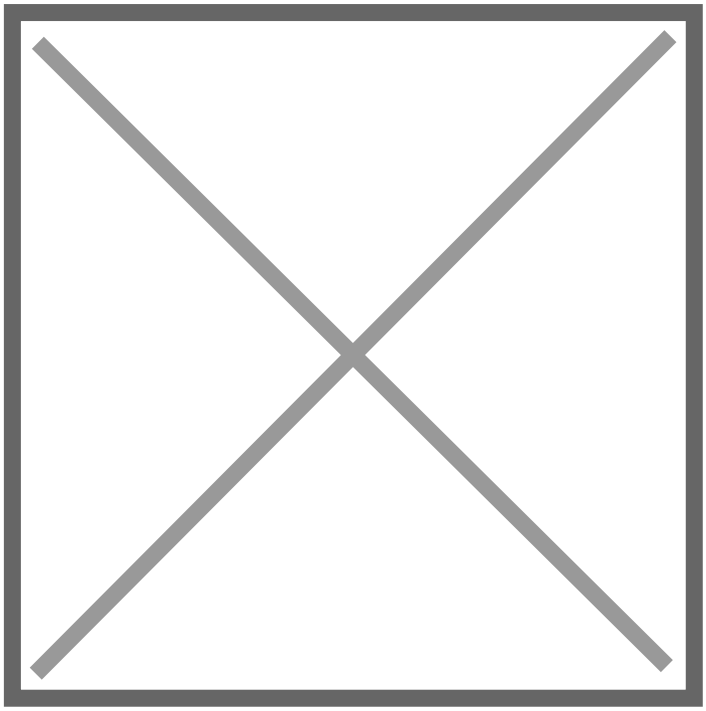
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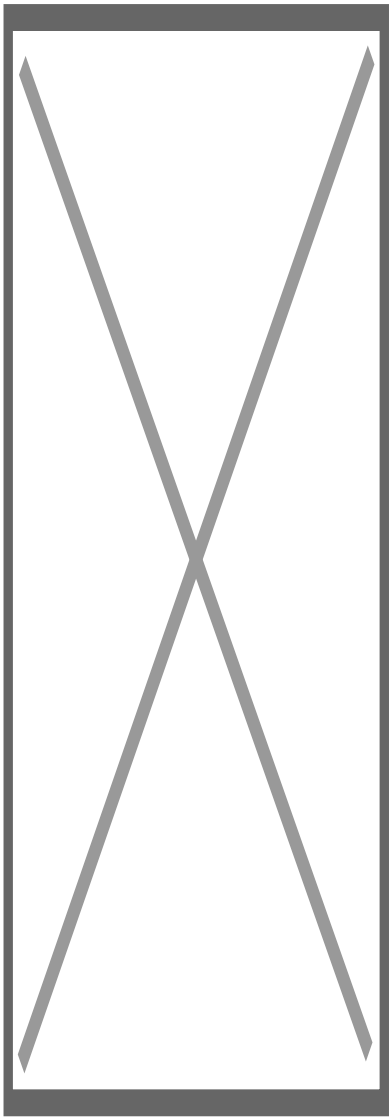
Serum Institute of India

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Rank 1

Serum Institute of India



Reaping rich dividends

After leading the race in MMR and Hep B vaccines in India, Serum Institute is now the largest manufacturer of measles and DTP vaccines in the world.

India's largest vaccine manufacturer, Serum Institute of India, clocked a total sales revenue of 987 crore for fiscal 2007-2008. The previous year's sales were Rs 950.95 crore and had a registered growth of 35 percent. Based in Pune, Serum has established a global presence in the vaccine market and exports its products to 140 countries. Leading the race in MMR and Hep B vaccines in India, Serum Institute of India has also been lauded for coming up with vaccine products in the country at affordable prices.

The company achieved many milestones in 2007-2008. In 2007, it announced the launch of its indigenously manufactured low-cost Haemophilus influenza type b conjugate vaccine under the brand name of HibPRO in India. HibPRO has been priced at Rs 375 for a monodose vial. HibPRO is a vaccine with clinically proven efficacy and safety at an affordable price. According to Dr Cyrus Poonawalla, "HibPRO has undergone series of clinical trials to prove its efficacy and safety in comparison with commercially available Hib conjugate vaccines. With the launch of HibPRO, Serum can extend the benefits of pentavalent or quadravalent vaccines at a very affordable price. These benefits are mainly fewer numbers of injections, lesser pain to the child and protection against multiple diseases such as H. influenza type b, Hepatitis-B, Diphtheria, Pertussis and Tetanus in one injection."

In the past, Serum's products have been supplied to international health agencies like the WHO, UNICEF, PAHO and also to over 140 countries across the globe. Its vaccines are being used in the national immunization programs of several countries.

