

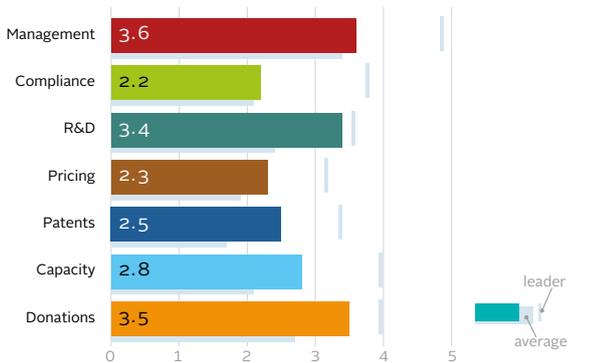
RANK	SCORE
4 [▲]	2.83
6 (2014)	

Merck KGaA



Stock Exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 49,613

Ranking by technical area



Ranking by strategic pillar



PERFORMANCE

Merck KGaA once again rises two places, having improved in most areas. It has access-related targets that align with the Sustainable Development Goals, and clearly holds third parties to the same ethical standards as its own employees. It engages in R&D partnerships and shares IP and clinical trial data for research purposes. It has filed to register a high proportion of its newest products in high-burden countries and it

adapts its brochures and packaging to suit local needs in multiple ways. However, it still applies equitable pricing to only a small portion of its products. It has one of the most transparent approaches to IP management, but has been fined for anti-competitive behaviour. It is now a leader in capacity building, with a range of initiatives, including a long-term project for identifying falsified medicines.

CHANGE SINCE 2014

- Newly aligns access targets with the Sustainable Development Goals.
- Does not publish progress made against access-to-medicine targets.
- Has improved its accountability for its sales agents' pricing practices.
- Has equitable pricing strategies for the same number of products as in 2014.
- Clearly indicates where it is prepared to waive patent rights, and where and what products it is prepared to license.
- Publishes information about the patents it holds in countries in scope.
- Has signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.
- Has launched a three-year malaria research collaboration with the University of Namibia, in support of national malaria control programmes in Namibia, Botswana and Zambia.

OPPORTUNITIES

Target local capacity building needs in Africa. Merck KGaA intends to strategically expand its presence in Africa between 2015 and 2020. The company can ensure its capacity building activities (including in manufacturing and areas outside the pharmaceutical value chain) continually respond to local needs, and draw on ongoing input from local stakeholders. The company can also evaluate impact and publish its findings.

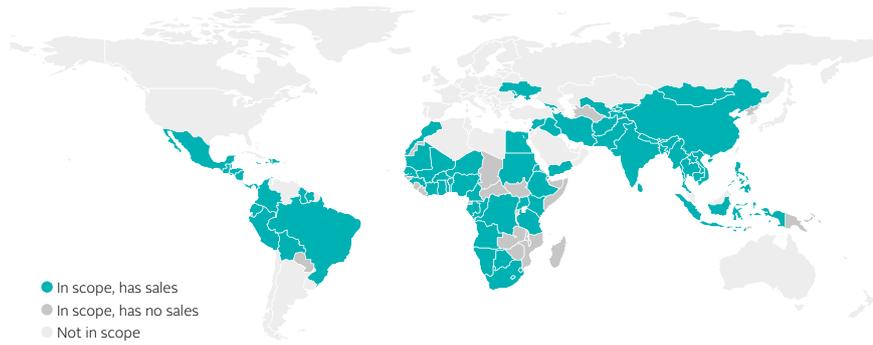
Expand equitable pricing strategy to more products. Merck KGaA can apply its equitable pricing strategy to more products, including all of its first line medicines for diabetes. It can take account of more socio-economic factors in its inter-country equitable pricing strategies.

Align access commitments and R&D early. Merck KGaA can build on its new "Access to Health in Developing Countries" charters, which focus on intellectual property rights and pricing, to ensure it makes access plans for its product candidates before they gain marketing approval. The company can put access provisions in place for its in-house (non-collaborative) R&D projects.

