Merck & Co., Inc.

Stock Exchange: New York Stock Exchange • Ticker: MRK • HQ: Kenilworth, New Jersey, United States • Employees: 69,000

PERFORMANCE

Falls to 12th place from 5th. Merck & Co., Inc.* delivers a below average performance in access planning for R&D, and falls in multiple areas. Yet it has increased public transparency across all Technical Areas.

Management: Falls 6 places to 10th, with governance for access placed at the executive committee level.

Compliance: Falls 4 places to 11th as its internal control framework does not meet all the criteria looked for by the index.

R&D: Falls 4 places to 15th as it reports a below-average application of access plans to its late-stage R&D projects.

Pricing: Holds 9th place as it publicly shares detailed registration information for some products, and registers them in a range of priority countries.

Patents: Rises two places to 2nd through increased transparency of its patent statuses via Pat-INFORMED and the comparatively broad geographic scope of its licence for the paediatric formulation of raltegravir (Isentress®).

Capacity: Falls 10 places to 15th. Strong focus on health system strengthening, however, weak evidence of engagement in other areas of capacity building.

Donations: Falls 5 places to 7th. While it delivers a strong performance through its ivermectin (Mectizan®) programme, it publicly discloses comparatively less about the scale and impact of other programmes.

OPPORTUNITIES

Expand equitable pricing for more products. The company can apply, for example, equitable pricing strategies to mometasone furoate (Asmanex®). This product is an on-patent first-line product on the 2017 WHO Model List of Essential Medicines (WHO EML) for the treatment of asthma. Data about the company’s approach to this product has not been disclosed. The company could apply these strategies to the following priority countries where the burden of disease is high, e.g., Bangladesh, Brazil, China, Dem. Rep. Congo, Ethiopia, India, Myanmar, Nepal, Nigeria, Tanzania and Uganda.

Systematically plan for access throughout the R&D process. Merck & Co., Inc. can improve its commitment to R&D for diseases and countries in scope by considering the unique needs of low- and middle-income countries throughout development. By setting clear, time-bound targets for systematically considering and incorporating different access plans into each project at different points of development, Merck & Co., Inc. can ensure that its projects, which include novel antibiotics and therapies for maternal health, reach more patients. This includes providing post-trial access to clinical trial participants and registering all new products in every country where a clinical trial for these products has taken place, following market approval.

Further expand access via use of voluntary licensing. Merck & Co., Inc. can expand its use of voluntary licensing as a mechanism for boosting the affordability and supply of key medicines in countries in scope. This could include expanding licensing to adult formulations of raltegravir (Isentress®). It can also assess the need for elbasvir/graoprevir (Zepatier®) in countries with a high prevalence of hepatitis C virus (HCV) genotype 1 or 4, with a view towards licensing.

Review sales incentive structures. Merck & Co., Inc. can decouple sales incentives from sales targets to better incentivise responsible sales practices. This is especially critical for a company that is a major producer of antibiotics. Removing an emphasis on sales targets is recognised as a mechanism for reducing the impact of unethical marketing on, for example, rational prescribing.

CHANGE SINCE 2016

- WHO used Merck & Co., Inc.’s investigational Ebola vaccine in the 2018 outbreak in the Democratic Republic of Congo.
- Joined Access Accelerated with two initiatives including the Access and Affordability Initiative. It has also committed to measure impact and share results publicly via Access Observatory.
- Completed the transition of management for the Informed Push Model to the government of Senegal in late 2017.
- Launched a new partnership with the Global Financing Facility (GFF), the Bill & Melinda Gates Foundation, and The UPS Foundation to improve supply chains in low- and middle-income countries, drawing on the experience of the Informed Push Model.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Announced an expansion of its ivermectin (Mectizan®) donation programme in 2017, to reach up to an additional 100 million people annually through 2025 as part of the global effort to eliminate lymphatic filariasis.

