

## "There should a reciprocal flow of vaccines amongst the countries in the Asia-Pacific region,"

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

Pune-based Serum Institute of India topped the list of "Top 20 Biotech Companies" in the 4th BioSpectrum-ABLE Survey of the Biotech Industry 2005-06 with total revenues of Rs 703 crore, edging past Biocon, the leader for the last three years. In an exclusive interview to N Suresh and Narayan Kulkarni, Dr Cyrus S Poonawalla, chairman, Serum Institute of India, shares his feelings on this development and the company's future course of action.

**What was your first reaction when you learnt that Serum Institute of India topped the "BioSpectrum-ABLE Survey, 2005-06" as India's top biotech company?**

It was a pleasant surprise! I was expecting this to happen in 2006-07, but my immediate reaction was to play down the success and that is why we didn't make too much hype out of this very exciting news.

**Serum Institute has been in the business for over three decades, yet this is the first time that it has been recognized as India's numero uno biotech company in India through a comprehensive survey. How did your staff and stakeholders take this news?**

As the stakeholders are my family members, there is not much excitement for them. But for the staff members, it definitely is a major morale booster. I, suppose, this would also help us in attracting good, skilled, trained and committed scientists and retaining the best talents, which is a major problem in the biotechnology industry in India.

**How did your customers, who are spread across the world, react to this development?**

No, it doesn't make much difference to our customers. Most of the vaccines, which we are related to, are sold to the government agencies-be it in India or globally. These government bodies are not concerned about corporate rankings. The United Nations (UN) agencies have already regarded us as the largest manufacturer of vaccines globally, not just in India. Even they are not keen on the rankings, whether we are the top biotech company or not.

However, from the general public perception, my personal standing in the society has naturally been enhanced because of this pleasant news and achievement. And, of course, it would be a major boost for us to hold on to this achievement, if we wished to go for an IPO in the near future-incidentally, we are not considering that at the moment.

**Serum Institute registered a growth of over 39 percent, as against a growth of 3 percent in 2004-05. What were the factors that contributed for this kind of growth?**

There are several reasons for this growth. To be honest with you, the growth was flat in 2004-05 because a lot of shipments were not executed owing to various reasons. So it is natural that a part of that-which should have gone in that year to sustain a growth of about 10-15 percent-has come into this year. So this is an abnormal growth. I don't want to take the credit by saying that we did a great job and that is why our growth is about 40 percent. This was one of the reasons.

There were a lot of postponements of consignments by our purchasers, possibly due to rescheduling of the dates of their campaigns. And to some extent, even the product. We also had our own share of constraints in sending out the shipments. It is a combination of both these factors, which led to this. And obviously, we are trying to see that this doesn't happen again so that we have a steady growth line. A lot of efforts were put in this year to make sure that the shipments went out in time. So that is major motivating factor to recover the lost ground.

The second reason, I think, was that Biocon didn't grow as much as it grew in the past few years. It registered about 6 percent growth. This drastically changed the balance in our favor.

Beyond that, we had launched a couple of products during the year in India like Q-Vac, combination vaccine and Td vaccine. And we even stepped up the sales of rabies and a range of other vaccines in India.

**Which are the products that will give you more returns this year?**

The combination vaccine that we have launched last year in India, received the WHO pre-qualification only in the last week of July 2006. It is a major milestone for us as ours is the first Indian company to get pre-qualification for combination vaccine from WHO to supply to the UN agencies. We expect the UNICEF and other UN agencies to procure this from us, as this vaccine is in acute shortage worldwide. And only the big pharmas are offering it and at exorbitant prices.

**Why is there a shortage of availability of combination vaccines worldwide?**

There are so many global players who are into the manufacturing of DPT and Hepatitis B vaccines but they don't have the pre-qualification from the WHO. It also took us nearly a year to get the pre-qualification from WHO. It is very cautious in giving the pre-qualification certificate. We launched our indigenously developed combination vaccine in India in July 2005 after we completed a rigorous process of following the clinical trials and have supplied a couple of millions of doses of the combination vaccine in India.

