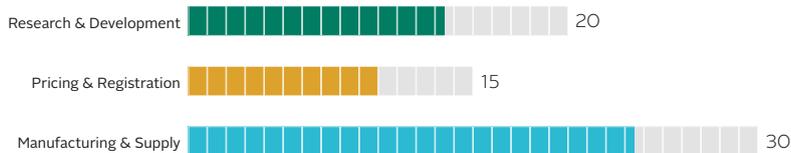


# GlaxoSmithKline plc

Stock Exchange: XLON  
 Ticker: GSK  
 HQ: Brentford, UK  
 Employees: 101,255

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained.

## PERFORMANCE

GSK is one of the largest vaccine companies in scope by revenue, portfolio size, pipeline size and geographic scope. For several key vaccines, it is one of a small number of producers, including for rotavirus and pneumococcal disease. GSK performs very well overall, leading in all three Research Areas. In Research & Development, it has the largest vaccine pipeline.

In Manufacturing & Supply, it has strategies to support access at a high level, strong internal supply-management processes and vaccine presentations that help overcome access barriers on the ground. It leads in Pricing & Registration with the most-structured vaccine pricing strategy. However, it has filed to register only some vaccines in low-income countries (LICs).

## SALES AND OPERATIONS

GSK operates through three divisions: pharmaceuticals; vaccines; and consumer health-care. It has sales in 92 countries in scope (including sales of products other than vaccines); sales in emerging markets account for about 25% of total sales. Among the companies in scope, GSK's vaccines division accounts for the highest share (15%) of overall revenue. In 2014, the company acquired Novartis's vaccine business (excluding influenza vaccines), while divesting its marketed oncology portfolio to Novartis. In 2015, GSK sold two meningococcal vaccines to Pfizer (Mencevax® and Nimenrix®). GSK's vaccines division now has 48 marketed vaccines. GSK also has a joint venture with Daiichi Sankyo, Japan Vaccine Co., Ltd., through which it sells vaccines in Japan.

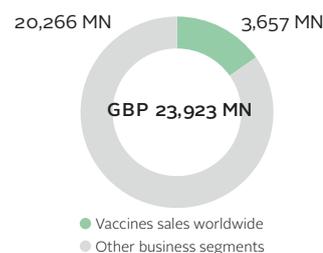
### Sales in countries in scope (all product types)



### Number of doses sold in 2015



### Sales by segment 2015



## VACCINE PORTFOLIO

GSK has 48 vaccines on the market for 19 diseases in scope, one of the largest portfolios of the companies evaluated. Its portfolio is diverse, ranging from traditional childhood vaccines (e.g., DTaP-containing combination vaccines) to newer vaccines with few other suppliers (e.g., for HPV, pneumococcal disease and rotavirus).

### Marketed vaccines

DT	1	HPV	1	TBE	1
DTP	2	Meningococcal	4	Td	1
DTPHepIPV	1	MMR	1	Tetanus	1
DTPHib	1	MMRV	1	Typhoid	1
DTPHibHep	1	Pandemic influenza	3	TyphoidHepA	1
DTPHibHepIPV	1	Pneumococcal disease	1	Varicella	1
DTPHibIPV	1	Polio	6	Viral hepatitis	4
DTPIPV	2	Rabies	1		
Hib	2	Rotavirus	1		
HibMen	2	Seasonal influenza	5	<b>Total</b>	<b>48</b>

## OPPORTUNITIES

**Make an overarching commitment to continuing supply of vaccines where needed.** While GSK commits to communicating its intentions with regard to altering its supply of vaccines, it can also make a clear commitment to continuing supply of its vaccines with few other suppliers.

**Develop access provisions for all late-stage candidates.** Among its peers, GSK has the largest number of late-stage projects and the most late-stage projects that are supported by plans to ensure access. GSK can, working with partners where relevant, develop similar plans for its other late-stage projects: its candidates for HIV,

hepatitis C, meningitis, pneumococcal (phase II), RSV (maternal), seasonal influenza and varicella. For those projects with access provisions in place, the company can strengthen and refine its plans as the vaccines approach market approval.

**File to register vaccines more widely where they are needed.** GSK can expand the availability of key vaccines in more LICs and middle-income countries (MICs), where needed, taking account of the availability of alternative products and domestic vaccine manufacturing, government demand and preferences and registration hurdles. This can provide purchasers with

more choice, create a more competitive environment and improve supply reliability.

**Work with stakeholders to reduce the price of key new vaccines.** GSK can continue to work with pooled procurers and self-procuring countries, e.g., with regard to its vaccines for pneumococcal disease (Synflorix®), rotavirus (Rotarix®) and HPV (Cervarix®), for all LICs and MICs, and particularly for Gavi-transitioning countries in the future and non-Gavi and non-PAHO countries at present. This can help increase the adoption of these vaccines in more MICs.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

**Proportionally low R&D investments.** As a proportion of its global vaccine revenue, GSK made relatively low investments in vaccine R&D targeting diseases in scope in 2014 and 2015, compared to other companies in scope. In absolute terms, its investment was relatively high.

**Largest vaccine pipeline.** GSK has a pipeline of 25 vaccine R&D projects, targeting at least 16 diseases in scope. GSK targets all seven diseases in scope prioritised by WHO for vaccine R&D: such projects account for 40% of its pipeline.

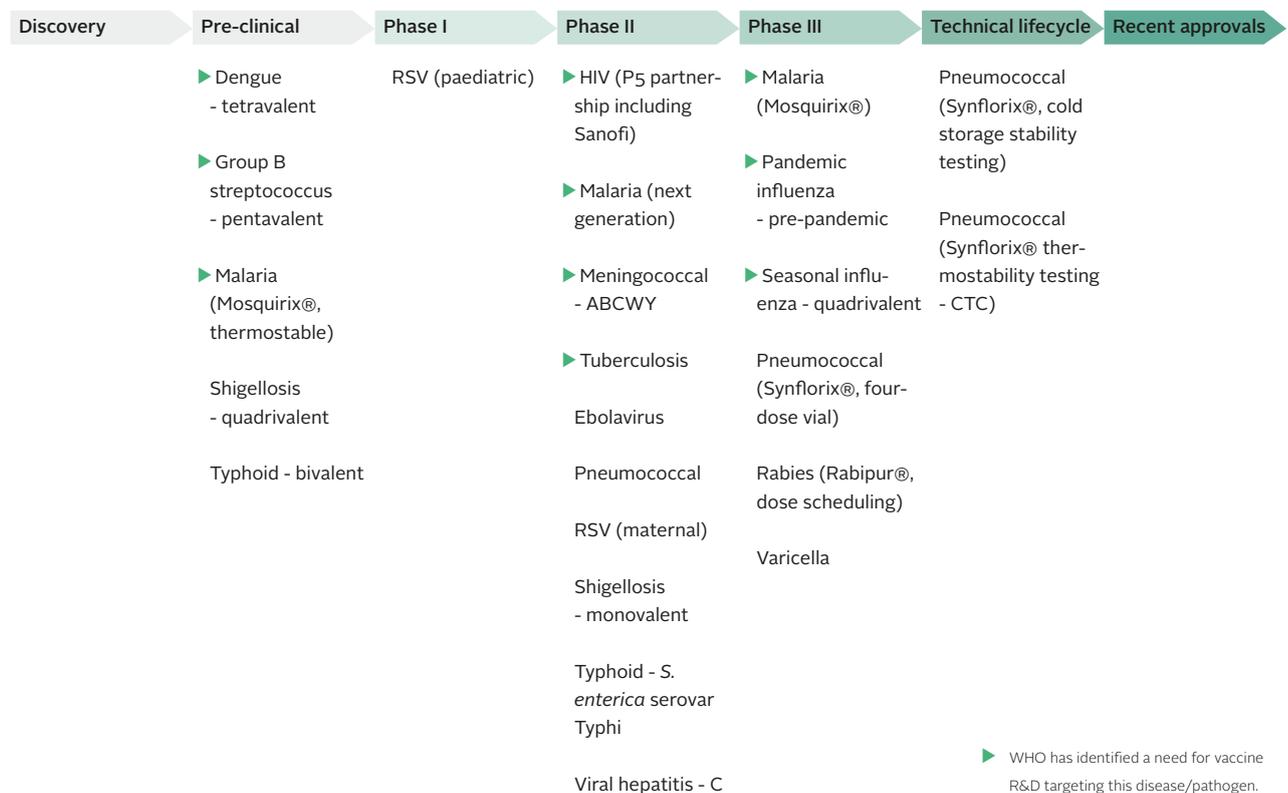
R&D projects (8/15). For example, GSK commits to making its shigellosis, TB and typhoid vaccine candidates affordable to countries in need.

