Merck & Co., Inc.

Index performance by Research Area

PERFORMANCE

Merck & Co., Inc. has one of the largest vaccine revenues, above average geographic scope and a medium-sized portfolio, including key vaccines with few producers (e.g., for HPV and rotavirus). It focuses less on vaccine R&D than peers in scope. Overall, it falls in the middle of the pack of companies. Merck & Co., Inc.’s performance in Manufacturing & Supply is above average, with the strongest commitment to maintaining supply. In Pricing & Registration, it publishes its vaccine pricing policy. It has filed to register some vaccines in only some low-income countries (LICs). It performs below average in Research & Development, with relatively low R&D investments and a relatively small vaccine pipeline.

SALES AND OPERATIONS

Merck & Co., Inc. (known as MSD outside the US and Canada) has three businesses: pharmaceuticals; vaccines; and animal health. For its entire portfolio (all products including vaccines), it has sales in 81 countries in scope. Merck & Co., Inc. had a vaccines joint venture in Europe with Sanofi Pasteur (Sanofi Pasteur MSD) which ceased operation at the end of 2016. The company will take its vaccine assets back-in-house. It now has 13 marketed vaccines.

VACCINE PORTFOLIO

Merck & Co., Inc. has 13 vaccines on the market for 14 diseases in scope, including three combination vaccines. Its portfolio is diverse, from traditional childhood vaccines (e.g., measles, mumps, rubella combination vaccines) to newer vaccines with few other suppliers, including for HPV (Gardasil®) and rotavirus (RotaTeq®).

OPPORTUNITIES

Strengthen internal process for aligning supply and demand. Merck & Co., Inc. can implement some or all of the strategies identified by the Index to strengthen its internal process for aligning supply and demand. For example, it could establish a clear process for escalation and action on identified supply issues; consider other suppliers when making supply allocation decisions; and set up a clear process for re-allocation of stocks in limited supply situations.

Apply a more specific pricing policy and reduce key vaccine prices. Merck & Co., Inc. can outline how it defines pricing tiers and explicitly state how it takes different countries’ ability to pay into account. In addition, it can work with stakeholders to reduce the price of key vaccines (e.g., Gardasil® for HPV and RotaTeq® for rotavirus) for all LICs and middle-income countries (MICs), particularly in the case of Gavi-transitioning countries in the future and current non-Gavi and non-PAHO countries. For this purpose, Merck & Co., Inc. can continue to work with pooled procurers and work directly with self-procuring countries. This can help increase the adoption of these vaccines in more MICs.

Invest more in R&D. Merck & Co., Inc. can invest more in vaccine R&D, and engage in new projects to develop and adapt vaccines that meet the needs of people in countries in scope. This will help the long-term sustainability of its vaccine business.

File vaccines for registration more widely where they are needed. Merck & Co., Inc. can expand the availability of existing and future key vaccines in more LICs and MICs, where needed, taking into account the availability of alternative products and domestic vaccine manufacturing, registration hurdles, and government demand and preferences. This can provide purchasers with more choice, create a more competitive environment, and improve supply reliability.
RESEARCH AREAS

RESEARCH & DEVELOPMENT

Proportionally low R&D investments. Compared to other companies measured, as a proportion of its global vaccines revenue, Merck & Co., Inc. made relatively low investments in vaccine R&D for diseases in scope in 2014 and 2015.

Relatively small vaccine pipeline. Merck & Co., Inc. has six R&D projects in its pipeline, including projects targeting Ebola virus and pneumococcal disease. It received approval for two vaccines during the period of analysis, as well as a thermostability label update for its HPV vaccine (Gardasil®).

Access provisions in place for two late-stage projects. Merck & Co., Inc. has at least one access provision in place for two out of its four late-stage projects. It applied for WHO prequalification for its HPV vaccine (Gardasil®), which is not yet available in countries in scope.

Vaccine pipeline

Merck & Co., Inc.’s pipeline is concentrated in late stages of development. Along with Pfizer, it received the highest number of relevant market approvals during the period of analysis. In addition to projects shown here, Merck & Co., Inc. has a further project for which data are confidential.

Discovery Pre-clinical Phase I Phase II Phase III Technical lifecycle Recent approvals

Pneumococcal - 15-valent (V114) Ebolavirus (V920) DTPHibHepIPV (Vaxelis®, in partnership with Sanofi) EMA, Feb 2016

HPV (Gardasil®) FDA, Dec 2014

HPV (Gardasil®, CTC label update) EMA

Pricing & Registration

Pricing strategy takes multiple factors into account. Merck & Co., Inc. states that it uses tiered pricing to (a) expand access and (b) to ensure sufficient return on its investment in R&D over time. The company does not provide details of its pricing tiers. The company’s access to vaccines policy takes multiple factors into account, including the country’s level of economic development, fiscal capacity for investments in health, and actual health spending, which could be seen as proxies for the country’s ability to pay.

Extension of Gavi prices to Gavi-transitioning countries. Merck & Co., Inc. is extending the current Gavi prices for its quadrivalent HPV vaccine (Gardasil®) and rotavirus vaccine (Rotarix®) through 2025 to Gavi-transitioned countries with gross national income per capita not exceeding USD 3,200.

Above-average transparency. Like its peers, Merck & Co., Inc. does not systematically publish all prices for its vaccines in all countries in scope. Unlike most of its peers, the company publishes its detailed vaccine pricing policy. It states that it does not have a policy permitting or prohibiting governments from disclosing prices: it leaves this to each government’s discretion.

Limited registration filing in LICs. Merck & Co., Inc. files the majority of its relevant vaccines for registration in some lower middle-income countries, like its peers. However, it files only some of its vaccines for registration in and only some LICs. Merck & Co., Inc. states that its decision to file for registration is based on where vaccines are needed. The company commits to seeking WHO prequalification of eligible vaccines to expedite access in LICs.

Manufacturing & Supply

Very strong in aligning supply and demand. Merck & Co., Inc. makes the strongest commitment to maintaining supply of its vaccines as long as they are needed, and notifies stakeholders of plans to alter supply. It prioritises public health needs when re-allocating limited stock.

Building manufacturing capacity in Brazil. Merck & Co., Inc. undertakes some vaccine manufacturing capacity building activities. It is undertaking a technology transfer with capacity building components for its HPV vaccine (Gardasil®), and is beginning a technology transfer for its hepatitis A vaccine (Vaqta®), both to Instituto Butantan in Brazil.

Above-average performance in addressing local logistics needs. Merck & Co., Inc. has implemented presentations and packaging to overcome local barriers for several vaccines, with a focus on cold-chain requirements. For example, Gardasil® has been approved for Controlled Temperature Chain use as it does not require constant refrigeration.