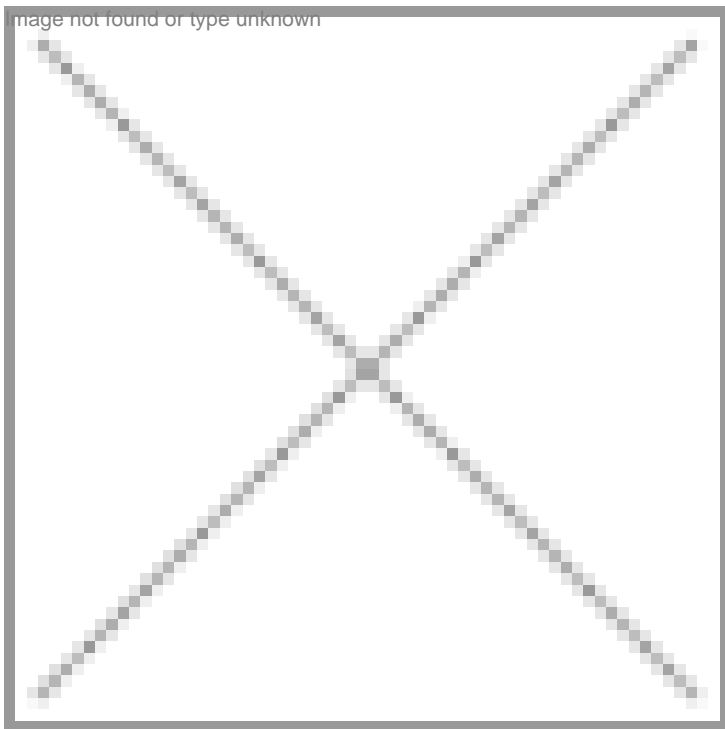


## “NRA is completely trained to meet the current GMP standards”

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Dr Cyrus Poonawalla, founder and chairman of Serum Institute of India, Pune

*Dr Cyrus Poonawalla, founder and chairman of India's leading manufacturer and global supplier company for vaccines, Serum Institute of India, is the visionary credited for making India the epicenter of the global vaccine industry. In an exclusive conversation with BioSpectrum, Dr Cyrus Poonawalla shares his views on the performance of the Indian vaccine market this year and reveals Serum's initiatives to help the world to combat against swine flu.*

**Last year, the Indian vaccine industry received a jolt with the WHO giving an ultimatum to the NRA to upgrade its GMP standards, what is its current status?**

The ultimatum given by WHO to those companies for not falling in line with the GMP standards, both in the private and public sector, is the best thing that happened in the past one year. This was a wake up call for the Indian vaccine industry wherein all vaccine manufacturers including Serum Institute had to upgrade the facilities. Here I would like to make a point and a clarification that manufacturing and production of these companies given an ultimatum were only suspended and these units were not closed down as commonly believed. They needed to upgrade their facilities which they may or may not have been able to do, because the current GMP manufacturing requirements are of very high standard, according to our schedule. Indian players had to come up with really good manufacturing facilities, follow a lot of systems and protocols which were not being followed strictly in the past. In this industry, upgradation to GMP standards and quality compliance are important issues which are vital for the sustained growth of the vaccine industry.

As of now, India has got the actual approval from WHO since they have put all their controls into position and the National Regulatory Authority (NRA) is now completely trained to meet the current GMP standards and most of the vaccine manufacturers in India have also improved their facilities. But, those who have not been given license will not be given

permission to carry on with their facility anymore.

**Does Serum Institute have any plans to manufacture vaccines for swine flu?**

We have been the only vaccine company in India which has been identified and given the go ahead by WHO for developing swine flu vaccines in the near future. We have taken up this challenge. But, at this stage we do not want to make tall and ambitious claims in terms of production and investment.

**In your perspective how is the Indian vaccine segment expanding?**

We have recognized that more players have come into the vaccine segment especially for the new pentavalent vaccines. This is a combination vaccine for DPT, hepatitis B and Hib (haemophilus influenza type B). We have witnessed the entry of around four to five new players into the vaccine market. This is a growing trend in India wherein the vaccine segment is now expanding and we will now see a number of vaccine manufacturers playing an important role in the supply of vaccines in India as well as abroad. That in a way should increase the total use of vaccines world wide.

**What are the other challenges confronting the Indian vaccine segment?**

The vaccine segment in India entirely depends on the amount of vaccines that the health ministry of India decides to procure to meet the country's need. The ministry is not procuring enough vaccines. The health ministry should take a serious note of this matter, buy vaccines and immunize all the children in India with the newer vaccines including the pentavalent vaccines. According to the WHO report, it is pitiful that the number of children immunized in India is far lower than countries like Bangladesh and the African countries. It is also appalling that the health ministry is not taking initiatives to provide immunization to children in India with hepatitis vaccines despite having the largest vaccine manufacturers here.

**In what respect has the vaccine industry been affected by the slowdown?**

I don't think that the vaccine industry has been affected by the recession and slowdown. Vaccine industry may get affected in the future, if the international donors cut back their donations and stop pumping in funds to the UN agencies.

Nayantara Som