**Largest number of late-stage projects with access provisions.** GSK has at least one access provision in place for around half of its late-stage

**Researching technologies for vaccine packaging and delivery.** GSK is developing technologies for vaccine packaging and delivery that aim to overcome barriers to access in low-resource settings.

### Vaccine pipeline

GSK has the largest vaccine pipeline among companies evaluated, with most projects in late stages of development. In addition to the projects shown here, GSK has a project for which data are confidential.



## GlaxoSmithKline plc (continued)

### PRICING & REGISTRATION

**Most detailed tiered pricing strategy.** GSK's strategy for public sector vaccine pricing comprises seven pricing tiers covering a range of markets. The lowest tier is applied to all Gavi-eligible countries. The other tiers are applied according to a combination of gross national income per country, target population coverage, duration of contract and committed volume. The number of tiers makes this strategy the most sensitive to each country's ability to pay, compared to peers' strategies.

**Commitment to offering lower prices to Gavi-transitioning countries.** In early 2015, GSK committed to freezing prices it offers to countries transitioning from Gavi support, so that they can purchase vaccines for pneumococcal, rotavirus

and HPV at significantly discounted prices for a decade after graduation.

**First company to make vaccine price commitment for humanitarian situations.** Outside the period of analysis, in September 2016, GSK became the first company to commit to supplying its pneumococcal conjugate vaccine (PCV) (Synflorix®) at USD 3.05 per dose to civil society organisations that fund and deliver immunisation programmes for refugees and displaced persons.

**Limited registration filing in LICs.** GSK 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 and in only some LICs. GSK states

that its decision to file for registration is based on where vaccines are needed and depends upon the regulatory procedures of each country. GSK commits to seeking WHO prequalification of eligible vaccines to expedite access in LICs.

**Above average transparency.** Like its peers, GSK does not systematically publish all prices for its vaccines in all countries in scope on its website. However, unlike most of its peers, it does publish its complete vaccine pricing policy. Like most peers, it states that it does not include non-disclosure clauses on vaccine prices in its contracts with governments and other procurers.

### MANUFACTURING & SUPPLY

**Leader in aligning supply and demand.** GSK takes a very strong approach to aligning vaccine supply and demand, implementing six of eight key practices identified by the Index in this area. Overall, it has regular processes for proactively coordinating with external stakeholders; and its internal process for ensuring sufficient supply is very comprehensive.

**Very active in building manufacturing capacity.** GSK is undertaking a relatively high number of activities to build global vaccine manufacturing capacity. It is running several technology transfer programmes with capacity building components (e.g., for the production of its diphtheria, tetanus and acellular pertussis vaccine (Boostrix®) in Brazil).

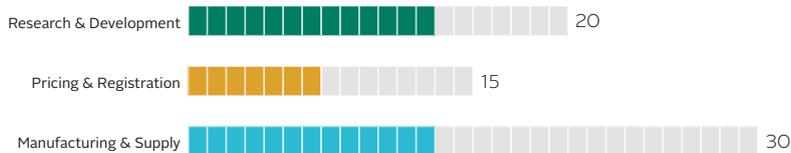
**Multiple vaccine presentations support access.** GSK has implemented a range of presentation and packaging types to help overcome local barriers to access. For example, the packaging of its rotavirus vaccine (Rotarix®) includes illustrations, to help avoid administration errors, as well as matrix (2D) barcodes to help improve the tracking of vaccines as they move through the supply chain.



# Johnson & Johnson

Stock Exchange: XNYS  
 Ticker: JNJ  
 HQ: New Brunswick, NJ, US  
 Number of employees: 127,100

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained.

## PERFORMANCE

Johnson & Johnson currently has relatively low vaccine revenues, reflecting its small portfolio size, volume of doses sold and geographic scope. However, its pipeline and R&D investments indicate a growing focus on vaccines. Overall, its performance is in the average range compared to other companies. It is a leader in Research & Development, making the largest investments in vaccine R&D and with a relatively large pipeline. In Pricing & Registration, it has filed to register vac-

cines in some low-income and lower-middle-income countries (LICs; LMICs). It has published only a very general commitment to affordable vaccine pricing. In Manufacturing & Supply, its performance is below average: while it has internal processes to align supply and demand, it is less active than peers in building manufacturing capacity, and has not implemented presentations or packaging to help overcome local access barriers for its two marketed vaccines.

## SALES AND OPERATIONS

Johnson & Johnson has three segments: consumer healthcare; pharmaceuticals; and medical devices. Its pharmaceuticals segment focuses on various therapeutic areas, including vaccines. Johnson & Johnson is present in 69 countries in scope. Sales in emerging and frontier markets account for 20% of total sales. Its vaccines are developed and produced by Janssen Vaccines & Prevention B.V. (part of Janssen Pharmaceutical Companies). Following the divestment of its oral typhoid and oral cholera vaccines, it now has two vaccines on the market.

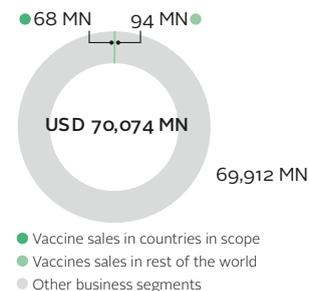
### Sales in countries in scope (all product types)



### Number of doses sold in 2015



### Sales by segment 2015



## VACCINE PORTFOLIO

Johnson & Johnson has two vaccines on the market for five diseases in scope, one of the smallest portfolios of the companies evaluated. Its portfolio is made up of a single hepatitis B vaccine (Hepavax®) and a diphtheria, tetanus,

whole-cell pertussis, hepatitis B and Hib combination vaccine (Quinvaxem®).

### Marketed vaccines

DTPHibHep	1
Viral hepatitis	1
<b>Total</b>	<b>2</b>

## OPPORTUNITIES

**Commit to communicating supply discontinuation plans.** Johnson & Johnson can commit to consistently communicating its intentions publicly when deciding to discontinue supply of a vaccine in future. This will allow stakeholders to adapt procurement and distribution plans early to minimise the risk of shortages and the potential impact on public health.

**Consider barriers to access of marketed products.** Johnson & Johnson can consider how

its marketed products may present barriers to access in resource-limited settings, in terms of supply chain management, storage and administration. As it expands its R&D activities, it can adapt its existing vaccines, where possible, to address these barriers. Beyond vaccine development, it can adapt vaccine packaging and package inserts to address barriers to access.

