GlaxoSmithKline plc

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.

SALES AND OPERATIONS

GSK operates through three divisions: pharmaceuticals; vaccines; and consumer healthcare. 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.

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).
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 low- and middle-income countries, 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 low- and middle-income countries, 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 middle-income countries.

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.

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

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.

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Technical lifecycle</th>
<th>Recent approvals</th>
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<tbody>
<tr>
<td></td>
<td>Dengue - tetravalent</td>
<td>RSV (paediatric)</td>
<td>HIV (P5 partnership including SanoFil)</td>
<td>Malaria (Mosquirix®)</td>
<td>Pneumococcal (Synflow®, cold storage stability testing)</td>
<td>Pneumococcal (Synflow®, four-dose vial)</td>
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<td></td>
<td>Group B streptococcus - pentavalent</td>
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<td>Malaria (next generation)</td>
<td>Pandemic influenza - pre-pandemic</td>
<td>Pneumococcal (Synflow®, thermostability testing - CTC)</td>
<td>Rabies (Rabipur®, dose scheduling)</td>
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<td></td>
<td>Malaria (Mosquirix®, thermostable)</td>
<td>Shigellosis - quadrivalent</td>
<td>Meningococcal - ABCWY</td>
<td>Seasonal influenza - quadrivalent</td>
<td>Varicella</td>
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<td></td>
<td>Shigellosis - monovalent</td>
<td>Typhoid - bivalent</td>
<td>Tuberculosis</td>
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<td>Typhoid - S. enterica serovar Typhi</td>
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<td>Ebola virus</td>
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<td>WHO has identified a need for vaccine R&amp;D targeting this disease/pathogen</td>
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<td></td>
<td>Viral hepatitis - C</td>
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<td>Pneumococcal</td>
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**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 low-income countries (LICs).** GSK files the majority of its relevant vaccines for registration in some lower middle-income countries (LMICs), 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.