Ensure access to mental health products on the WHO EML. Merck KGaA is the only company targeting all mental health conditions in scope. It can assess access barriers for these conditions and ensure the availability and affordability of its mental health products, especially those listed on the WHO Model Essential Medicine List

(EML), in all low- and middle-income countries that need them. It can align with demand and with the availability of alternative products in specific countries.

Sales in countries in scope



SALES AND OPERATIONS

Merck KGaA reorganised its business in October 2014 and now operates through three business sectors: Healthcare (comprising the Biopharma, Consumer Health, Allergopharma, and Biosimilars businesses), Life Science and Performance Materials. The Healthcare business focuses on: oncology, immunology, neurology, endocrinology and cardiovascular diseases. In November 2014, the company announced a part-

nership with Pfizer to jointly develop and commercialize immuno-oncology products. About one third of Merck KGaA's sales are generated in emerging markets and the company has operation in 77 countries within the scope of the Index.

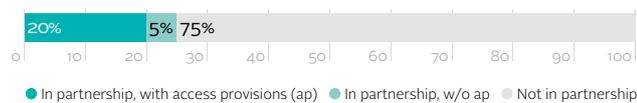
PORTFOLIO AND PIPELINE

Merck KGaA has a mid-sized portfolio of 58 products for diseases relevant to the Index. It has a mid-sized pipeline of 20 R&D projects that address the needs of people in countries in scope.

Its R&D focuses on malaria and schistosomiasis, as well as diabetes. Merck KGaA is developing diagnostics for HIV/AIDS and malaria that target needs in countries in scope. It is also working with Instituto de Biologia Experimental e Tecnológica to develop a screening platform for the discovery of new anti-malarials. Over half of the company's projects target high-priority product gaps with low commercial incentive. Since 2014, Merck KGaA's collaborative project to develop a paediatric formulation of praziquantel moved from pre-clinical to phase II of clinical development.

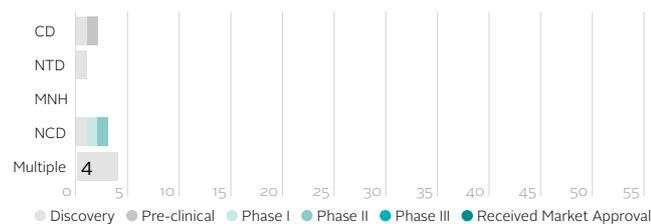
To date, the company's focus for low- and middle-income countries has been on medicines and diagnostics. Merck KGaA's relevant portfolio has a strong focus on non-communicable diseases (NCDs), covering: all mental health conditions in scope; hypertensive and ischaemic heart disease; and diabetes.

Pipeline projects



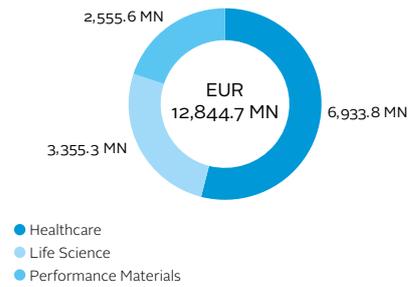
Merck KGaA collaborates with Astellas in the Pediatric Praziquantel Consortium, which plans to promote access to a new formulation of praziquantel, for example, via procurement by established organisations.

Pipeline by stage of development

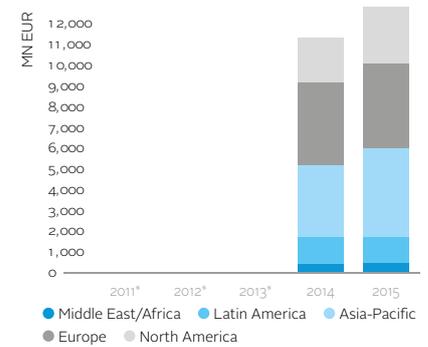


Merck KGaA's innovative pipeline includes four new investigational medicines, all in early stages of development, for malaria and Neglected Tropical Diseases (NTDs).