**Develop and publish a more specific pricing policy.** Johnson & Johnson can outline how it

defines the pricing tiers of its pricing policy, and include non-Gavi and non-PAHO country governments in its strategy, with a consideration of these countries' ability to pay. By publishing a more specific pricing policy, which applies to new and existing vaccines, Johnson & Johnson can improve its accountability and ensure that self-financing countries have a better understanding of how to negotiate prices.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

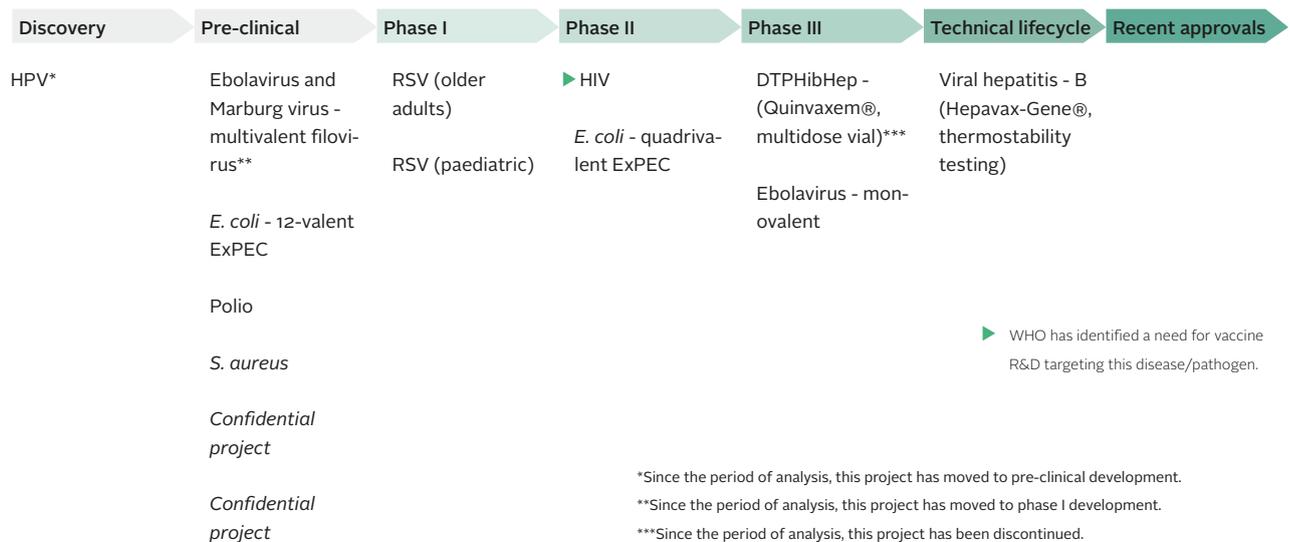
**Largest R&D investments.** Johnson & Johnson made the largest investments of companies evaluated in vaccine R&D targeting diseases in scope in 2014 and 2015, both in absolute terms (USD 717.3 mn) and as a proportion of its vaccine revenue (253%).

**Relatively large vaccine pipeline.** Johnson & Johnson has 14 R&D projects in its pipeline, targeting at least 13 diseases in scope. One of its projects targets a disease prioritised by WHO for vaccine R&D: its phase II HIV vaccine candidate.

**Access provisions in place for three late-stage projects.** Johnson & Johnson has at least one access provision in place for three out of its four late-stage projects. For example, it aims to register its Ebolavirus and HIV vaccine candidates in countries where clinical trials take place. These two vaccines are being trialled in six and four countries in scope respectively.

#### Vaccine pipeline

Johnson & Johnson has the largest number of projects in pre-clinical development.



### PRICING & REGISTRATION

**General pricing strategy.** Johnson & Johnson makes a broad commitment to using a tiered pricing approach for key vaccines in developing countries. However, it only provides UNICEF and PAHO as examples of procurers for whom it differentiates prices (based on countries' wealth). It is not clear how the company takes affordability into account for non-Gavi, non-PAHO self-procuring countries. As part of its pricing strategy, the company states that vaccines specifically developed for poorer countries and not sold in affluent markets must stay profitable in order to sustain production, uphold quality and recoup investments.

**Extends Gavi prices to Gavi-transitioning countries.** In January 2015, Johnson & Johnson extended its pledge to make its pentavalent vaccine (Quinvaxem®) available at Gavi prices to transitioning countries over the next five years.

**On-average performance in registration filing.** Johnson & Johnson has filed to register both of its relevant vaccines in some LICs and some LMICs. Johnson & Johnson's policy is to file for registration in countries where there is a medical need, taking into account regulatory and market hurdles.

**On-average transparency.** Like its peers, Johnson & Johnson does not systematically publish all prices for its vaccines in all countries in scope. Unlike leaders in this area, it only discloses a high-level version of its general pricing policy, with limited detail. Like most of its peers, it states that it does not include non-disclosure clauses regarding vaccine prices in its contracts with governments and other procurers.

### MANUFACTURING & SUPPLY

**Above average performance in aligning supply and demand.** Johnson & Johnson has an above-average approach to ensuring sufficient vaccine supply. It makes a strong commitment to staying in vaccine markets where needed, and has a relatively comprehensive internal process for preventing and responding to shortages.

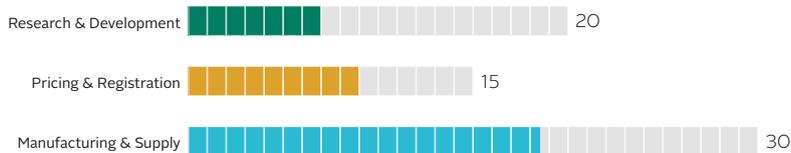
**Some activity in building manufacturing capacity.** Johnson & Johnson undertakes a relatively small number of activities to build vaccine manufacturing capacities in countries in scope. It provides operational and technology support to Vabiotech in Vietnam, a state-owned company producing vaccines for cholera, hepatitis A and B, and Japanese encephalitis.

**Limited focus on vaccine presentations that support access.** Johnson & Johnson's performance is comparatively weak when it comes to ensuring its marketed products help to support access on the ground. It has adaptations in development, but has not yet implemented relevant presentations or packaging for marketed products.

# Merck & Co., Inc.

Stock Exchange: XNYS  
 Ticker: MRK  
 HQ: Kenilworth, NJ, US  
 Employees: 68,000

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained.

## 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.

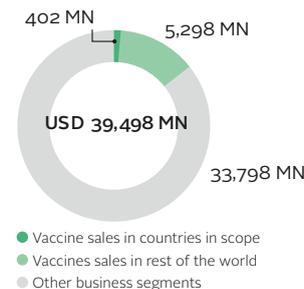
### Sales in countries in scope (all product types)



### Number of doses sold in 2015



### Sales by segment 2015



## 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®).

### Marketed vaccines

DTPHibHepIPV	1	Rotavirus	1
Hib	1	Tuberculosis	1
HPV	2	Varicella	2
MMR	1	Viral hepatitis	2
MMRV	1	<b>Total</b>	<b>13</b>
Pneumococcal disease	1		

## 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

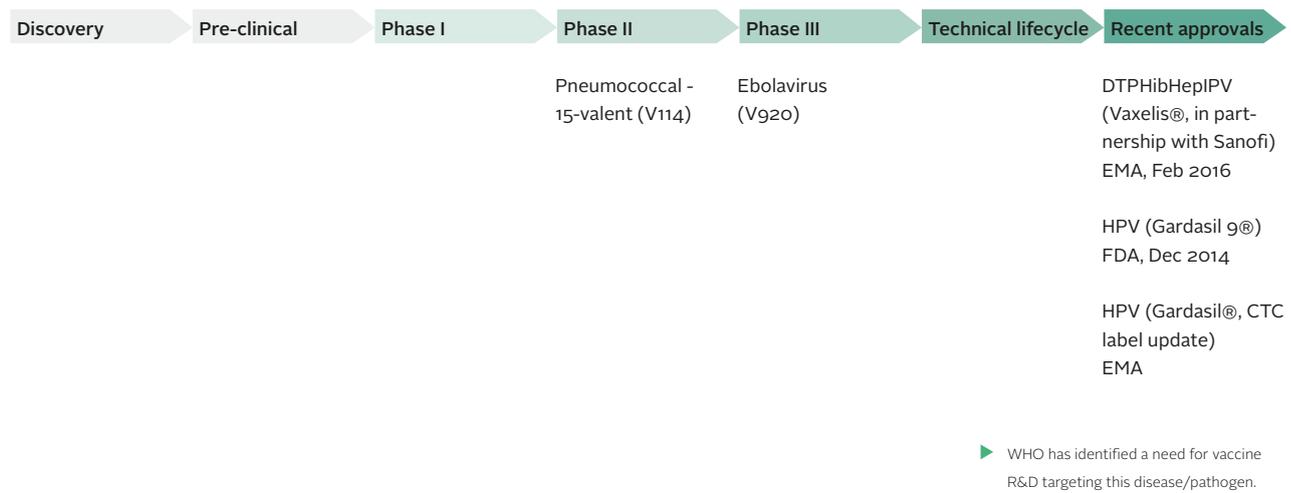
**Proportionally low R&D investments.** Compared to other companies measured, as a proportion of its global vaccines revenue, Merck & Co., Inc. made relatively low investments in vaccine R&D for diseases in scope in 2014 and 2015.

