Merck KGaA

Stock Exchange: Frankfurt Stock Exchange • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 57,036

PERFORMANCE IN THE 2021 INDEX

8th place. Merck KGaA (Merck) has an average performance. It shows a strong performance in planning for access and transparency of access activities, publicly disclosing its commitment and outcomes. The company leads in sharing intellectual property, yet its equitable access approach for specific products and markets is below average.

Governance of Access: 7th place. Merck has an average performance in this area. It has an access-to-medicine strategy and publicly discloses commitments and outcomes of its related activities. While having compliance controls in place, it demonstrates limited evidence of how it monitors these controls.

Research & Development: 5th place. Merck performs well in this area. The company’s late-stage priority R&D projects are covered by an access plan. It has a structured process in place to develop access plans during R&D, commits itself to registering trialled products and engages in R&D capacity building activities.

Product Delivery: 8th place. Merck is a middle-performing company in this area. It shares many IP assets with third-party researchers and publicly pledges not to enforce patents. Yet, it performs below average in access strategies, with a strategy in place only for certain products and markets. The company has a strong approach to donations.

OCCUPORTUNITIES FOR MERCK

Plan for expansion of vaccine manufacturing initiative. Merck started a pilot in Kenya, the Merck Africa Vaccine Initiative (MAVI), to develop integrated solutions to deploy innovative manufacturing technologies that enable local vaccine manufacturing across Africa. The company can start planning the expansion of the initiative once the pilot proves successful.

Expand access to cancer treatment avelumab (Bavencio®). Merck can file avelumab (Bavencio®) for registration in more high-burden countries such as Ukraine, Egypt and Mali. Furthermore, the company can expand equitable access strategies for avelumab to lower-middle income countries and low-income countries. By applying an equitable pricing strategy in countries that have the capacity to administer this drug, Merck can help reduce inequity in access to cancer treatment.

Apply access planning to more R&D projects and consider affordability. Merck applies access plans to 33% of its late-stage R&D projects. These plans range from registration commitments to equitable pricing strategies. Merck can plan for access for all late-stage R&D projects. The company can plan for both registration and affordability as well as availability for all its late-stage R&D projects, including new indications of its avelumab (Bavencio®), such as breast and brain cancer.

CHANGE SINCE THE 2018 INDEX

• Renewed partnership with WHO on praziquantel donation to Merck Schistosomiasis Elimination Program, targeting school-aged children.
• Merck Africa Vaccine Initiative (MAVI): Merck started a pilot in Kenya with the Government and a local investor as a proof of concept.
• Supports the clinical development of novel antibiotics via the AMR Action Fund.
• Engaged in ten new sharing IP arrangements, e.g. via WIPO research (NTDs), via the COVID-19 Therapeutics Accelerator initiative.
• Expanded PAVON initiative for mapping malaria from three to 11 countries.
• Started a new partnership with China Cardiovascular Association, Heart Failure Center Program, for diagnosis and treatment.
• Joined CAMP-N Supply Chain Technical Working Group for NCD medicines.
• Collaborates with local distributors on Access Delivery Mentorship in Tanzania.
• Publicly shares prerequisites for granting post-study access to investigational products in Position Statement on Post-Study Access.

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.
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPEC FOR DISEASES AND COUNTRIES IN SCOPE
Merck has a total of 86 R&D projects featuring an average-sized priority R&D pipeline compared to its peers: 35 projects. Remarkably, Merck has the fourth largest pipeline as almost 41% of its R&D projects target priority diseases. The other 51 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on schistosomiasis (14 projects). Of the projects targeting other diseases in scope, the focus is on oncology (44).

18 R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (16). Evidence of access planning was in place for 33% of these projects: 2 targeting a priority disease and 4 addressing a public health need in LMICs.

