

## Vaccine King

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*With a record sales of Rs 950.95 crore in 2006-07, Serum Institute of India continues to be a leader in the vaccines market.*

Business: Manufacturing and marketing of vaccines and immuno-biologicals

CEO: Dr C S Poonawalla (CMD)

Biotech Revenue: Rs 950.95 crore

Start-up Year: 1966

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Amidst stiff competition in vaccines market, Serum Institute of India Ltd continued its leadership position in the vaccines business with a record sales of Rs 950.95 crore in 2006-07 registering a growth of 35 percent over the previous year's sales revenue of 703 crore. Over 80 percent of its sales are from overseas market with little from the Indian market. Serum Institute supplies vaccines to more than 130 countries across the world and it leads in MMR and Hep B vaccines in India. Its subsidiary company, Serum International, generated Rs 42 crore in 2006-07 against the previous year's sales of Rs 36 crore, registering a growth of over 16 percent. With this, the group turnover of Serum Institute has touched Rs 992.95 crore for 2006-07.

During 2005-06, Serum Institute registered a growth of 39.21 percent against the previous year's meager growth of 2.85 percent. The exports turnover in 2005-06 was Rs 550 crore. During 2004-05, Serum Institute of India's sales touched Rs 505 crore as against last year's sales of Rs 491 crore.

Serum Institute of India has taken many initiatives during 2006-07. It launched its indigenously developed HIB vaccine. It has a capacity to produce over 100 million doses of the vaccine. Serum Institute will supply this new age vaccine to GAVI (Global Alliance for Vaccines and Immunization), PAHO (Pan American Health Organization) and UNICEF. Dr Cyrus Poonawalla, chairman and managing director, Serum Institute of India, said, "With HIB vaccine, Serum Institute achieves one more milestone in its quest for providing high quality vaccines at affordable prices. Serum Institute is the only indigenous manufacturer of HIB vaccine in India today unlike other vaccine manufacturers who import the bulk. HIB vaccine is fully manufactured in India. Serum Institute has invested significantly in R&D and these efforts are yielding results."

Serum Institute will supply the HIB vaccine at a low price compared to the MNC prices. It has established its credentials by providing quality vaccines to global healthcare agencies, thereby reducing mortality rates due to diseases like measles. The vaccine will also be available as SiiHIB Pro.

Besides launching HIB vaccine, it picked up a 14 percent stake in Lipoxen PLC, a biopharmaceutical company specializing in the development of differentiated biologicals, vaccines and oncology drugs. Lipoxen has raised \$5 million in new funds from the Serum Institute of India through a subscription agreement and associated warrant agreement. "We are excited about our strategic investment in Lipoxen and feel their technology is a key component to our strategy to create high value differentiated biologics and vaccines. Our investment and increased strategic collaboration was prompted by Serum's desire to become a large contributor in the biopharmaceutical world and by the very positive preliminary scientific data," Dr Poonawalla said.

Serum Institute has entered into another agreement with Akorn of USA for definitive development and exclusive distribution rights for rabies monoclonal antibody. The term of the agreement is ten years following the first commercial sale of products. As part of the agreement, Serum has agreed to appoint Akorn as the exclusive distributor for rabies monoclonal antibody. In exchange for Akorn receiving exclusive marketing and distribution rights to North, Central, and South America, Akorn has agreed to help fund product development through milestone payments. These milestone payments include the successful completion of Phase I, Phase II, and Phase III clinical trials leading to eventual receipt of CBER approval for a BLA license. BLA approval is targeted to occur in 2012 and Akorn expects to fund these milestone payments with cash flow provided from operations. Serum also granted Akorn the first option right to obtain exclusive marketing rights in North, Central, and South America for a second monoclonal antibody product, Anti-D human monoclonal antibody. Additionally, Serum has granted Akorn the first option right to expand the territory to include Europe in exchange for annual product sales requirements in Europe.

Serum Institute is also involved in supporting the development of vaccine critically needed in poorest countries like Africa. It was involved in the Meningitis Vaccine Project (MVP), a partnership between the World Health Organization (WHO) and Seattle-based non-profit, PATH, and has completed the Phase I clinical trial of a new conjugate vaccine against serogroup. The Serum Institute and MVP will now proceed to test the vaccine in Africa where the new vaccine will become part of the public health arsenal. Since the vaccine will be licensed in India, it could also be used in this country, where small outbreaks of serogroup A meningococcal disease occur sporadically. The underlying technology for the new conjugate vaccine was developed by the Centre for Biologics Evaluation and Research of the USFDA. Dr Cyrus Poonawalla said, "We believe in health for all and in reaching out to the poorest countries in the remotest places."

Since its inception, Serum Institute has placed great reliance on its R&D function. The generous investment in men, machines and materials yielded rich returns. A distinctly separate autonomous body, Serum Institute of India Research

Foundation, was instituted in 1977 with a focus on research in the fields of medical sciences and in natural and applied sciences. The success story of the Foundation includes the 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.

Now its endeavor is to improve the health of world's children by preventing diseases through immunization. In this regard it has under taken many R&D initiatives such as development of better adjuvants, heat stable vaccines, DNA rabies vaccines, conjugate vaccines. Besides it has other products in the pipeline like tetravalent DTP- Hib combination vaccine, pentavalent combination vaccine (DTP-HB-Hib) which is the most sought after by GAVI, UNICEF, WHO and World Bank, Lyophilized HDC vaccine, meningococcal A conjugate vaccine and percutaneous BCG vaccine for superficial bladder cancer.

Serum Institute has set up the country's first biotech SEZ under the name Serum Bio Pharma Park in Pune during early 2006. The entire project will be completed in phases by 2010 at an estimated cost of Rs 1,200 crore. In the Phase I, it will invest a minimum of Rs 500 crore. About one billion doses of various vaccines are expected to be produced on an annual basis from this SEZ.