*All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are accessible through other sources. In 2018, Merck & Co., Inc. declined to submit data to the Access to Medicine Index.
**PIPELINE** for diseases and countries in scope

Mid-sized pipeline: 50 R&D projects for diseases in scope (47 medicines; 3 preventive vaccines).

Clinical candidates: 27, including heat-stable carbetocin for the prevention of postpartum haemorrhage and a preventive vaccine for Ebola.

Regulatory approvals: 17, including raltegravir (Isentress®) for the treatment of HIV/AIDS in infants weighing more than 2 kg.

R&D focus: non-communicable diseases (cancer and diabetes mellitus), communicable diseases (HIV/AIDS, lower respiratory infections) and neglected tropical diseases (Chagas disease).

Access provisions: for 7 projects, most commonly applied through access-oriented partnerships.

**Projects in the pipeline: 50**

<table>
<thead>
<tr>
<th>Category</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Pre-clinical</th>
<th>Received Market Approval</th>
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<tbody>
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<td>Communicable*</td>
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<td>6</td>
<td>0</td>
<td>3</td>
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<tr>
<td>Neglected tropical</td>
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</tr>
<tr>
<td>Maternal and neonatal</td>
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<td>Non-communicable</td>
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<tr>
<td>Multiple categories</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

Merck & Co., Inc.’s Phase III rVSV-ZEBOV vaccine was used by WHO to vaccinate those at greatest risk of contracting Ebola in the 2018 Ebola outbreak in the Democratic Republic of Congo.

Projects for R&D priority targets with access provisions: 7

<table>
<thead>
<tr>
<th>Priority R&amp;D*</th>
<th>7</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest of pipeline</td>
<td>38</td>
<td>0</td>
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</table>

Of Merck & Co., Inc.’s 50 R&D projects, seven are supported by access provisions: e.g., heat-stable carbetocin will be made available at comparable prices to oxytocin and submitted for WHO prequalification. Two of its 44 late-stage projects have provisions.

**BUSINESS CONTEXT**

Two business units: Human Health and Animal Health. Human Health is divided into pharmaceuticals and vaccines. Its pharmaceuticals unit has four therapeutic areas (primary care and women’s health; hospital and specialty; oncology; and diversified brands). Its vaccine portfolio focuses on traditional childhood vaccines and newer vaccines with few other suppliers, including for HPV and rotavirus.

M&A news: 2016 conclusion of joint vaccines venture with Sanoﬁ in Europe to independently manage their product portfolios.

Presence in emerging markets: In 2016, Merck & Co., Inc. reported sales in 81 countries in scope. Data for 2018 not available. It reports that around 25% of its sales in 2017 came from the region of Europe, Middle East and Africa.

**PORTFOLIO** for diseases and countries in scope

Mid-sized portfolio: 58 products for diseases in scope (41 medicines; 10 preventive vaccines; 6 contraceptive methods; 1 vector control product).

Portfolio focus: non-communicable diseases (hypertensive heart disease and diabetes mellitus), communicable diseases (HIV/AIDS and viral hepatitis C) and maternal & neonatal health conditions (contraceptive methods).

Essential medicines: 58% of Merck & Co., Inc.’s medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

First-line treatments: 53% of Merck & Co., Inc.’s medicines and vaccines have first-line indications for diseases in scope.

**Products on the market: 58**

- **Communicable**
  - WHO EML: 20
  - Non-WHO EML: 29

Merck & Co., Inc.’s portfolio includes products such as the HIV integrase inhibitor raltegravir (Isentress®), two preventive vaccines for lower respiratory infections and six contraceptive methods.

Essential medicines with first-line indications: 26

- WHO EML First-line products: 20
- WHO EML Other: 7
- Non-WHO EML First-line products: 0
- Non-WHO EML Other: 29

Of Merck & Co., Inc.’s 50 R&D projects, seven are supported by access provisions: e.g., heat-stable carbetocin will be made available at comparable prices to oxytocin and submitted for WHO prequalification. Two of its 44 late-stage projects have provisions.