PORTFOLIO AS SELECTED FOR ANALYSIS BY THE INDEX
Merck has 13 medicines in scope, 3 of which are on patent. 38% of these medicines (5) are on WHO’s EML. In addition, the company markets 2 diagnostics. The off-patent medicines target mainly non-communicable diseases (NCDs): cardiovascular diseases (5), diabetes (2) and cancer. One medicine targets malaria and one targets schistosomiasis and other neglected tropical diseases (NTDs). The on-patent medicines target NCDs: oncology and diabetes. The diagnostics in scope are for HIV (2).

Access strategies were analysed for 7 products on Merck’s portfolio – nationally procured HCP-administered (2) and self-administered products (5).

Breakdown of projects

<table>
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<th>Category</th>
<th>Pre-clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Approval</th>
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<td>3</td>
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<td>2</td>
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<tr>
<td>Addresses needs of LMICs*</td>
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<td>3</td>
<td>28</td>
<td>4</td>
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<tr>
<td>Other projects in scope</td>
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<td>2</td>
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</tbody>
</table>

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, 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.

**Neglected Tropical Disease, while also communicable, are highlighted separately throughout the Index.

Projects 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 KGaA

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives and a business rationale. Merck has an average performance. 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, including neglected tropical diseases (NTDs) and diabetes mellitus. The highest responsibility for access lies indirectly with the board, namely with the Head of Corporate Affairs.

Does not publicly disclose its approach to financial and non-financial access-related incentives at the executive level. Merck has an average performance. Merck discloses to the index, but not publicly, whether it incentivises its in-country managers and senior executives to perform on access to medicine with financial and non-financial rewards. There is no publicly available evidence that the CEO is also incentivised toward access goals.

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. It consistently shares outcomes of its access-to-medicine activities, for example through the IFPMA Global Health Progress platform.

Has an average performance in responsible promotional practices. Merck’s sales agents are not solely incentivised on sales volume targets. More details on how the company addresses sales incentives for agents are unavailable. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities), unless required by local regulations, e.g. in Brazil.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Merck performs relatively poorly, demonstrating some of the 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. It does not, however, demonstrate evidence of a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment. It reports having in-country compliance officers evaluating risks based on the business sector in all respective legal entities or departments.

PUBLICLY SUPPORTS THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH.

Merck publicly shares general support of the Doha Declaration on TRIPS and Public Health, but expressing reservations on the implementation of its provisions. That is, it highlights compulsory licensing as a risk of undermining innovation. There is no evidence of a policy to dissent from industry association positions on these.

RESEARCH & DEVELOPMENT

Access planning processes encompass all projects in 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 for diseases in scope. In general, Merck begins developing access plans for R&D projects in Phase II or earlier of clinical development. The process is for both its in-house and collaborative R&D projects.

An average-sized priority R&D pipeline compared to its peers, with access plans in place. Merck has 35 projects including two late-stage candidates in its pipeline that target a priority product gap. The company focuses mainly on schistosomiasis. There is evidence of access plans for both Merck’s late-stage candidates, which are two different praziquantel formulations. The access plan for the praziquantel paediatric formulation includes a commitment for WHO prequalification, priority registration in high burden African countries and non-exclusive licenses in agreement with the Pediatric Praziquantel Consortium partners to generics or local drug manufacturers in endemic countries.

Many projects address a public health need in LMICs, with 25% of the late-stage projects covered by access plans. In this analysis, Merck has 16 late-stage R&D projects that target a disease and/or product gap not yet designated as a priority by global health stakeholders. These programs are all deemed by the Index to offer a clear public health benefit for people living in LMICs. Primarily, these projects have clinical trials in countries in scope and/or are first-in-class molecules. Most target cancer. Merck provides evidence of access plans for four of these projects. These plans range from registration commitments to equitable pricing strategies for some projects. Notable is a combination therapy with bintrafusp alfa, a potential first-in-class TGF-beta receptor 1 inhibitor, to treat gallbladder cancer. The company commits itself to registering the product in four countries in scope and applying a pricing strategy based on ability to pay.

