

RANK	SCORE
5	3.72
8 (2021)	

Merck KGaA

Stock exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 60,334

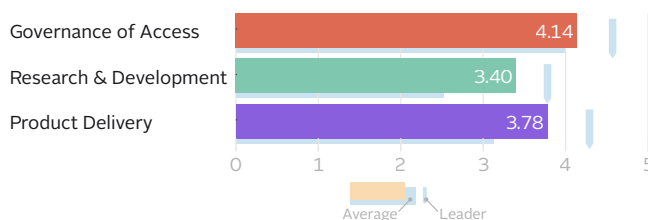
PERFORMANCE IN THE 2022 INDEX

5th place. Merck performs strongly and is now in the top five of the Index. Merck excels in R&D access planning and it performs well in its approach to patent transparency. It also engages in high-quality capacity building initiatives across all fields and has an average performance in Governance of Access.

Governance of Access: 10th place. Merck has an average performance in this area. It has a clear access-to-medicine strategy that is integrated into its overall corporate strategy, but it does not extend across its pipeline and portfolio. It discloses the outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, but it provides limited evidence on access-related incentives for its CEO and no evidence of access-related incentives for in-country and regional managers.

Research & Development: 4th place. Merck performs strongly in this area. The company has a structured access planning

How score was achieved



framework in place and has access plans for all late-stage candidates. The company excels in R&D capacity building.

Product Delivery: 5th place. Merck performs well in this area. Merck performs strongly in sharing intellectual property assets with third-party researchers. It has improved in its approach to equitable access strategies, yet the focus is mostly on upper-middle and lower-middle income countries. Merck engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply and health systems strengthening).

OPPORTUNITIES FOR MERCK KGAA

Improve the quality of access plans for R&D projects for cancer. Merck has access plans in place for all late-stage R&D candidates. Most of these plans, focus solely on registration in countries in scope of the Index. Merck can expand its access plans beyond registration to consider more access components such as equitable pricing and licensing.

Expand manufacturing capacity building efforts beyond vaccines. Merck started the Merck Africa Biologics and Vaccine Initiative (MABVI), which aims to develop integrated solutions to deploy innovative manufacturing technologies that enable local biologics manufacturing across Africa. The initiative is currently active in eight countries in scope of the Index and focuses on vaccines. Merck can expand this initiative to focus on further products such as biological treatments. The company can also regularly monitor and share impact.

Expand access to cancer treatments. Merck implemented access strategies for avelumab (Bavencio®) in at least one upper-middle income country and one lower-middle income country. The company can increase patient reach through registration, equitable pricing and/or non-exclusive voluntary licensing, especially in countries where the burden of bladder cancer is the highest such as Egypt, Armenia and the Republic of Moldova.

CHANGES SINCE THE 2021 INDEX

- Added “country segmentation” to compliance risk management in all countries where Merck actively operates to classify countries in terms of their risk exposure.
- Donated research instruments and materials to the Eijkman Institute for Molecular Biology to support in its efforts in accelerating COVID-19 vaccine development research in Indonesia.
- The Merck Family Foundation donated EUR 100,000 to Business for Health Solutions (BHS), an initiative in which Merck employees dedicate time to build capacity in the local African healthcare sector. The initiative will be expanded to up to six healthcare companies in western Africa.
- Expanded its long-term donation programme to adult treatment for the elimination of schistosomiasis in Rwanda.
- Successfully completed the clinical development of the potential new medication (arpraziquantel) to treat schistosomiasis in children as of 6 years of age and below.
- Submitted the WHO prequalification dossier of an optimised praziquantel (Cesol® 600) formulation.

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.

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.

SALES AND OPERATIONS

Business segments: Electronics, healthcare and life sciences.

Therapeutic areas: Endocrinology, fertility, general medicine, immunology, immun-oncology and neurology.

Product categories: Diagnostics, innovative medicines and medical devices.

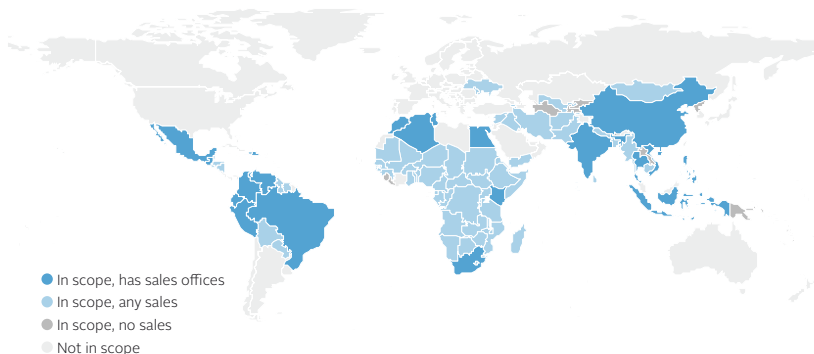
M&A news: Merck KGaA acquired Exelead in February 2022 for approximately USD 780 million.