**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 9®), 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.



### 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 (RotaTeq®) 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 and in 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.

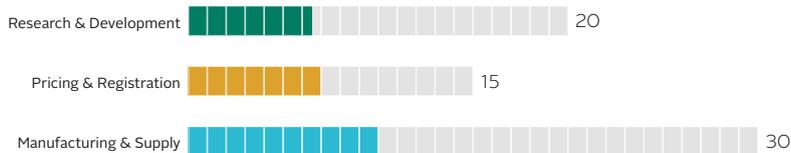
**Building manufacturing capacity in Brazil.** Merck & Co., Inc. undertakes some vaccine manufacturing capacity building activities. It is undertaking a technology transfer with capacity building components for its HPV vaccine (Gardasil®), and is beginning a technology transfer for its hepatitis A vaccine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

# Pfizer Inc.

Stock Exchange: XNYS  
 Ticker: PFE  
 HQ: New York, NY, US  
 Number of employees: 97,900

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained.

## PERFORMANCE

Pfizer has one of the largest vaccine revenues, a small portfolio and pipeline, and on-average geographic scope. It is the largest PCV producer, supplying 70% of the global market with Prevenar 13®. Overall, it falls short in multiple areas compared to peers. In Pricing & Registration, although Pfizer newly publishes its tiered pricing policy, it is the only company

that states it supports the use of price confidentiality provisions. The company performs below average in Research & Development, with a relatively small pipeline, and is lagging in several aspects of Manufacturing & Supply. It makes no commitment to notify stakeholders in advance when reducing or ceasing supply of vaccines.

## SALES AND OPERATIONS

Pfizer has two segments: Pfizer Innovative Health (including vaccines) and Pfizer Essential Health. The company has sales in 86 countries in scope. Of all companies in scope, it has the highest vaccines revenue, largely due to its PCV (Prevenar 13®). It recently purchased three meningococcal vaccines: from GSK (Mencevax® and Nimenrix®) and Baxter (NeisVac-C®). It now has six marketed vaccines.

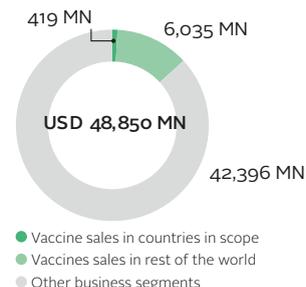
### Sales in countries in scope (all product types)



### Number of doses sold in 2015

Data confidential

### Sales by segment 2015



## VACCINE PORTFOLIO

Pfizer has six vaccines on the market for three diseases in scope. Its portfolio comprises four vaccines for meningococcal disease (Mencevax®, NeisVac-C®, Nimenrix®, Trumenba®), one for pneumococcal disease (Prevenar 13®) and one for tick-borne encephalitis (FSME-IMMUN/TicoVac®).

### Marketed vaccines

Meningococcal disease	4
Pneumococcal disease	1
TBE	1
<b>Total</b>	<b>6</b>

## OPPORTUNITIES

**Commit to continuing supply and communicating future supply plans.** Pfizer can commit to staying in vaccine markets with few or no other suppliers. It can also commit to communicating its intentions publicly when deciding to discontinue supply of a vaccine in the future, as necessary. Notifying stakeholders in advance will help them to adapt procurement and distribution plans early to minimise the risk of shortages and potential public health impact.

**Limit use of price confidentiality provisions.** Pfizer can limit its use of confidentiality provisions

to help promote a more competitive market and a clearer understanding of pricing problems.

**Work with stakeholders to reduce the price of key vaccines.** Pfizer can continue to work with pooled procurers and with self-procuring countries, e.g., with regard to its PCV (Prevenar 13®), for all low- and middle-income countries (LICs; MICs), particularly for Gavi-transitioning countries in the future and non-Gavi and non-PAHO countries at present. This can help increase the adoption of these vaccines in more MICs.

**Expand R&D activities and pair them with access strategies.** Pfizer can 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. Further, by committing to and developing strategies to ensure access to its projects targeting diseases with no existing vaccines, Pfizer has a key opportunity to address unmet needs of populations in LICs and MICs.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

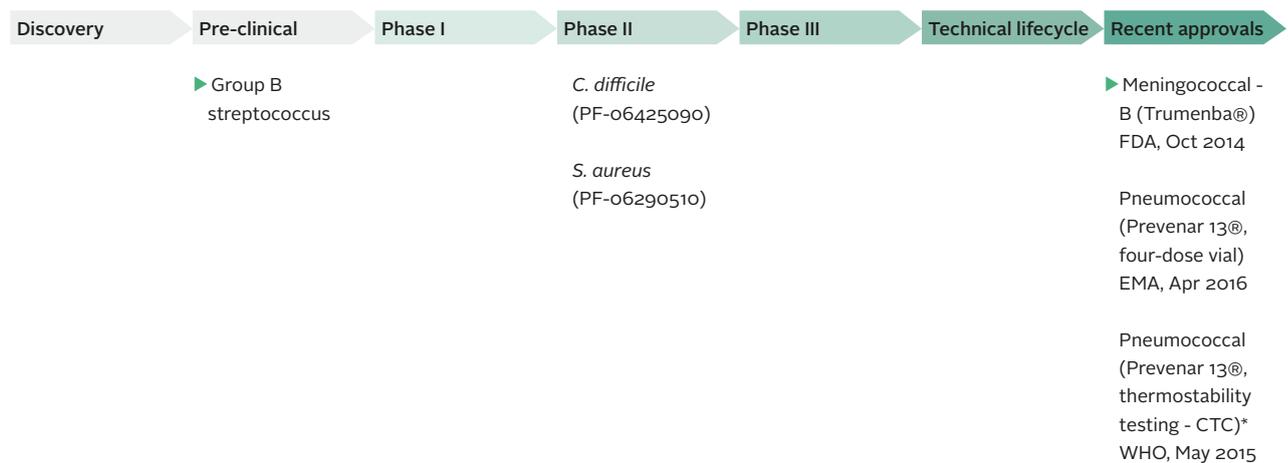
**Proportionally low R&D investments.** Pfizer invested USD 676.3 mn in vaccine R&D targeting diseases in scope in 2014 and 2015. Relative to other companies measured, this makes up a low proportion of its global vaccines revenue (6%). In absolute terms, the investment was relatively high.

**Relatively small vaccine pipeline.** Pfizer has six R&D projects, targeting *C. difficile*, Group B streptococcus and *S. aureus* infections. During the period of analysis, it received three approvals for vaccine R&D projects targeting meningococcal and pneumococcal diseases. Two of its projects target diseases prioritised by WHO for vaccine R&D.

**Access provisions in place for one late-stage project.** Pfizer has at least one access provision in place for one of its four late-stage projects. Prior to receiving regulatory approval, it committed to applying for WHO prequalification for a four-dose presentation of its PCV (Prevenar 13®). The presentation was approved by the EMA in April 2016 and WHO prequalification was granted in July 2016.

#### Vaccine pipeline

Pfizer, along with Merck & Co., Inc., had the highest number of relevant market approvals during the period of analysis.



\*Since the period of analysis, the CTC claim on the single-dose vial of Prevenar 13® was withdrawn, as per request by the EMA, to ensure both vial presentations would have a harmonised label regarding CTC usage.

