

RANK	SCORE
<b>4=</b>	<b>2.90</b>
4 (2016)	

# Merck KGaA

Stock Exchange: Frankfurt Stock Exchange • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 50,000

## PERFORMANCE

Merck KGaA turns in a strong performance and holds fourth place. It is innovative with its Merck Global Health Institute, and shows particular strength in targeting R&D priorities and in minimising the risk of corruption and unethical marketing.

**Management:** Rises 2 places to 8<sup>th</sup> establishing a new sustainable business model: Curafa™, targeting populations in remote areas in Kenya.

**Compliance:** Rises 9 places to 2<sup>nd</sup>. One of the largest risers, it applies its code of conduct to third parties and non-sales-based incentives are in place for sales agents.

**R&D:** Holds 2<sup>nd</sup> place, newly creating the Merck Global Health Institute. A comparatively large proportion of its pipeline aims to address R&D priorities.

**Pricing:** Falls 5 places to 11<sup>th</sup>, overtaken by stronger performers, with comparatively weak registration commitments.

**Patents:** Falls 2 places to 7<sup>th</sup>, performing marginally poorer in new IP agreements reached over the period of analysis.

**Capacity:** Maintains 6<sup>th</sup> place, with a strong focus on local manufacturing, including technology transfer.

**Donations:** Rises from 6<sup>th</sup> to 5<sup>th</sup> place with a long-term commitment to eliminate schistosomiasis in 37 countries.

## OPPORTUNITIES

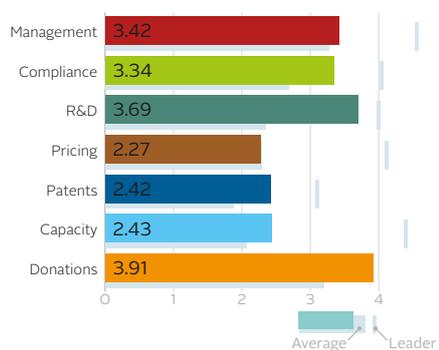
**Refine access plans for all current and future Merck Global Health Institute projects.** Merck KGaA can further develop its access plans for R&D projects conducted through the Merck Global Health Institute. Currently, Merck KGaA commits to address affordability by minimising development and manufacturing costs to lower the final cost of products. It can build on this commitment by also committing to apply pricing strategies that consider ability to pay, and committing to register products in all endemic countries (for schistosomiasis and malaria) and in all countries in scope (for antimicrobial resistance).

**Expand availability and affordability of avelumab (Bavencio®).** Merck KGaA can work to develop additional access plans for its current and future indications of avelumab (Bavencio®), an anti-cancer drug that is FDA-approved for a number of cancer types within the scope of the Index. By making this treatment available in countries in scope that have the capacity to administer this drug (including Brazil, India and China) Merck KGaA can help reduce inequity in access to cancer treatment.

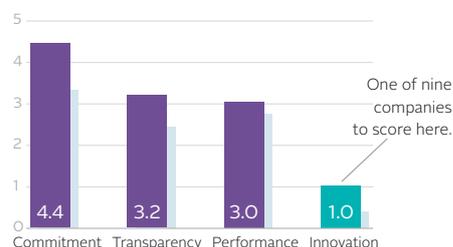
**Register broad spectrum antibiotics in countries in need.** Currently, Merck KGaA does not register cefixime (Denvar®) in any priority countries for diseases for which the antibiotic is indicated (kidney diseases, lower respiratory infections, meningitis, or gonorrhoea). It is both on the 2017 WHO Model List of Essential Medicines (WHO EML) and is a first-line treatment. While antibiotic resistance must be considered, many priority countries currently lack access to essential products to treat these infections. Merck KGaA can file cefixime for registration in priority countries.

**Consider equitable pricing strategies for additional first-line, WHO EML products.** Merck KGaA's gentamicin (Refobacin®) for kidney diseases; lower respiratory infections; maternal sepsis; meningitis; and neonatal sepsis and infections is an off-patent first-line product on the WHO EML with no access plans in place. The company could provide equitable pricing strategies for corresponding priority countries. Similarly, Merck KGaA's itraconazole (Candistat) for meningitis is an off-patent, first-line product on the WHO EML with no access plans in place. The company could apply equitable pricing strategies to these products in priority countries including, Angola, Chad, Congo, Dem. Rep., Ethiopia, India, Nigeria and Uganda.

