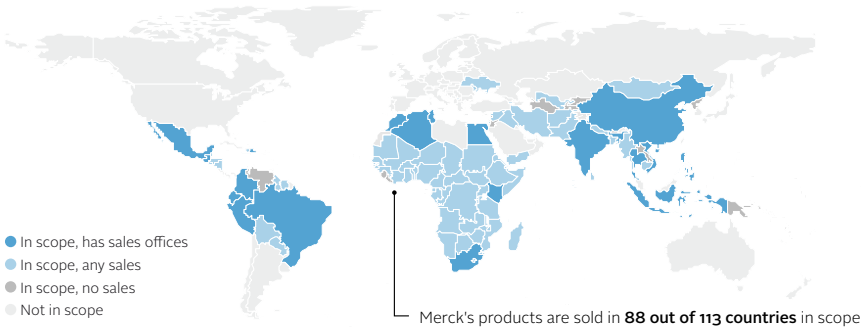
Therapeutic areas: Cardiovascular, fertility, metabolism & endocrinology, neurology & immunology, oncology
Product categories: Diagnostics, innovative medicines, medical devices

M&A news: Merck acquired M Chemicals Inc. for EUR 110mn in 2023.

Net sales by segment (2023) – in EUR

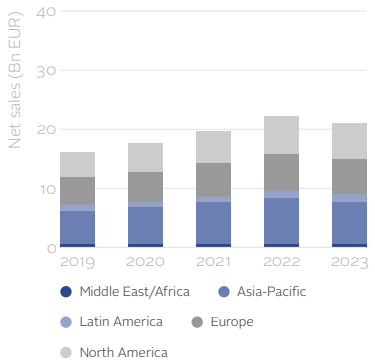
Life sciences	9.28 bn
Healthcare	8.05 bn
Electronics	3.66 bn
Total	20.99 bn

Sales in countries in scope



Merck's products are sold in **88 out of 113 countries** in scope of the Index. Merck has sales offices in 19 countries and sells via suppliers and/or pooled procurement in an additional 69 countries.

Sales by geographic region

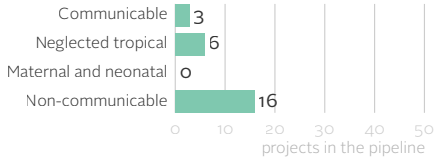


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

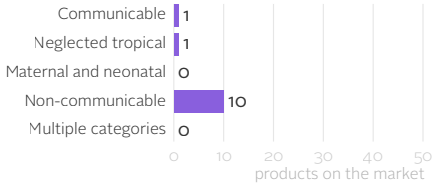
PIPELINE *for diseases in scope*
Merck has 25 R&D projects in scope, 9 of which target priority diseases, focusing on schistosomiasis (6) and malaria (3). The remaining 16 projects target other diseases in scope, namely cancer. Of the 25 R&D projects, 6 are in late-stage development, with evidence of access planning for 100% (6/6) of these.

PORTFOLIO *as selected for analysis by the Index*
Merck has 12 products in scope, including 11 medicines; 3 of the medicines are listed on the WHO EML and 2 are on patent. In addition, the company markets one diagnostic for HIV, which is listed on the WHO EDL. Most of Merck's medicines treat non-communicable diseases, including cardiovascular diseases (4), cancer (3) and diabetes (3). In addition, it also has 1 medicine targeting neglected tropical diseases.

25 projects in the pipeline



12 products in the portfolio



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Phase IV	Approval	Other	Total
Targets established R&D priorities	2	2	1	1	0	0	2	1	9
with access plan				1	0	0	2		3
Other projects in scope			11	2	1	0	0	2	16
with access plan				2	1	0	0		3

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines *on patent*	0	2			2
off patent	3	6			9
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			1		1
Other				0	0

Merck KGaA

GOVERNANCE OF ACCESS RANK 11 SCORE 3.92

11th place. Merck performs above average in this Technical Area. The company provides evidence of a patient reach process that covers most products and countries in scope of the Index, and has a measurable patient reach goal. However, it does not provide the underlying methodology details publicly. Further, Merck only publicly discloses information on transfers of value to healthcare professionals in countries in scope of the Index if required by law or local regulation.

The highest responsibility for access lies directly with the CEO of Healthcare at Merck, who manages Global Health on behalf of the Executive Board. Merck has financial and non-financial access-related incentives at the executive level. It has a Long-Term Incentive Plan (LTIP) in place for the CEO, senior executives, and regional managers, which includes three sustainability indicators. One of these refers to the number of people treated with Merck's products.