▶ WHO has identified a need for vaccine R&D targeting this disease/pathogen.

### PRICING & REGISTRATION

**Pricing strategy with one of the highest numbers of tiers.** Pfizer's pricing strategy includes six tiers. The lowest tier includes Gavi-eligible, Gavi-transitioning and any other LICs. Pfizer assesses affordability on the basis of Gross National Income per capita. Its prices are also influenced by the relevant government's commitment to immunisation, the degree of innovation the vaccine represents, and the required investments in the vaccine. Relative to its peers' commitments, Pfizer's pricing strategy is one of the most sensitive to each country's ability to pay, given the number of the tiers.

**New humanitarian commitment for Prevenar 13®.** Outside the period of analysis, Pfizer committed to providing its PCV to Gavi at USD 3.05, effective January 1st 2017, in the multi-dose vial presentation, and to specified NGOs for humanitarian emergencies. Pfizer has also committed to providing the Gavi price to Gavi-transitioning countries through 2025.

**Below average in transparency.** Similar to peers, Pfizer does not systematically publish all prices for its vaccines in all countries in scope. It publishes full details of its vaccine pricing policy.

Unlike all other peers, it states that price confidentiality provisions mitigate a major risk for governments and manufacturers: i.e., that discounted prices are used as reference prices by purchasers (e.g., another country) for whom it is neither intended nor appropriate.

**Average in registration filing.** Pfizer files to register the majority of its relevant vaccines in some of both LICs and lower-middle income countries.

### MANUFACTURING & SUPPLY

**Lacking commitments to ensure supply.** Pfizer's processes and strategies to align supply and demand are less comprehensive than other companies evaluated. It does not commit to staying in vaccine markets where there are few or no other suppliers, nor to communicating its plans externally when reducing or ceasing supply.

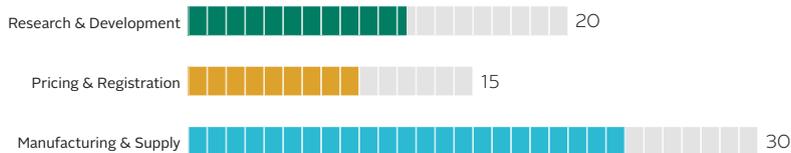
**Some activity in building manufacturing capacity in countries in scope.** Pfizer has a relatively small number of vaccine manufacturing capacity building activities. From 2015 to 2020, it is undertaking a technology transfer for the manufacture of its PCV (Prevenar 13®) to the Biovac Institute of South Africa.

**Below average in addressing local logistics needs.** Pfizer has adapted its PCV Prevenar 13® to overcome local barriers. If correctly refrigerated, the multi-dose vial can be used for 28 days after opening. The company does not adapt its products' package inserts or packaging to support rational use by health workers.

# Sanofi

Stock Exchange: XPAR  
 Ticker: SAN  
 HQ: Paris, France  
 Employees: 115,631

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained.

## PERFORMANCE

Sanofi's vaccine portfolio size, revenue, volume of doses sold, and geographic scope are among the largest of companies in scope. It markets the world's first dengue vaccine (Dengvaxia®). Overall, the company's performance in the Index is strong. It performs above average in Research & Development, with a relatively large pipeline. Sanofi's per-

formance is strong in all areas of Manufacturing & Supply. In Pricing & Registration, Sanofi is the leader in registration, with the majority of its relevant vaccines filed to be registered in 30-50% of countries in scope. It makes a general commitment to ensuring the prices of its vaccines are sustainable and equitable.

## SALES AND OPERATIONS

Sanofi consists of five business units: vaccines; diabetes and cardiovascular; general medicines and emerging markets; specialty care; and animal health. For its entire portfolio, Sanofi has sales in 96 countries in scope. About one-third of all sales are made in emerging markets. Sanofi Pasteur is the vaccines division of Sanofi, and includes the company's India-based affiliate Shantha Biotechnics. Sanofi Pasteur had a vaccines joint venture in Europe with Merck & Co., Inc. (Sanofi Pasteur MSD), which ceased operation at the end of 2016. The company will take its vaccine assets back in-house. It now has 38 marketed vaccines.

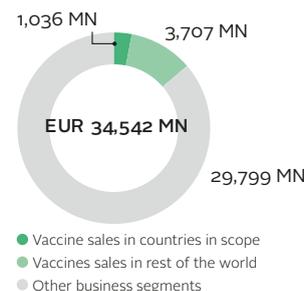
### Sales in countries in scope (all product types)



### Number of doses sold in 2015



### Sales by segment 2015



## VACCINE PORTFOLIO

Sanofi has 38 vaccines on the market for 18 diseases in scope, one of the largest portfolios of the companies measured. Its portfolio covers a wide range, including many vaccines recommended by the WHO for routine immunisation (e.g., for diphtheria, hepatitis B, Hib, pertussis, polio and tetanus).

### Marketed vaccines

Cholera	1	DTP	2	MMR	1	Typhoid	1
Dengue	1	DTP/IPV	3	Pneumococcal	1	Typhoid/HepA	1
DT	1	Hib	1	disease	1	Viral hepatitis	2
DTP/Hib/Hep	1	JE	1	Polio	3	Yellow fever	2
DTP/Hib/Hep/IPV	1	Measles	1	Rabies	1		
DTP/Hib/IPV	3	Meningococcal	5	Seasonal influenza	5		
DT/IPV	1	disease	3	Tetanus	1	<b>Total</b>	<b>38</b>

## OPPORTUNITIES

**Strengthen internal process for aligning supply and demand.** Sanofi can consider implementing some or all of the key strategies identified by the Index to further strengthen its internal process for aligning supply and demand. For example, it can commit to taking steps to ensure access to vaccines where they are needed in the event of a shortage.

**Define and publish a clear pricing strategy for vaccines.** Sanofi can define what its pricing strategy is for governments that do not procure vaccines through UNICEF, and ensure it takes these countries' ability to pay into account. It can also publish its pricing strategy for vaccines.

**Strengthen approach to access provisions for late-stage vaccine candidates.** Applying lessons learned from its dengue vaccine (Dengvaxia®),

Sanofi can consider the value of all its late-stage vaccine candidates to countries in scope and, as appropriate, develop plans to facilitate access to them in such countries. For those projects with at least one access provision in place, Sanofi can continue to strengthen and refine its access commitments and strategies to ensure the vaccines are made rapidly accessible upon approval.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

**Proportionally low R&D investments.** Sanofi invested USD 214.7 mn in vaccine R&D targeting diseases in scope in 2014 and 2015. As a proportion of its global vaccine revenue, this is relatively low (2%) compared to other companies in scope, but comparatively high in absolute terms.

**Relatively large vaccine pipeline.** Sanofi has 14 R&D projects, targeting at least 15 diseases in scope. Five of these diseases have been prioritised by WHO for vaccine R&D.

**Access provisions in place for over half of late-stage projects.** Sanofi has the second-largest number of late-stage projects with at least one access provision in place (6/10 or 60%). For example, it plans to apply for WHO prequalification for its vaccine candidates for meningitis and rabies.