Merck's products are sold in 89 out of 108 countries in scope of the Index. Merck has sales offices in 20 countries, and sells via suppliers and/or pooled procurement in an additional 69 countries.

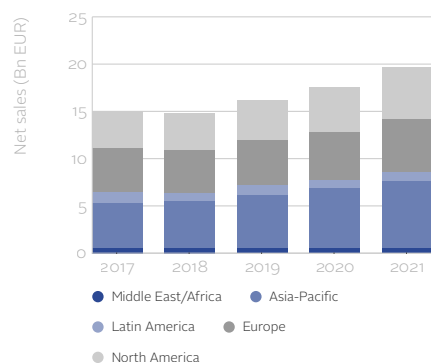
Net sales by segment (2021) – in EUR

Life sciences	8.99 bn
Healthcare	7.09 bn
Electronics	3.61 bn
Total	19.69 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

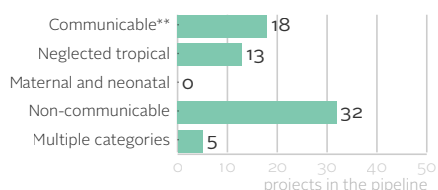
PIPELINE for diseases in scope

Merck has a total of 68 R&D projects in scope with 33 of these projects targeting priority diseases. The other 35 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on schistosomiasis (13 projects) and malaria (11). Of the projects targeting other diseases, the focus is on oncology (34). Thirteen R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (10).^{*} Evidence of access planning was in place for 100% of these projects.

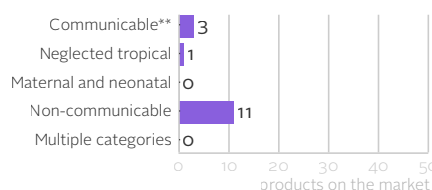
PORTFOLIO as selected for analysis by the Index

Merck has 13 medicines in scope, two of which are on patent. 38% of these medicines (5) are on the WHO EML. In addition, the company markets two diagnostics for HIV/AIDS. The off-patent medicines target non-communicable diseases (9) such as cardiovascular diseases (5), cancer (1) and diabetes (3). Furthermore, the company markets chloroquine for malaria and praziquantel for parasitic worm infections. The on-patent medicines target cancer (2).

68 projects in the pipeline



15 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	17	0	1	1	0	2	12	33
Addresses needs of LMICs*			13	7	1	2	0	23
Other projects in scope			4	4	0	0	4	12

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	0	2			2
off patent	5	6			11
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			2		2
Other [‡]				0	0

^{*}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 KGaA

GOVERNANCE OF ACCESS

RANK 10

SCORE 4.14

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. Merck performs well. It has a Global Health strategy focused on availability, affordability, awareness and accessibility. The strategy covers some of the therapeutic areas in which the company is involved, with a focus on the elimination of schistosomiasis, malaria, and the prevention and control of non-communicable diseases (NCDs) in LMICs. The highest responsibility for access lies directly with the CEO of Healthcare at Merck, who manages Global Health on behalf of the Executive Board.

Provides evidence of financial and non-financial access-related incentives at the executive level. Merck performs well. It incentivises the CEO and other senior executives with objectives related to sustainability. It publicly states that the CEO's Long-Term Incentive Plan (LTIP) is connected to a Sustainability Factor consisting of three sustainability indicators, and the goal of the first indicator is to achieve human progress for more than one billion people by 2030 through sustainable science and technology.

Publicly discloses outcomes of its access-to-medicine activities. Merck performs

strongly in transparency of access activities. It publicly discloses commitments, including on combating NCDs, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Sustainability Report.

Has an average performance in responsible promotional practices. Merck's sales agents are not solely incentivised on sales volume targets. However, additional details on how the company addresses sales incentives for sales agents are unavailable. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by law or by local regulations, though it has policies and procedures in place limiting transfers of values to healthcare professionals.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Merck performs strongly, demonstrating evi-

dence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. 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. Merck publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on the implementation of its provisions. That is, it highlights compulsory licensing as a risk of undermining innovation. 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, Merck, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 4

SCORE 3.40

Access planning processes encompass all projects in the pipeline. Merck has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Merck begins developing access plans for R&D projects in Phase II or earlier of clinical development.

