Serum Institute of India Pvt. Ltd.

**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 anti-toxins 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.

**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).

**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, 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.