65% of Merck & Co., Inc.’s medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., the HPV vaccine Gardasil® and a contraceptive etonogestrel implant (Implanon®; Nexplanon®).

Sales by segment (2017) - USD

- Pharmaceuticals: 35,390 MN
- Animal Health: 3,875 MN
- Other Revenues: 857 MN
- Total: 40,122 MN

Sales by geographic region

- Rest of World: 40,122 MN
- Europe/Middle East/Africa: 36,706 MN
- Asia-Pacific: 2,224 MN
- Latin America: 1,660 MN
- Japan: 116 MN
- USA: 70 MN

Statistics relate only to diseases and countries in scope.

* Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.

**See Appendix IV for definition.
Merck & Co., Inc.

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT
RANK 10  SCORE 3.34

Has a strong access-to-medicine strategy with executive-level responsibility. Merck & Co., Inc. is one of 14 companies that performs strongly with regards to its access-to-medicine strategy which includes access-related goals, and aligns with its corporate strategies. The strategy centres around R&D, manufacture and supply, registration, commercialisation and community investment. The highest level of responsibility for access sits with the executive committee, which reports to the board.

Financial and non-financial access-related incentives to reward employees. Merck & Co., Inc. 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 a human resources performance strategy to reward employees.

One of 16 companies working on impact measurement. Merck & Co., Inc. 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 activities based on its Institutional Business Africa principles, the company reports having vaccinated 120,000 girls in Rwanda for HPV. Furthermore, it is one of the companies that is measuring the impact for at least one access initiative, the Informed Push Model.

Discloses who it engages with, incorporates local perspectives into strategies. Merck & Co., Inc. publicly discloses which stakeholder groups it engages with on access issues, but it does not publicly share its process for selecting who to engage with, nor its policy for ensuring responsible engagement. It does incorporate local stakeholder perspectives into the development of access strategies.

MARKET INFLUENCE & COMPLIANCE
RANK 11  SCORE 2.60

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Merck & Co., Inc. has a code of conduct relating to ethical marketing and anti-corruption. The company provides regular compliance training for employees via classroom courses and online classes. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets.

Internal control framework meets some Index criteria. Merck & Co., Inc.’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 both internal and external resources and applying to third parties, in all countries the company operates in. 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.

Average transparency regarding access-related practices. Merck & Co., Inc. publicly discloses its policy positions on access-related topics (e.g., its position on intellectual property and counterfeits medicines). It does not disclose political contributions in countries in scope. The company discloses its membership of relevant institutions and whether it provides financial support. It publicly shares standards for engagement with stakeholder groups through its code of conduct. It does not, however, publicly disclose its policy approach to payments made to healthcare professionals in countries in scope.

RESEARCH & DEVELOPMENT
RANK 15  SCORE 1.78
PROJECTS: 50 IN CLINICAL DEVELOPMENT: 27

Publicly commits to R&D to meet public health needs. Merck & Co., Inc. 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 including internal assessments and calls for action from external sources like WHO. It does not report time-bound strategies for completing R&D projects for diseases in scope. Merck & Co., Inc. has a mid-sized pipeline in the Index with 50 projects. For diseases in scope where priorities exist, Merck & Co., Inc. is active in 18 projects; 12 of these target priority R&D gaps.

Access provisions in place for 5% (2/44) of late-stage candidates. Merck & Co., Inc. has a clear process in place to develop access plans during R&D. The process considers some R&D projects for diseases in scope, namely projects for neglected tropical diseases in least-developed countries. Information is publicly available on project-specific access provisions for two of Merck & Co., Inc.’s late-stage R&D projects: heat-stable carbetocin for the treatment of postpartum haemorrhage and its rVSV-ZEBOV Ebola vaccine candidate. Both projects are being conducted in partnership.

Public policy to ensure post-trial access; no stated commitment to registering trialed products. Merck & Co., Inc. has a publicly available policy for ensuring post-trial access to treatments for clinical trial participants. However, the policy is not completely aligned with the standards set in the Declaration of Helsinki. Merck & Co., Inc. does not state a commitment to registering newly approved products in all countries where clinical trials for these products have taken place.