An average-sized priority R&D pipeline compared to its peers, with evidence of access plans in place for 100% (3/3) of late-stage candidates. Merck has 33 projects, including three late-stage candidates that target a priority product gap. The priority pipeline focuses mainly on schistosomiasis and malaria. There is evidence of access plans for all three of Merck's late-stage candidates. Notably, the access plan for the potential new treatment option for schistosomiasis (arpraziquantel) includes plans for

WHO prequalification, priority registration in high burden African countries, engagement with access-oriented funding organisations and local manufacturing arrangements to ensure equitable and sustainable access and supply.

Many projects address a public health need in LMICs,* with 100% (10/10) of late-stage candidates covered by access plans. In this analysis, Merck has ten late-stage R&D projects that target a disease and/or product gap not yet designated 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 are first-in-class molecules. All target cancer. Merck provides evidence of access plans for all ten of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Merck does not disclose disaggregated R&D investment data to global health organisations.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. Merck leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, Merck partners with Seeding Labs, to improve access to lab equipment for the scientific community in countries in scope of the Index. Additionally, Merck is the founding sponsor of the TeleScience platform, an online platform that provides teaching and training to scientists 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 5

SCORE 3.78

Public commitment not to enforce patents in countries in scope. Merck publicly pledges to neither file for nor enforce patents. This commitment applies to all Least Developed Countries and LICs as well as in a subset of LMICs and UMICs, a total of 90 countries in scope of the Index.

Publicly discloses detailed information on patent status. Like most of its peers, Merck publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Additionally, Merck discloses the type of patents and their expiry dates on its website for a subset of products in scope of the Index.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Merck engaged in 17 new IP-sharing agreements with third-party 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.

No use of licensing agreements. Merck does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register new products in six countries in scope on average. Merck did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely registered is bisoprolol (Concor®/Concor® COR), indicated for cardiovascular diseases, filed in 63 countries relevant to the Index, including four high burden countries (Republic of Moldova, Syrian Arab Republic, Ukraine and Uzbekistan) and ten LICs.

Merck is not eligible for assessment of supra-nationally procured products.

Has access strategies for some healthcare practitioner-administered products in scope of this analysis. Merck has an average performance in this area. For one of the two products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC). The company makes efforts to reach additional patients using pricing mechanisms that consider payers' ability to pay and has implemented strategies to ensure patients' access to a product not available on the market yet. Merck provides evidence of how patient reach has been increased through the approaches used in the UMIC and LMIC country examples.

Has access strategies for its self-administered products for some countries in scope of this analysis. Merck performs below average in this area. The company provides examples of access strategies which consider affordability in UMIC and LMIC contexts for three of the five products assessed. Evidence of access strategies in LICs was not provided. Merck makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, in Egypt, the company participates in tenders to supply the diabetes medicine metformin/glibenclamide (Glucovance®) and it has initiatives to assist patients in disease management. The company provides evidence of the number of patients reached by this product in Egypt and Mexico.

Three of the five manufacturing capacity building initiatives included meet all Good Practice Standards. Merck's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, the Pediatric Praziquantel Consortium aims to reduce the global disease burden of schistosomiasis by addressing the medical need of infected children aged six and below. One of the goals of this program, led by Merck, is to establish a sustainable and affordable manufacturing and supply chain that involves sites in LMICs. This initiative meets all GPS.

Three of the five supply chain capacity building initiatives included meet all Good Practice Standards. Merck's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. Merck has been a member of CAMP-N Supply Chain Technical Working Group since its launch in 2017. This coalition of government agencies, private sector entities, non-governmental organisations, philanthropic foundations and academic institutions is dedicated to increasing access to medicines and health products for NCDs. This initiative meets all GPS.

Two of the five health systems strengthening initiatives included meet all Good Practice Standards. Merck's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all GPS than what is average for this indicator. For example, Merck and the NALA Foundation Partnership to Eliminate Schistosomiasis combines treatment, research and development and health education and WASH (water, sanitation and hygiene) to support the elimination of this neglected tropical disease in Ethiopia. This initiative meets all GPS.

The company has engaged in both scaling up and piloting one inclusive business model.

Merck performs above 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. CURAFA™ points of care for integrated healthcare services, piloted in Kenya, aim to provide primary healthcare access to underserved populations in low-income communities in emerging economies.

Performs above average in terms of ensuring continuous supply of medicines in LMICs.

Merck is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Merck provides evidence of reporting confirmed SF medicines to the relevant national health authorities within ten days. 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 health authorities in less than ten days.

Donates in response to expressed need and monitors delivery. Merck 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 one structured donation programme for neglected tropical diseases or malaria. Since 2007, Merck has publicly committed to supporting the elimination of schistosomiasis by donating praziquantel (Cesol®) in 43 countries in scope of the Index until goals are reached.