Net sales by business sector (2015)

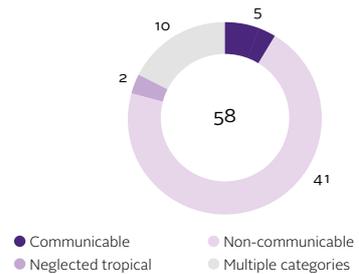


Net sales by region



*Due to a change in company reporting practices, numbers from 2011, 2012, 2013 and 2014 are incomparable.

Products per disease category



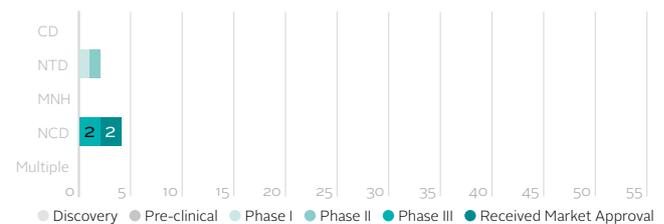
Merck KGaA's medicines portfolio has a strong focus on NCDs. Its four diagnostics address HIV/AIDS, malaria, and TB.

First-line treatments and essential medicines



Merck KGaA has 45 medicines listed on the WHO EML and/or as first-line treatments: e.g., bisoprolol/amlodipine, metformin (Glucophage®) and praziquantel.

Adaptive medicines and vaccines



Merck KGaA is adapting several products, including: a fixed-dose combination; pre-diabetes expansion; and smaller tablet of metformin (Glucophage®) to target countries in scope.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 10 SCORE 3.6

Overtaken by peers, drops four places. Merck KGaA falls from 6th to 10th position in this area. It has maintained its performance in absolute terms, but has been overtaken by peers who improved their performance.

Access unit embedded in all company businesses. Merck KGaA has an Access to Health (A2H) unit embedded within all core functions and operating across all businesses. Its access strategy is supported by its "Four As of Access to Medicine" approach. This aims to leverage the company's core competencies and expertise across the health value chain. For Merck KGaA, the four As refer to the availability, affordability, accessibility and awareness of medicine.

Some transparency on access-related outcomes. Merck KGaA is not transparent with regards to all access-related information. The company publishes on its website its commitments and objectives, but does not disclose complete information and updates on overall performance.

Mid-ranking performance on stakeholder engagement. The company takes a strategic approach to stakeholder engagement and is generally transparent with the related information. Nevertheless, it does not provide information on how its subsidiaries manage their local stakeholder engagement activities. Among other activities, Merck KGaA hosts the Merck Access Dialogue Series, a platform for sharing innovation and best practices around barriers to access.

► **Innovation: scale up of pilot initiative.** The Su-Swastha programme, identified by the Index as innovative in 2014, has been scaled up in the past two years. The project aims to increase access to quality healthcare products at an affordable price in rural India, and to address the lack of healthcare infrastructure in rural areas.

► **Best practice: benchmarking access targets.** Merck KGaA is realigning all of its targets for its access initiatives to the Sustainable Development Goals.

MARKET INFLUENCE & COMPLIANCE

RANK 11 SCORE 2.2

Improvements in ethical marketing result in rise of three places. Merck KGaA moves from 14th to 11th position in this area. This is due to improved practices regarding ethical marketing and to having a thorough auditing system, which also applies to third parties.

Specific guidance on marketing conduct. In addition to its code of conduct, Merck KGaA has 34 global policies that provide detailed guidance to its employees on topics related to marketing, such as sponsorship of events, engagement with healthcare professionals, etc. However, Merck KGaA does not provide information about its marketing activities or the payments it makes to patient and physician organisations (or similar) in countries within scope.