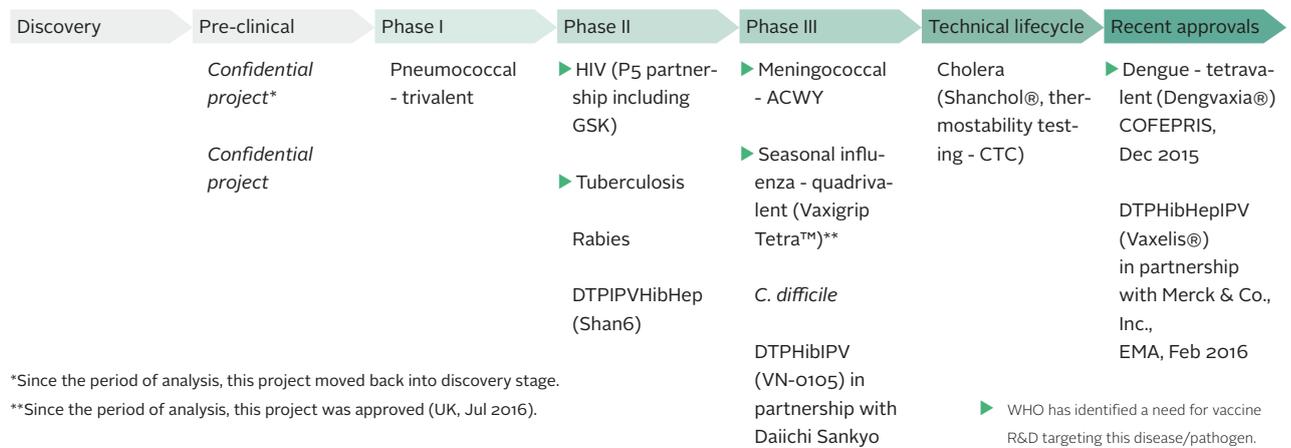
**Researching Micropellet technology.** Sanofi is developing technologies for vaccine delivery and packaging targeted at resource-limited set-

tings, for example by exploring Micropellet technologies for the development of thermostable vaccines. It is also collaborating on vaccine technology development for developing countries through the Global Health Vaccine Center of Innovation.

#### Vaccine pipeline

Sanofi has the second largest number of R&D projects nearing potential approval.

Since the period of analysis, Sanofi has a new discovery-stage project for a disease in scope.



### PRICING & REGISTRATION

**General pricing strategy.** Sanofi makes a general commitment to ensuring the prices of its vaccines are sustainable and equitable. It applies a tiered pricing approach to countries that procure its inactivated polio vaccine (IPV) in a 10-dose vial through UNICEF. For its other vaccines procured through UNICEF, Sanofi complies with the Most Favored Nation Clause, through which Sanofi agrees to give UNICEF the best terms it makes available to any other buyer. However, it is not clear how Sanofi prices vaccines for non-Gavi and non-PAHO countries that self-procure, or whether it takes these countries' ability to pay into account.

**Extension of Gavi prices to Gavi-transitioned countries.** Sanofi commits to offering Gavi-level pricing in its UNICEF tender to Gavi-transitioned countries until the end of 2018. This applies to its yellow fever (Stamaril®) and pentavalent (Shan5®) vaccines.

**Average transparency.** Similar to peers, Sanofi does not systematically publish all prices for its vaccines in all countries in scope. Sanofi publicly discloses its pricing policy for one relevant marketed vaccine (its IPV, Imovax®), but does not disclose a general pricing strategy, unlike leaders in this area. Like most of its peers, it states that

it does not include non-disclosure clauses on vaccine prices in its contracts with governments and other procurers.

**Leader in registration filing.** Sanofi files to register the majority of its relevant vaccines in 30-50% of the low-income countries (LICs) and lower middle-income countries in scope. As the company has a large vaccine portfolio, this applies to a relatively large number of vaccines. Sanofi also commits to seeking WHO prequalification of eligible vaccines to expedite access in LICs.

### MANUFACTURING & SUPPLY

**Strong in aligning supply and demand.** Sanofi demonstrates strong commitments and processes to align supply and demand, including clear processes for proactively engaging with purchasers. Internally, the company regularly reviews demand, has a clear process for escalating issues, and scales up production and/or real-locates stock when needed.

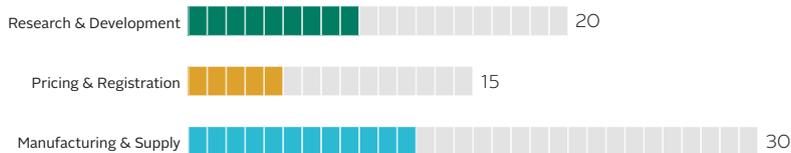
**Leader in building manufacturing capacity.** During the period of analysis, Sanofi had the highest number of vaccine manufacturing capacity building activities. It has undertaken long-term, manufacturing technology transfers in a range of countries in scope, including for several vaccines in Latin America.

**Leader in addressing local logistics needs.** Sanofi has presentations or packaging to help overcome local access challenges for approximately a quarter of its vaccines in scope. For example, to prevent waste, its inactivated polio vaccine (Imovax Polio®) can be used for 28 days once opened (if correctly refrigerated).

# Serum Institute of India Pvt. Ltd.

Stock exchange: privately held  
 Ticker: -  
 HQ: Pune, India  
 Employees: unknown

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained.

## PERFORMANCE

Serum Institute of India produces the largest volume of vaccines and has the largest geographic scope of companies evaluated, with a relatively large pipeline and medium-sized portfolio and revenue. Many of the vaccines it produces are for diseases recommended by WHO for routine immunisation for children. The company's high-volume, low-cost business model is clearly access-oriented. However, its approach

to providing access to vaccines is less transparent and less structured than other companies. For example, in Pricing & Registration, Serum Institute of India does not publish details of its vaccine pricing strategy. The company performs well in filing vaccines for registration in low- and middle-income countries. It falls in the middle of the pack in Research & Development, and below average in Manufacturing & Supply.

## SALES AND OPERATIONS

Serum Institute of India is a subsidiary of the Poonawalla Group, a privately held, family-owned business. Serum Institute of India's portfolio focuses on vaccines: it is one of the world's largest vaccine producers by number of doses. Its portfolio also includes products such as antitoxins and antivenoms, anemia and hormone treatments, and vitamin supplements. Its vaccines are sold in 84 countries in scope. In 2012, Serum Institute of India acquired Bilthoven Biologicals, a Dutch company producing several vaccines, including an IPV. Serum Institute of India now has 23 vaccines in its portfolio.

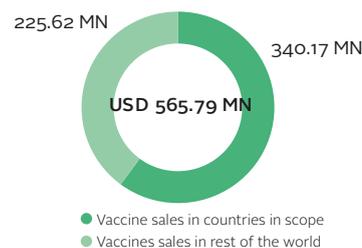
### Sales in countries in scope (vaccines)



### Number of doses sold in 2015



### Sales by segment 2015



## VACCINE PORTFOLIO

Serum Institute of India has 23 vaccines on the market for 14 diseases in scope. Its portfolio is diverse, including many vaccines recommended by WHO for routine immunisation (e.g., DTWP-containing combination vaccines, and vaccines for meningococcal A and polio).

### Marketed vaccines

DT	1	Meningococcal disease	1	Rubella	1
DTP	1	MMR	1	Seasonal influenza	1
DTPHep	1	MR	1	Td	1
DTPHib	1	Mumps	1	Tetanus	1
DTPHibHep	1	Pandemic influenza	1	Tuberculosis	1
Hib	1	Polio	3	Viral hepatitis	2
Measles	1	Rabies	1		
				<b>Total</b>	<b>23</b>

## OPPORTUNITIES

**Strengthen its processes for aligning supply and demand.** Serum Institute of India can develop – and share with stakeholders – clear and structured processes for aligning supply of their vaccines with global demand. Effective and transparent processes (including making information publicly available, where appropriate) will support stakeholders' planning and contribute to the sustainability of the company's business.

**Develop and publish a pricing strategy for vaccines.** Like peers, Serum Institute of India can publish what its pricing strategy is for Gavi and PAHO countries, as well as countries that procure through UNICEF. It can also specify its pricing policy for governments that self-procure, explicitly stating how it takes these countries' ability to pay into account and what other factors it considers when pricing its vaccines.

