

What awaits the Indian biotech industry in 2015?

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We expect tremendous amount of innovation to occur in the vaccine and biosimilar industry. The sector will see a host of new vaccine launches that will address public health, and also help the nation reduce the disease burden. In the vaccine sector, the big trends to watch out for are 'Make in India' molecule thrust and the maturity of R&D in India.

Rotavac, the first novel vaccine not only from India but also from the developing world, a unique social innovation project, an Indo-US bilateral program under the aegis of Department of Biotechnology (DBT), the Society for Applied Studies, and Bharat Biotech spearheaded by Dr MK Bhan, Dr VijayRaghavan and Dr TS Rao, is a giant realization of the 'Make in India' vision.

Rotavac brought together the experience and expertise of Indian and international researchers as well as the public and private sectors. The vaccine is expected to roll out in the market in 2015. The development of Typhoid Conjugate vaccine indigenously by Bharat Biotech is also another shining example of 'Make in India' vision. The maturity of India's R&D program is yet another significant milestone, reflected with the publication of articles on Rotavac by the world's most respected and widely acknowledged medical journal *Lancet*.

One of the biggest challenges that Indian sector have to counter is the dynamic policy change China has made to fuel the growth of vaccine and biosimilar sector in their country. These changes will impact the Indian industry competitiveness in the global UNICEF and private markets.

The Chinese government, since the last 5 years, has closed many public sector units and many have been privatized to ensure that they meet the new GMP regime. With the deadline to meet the GMP norms closing on December 31, many of the Chinese companies have upgraded their facilities and those which do not meet those standards will be shut down starting January 1, 2015. The closure of PSUs in China has also led to the shortage of Chicken Pox vaccine in the markets.

To push the sector forward, the Chinese government helps their industry by subsidizing the Capex (capital expenditure) in the

sector to enable the domestic companies meet the GMP standards which constantly changes.

The new policy push will also make Chinese vaccine and biosimilar companies become highly competitive in the UNICEF and other private markets in the world. Beginning 2015, the cost of Chinese vaccine is also expected to go up as a result of their creation of world standard facilities with huge investments. In the biosimilar sector we will see China and Korea emerge as the top nations. These two nations put together, will have the largest biosimilar projects in the world. Their investments to create global standard facilities meeting the GMP will create a significant impact in the worldwide market. They will also meet majority of the global requirements.

The Indian companies hopes the government will continue to extend its support and also formulate fresh policy changes to help them remain competitive in the global markets as well as stimulate 'Make in India' vision. Moving forward it is important for Indian companies to maintain consistent global standards in its R&D and manufacturing programs to remain globally competitive. As Indian companies upgrade their facilities to meet global standards, there will be change in pricing strategies in the Indian products as well.

As a company, we persist to maintain consistent growth, however, the year 2014 has been a year of moderate growth, and this is due to delay in announcing the launch of National Immunization Programs and also a trivial delay in the launch of our new vaccine. We are very upbeat and we hope 2015 will be a growth acceleration year as our new vaccines will begin to contribute to our revenues in a large manner.

In the coming year, our biggest dream is to offer the world Rotavac, the first molecule developed in India and from the developing world under the PPP program, which is ready for launch. We also hope to play a significant role to make India typhoid-free nation. Another significant aspect that will contribute to our business growth curve in a big way is the roll out of National Immunization Program, and the inclusion of Rotavac, Measles & Rubella and JE for adults in the National Immunization Pilot program in the country by the government of India. We will continue to invest in R&D of new molecules to solve public health problems of emerging countries with a focus on neglected diseases.

Currently, there is a lot of inconsistency in the market. We expect far more stability in the market post the budget announcement in 2015. As said earlier, we expect significant acceleration in development of indigenous molecule.

The first big step in accelerating the growth of domestic vaccine industry is the inclusion of Rotavac, JE for adults, and Measles & Rubella in the National immunization program pilot project that will roll out soon in many Indian states.

Rotavac inclusion in the National Immunization Pilot project is a big push to the sector that represents the successful research and development of a novel vaccine from the developing world with global standards.

Rotavac is a very important scientific breakthrough from India against rotavirus infections, the most severe and lethal cause of childhood diarrhea, responsible for approximately 100,000 deaths of small children in India each year. The fully indigenous vaccine was developed through a unique social innovation partnership that brought together the experience and expertise of Indian and international researchers as well as the public and private sectors. Rotavac is also one of the largest efficacy trials conducted ever in India.

The 'Swachh Bharat Abhiyaan' kick started by the Prime Minister of India is a positive sign for the industry too as vaccine becomes an integral part of the strategy to make India a healthy nation besides advocating the practice of clean and hygienic environment. We also hope the PPP in the sector will fuel tremendous growth in the domestic industry in the coming years as we set to accomplish 'Make in India' dream.