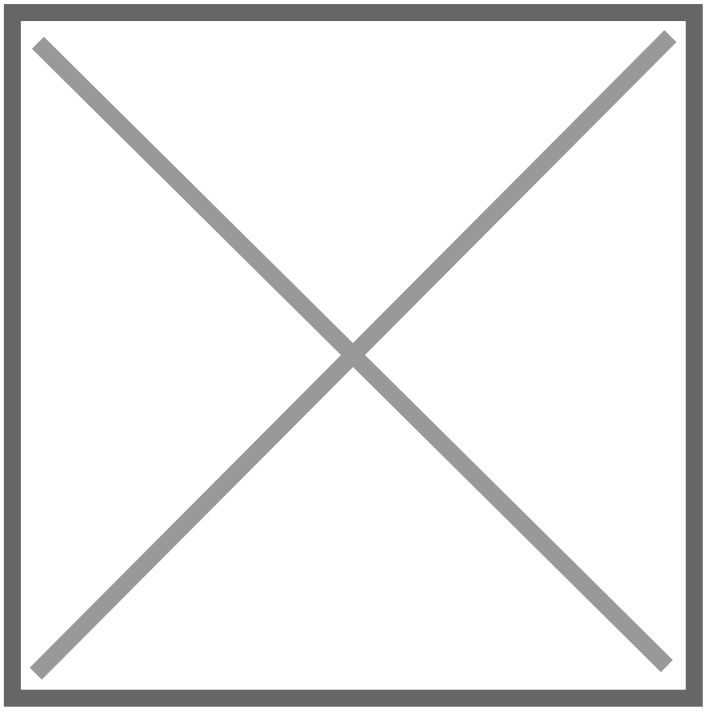
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India eyes new generation vaccines

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Indian manufacturers are now looking at newer vaccines to bolster their margins and revenues.

The Indian vaccine industry struggling with market satu- ration, price erosions leading to shrinking profit margins in the recent years has witnessed a spurt with emergence of new vaccines like HIV, rotavirus, malaria, tuberculosis and human papilloma virus. This has been fueled with consistent and dedicated interests from the Government of India and erstwhile organizations like the WHO, GAVI (Global Alliance for Vaccines & Immunization), UNICEF, Indo-US Vaccine Action Program and others. These organizations have recognized players from India like the Serum Institute of India, Panacea Biotec, Shantha Biotechnics and Chiron as pre-qualified vaccine manufacturers and procure vaccines from them at competitive prices. Besides Bharat Biotech International, Biological E and Cadila Pharmaceuticals are doing research in developing new vaccines in collaboration with national and international organizations.

However, Utkarsh Palnitkar, director, life sciences, Ernst & Young India has pointed out that unlike most of the biopharmaceutical markets, vaccines possess certain distinct facets which enhance India's competitiveness. These include the presence of large institutional buyers, the generics-driven nature of the market and relatively lesser interest from large multinational players, who are increasingly focusing on developing blockbuster drugs.

Dr Jayashree Mapari, senior research analyst with healthcare team, Frost & Sullivan India, said, " In India new generation vaccines are being developed in close cooperation with premier research institutes like the National Institute of Cholera & Enteric Diseases, Kolkata, National Institute of Immunology, Jawaharlal Nehru University and All India Institute of Medical Sciences, all in New Delhi, Central Drug Research Institute, Lucknow, Institute of Microbial Technology, Chandigarh, Indian Institute of Science Bangalore, Center for DNA Fingerprinting & Diagnostics Hyderabad, National AIDS Research Institute, and National Institute of Virology, both at Pune."

Bharat Biotech International Ltd has partnered with US-based Novavax to develop avian influenza vaccine for India and other developing countries from South East Asia. This initiative is in close conjunction with the Department of Biotechnology (DBT) and will therefore be a significant step in the public-private partnership development in public interest.