**Continue to engage in strong, adaptive R&D.** Serum Institute of India can continue to develop its strong and unique R&D model, which focuses on developing vaccines with characteristics aimed at improving access in low- and middle-income countries (LICs; MICs). This will help the long-term sustainability of its vaccine business.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

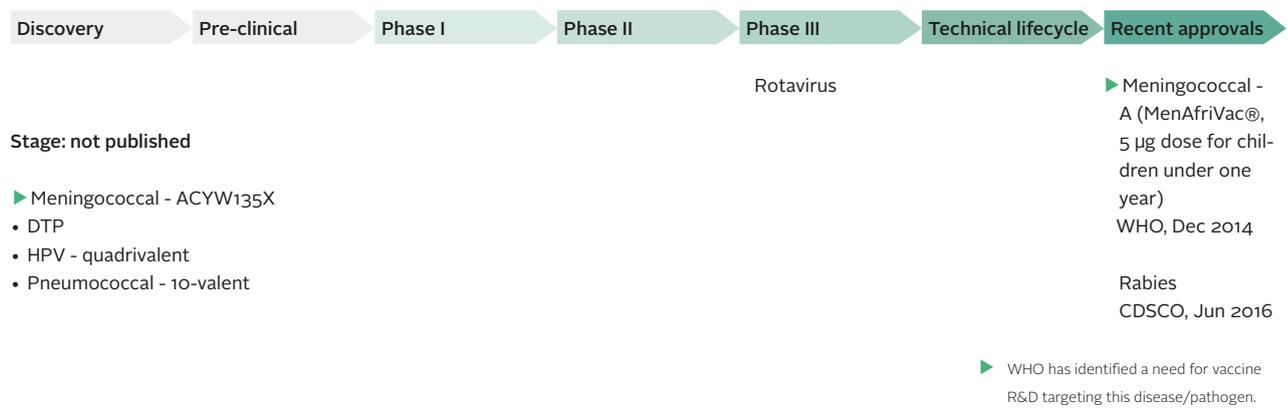
**Proportionally low R&D investments.** Compared to other companies measured, as a proportion of its global vaccines revenue, Serum Institute of India made relatively low investments in vaccine R&D targeting diseases in scope in 2014 and 2015.

**Relatively large vaccine pipeline.** Serum Institute of India has 12 R&D projects in its pipeline, as indicated by publicly available sources. Two of its projects target meningococcal disease, which is prioritised by WHO for vaccine R&D.

**Access provisions in place for half of late-stage projects.** For example, its meningococcal vaccine, MenAfriVac®, was developed in partnership with WHO and PATH with affordability in mind. The recently approved 5 µg dose was priced at USD 0.49 per dose in 2016. The total number of late-stage projects with at least one access provision in place is confidential.

#### Vaccine pipeline

Serum Institute of India has a relatively large pipeline compared to other companies evaluated. Data for this figure is based on public pipeline during the period of analysis ([www.seruminstitute.com/content/prod\\_pipe.htm](http://www.seruminstitute.com/content/prod_pipe.htm), accessed 28 April 2016), using additional public sources for recent approvals. Public sources also indicate Serum Institute of India has five additional vaccine R&D projects (not in figure): they target dengue, HPV, rotavirus, seasonal influenza and tuberculosis. Serum Institute of India has further, additional projects for which all data are confidential.



### PRICING & REGISTRATION

**General pricing strategy.** Serum Institute of India has a general policy of making vaccines available at affordable prices and has shown evidence of proactively taking steps to ensure affordable prices in LICs and MICs. Its meningococcal A vaccine (MenAfriVac®), developed for African markets by the Meningitis Vaccine Project, is offered at USD 0.64 per dose. Serum Institute of India intends to sell its pneumococcal vaccine for USD 2 per dose to Gavi countries, if and when it is approved. While Serum Institute of India has received support from partners for

both vaccines, the company is an integral contributor, ensuring the supply of these vaccines.

**Pricing strategy not published.** Like its peers, Serum Institute of India does not systematically publish all prices for its vaccines in all countries in scope. Unlike its peers, however, it does not publish even a general pricing strategy for vaccines. The company's stance on price confidentiality provisions is confidential.

**Above-average performance in filing for registration.** Serum Institute of India files to register the majority (>50%) of its relevant vaccines in 30-50% of LICs and some lower-middle income countries. Serum Institute of India has a large vaccine portfolio, so this is a relatively good performance. The company's policy is to file to register vaccines wherever there is market potential, whether that entails supplying vaccines directly to governments, private parties or through UN agencies.

### MANUFACTURING & SUPPLY

**Strong commitments but processes to align supply and demand appear less structured.** Serum Institute of India states that it commits to staying in vaccine markets in which there are few other suppliers. However, it is unclear whether the company has strong processes to support ongoing alignment of supply and demand.

**Builds manufacturing capacity through the Developing Countries Vaccine Manufacturers Network (DCVMN).** Serum Institute of India is a member of the DCVMN, an alliance of 50 manufacturers that supports capacity building through information and expertise sharing among its members.

**Some vaccine presentations support access.** Some of Serum Institute of India's vaccine presentations help address local access barriers. For more than two-thirds of its vaccines, it provides several dosage options. These options help to support purchasing decisions based on local needs.

# Daiichi Sankyo Co., Ltd.

Stock Exchange: XTKS  
 Ticker: 4568  
 HQ: Tokyo, Japan  
 Employees: 15,249

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained. Daiichi Sankyo was evaluated in one Research Area: Research & Development.

## PERFORMANCE

Daiichi Sankyo's vaccine business is currently focused on the Japanese market, and there is evidence it is increasing its focus on vaccine R&D. Its pipeline includes combination vaccines for diseases recommended by WHO for routine immunisation for children. Daiichi Sankyo performs below average in Research & Development, with a relatively small pipeline and no access plans in place for late-stage projects. Daiichi Sankyo currently markets vaccines only in Japan, and not in coun-

tries in scope. It states that it has processes for preventing vaccine shortages, including coordinating supply plans with stakeholders and scaling up production capacity. The company is partnering with the Japan International Cooperation Agency (JICA) to build the vaccine manufacturing capacity of POLYVAC in Vietnam. It is part-way through a five-year project to provide technical cooperation for the production of a measles and rubella combination vaccine (started in 2013).

## SALES AND OPERATIONS

Daiichi Sankyo has four business units: innovative pharmaceuticals; generics; vaccines; and over-the-counter medicines. For its entire portfolio, Daiichi Sankyo has sales in 44 countries in scope of the Index. Its vaccines business unit comprises Kitasato Daiichi Sankyo Vaccine Co., Ltd., which is responsible for R&D, production and sales, and Japan Vaccine Co., Ltd. (a joint venture with GSK), which conducts late-phase clinical development and sales. Daiichi Sankyo has 11 marketed vaccines.

### Sales in countries in scope (all product types)



### Sales by segment 2015



### Number of doses sold in 2015



## VACCINES PORTFOLIO

Daiichi Sankyo has 11 vaccines on the market for nine diseases in scope. Its portfolio focuses on traditional childhood vaccines, including for diphtheria, tetanus, pertussis, measles, mumps and rubella (including four combination vaccines). It also has a seasonal influenza vaccine and two pandemic influenza vaccines.

### Marketed vaccines

DT	1	Pandemic influenza	2
DTP	1	Rubella	1
DTPIPV	1	Seasonal influenza	1
Measles	1	Tetanus	1
MR	1		
Mumps	1	<b>Total</b>	<b>11</b>

## OPPORTUNITIES

**Continue strong investments in R&D.** As the company's vaccine business grows, Daiichi Sankyo can continue to make vaccine R&D investments that represent a high proportion of its vaccine revenue in vaccine R&D. This will help the long-term sustainability of its vaccine business.

**Expand manufacturing capacity building activities.** Daiichi Sankyo can build on its experience in providing technical cooperation, for example to POLYVAC in Vietnam, to undertake further vaccine manufacturing capacity building activities with manufacturers in other countries in scope of the Index.

**Direct efforts towards product attributes that address key barriers to access.** As its discovery-stage projects progress, factors such as cost of production, dose schedule, dose presentation and temperature stability need to be considered to address barriers to access. This process can be facilitated by working with external stakeholders to identify what product attributes are most desirable to address population needs, balanced with technical considerations.