**Why is the big pharma not eager to enter the combination vaccines race?**

While some of them have the vaccines, others don't. Nonetheless, I think, this product (combination vaccine) doesn't interest them because of the low price realization and they were already aware that the Serum Institute has come out with this product. The big pharma is concentrating on combination vaccine (i.e., pentavalent vaccine), which will give them the value in dollars and not in cents. That is the bottomline.

**What about the Chinese companies?**

The Chinese GMP is very poor and I am very much concerned about their biologicals. Only developing countries like India

are allowing the products from China to enter their markets. China doesn't allow the Indian vaccines into their market. We are freely allowing their products (vaccines) to come into India and invade our market. This is not a fair and proper-level playing field. The Indian government should take serious note of this so that there should be a reciprocal flow of vaccines between the countries in the Asia Pacific region. For example, China is not allowing shipment of Indian vaccines into its territory, though Hepatitis vaccine from China is allowed to be imported into India. And the Chinese are unreceptive on this and use the stick of regulatory issues, to keep Indian products out.

**The Serum Institute launched Q-Vac, combination vaccine, and Td-Vac, tetanus and diphtheria vaccine, in 2005-06. Will Serum launch any new products during the current financial year 2006-07?**

We are expecting to launch two products this year. The first one will be hemophilia's influenza vaccine. It will be followed by pentavalent combination vaccine (DPT-Hib-HepatitisB) in early 2007. These two are going to be major growth drivers for us. We are also launching Percutaneous BCG vaccine for superficial bladder cancer.

**What is the potential for these products in the global market?**

For the pentavalent vaccine, we expect to capture a substantial market from the big pharma. We expect to launch the product at one-third of their price. You will be surprised to know that doctors are encouraging this product and they have indicated to us that we should launch our products just a little below the GSK's price, i.e., double the price of what we would like to launch, and that medical professionals and retail chemists should get huge margins from the manufacturer, a driving force for the product to be marketed. My objective is that my people should get our products at competitive prices and we expect to do better.

My marketing people say that we have to sail with the tide. And we slash the prices for supplies to the Indian government. Let us see what best can be done. The sale of these combination vaccines in India and abroad is only going to be through these immunization agencies. The sales from other markets are going to be rather marginal.

**Should the industry take up with the medical community the pricing issue?**

I would love the industry to take up the issue. But I don't think they have got the will power to do it as I see, especially the multinationals, because it suits their philosophy. On one hand they cannot lower their prices and on the other, they are still the dominant players globally.

The real growth of sale of these kind of products like combination vaccines can only be seen if the government of India includes these products in its national immunization program. It's a great pity and shame that the Indian government has not yet done this, while neighboring countries like Bangladesh, Nepal and Pakistan are introducing all the vaccines including the Hepatitis B vaccine in their national programs. The reason is best known to them.

**You have already invested Rs 200 crore to set up the Bio Pharma Park, the country's first private sector specific SEZ at Pune. What is the current status of the Serum Bio Pharma Park?**

On July 27, we got the nod from the government for the installation of the equipment at the SEZ. It will be fully operational from next year. We intend to invest another Rs 500 crore very easily next year on the expansion of the Biotech SEZ. However, there is no clarity on many of the policies, which is hampering the progress. The commerce ministry is right, but the finance ministry is unnecessarily coming in the way.

**Do you have any plans to have a separate division on clinical research within the Serum Institute to do clinical trials?**

No. We don't intend to have a separate division on clinical research. In fact, we would like to identify some clinical research organizations, which are dynamic and outsource the business to them. It would be a win-win situation for both of us, as they are more focused on it and give quicker results.

**What are your strategies in the next 5-10 years in order to become a global biotech player?**

I have been urged to now look at the US and European markets, as the same products on registration will fetch us a higher realization of 10-20 times the current price of the product. We have been putting in the place, especially in our new SEZ, the infrastructure, which will be of global standards. This is a new thrust area where we have to invest lot of money, time, and resources, as it would be very rewarding.

We are also working on some of the products like pegylated version of EPO, a recombinant biotech product and anti-cancer drugs, which will give us an opportunity for diversification from the vaccines business. However, our focus at the Serum Institute will continue to be on the vaccines business. We have also been working on New Drug Delivery Systems (NDDS) in

collaboration with the WHO for the last couple of years on measles vaccine through the aerosol route. It is in Phase-III trials in Mexico and India. But it is difficult to say when we will launch this in the market.