Performance by technical area



Performance by strategic pillar



## CHANGE SINCE 2016

- Joined the Drugs for Neglected Diseases initiative's NTD Drug Discovery Booster to accelerate the development of early-stage projects for Chagas disease and leishmaniasis.
- Signed a Memorandum of Understanding in December 2017 to support the development of a new vaccine manufacturing plant in Ghana.
- Joined Access Accelerated with multiple initiatives including the Merck Capacity Advancement Program. It has committed to measure impact and share results publicly via the Access Observatory.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Established the Merck Global Health Institute to accelerate R&D, incorporate access provisions and build capacity for projects and initiatives targeting schistosomiasis, malaria and bacterial infections.

**PIPELINE** for diseases and countries in scope

**Mid-sized pipeline:** 74\* R&D projects for diseases in scope (59 medicines; 7 diagnostics; 6 platform technologies; 2 vector control products; 1 therapeutic vaccine).

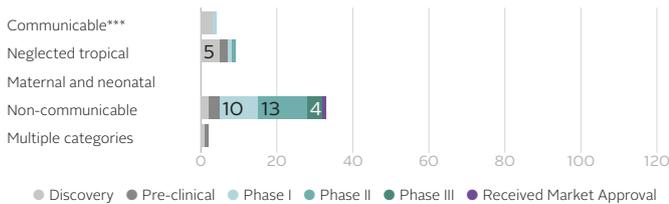
**Clinical candidates:** 30, including praziquantel for the treatment of schistosomiasis in children and atacicept for the treatment of kidney diseases.

**Regulatory approvals:** 1, avelumab (Bavencio®) for the treatment of bladder cancer.

**R&D focus:** non-communicable diseases (cancer, diabetes, hypertensive heart disease and kidney diseases), communicable diseases (malaria) and neglected tropical diseases (schistosomiasis).

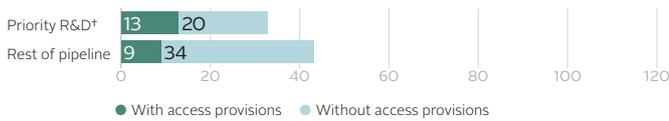
**Access provisions:** for 22 projects, most commonly registration commitments.

**Projects in the pipeline: 74\*\***



Merck KGaA is the lead of the Pediatric Praziquantel Consortium. It is responsible for the clinical development programme and acts as sponsor of clinical trials for a paediatric formulation of praziquantel to treat schistosomiasis.

**Projects for R&D priority targets with access provisions: 13**



Of Merck KGaA's 74 R&D projects, 22 are supported by access provisions: e.g., avelumab (Bavencio®), in development for many cancer types, includes registration commitments for each indication developed in-house. Six of its 19 late-stage projects have provisions.

**BUSINESS CONTEXT**

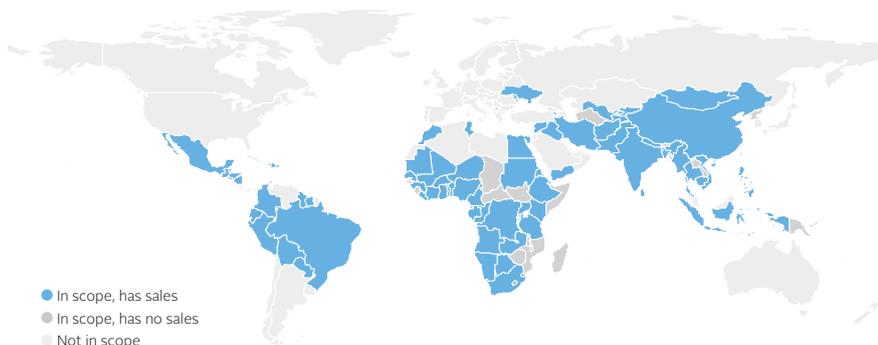
**Three business units:** Healthcare; Life Science; and Performance Materials. Its Healthcare business has seven therapeutic areas (allergen immunotherapy; consumer health; endocrinology; general medicine; fertility; neurology and immunology; and oncology).

**M&A news:** 2017 divestment of biosimilar business, focused on oncology and autoimmune diseases, to Fresenius Kabi. 2018 ongoing divest-

ment (expected to conclude fourth quarter 2018) of global Consumer Health business to Procter & Gamble.

**Presence in emerging markets:** In 2018, Merck KGaA reports sales in 76 countries in scope; similar to reported sales in the 2016 Index. It reports that around 40% of its sales in 2017 came from Middle East, Africa, Asia-Pacific and Latin America.

**Sales in countries in scope**



Statistics relate only to diseases and countries in scope.  
 \*Projects that target multiple product types are counted more than once.