PRICING, MANUFACTURING & DISTRIBUTION
RANK 9  SCORE 2.31
PRODUCTS: 58
COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 16

Does not publicly commit to intra-country pricing or report a commitment to file to register new products in scope. Merck & Co., Inc. 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. This does not explicitly apply to future products. However, it does not commit to implementing intra-country pricing strategies.

Almost a third of new products in scope filed for registration in the majority of priority countries. Merck & Co., Inc. has filed 30% 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). It also publicly shares detailed registration information for some of its products.

28% of products have equitable pricing strategies targeting priority countries. Merck & Co., Inc.’s overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies
for 28% of its products for diseases in scope. These strategies apply to an average of 46% of priority countries. Half of its equitable pricing strategies apply both inter- and intra-country pricing; these take an average of three socioeconomic factors into account.

Has both globally consistent recall guidelines for countries in scope and processes to track products. Merck & Co., Inc. 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**

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<th>SCORE 2.94</th>
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Publicly discloses detailed information on patent statuses. Like most of its peers, Merck & Co., Inc. 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.

Uses licensing to enable generic supply. Merck & Co., Inc. has a non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence, for its paediatric formulation of raltegravir (Isentress®), encompasses 89 countries including 58 middle-income countries in scope. It has not issued any non-assert declarations for products in scope.

Comparatively few IP assets shared with 3rd-party researchers. During the period of analysis, Merck & Co., Inc. newly shared one IP asset with third-party researchers developing products for diseases in scope. The assets shared include performing assays for drug discovery with George Washington University located in the USA. This new agreement is in addition to previously agreed IP sharing agreements with, for example, the University of California, San Diego, Walter and Eliza Hall Institute of Medical Research, DNDi and the Macrofilaricidal Drug Accelerator Program.

Public commitment not to enforce patents in countries in scope. Merck & Co., Inc. commits publicly to neither enforce nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries.

**CAPACITY BUILDING**

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Five initiatives included for evaluation. Merck & Co., Inc. has five 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 & Co., Inc.’s initiatives were identified for selection based on publicly available information.

**BEST PRACTICES**

Continued commitment to combat NTDs. GLOBAL

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

Informing Push Model strengthens supply chain for contraceptives. SENEGAL

Model removes the burden of tracking and ordering inventory from pharmacies by using logistics operators to regularly deliver and track supplies to ensure sufficient stock.

Merck for Mothers invests $500 million to improve maternal health.

GLOBAL

A $500 million, 10-year initiative, to design scalable solutions to help end preventable maternal deaths.

**PRODUCT DONATIONS**

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<th>RANK 7</th>
<th>SCORE 3.58</th>
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RESPONDS TO EMERGENCIES AND HUMANITARIAN ISSUES AND TRACKS DELIVERY. Merck & Co., Inc. donated medicines on the request of relief agencies. For example, during the period of analysis, it donated various products in Haiti. The company discloses that such ad hoc donations are aligned with international guidelines (issued by WHO), and it works, for example, with Direct Relief, Americares and MAP International to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

Three donation programmes covering diseases and countries in scope. Merck & Co., Inc.’s programmes are focused on neglected tropical diseases (NTDs), namely lymphatic filariasis, onchocerciasis and river blindness. All three programmes are carried out in collaboration with partners such as WHO and Afya. Its NTD programme for lymphatic filariasis supplies ivermectin (Mectizan®) in 27 countries and has been ongoing since 1987. In 2016, Merck & Co., Inc. reports that 141 million treatments were approved for lymphatic filariasis.

Addresses long-term access by aiming to eliminate disease. Merck & Co., Inc. commits to long-term structured donation programmes by aiming to eliminate the diseases targeted. For its ivermectin (Mectizan®) programme, the company is committed to continuing to donate as much ivermectin (Mectizan®) as is necessary to eliminate river blindness globally, and to eliminate lymphatic filariasis in African countries and in Yemen.

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