**Make investigational vaccines, if approved, accessible in countries in scope.** This involves making commitments and developing strategies as early in development as possible to ensure vaccines are accessible, once on the market.

Aligning these plans with those of vaccine procurers and other stakeholders will help ensure the company meets access needs, and provide it with greater predictability regarding the future market for these vaccines.

**Expand processes for responding to vaccine shortages.** As Daiichi Sankyo expands its vaccines business beyond Japan, it can work with relevant national and global health stakeholders to help expand and adapt its current processes for preventing and responding to vaccine shortages. A structured and predictable process will support the company's engagement with national and global health stakeholders and help ensure sustainability.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

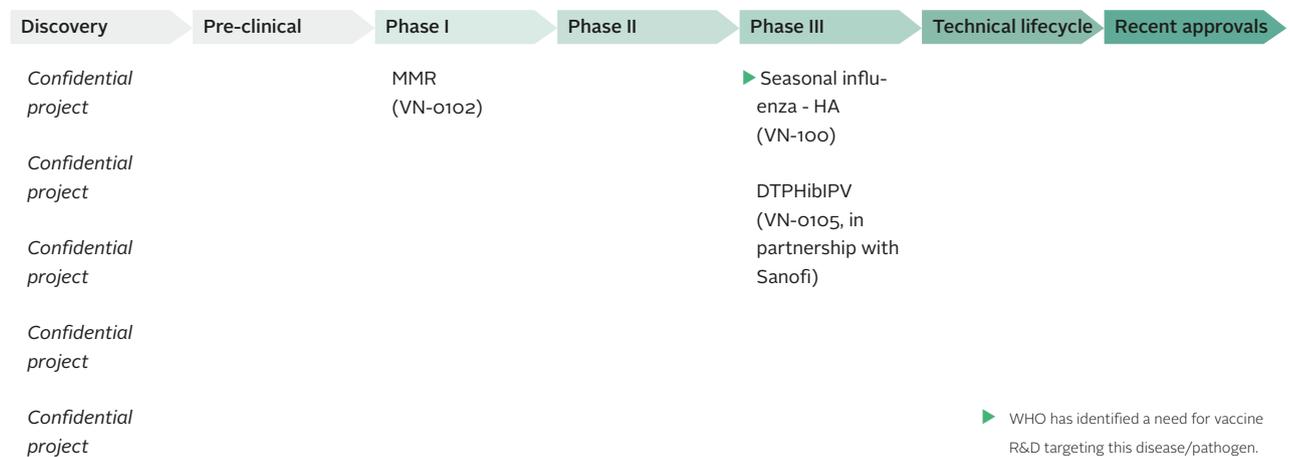
**Proportionally high R&D investments.** As a proportion of its global vaccine revenue, Daiichi Sankyo made relatively high investments into vaccine R&D targeting diseases in scope in 2014 and 2015, compared to other companies in scope.

**Relatively small vaccine pipeline.** Daiichi Sankyo has eight R&D projects, including a vaccine candidate for seasonal influenza: influenza is prioritised by WHO for vaccine R&D. It also has two combination vaccine candidates (DTPHiBPV and MMR).

**No evidence of access provisions.** Daiichi Sankyo does not provide evidence that it has access provisions for its two late-stage R&D projects.

### Vaccine pipeline

Daiichi Sankyo has the largest number of discovery-stage vaccine R&D projects among companies evaluated.



# Takeda Pharmaceutical Co., Ltd.

Stock Exchange: XTKS  
 Ticker: 4502  
 HQ: Osaka, Japan  
 Employees: 31,168 (consolidated)

## Index performance by Research Area



The number of cells represents the maximum possible score. Coloured cells represent points attained. Takeda was evaluated in one Research Area: Research & Development.

## PERFORMANCE

Takeda currently markets vaccines in Japan only and is growing its vaccine pipeline, including R&D projects for dengue and chikungunya (both neglected tropical diseases). Takeda performs above average in Research & Development, and has clear access provisions for its late-stage vaccine candidate. While it does not currently market vaccines in countries in scope, it is taking steps to support affordability and supply of vaccines in its pipeline. For example, from 2016, Takeda has been developing a low-cost IPV with support from the Bill & Melinda Gates Foundation. As part of the worldwide

polio eradication strategy, Takeda will produce at least 50 million IPV doses per year for supply to more than 70 developing countries. For this vaccine, Takeda is committed to a ceiling price for Gavi countries through UNICEF, and intends to extend Gavi-level prices to Gavi transitioning countries for a number of years post-transition. Pricing for non-Gavi-eligible countries will take into account (among other criteria) the cost of goods, country GDP per capita, procurement conditions, terms and impact of competition.

## SALES AND OPERATIONS

Takeda's three business segments are ethical drugs (including vaccines); consumer health care; and other (including industrial chemicals). The ethical drugs division accounts for the largest share of revenue (around 90%). For its entire portfolio, Takeda has sales in 29 countries in scope of the Index. Its vaccines business unit currently markets seven vaccines in Japan only.

### Sales in countries in scope (all product types)



### Number of doses sold in 2015



### Sales by segment 2015



## VACCINE PORTFOLIO

Takeda has seven vaccines on the market for six diseases in scope. Its portfolio comprises a diphtheria and tetanus combination vaccine, a tetanus vaccine, vaccines for measles, mumps and rubella including a MR combination vaccine, and a pandemic influenza vaccine.

### Marketed vaccines

DT	1	Rubella	1
Measles	1	Tetanus	1
MR	1		
Mumps	1		
Pandemic influenza	1	<b>Total</b>	<b>7</b>

## OPPORTUNITIES

**Continue to make strong investments in R&D.** As its vaccine business grows, Takeda can continue to make R&D investments that represent a high proportion of its vaccine revenue.

**Expand processes to respond to vaccine shortages.** Takeda is taking steps to support sufficient vaccine supply. As it expands its vaccine business outside Japan, it can work with relevant national and global health stakeholders to expand and adapt its processes for preventing and responding to vaccine shortages. It can also commit to continuing supply of vaccines outside Japan for which there are few or no other suppliers.

**Aim toward product attributes that meet needs of populations in scope.** Takeda should continue its efforts to identify what product attributes are most desirable for addressing population needs. Expanding on its commitment to develop multi-dose vials of certain vaccine candidates in response to WHO recommendations, Takeda can consider factors such as dose schedule and temperature stability for all its vaccine R&D.

**Continue to share expertise with local manufacturers.** As demonstrated by its partnership for chikungunya vaccine development in India, Takeda has valuable expertise that it can share

with vaccine manufacturers and developers in countries in scope. In that way, it can contribute to improving global vaccine manufacturing expertise and supply. In assessing capacity building opportunities, the company should consider how it could draw upon its expertise to assess and respond to local capacity building needs.

**Put pricing strategies in place for new vaccines.** Takeda is researching affordability for its future vaccines for chikungunya, dengue and enterovirus 71, and should strive to ensure that these future vaccines are affordable for both Gavi and non-Gavi low-and middle-income countries.

## RESEARCH AREAS

### RESEARCH & DEVELOPMENT

**Proportionally high R&D investments.** As a proportion of its global vaccine revenue, Takeda made relatively high investments into vaccine R&D targeting diseases in scope in 2014 and 2015, compared to other companies in scope.

**Relatively small vaccine pipeline.** Takeda has four R&D projects. It is working to develop vaccines against chikungunya, dengue, enterovirus 71 and polio. Dengue is prioritised by WHO for vaccine R&D.

**Access provisions in place for late-stage project.** Takeda intends to seek WHO prequalification for TAK-003, its phase III live-attenuated tetravalent dengue vaccine candidate. Takeda will prioritise registration in countries where clinical trials have taken place and in countries with the highest medical needs.

#### Vaccine pipeline

Takeda's live-attenuated tetravalent dengue vaccine candidate, TAK-003, is approaching potential regulatory approval.



▶ WHO has identified a need for vaccine R&D targeting this disease/pathogen.