Achieving a degree of transparency in lobbying activities. Merck KGaA states publicly that it does not make financial contributions to holders of or candidates for political office, political parties or related organisations. It discloses its memberships of industry associations, but does not provide information about the financial contributions it makes to those associations. It has a conflict of interest policy.

Multiple breaches of codes of conduct. Merck KGaA has been found in breach of codes of conduct four times during the period of analysis. All cases related to unethical marketing practices in countries out of the Index scope.

Audit system applies to third parties. Merck KGaA conducts audits as part of its general review process. It checks the company's facilities to ensure they comply. The audit programme also covers anti-corruption. It contractually requires third parties and their subcontractors to follow compliance obligations, including anti-bribery, labour standards and environmental regulations.

RESEARCH & DEVELOPMENT

RANK 2 SCORE 3.4

R&D commitments linked to public health rationale. Merck KGaA commits to innovating internally and through external engagement and collaboration. For infectious diseases, the company commits to addressing unmet needs in developing countries, according to defined

global health priorities. Merck KGaA has promised to continue allocating 20% of its revenue to R&D.

Commitment to R&D partnerships, but no policy. Merck KGaA commits to sharing intellectual property with institutions carrying out R&D for diseases in scope. However, the company has no clear policy for ensuring these features or other access-oriented terms are systematically included in its R&D partnerships.

Comprehensive policy to ensure clinical trials are conducted ethically. Merck KGaA has policies and takes measures to ensure its clinical trials are conducted ethically. Its policies are strong: they include measures on scientific requirements, research protocols and post-trial provisions.

High transparency around clinical trials. The company upholds high standards of clinical trial data transparency. Access to patient-level data is provided to scientific researchers upon request via the company's own portal. Requests are processed by an internal committee and denied applications are sent for review by a panel including independent members.

► **Innovation: signing on to combat antimicrobial resistance.** Merck KGaA signed the Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance in January 2016, thereby committing to investing in R&D that aims to meet public health needs.

Shares intellectual property with several partners. Merck KGaA shares intellectual property for malaria, TB and NTD research with several partners, including the Drug for Neglected Diseases Initiative, Medicines for Malaria Venture, University of Yaoundé and University of Cape Town.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 6 SCORE 2.3

Rises three places due to consistent performance. Merck KGaA rises three places from 9th. It is one of the leaders in providing data on price points and volumes of sales (to demonstrate implementation of pricing strategies) and performs well in filing to register products where they are needed.

Limited consideration of socio-economic factors. Merck KGaA has equitable pricing strategies for the same products as in 2014. The strategies mainly cover hypertensive heart disease, ischaemic heart disease and diabetes. 11% of its marketed products for high-burden diseases have pricing strategies that target priority countries, reaching 12% of the corresponding priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). The company considers the availability of public financing systems in its intra-country equitable pricing strategies, and only considers affordability for its inter-country equitable pricing strategies.

Mixed registration performance. Merck KGaA has registration targets for products for a subset of relevant diseases in a sub-set of low-income countries. It does not publish its criteria for deciding where to register products, or the actual registration status of its products. However, it has filed to register more than half (80%) of its newest products in at least a few priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). Many of these products were first registered in 2008 or 2009.

Consistent recall guidelines. Merck KGaA has globally consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. Merck KGaA does not publish its drug recalls.

Language, environmental and demographic needs considered in brochures and packaging. Merck KGaA adapts brochures and leaflets to local languages so that local populations can understand important information. To address hot and humid conditions, Merck KGaA uses blister packs and is developing anti-tamper packaging, for example, to reduce the risk of children accidentally opening its products.

PATENTS & LICENSING

RANK 5 SCORE 2.5

Continuing strong performance. In 2014 Merck KGaA set a new bar for the transparency and clarity of its approach to IP management. This continues to earn Merck KGaA a place among the higher ranking performers.