\*\*Figure excludes 26 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

**PORTFOLIO** for diseases and countries in scope

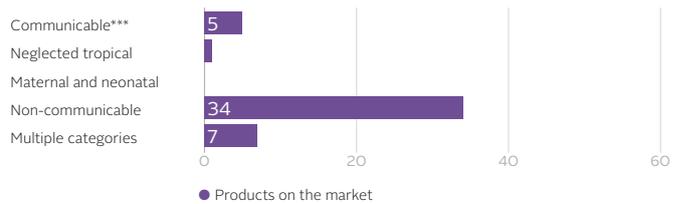
**Mid-sized portfolio:** 47 products for diseases in scope (46 medicines; 1 diagnostic).

**Portfolio focus:** non-communicable diseases (hypertensive heart disease, ischaemic heart disease and diabetes mellitus) and communicable diseases (lower respiratory infections).

**Essential medicines:** 59% of Merck KGaA's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

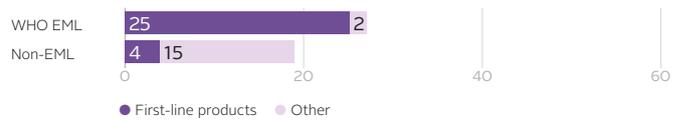
**First-line treatments:** 63% of Merck KGaA's medicines have first-line indications for diseases in scope.

**Products on the market: 47**



Merck KGaA's portfolio includes products such as the oral fixed-dose combination metformin/glibenclamide (Glucovance®) for the treatment of type 2 diabetes mellitus and the antifungal drug itraconazole (Candistat™).

**Essential medicines with first-line indications: 25**



67% of Merck KGaA's medicines are listed on the WHO EML and/or as first-line treatments: e.g., the anthelmintic agent praziquantel (Cestox®) and the antibiotic ofloxacin (Harpoon®).

**Net sales by segment (2017) - EUR**

Healthcare	6,999 MN
Life Science	5,881 MN
Performance Materials	2,446 MN
<b>Total</b>	<b>15,326 MN</b>

**Net sales by geographic region**



\*\*\*Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.  
 \*See Appendix IV for definition.  
 ‡2013 data not comparable due to changes in company reporting practices

# Merck KGaA

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 8 SCORE 3.42

**Has a strong access-to-medicine strategy with executive-level responsibility.** Merck KGaA is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy centres around ensuring its products are accessible through four approaches: availability; affordability; awareness; and accessibility. The highest level of responsibility for access sits with an executive manager.

**Financial and non-financial access-related incentives to reward employees.** Merck KGaA performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include grants and *ad hoc* awards.

**One of 16 companies working on impact measurement.** Merck KGaA measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments, objectives, targets and performance information. For example, for its charter on access to health in developing countries, Merck KGaA reports on its activities to achieve targets aligned with United Nations Sustainable Development Goals (SDGs). Furthermore, it is part of the Access Accelerated initiative, which includes a commitment to evaluate impact.

**Discloses who it engages with, incorporates local perspectives into strategies.** Merck KGaA publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with in its 2017 Corporate Responsibility Report; e.g., it adopts a needs-based approach to establish partnerships which can promote access. It does not publicly share its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

### MARKET INFLUENCE & COMPLIANCE

RANK 2 SCORE 3.34

**Has measures to ensure third-party compliance with ethical marketing and anti-corruption**

**standards.** Merck KGaA has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training via online classes for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents' rewards are not solely based on sales targets. Instead, it rewards other qualities such as ethical behaviour in the workplace.

**Internal control framework meets some Index criteria.** Merck KGaA's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving internal resources, applying to all third parties and all countries where they operate. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

**Above average transparency regarding access-related practices.** Merck KGaA publicly discloses its policy positions on access-related topics. For example, it publishes its position on drug shortages, ethical business practices, intellectual property rights, and it publicly supports the Doha Declaration. It is one of the few companies in scope to have a policy that prohibits political financial contributions, and it shares its position on responsible engagement in its code of conduct. It publicly discloses its membership and financial support of relevant organisations to access. It does not, however, publicly disclose its policy approach to payments made to health-care professionals in countries in scope.

### RESEARCH & DEVELOPMENT

RANK 2 SCORE 3.69  
PROJECTS: 74 IN CLINICAL DEVELOPMENT: 30

**Publicly commits to R&D to meet public health needs.** Merck KGaA has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Merck KGaA has a mid-sized pipeline in the Index with 74 projects. For diseases in scope where priorities exist, Merck KGaA is active in 32 projects; all 32 of these target priority R&D gaps.

**Access provisions in place for 26% (5/19) of late-stage candidates.** Merck KGaA has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope. In general, Merck KGaA develops access plans for R&D projects when entering clinical development. To date, Merck KGaA has project-specific access provisions in place for six of its late-stage R&D projects. Five are being conducted in partnership.