Public policy to ensure post-trial access; commits itself to registering trialled products. Merck has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a life-threatening, chronic or seriously disabling illness. Once a product is approved, Merck commits itself to registering it in all countries where clinical trials for the product have taken place. The policy states that it takes into account local affordability in any given country. Details of which are not available.

Two R&D capacity building initiatives meet all Good Practice Standards. Merck performs above average in this indicator. Five initiatives were included for analysis. Two initiatives met all Good Practice Standards:
- Merck’s collaboration with Makerere University’s in Uganda, focusing on antimicrobial resistance research and building national infection control programme capacity by training medical students at the National Referral and Training Hospital, the Mulago Hospital.
- Partnership with Seeding Labs for the Instrumental Access Programme, providing equipment and training to scientists and universities in LMICs.

PRODUCT DELIVERY

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 low-income countries as well as in a subset of lower-middle income countries and upper-middle income countries.

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. This information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Merck has shared many IP assets with third-party researchers developing products for diseases in scope. This includes ten IP assets shared with research institutions and drug discovery initiatives, such as COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard.

† Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiatives align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.
Assets shared include molecule libraries and sets of target-specific compounds for drug discovery.

No use of non-assert or licensing arrangements. Merck does not engage in voluntary licensing nor has it issued any non-assert declarations for products in scope. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register some new products in the majority of high burden countries. Merck has filed 70% of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, cetuximab (Erbitux®) for colorectal cancer has been filed for registration/registered in six high burden countries in scope, including Thailand and Moldova.

No supranationally procured products. Merck has no products eligible for scoring in this indicator.

Has access strategies for some healthcare practitioner-administered products in scope of this analysis. Merck performs below average in this area. The company provides examples of access strategies which consider affordability of products at all assessed income levels (UMIC, LMIC, LIC) for one of the two products assessed. The company makes efforts to reach additional patients using equitable pricing strategies. For example, in China, for cetuximab (Erbitux®), a treatment for colorectal cancer, it applies equitable pricing strategy to list the product on the national reimbursement drug list, and previously offered a patient assistance programme to reduce co-pay for low income patients to increase affordability and access. Merck is able to provide evidence of how patient reach has been increased through the approaches used.

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 of products at all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. For the other products, it falls short providing example in one or two of the countries type. It makes efforts to reach additional patients through the use of equitable pricing strategies. For example, in South Africa, for bisoprolol (Concor®), the company participates in tenders in the public sectors and has a ‘clone’ strategy, where they offer price reduction for the clone Betacor® to list it on all payer formularies to increase access for low-income patients. Merck is able to provide evidence of how patient reach has been increased through the approaches used.

One supply chain capacity building initiative meets all Good Practice Standards. Merck has an average performance in this area. The company submitted the maximum of five initiatives, of which two met all criteria for inclusion. The access delivery mentorship programme in Tanzania met all Good Practice Standards.§ The programme provides four local distributors with supply chain and delivery support to strengthen last-mile delivery.

Three health system strengthening initiatives included for evaluation. Merck performs below average in this area. The company submitted the maximum of five initiatives, of which three met all criteria for inclusion: 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. The initiatives did not meet all Good Practice Standards. For example, Merck’s aims to enhance integrated disease management for women’s health in Cameroon through, amongst others, HPV screening, HIV screening, FGS diagnosis, precision mapping of schistosomiasis endemic areas and health worker training. However, Merck did not sufficiently demonstrate how it aims for sustainability.

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One manufacturing capacity building initiative meets all Good Practice Standards. Merck has an average performance in this area. The company submitted the maximum of five initiatives, which all met all the criteria for inclusion. One initiative met all Good Practice Standards.§ For this initiative, Merck aims to create manufacturing process robustness by enabling its Contract Manufacturing Organisations to deal with quality issues in a proactive manner through the implementation of a ‘Continuous and On-going Process Verification’ roll-out in six countries in scope of the Index.

Publicly commits to achieving elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Merck publicly commits itself to eliminating schistosomiasis by donating praziquantel (Cesol®) in 42 countries since 2007.