Comprehensive access-to-medicine strategy integrated within the overall corporate strategy. Its strategy covers all therapeutic areas in which the company is involved. Merck publicly discloses its commitments to access to medicine, along with company-specific measurable targets, goals and objectives. Reporting is clear, linked to these goals, centrally available, and updated regularly in its Sustainability Report.

Shows comparatively moderate-level commitment to responsible business practices. Merck's sales agents are not solely incentivised on sales volume. It reports using a balanced score card approach to incentivise sales agents. Merck commits to transparency in its cooperation with healthcare professionals in its code of conduct and has a public position on responsible interactions with health systems. However, it discloses to the Index, but not publicly, the legitimate need for interactions with healthcare professionals and the limits on transfers of value to them. 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 robust set of controls to promote ethical conduct and mitigate risk to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Merck performs strongly in this respect. It has policies to mitigate non-compliance risks, including processes to ensure third-party compliance with company standards, fraud-specific risk assessments and region or country risk-based assessments. Merck lacks a framework, but its code of conduct guides ethical employee decision-making. No breaches in countries in scope were found in the period of analysis.

Merck publicly supports the Doha Declaration on TRIPS and Public Health. However, it expresses reservations on some provisions of TRIPS flexibilities, namely compulsory licensing. Merck states that compulsory licensing risks undermining innovation.

Fulfils some criteria across three processes for measuring and reporting patient reach. For its healthcare portfolio process, which covers most of its products and most countries in scope of the Index, Merck provided details of the methodology elements under an NDA. The resulting patient reach numbers are published, but as 2023 was the first year of reporting, no improvements could be demonstrated. The process has a measurable patient reach goal but no associated health outcomes goal was identified.

RESEARCH & DEVELOPMENT RANK 6 SCORE 2.97

6th place. Merck performs above average in this Technical Area. The company's pipeline has both priority and non-communicable disease (NCD) projects, although the number of projects has declined. It has an access planning framework in place and publicly commits to access planning from Phase II onwards, applying this to all late-stage candidates. However, access plans for NCD projects focus mostly on registration preparation in emerging markets. Merck does not publicly disclose disaggregated R&D investment data, but it does perform strongly 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.

Average-sized priority R&D pipeline, compared to peers, with access plans in place for 100% (3/3) of the late-stage candidates. Priority R&D pipeline of 9 projects, including 3 late-stage projects that target a priority gap. The company focuses on schistosomiasis and malaria as priority areas. Of Merck's 3 late-stage candidates targeting a priority product gap, all (100%) have evidence of an access plan in place, mostly focusing on supply and demand plans, WHO prequalification and registration preparation.

Small-sized pipeline, compared to peers, addressing other diseases in scope, with 100% (3/3) of late-stage projects covered by access plans. Merck has 3 late-stage R&D projects targeting diseases in scope that have not been established as a priority by global health stakeholders. All 3 projects target cancer and have evidence of access plans, including registration preparation.

Merck 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).

Four of the five R&D capacity building initiatives included for analysis meet all Good Practice Standards (GPS). One example is an initiative through which Merck partners to train young scientists from LMICs through an online platform in, among others, drug discovery and development sciences.

Merck KGaA

PRODUCT DELIVERY RANK 9 SCORE 3.25

9th place. Merck performs above average in this Technical Area. The company has access strategies in place for its products and reports some data on their outcomes. However, strategies are mostly in upper-middle and lower-middle-income countries. It engages in some capacity building initiatives that meet all Good Practice Standards. However, it engages in fewer intellectual property sharing agreements compared with the last Index.

Merck registers products in 30 countries in scope on average. For the 1 newer product* analysed, it registers in 5 countries in scope, and it registers 78% of products assessed in at least 1 of the 10 countries with the highest disease burden. The company's bisoprolol (Concor®/Concor® COR), indicated for cardiovascular diseases such as hypertension, angina and arrythmia, is most widely registered, totalling 67 countries in scope. The company reports engaging in mechanisms to facilitate registration, for example, through the European Medicines Agency EU-M4all (former Article 58).

Merck is not eligible for assessment of supranational access strategies because it has no products in scope that are supranationally procured.