Serum Institute of India Ltd supplies vaccines to over 137 countries across the world and has been partnering with Chiron for development of a meningitis vaccine. It also has a tie-up with Gates Foundation and PATH for accessing testing technology at international level for developing pneumococcal vaccine. In the case of aersol measles vaccine for improved vaccine delivery system, Serum Institute is working with ICMR and WHO. It has also entered into partnership with John Hopkins, ICMR for Hib vaccine development. Indian Immunologicals is collaborating with the Indian Institute of Science to develop a DNA vaccine for rabies. Shantha Biotechnics is developing a cholera and typhoid vaccines in cooperation with International Vaccine Institute of

Korea, and rotavirus in conjunction with NIH. Shantha is also planning a vaccine for rotavirus and varicella zoster.

R&D scenario

Some institutes in India along with the industry are trying to develop vaccines against TB, HIV and rotaviral diarrhoea. These efforts are still in the initial stages.

Dr PK Ghosh, president, Cadila Pharmaceuticals Ltd said, "The use of Mycobacterium w is being explored by us to find its utility in tuberculosis for reducing sputum conversion period substantially as a therapeutic vaccine, when this is used in conjunction with the regular anti-tubercular chemotherapy. This project holds great hope for success. We also have approaches for developing therapeutic HIV vaccine, but the efforts are still at the preliminary stages. Our company in collaboration with the government and certain other institutes, proposes to spend a substantial sum during the next one decade. I am not quite sure if we shall be able to see successful Indian developments in the form of marketed vaccines against malaria during the next decade."

Speaking about the R&D efforts being carried out at Shantha Biotechnics, Varaprasad Reddy, managing director, Shantha Biotechnics, said, "Our investment into R&D is 25 percent of our annual turnover till date since our inception in 1993. We have spent Rs 87 crore in R&D. This is nearly 33 percent of cumulative turnover that we achieved in the last nine years of our commercial existence. Shantha's investments into R&D are probably the highest in the country as the national average in the country is 0.5 percent of its turnover. Among all the biotech companies, Shantha has the largest R&D facility of world class and around 103 people are working in the R&D lab."

"We believe in doing research in the field of medical sciences and in natural and applied sciences. There is no need to reinvent the wheel. Developing a vaccine will cost anywhere around Rs 30Ã¢â?¬â??40 crore excluding the cost involved in doing the basic research. We have been investing about 7Ã¢â?¬â??10 percent of our total sales turnover. It includes training and upgrading of the infrastructure. There are about 70 scientists working at the Serum Institute including a few scientists who have worked in MNCs abroad. We are looking at increasing our scientific team," said Dr SV Kapre, executive director, Serum Institute of India Ltd.

Sharing similar views, KV Balasubramaniam, managing director, Indian Immunologicals Ltd said, "Investments have to be made both in good facilities and in developing talents of our researchers. Indian Immunologicals has an independent R&D center set up with an initial investment of Rs 15 crore with about 40 scientists working on modern immuno-biology covering recombinant products, plant cell derived products and monoclonal antibodies. We spend 5 percent of our sales on research and this is expected to significantly rise in the coming years."

He further said, "Indian companies are now in various stages of launching conventional or combined vaccines, which are biosimilar. Most of these companies will be working on new generation vaccines only in the second phase. There is more science involved in the new generation vaccines such as DNA vaccines, peptide vaccines and edible vaccines. It also involves negotiating the patent thickets and actively seeking out select know-how licensing under the new IPR regime. This needs investments in basic research and higher level of knowledge from a more competent band of researchers. In my opinion, it will take at least five years before a new truly generation vaccine discovered by an Indian company is successfully commercialized. We expect our DNA rabies vaccine and plant cell derived vaccines to be in this list."

Road blocks

Although the vaccine industry in India is currently flooded with many companies developing newer vaccines, it might still prove an uphill task for India to establish itself as an innovator of vaccines. There are many factors that are coming in the progress of innovation of new generation vaccines from Indian companies like: lack of sufficient funds to support the R&D initiatives; lesser interests from companies to invest into R&D in comparison to commercial development, lack of coordinated efforts from the medical fraternity to support clinical trials; absence of central record/proper health record facilities dampening the efforts of the research community; uncertainties clouding the interests of MNCs with manufacturing bases in India for technology transfer to India and development of newer vaccines and lack of sufficient skilled manpower to support R&D for vaccine development are acting as bottlenecks.

Narayan Kulkarni