Broad policy of not filing for or enforcing patents. Merck KGaA has published lists of countries where it promises not to file for or enforce patents. This comprises 90% of countries within the Index scope.

Open to requests for non-exclusive licences. While Merck KGaA does not yet engage in non-exclusive voluntary licensing, it publicly notes that it would welcome requests from quality manufacturers, focused on non-communicable diseases.

Evidence of anti-competitive behaviour. Merck KGaA has been fined by CADE, the Brazilian competition regulator, for engaging in anti-competitive behaviour (preventing distributors from working with generic manufacturers). At the time of analysis there was no record of an appeal being made.

Discloses patent statuses. Merck KGaA discloses information about the statuses of the patents (including patent type and INN) it holds in countries in scope (for diseases in scope).

► **Best practice: Clarity in approach to Intellectual Property.** Merck KGaA indicates where it holds patents, where it will not file for or enforce patents, its preparedness to license, in which disease area, and an indication of the terms. This clear approach gives confidence to third parties.

CAPACITY BUILDING

RANK 6 SCORE 2.8

Strong performance in meeting local capacity building needs. Merck KGaA has improved since 2014. It is active in all areas measured by the Index and demonstrates key strengths in building R&D and manufacturing capacity. The company has several best practices, and targets local needs through many of its activities.

Strong in building R&D capacity. Merck KGaA has a relatively large number of partnerships with local research organisations to build R&D capacity in sub-Saharan Africa. Some partnerships specifically address local needs, e.g., its malaria research programme with the University of Namibia to support governmental malaria control programmes in southern Africa.

Active in building capacity outside the value chain. Merck KGaA's philanthropic approach aims for sustainable and measurable results, but does not clearly target local needs. In practice, the company aims to fill local skills gaps outside the pharmaceutical value chain, through partnerships with the Indonesian and Philippine governments.

► **Best practice: approach to building capacity in manufacturing.** Merck KGaA applies a single quality standard to all its manufacturers (in-house and third-party), facilitated through an extensive global information-sharing system. The company provides an additional layer of support, expertise and regular training to local third-party plant managers through its Virtual Plant Team.

► **Best practice: supporting developing country vaccine manufacturers.** Merck KGaA has a partnership with the Developing Countries Vaccine Manufacturers Network to support the network's continuing education activities. The company shares expertise on safety and quality in

biologic manufacturing with network members (including vaccine manufacturers in Bangladesh, Egypt and Vietnam).

► **Best practice: building capacity to help detect suspected falsified medicines.** Through the Global Health Pharma Fund, Merck KGaA's Minilabs initiative has provided over 700 low-cost, portable laboratories (including donated laboratories), and related training to healthcare professionals in more than 90 countries around the world to help control falsified medicines.

PRODUCT DONATIONS

RANK 6 SCORE 3.5

Drops two positions. Merck KGaA has dropped from 4th to 6th position. It has one of the largest structured donation programmes: the Merck Praziquantel Donation Programme. It has not started new programmes or made *ad hoc* donations during the period of analysis.

Continues efforts to control schistosomiasis. Since 2007, Merck KGaA has supported the WHO in its efforts to control schistosomiasis in Africa. In 2012, the company renewed its commitment, pledging to increase the number of annually donated tablets of praziquantel (Cesol®) to 250 million tablets.

Complies with WHO donations guidelines. Merck KGaA has policies and regulations in place that list the requirements and the process governing its donations. It complies with WHO guidelines.

Monitoring is mainly the responsibility of partners. For its structured donation programme, the Merck Praziquantel Donation program, Merck KGaA is not involved in distribution, monitoring or reporting activities. WHO is responsible for these activities, and performs impact assessments.

Does not engage in emergency relief or humanitarian aid. Merck KGaA did not provide any relevant emergency relief or humanitarian aid donations during the period of analysis. It donated seven Minilabs in African countries in 2015.

Disclaimer

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