Access strategies for healthcare practitioner (HCP)-administered products, with outcomes mostly tracked and shared. Merck provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC), for 1 of the 2 oncology medicines assessed, cetuximab (Erbitux®). The company demonstrates some efforts in considering payers' ability to pay in its strategies, such as implementing affordability-based patient support programmes. Merck also reports some health system strengthening initiatives. For example, in Egypt (LMIC), it provides support for improving diagnosis and treatment outcomes of colorectal cancer through molecular testing and education programs for HCPs. For all strategies analysed, the company has goals to increase access to its products and provides evidence of increasing patient reach. Merck also shows efforts in improving and monitoring patient adherence to treatment. For example, for its product avelumab (Bavencio®), it monitors duration of treatment through its patient access programme in India (LMIC) and provides evidence of increased adherence following the implementation of the programme.

Quality of access strategies for self-administered products varies across products and countries, supported by some information on outcomes. For 2 of the 5 products selected for analysis, Merck provides access strategy examples in all 3 country income classifications (UMIC, LMIC, LIC). The company demonstrates efforts in considering the different payers' ability to pay in its pricing strategies and applying differential pricing. For its oncology product, tepotinib (Tepmetko®), Merck has implemented a patient access programme (PAP) for self-paying patients in India (LMIC), where it also subsidises testing to support screening and early diagnosis. For the other examples assessed, additional strategies are more limited. The company has goals to increase access and affordability of all its products, and, in some cases, it shares plans to progress the strategy. For almost all products analysed, Merck provides evidence of patient reach. For tepotinib (Tepmetko®), the company also monitors and shares data on duration of treatment via its PAP in India, to monitor patient adherence.

Merck publicly commits not to file for or enforce patents for all products in 90 countries in scope. This includes all least developed countries and LICs, as well as many LMICs and UMICs. The list of countries to which the commitment applies is publicly available.

Publicly discloses product patent status for countries in scope. Merck 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, Merck discloses the type of patents and their expiry dates in countries in scope on its website, for a subset of products in scope.

Merck does not engage in non-exclusive voluntary licensing for products in scope.

Three of the four manufacturing capacity building initiatives included for analysis meet all GPS. For example, Merck transferred technology for formulation, fill and finish and packaging of metformin (Glucophage®) between two contract manufacturing organisations in China. Merck reports it will transfer specific manufacturing skills for the diabetes treatment as well as specifics of quality and Good Manufacturing Practice.

Three of the four supply chain capacity building initiatives included for analysis meet all GPS. For example, Merck supports Business for Health Solutions in an initiative aiming to improve access to quality-assured healthcare products for 1.2mn beneficiaries in 10 countries. The initiative will focus on building supply chain skills of employees in 4 to 6 West African healthcare enterprises.

All 3 health system strengthening initiatives included for analysis meet all GPS. In 1 initiative, Merck supported the Indian employees state insurance company and India Railways to increase awareness, early detection and treatment for head and neck cancer. Merck educated 1,500 healthcare professionals and reached over 1mn through public awareness campaigns.

Merck newly engaged in 2 IP-sharing agreements with public research institutions to accelerate drug development. In 1 agreement, the company shares the Merck Mini Library with the University of Aberwysth to accelerate research for leishmaniasis. The company also remains engaged in existing agreements.

Fulfils all criteria for ad hoc donations. Merck 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.

Merck publicly commits to continue long-term donation programme to support the elimination of schistosomiasis. Its programme is active in 45 countries in scope, with the company pledging to donate praziquantel (Cesol®) until schistosomiasis is eliminated as a public health problem.

Fulfils most criteria for mechanisms to ensure continuous supply in LMICs. For example, Merck is using its 'go-to-market' model to improve distribution of products in 21 countries in scope (e.g., Ethiopia, Uganda). By building warehouses in Kenya and Botswana, Merck aims to reduce time to supply products and is considering local manufacturing capacity.

Merck has a policy for reporting substandard and falsified medicines in countries in scope. It provides evidence of reporting cases to national or local regulatory authorities within 10 days, and of reporting to WHO Rapid Alert if required. When authorities request a visual assessment of an obvious counterfeit product (e.g., obvious artwork errors or a non-existing batch number), Merck commits to provide conclusions of the assessment to the relevant regulatory authorities in less than 10 days.

No evidence of inclusive business models that meet inclusion criteria. However, Merck engages in initiatives that address access needs of neglected populations. For example, Merck is partnering with Axios International to improve access to bladder cancer treatment avelumab (Bavencio®) for low-income populations in Egypt.

*Products that received their first marketing authorisation within the last 5 years.