**Policy to ensure post-trial access; commits to registering trialed products.** Merck KGaA has a policy for ensuring post-trial access to treatments for clinical trial participants. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Merck KGaA commits to registering it in all countries where clinical trials for the product have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 11 SCORE 2.27  
PRODUCTS: 47  
COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 14

**Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope.** Merck KGaA does not commit to filing its newest products for registration in countries in scope within one year of first market approval. It publicly commits to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. Its public commitments also apply to intra-country equitable pricing strategies, albeit to only some of its products.

**No new products in scope filed for registration in the majority of priority countries.** Merck KGaA has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for diabetes mellitus, is registered in four out of 12 possible priority countries. It also does not publicly share registration information for any of its products.

**30% of products have equitable pricing strategies targeting priority countries.** Merck KGaA's overall performance is average compared to

peers in equitable pricing. It demonstrates evidence of equitable pricing strategies for 30% of its products for diseases in scope. These strategies apply to an average of 23% of priority countries. Some of these strategies apply inter-country pricing; these take into account an average of four socioeconomic factors. However, all of its equitable pricing strategies apply intra-country pricing; these take an average of three socioeconomic factors into account. Merck KGaA also applies equitable pricing strategies to 9 further products informed by a public health rationale.

**Has both globally consistent recall guidelines for countries in scope and processes to track products.** Merck KGaA has guidelines for drug recalls that apply to all countries in scope. It has processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

## PATENTS & LICENSING

RANK 7 SCORE 2.42

**Publicly discloses detailed information on patent statuses.** Like most of its peers, Merck KGaA publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

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

**Shares some IP assets with 3<sup>rd</sup>-party researchers.** Compared to its peers, Merck KGaA shares some IP assets with third-party researchers developing products for diseases in scope. It shares four in total with research institutions and neglected disease drug discovery initiatives, such as the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases initiative (DNDi). The assets shared include molecule libraries and performing assays for drug discovery.

**Public commitment not to enforce patents in countries in scope.** Merck KGaA commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies to most Least Developed Countries, low-income countries, and in a subset of lower-middle income countries and upper-middle income countries.

## CAPACITY BUILDING

RANK 6 SCORE 2.43

**14 initiatives included for evaluation.** Merck KGaA has 14 capacity building initiatives that were included for analysis by the Index: i.e., the

initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Merck KGaA submitted the maximum.

**Strong focus on enhancing local manufacturing.** Merck KGaA has initiatives which meet inclusion criteria in all five areas of capacity building. It performs strongest in manufacturing capacity building, including initiatives for training third-party manufacturers and technology transfers.

**Two initiatives meet all applicable good practice standards:**

- Virtual plant teams
- Product Development Partnerships in Brazil

Merck KGaA's remaining included initiatives typically have goals in place, but fall short on monitoring their progress and outcomes.

**Does not provide evidence of reporting substandard or falsified medicines within the recommended timeframe.** Merck KGaA has a policy for reporting cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert. However, it does not require reporting to occur within the time frame of seven days looked for by the Index.\*

## PRODUCT DONATIONS

RANK 5 SCORE 3.91

STRUCTURED DONATION PROGRAMMES: 1

**Responds to emergencies and humanitarian crises and tracks delivery.** Merck KGaA donated medicines on the request of relief agencies. For example, during the period of analysis, it donated products in Yemen. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO), and it works, for example, with the German Red Cross to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

**One donation programme covering diseases and countries in scope.** Merck KGaA's programmes are focused on neglected tropical diseases (NTDs). The programme is carried out in collaboration with WHO. Its programme for schistosomiasis supplies praziquantel (Cesol®) in 37 countries and has been ongoing since 2007. In 2016, Merck KGaA reported donating more than 200 million praziquantel (Cesol®) tablets to WHO.

**Addresses long-term access by aiming to eliminate disease.** Merck KGaA commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For example, its praziquantel (Cesol®) programme aims to eliminate schistosomiasis in 37 countries.

## BEST PRACTICES

**Continued commitment to combat NTDs.**

GLOBAL

One of five companies running donation programmes to eliminate or eradicate NTDs.

## INNOVATIVE PRACTICES

**Curafa™ programme establishes primary healthcare centres in Kenya**

KENYA

Local primary healthcare facilities that provide pharmacy and nursing services, prescription and over-the-counter medications, and access to insurance schemes and healthcare financing.

**Merck Global Health Institute partners up to accelerate R&D for bacterial infections, schistosomiasis and malaria**

GLOBAL

Institute setting up R&D partnerships to develop projects to target bacterial infections, schistosomiasis and malaria present in low- and middle-income countries.

\*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.