

## India's first swine flu Vaccine developer

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*Pune-based Serum Institute of India has consolidated its #1 position in the country for the fifth year in a row.*



Serum Institute of India clocked a total sales revenue of Rs 1,114 crore for FY 2008-09 as against Rs 987 crore for FY 2007-08. Serum's products have been supplied to international health agencies like the WHO, UNICEF and PAHO and to over 140 countries across the globe. Its vaccines are being used in the National Immunization Program's of several countries. Measles and rubella virus vaccine is being used in catch-up and mop-up campaigns in several countries in their quest to control the incidence of measles and rubella.

Serum Institute has the capacity to produce over 10 crore doses of vaccines. Serum Institute supplies new age vaccine to Global Alliance for Vaccines and Immunization (GAVI), Pan American Health Organization (PAHO) and UNICEF. Serum Institute is one of the manufacturers of Hib vaccine in India and is given to infants along with DPT or alone. Earlier efforts by UNICEF for Hib immunization met with little success as the prices were very high, which led to limited access of the vaccine in many poor countries. Serum Institute supplies the Hib vaccine at a low price compared to the MNC prices. The vaccine is available under the brand name, SiiHIB Pro.

From its inception, Serum Institute stressed upon R&D as an important focus area. It has invested significantly in R&D and these efforts are yielding results. Established in 1977, as a distinctly separate autonomous body, Serum Institute of India Research Foundation works with an objective of enhancing research in the fields of medical sciences and in natural and applied sciences. The foundation has several outstanding achievements to its credit; the document, information support for immunization programme in India, referred to by health planners of the Government of India while formulating the seventh Five-Year Plan, was researched and compiled by the foundation in 1984 and again in 1989. This was a computerized demographic study with 44 variables. Other notable successes were, pilot production of measles vaccine on human diploid cells; industrial column chromatography and affinity chromatography for separation of immunoglobulins; monitoring of quality of vaccines in the field; clinical trials of new products; clinical trial of human diploid cell rabies vaccine in laboratory workers.

Serum has several milestone achievements to its credit. It went into a partnership with Syracuse University (SU) and has awarded \$250,000 to a team of SU researchers led by Robert Doyle, assistant professor of chemistry in the College of Arts and Sciences, to develop new oral vaccines against tetanus and rotavirus, a severe form of diarrhea that affects infants and young children worldwide. Serum was also recently commissioned by WHO to develop a vaccine against latest strain of H1N1 flu virus. This development makes Serum one of the select few organizations in the world to have been commissioned to develop the vaccine by WHO. Vaccines against the H1N1 virus already exists, but, they are unlikely to be effective against the latest strain of the virus, which has already claimed many lives in the US and Mexico and has already hit India. Its scientists are working on developing the vaccine against the new strain of the deadly H1N1 influenza virus. Dr SD Ravetkar, senior director, Serum Institute of India, said, "The number of vaccine doses will depend on WHO's needs and we will build our facility accordingly. They have not given any numbers as such and we are in the process of developing the vaccine."

Serum is also on the verge of launching its meningitis vaccine. The company has invested about Rs 80 crore on this project. Dr Cyrus S Poonawalla, chairman and founder, Serum Institute of India, said, "This will be a landmark initiative for us because this is another vaccine which we are doing in collaboration with PATH, an international, nonprofit organization, especially for African countries and Haj tourists. We will be the only company in the country for years to come, with such a vaccine."

The company now also has a focus on products beyond the vaccines. "We have ventured a little late into biopharmaceutical market and technology development took some time but as usual we will be able to adjust to the heavily competitive pricing. We are looking at some novel and innovative ways to develop biopharma drugs, the initiative was rolled out three years ago. The company is working on novel vaccines and also on Novel Drug Delivery System (NDDS) initiatives. This is a very niche area and the initial results that we have been getting for these vaccines are quite encouraging," said Dr Ravetkar. At present several other vaccines are under development like the rotavirus vaccines and monoclonal antibodies for rabies.

Serum Institute has also got an approval from the US FDA for its oncology facility, the construction of which started in 2006 and would be fully commissioned in a few months time. A world-class facility for its pentavalent vaccines has also been developed.

Towards the end of 2008, Serum had hiked its holding in Panacea Biotec on October 14, 2008 through bulk deal at Rs 220 per share. Part of this equity stake was bought from South Korean asset management firm, Mirae. Serum Institute of India now has close to seven percent stake in the Delhi-based Panacea Biotec. This deal is significant as Serum Institute and Panacea are the top two Indian firms in the vaccine business.

Serum Institute of India has also set up Serum Bio Pharma Park, India's first biotech special economic zone (SEZ). This was inaugurated in 2006. The park is adjoining Serum Institute's existing manufacturing unit and is a sector-specific SEZ meant for biotechnology and pharmaceutical products. The SEZ will allow Serum Institute of India to avail various tax benefits such as income tax and import duty on capital goods. This has encouraged a lot of foreign companies to partner with Serum Institute of India to avail and share these benefits. The SEZ is located on 55 acres of area in Hadapsar, Pune. Serum Institute will have 5-6 units in the SEZ.

The project is due to be completed by 2012-13 and Serum is investing close to Rs 1,200 crore on the project. This investments have been divided in various phases. The phase-I investment will be a minimum of Rs 500 crore. Serum Biopharma Park as developers would raise funds through internal accruals of the company as well as external borrowings from financial institutions. About 100 crore doses of various vaccines are expected to be produced on an annual basis from this special economic zone. The new zone would manufacture vaccines for pneumonia, rotavirus and combination vaccines for meningitis, influenza and Hib. Oncological products for the US and EU markets are also expected to be manufactured at the new facility. The premises have already been prequalified by WHO.

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