The MR vaccine is being used in catch-up and mop-up campaigns of several countries in their quest to control the incidence of measles and rubella. One of them is the HIB vaccine launched in March 2007. Serum Institute has a capacity to produce over 100 million doses of the vaccine. The company supplies this new age vaccine to GAVI (Global Alliance for Vaccines and Immunization), PAHO (Pan American Health Organization) and UNICEF. Dr Poonawalla, informed, "Serum Institute is the only indigenous manufacturers of HIB vaccine in India today unlike other vaccine manufacturers who import the bulk. HIB vaccine is fully manufactured in India." The company 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 has placed great reliance on its R&D function. Established in 1977 as a distinctly separate autonomous body, the main objective of Serum Institute of India Research Foundation is to conduct 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 the health planners of the government while formulating the seventh Five-Year Plan, was researched and compiled by the Foundation in the year 1984 and again in 1989. This was a computerized demographic study with 44 variables. Other notable successes include 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 Institute of India has set up Serum BioPharma Park, India's first biotech Special Economic Zone (SEZ) and developments on this project are still in the process. 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 will be spread across 55 acres in Hadapsar, Pune. Serum Institute will have 5-6 units in the SEZ. The project is expected to be completed by 2010. An investment of Rs 1,200 crore by Serum has been made for the purpose. This investment has been divided in various phases The phase I investment will be a minimum of Rs 500 crore for Serum BioPharma Park as developers would raise funds through internal accruals of the company as well as external borrowings from financial institutions. "The SEZ, which has currently been allocated 55 acres of notified land in phase I would, based on availabilities and opportunities, be gradually expanded to 250 acres. The SEZ will stimulate economic activities by offering larger employment opportunities, attract substantial investments for export production and render services abroad to earn more foreign exchange", Dr Poonawalla hinted.

"India could be derecognized by WHO if NRA is not improved by October"

-- Dr Cyrus S Poonawalla, chairman, Serum Institute of India

The Indian vaccines industry is passing through a major crisis, says Dr Cyrus S Poonawala, chairman, Serum Institute of India, the largest vaccines manufacturer in the country and a leading global supplier of vaccines. Dr Poonawalla points out the crisis has reached critical levels and vaccine and biologicals industry could collapse, if the NRA issue is not resolved at the policy level before this October. It's time to act and act fast. Excerpts from an exclusive interview:

What is the status of the vaccines availability in the country?

First of all, I must clarify that there is a false impression being created that there is a vaccine shortage and consequently the price hike of basic vaccines because of the fallout of the public sector undertakings shut down by the Government of India under the strong advice of WHO who found on repeated inspections that there was a total breach of GMP by the public sector undertakings. I strongly feel that the substandard manufacturing facilities have been very rightly shut down. For the health ministry, there is no other alternative. Therefore it is very unfair to say that this was done to help the private sector. In fact, it is the other way round. The health ministry's procurement department is trying to squeeze the private sector to supply vaccines at the same level of cost and price as the public sector was doing which is impossible. Though as a gesture, the Serum Institute of India and all other private vaccine key players have agreed to do this for the current year at a cost, the health ministry must realize that if they insist on private sector supplying vaccines with their high GMP standards and in compliance with the WHO guidelines, then we will also fall sick like the public sector undertakings because of the cost of upgradation, R&D, high QA and QC requirements that have to be maintained. So there should be a re-look on the procurement policy of the Government of India which is the root cause of all the trouble of not having sufficient vaccines on time for the program. For example, months after the tenders are thrown open and bids are received, the procurement department and the health ministry won't release orders in time and then at the eleventh hour they want the vaccines to be supplied which is not possible.

It is internationally a known fact that vaccines need at least a gestation period of six to nine months for bulk preparation and formulation, QC testing and reassessing by the National Control Laboratory. This is an area which can be easily streamlined if the vaccine industry is supported.

The BCG Vaccine Laboratory has slammed the government for shutting down the institute ...

The allegations made by the BCG Vaccine Laboratory, Guindy, that the institute was closed down because of the vested interests and private sector is totally baseless and it is entirely documented fact that they were not following good manufacturing practices. These units that are shut down can be fruitfully run without any disruption or loss of jobs to the employees who are well trained and could be utilized for test analysis, QA release and may be some R&D activities.

What are some of the major challenges engulfing the vaccines industry in India?

The main challenge of the private industry is to continue the supply affordable vaccines and especially the newer vaccines like the DPT-Hepatitis B combination vaccines, MMR vaccines and later on the 5-in-1 pentavalent vaccines. But this will all be possible when the health ministry also releases the requirements and forecasts like the UNICEF does for a three-year period. The health ministry has become totally unaccountable for its performance both at the procurement stage and implementation of the program.

For e.g., the immunization level in Africa and other countries like Bangladesh and Sri Lanka is much higher than in India and this is a pity because India is now a global hub for low cost vaccines. A classic example is Hepatitis B vaccine, it is available in abundance but there is very little procurement till date. The only correct decision the health ministry has taken till date is that they have rightly decided to discontinue the manufacture of vaccines in the public sector which was totally in breach of the national and international GMP norms. However, the policy for encouraging procurement and making available the vaccines at the lowest cost is pitiable.