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Why Indian vaccine industry should innovate?

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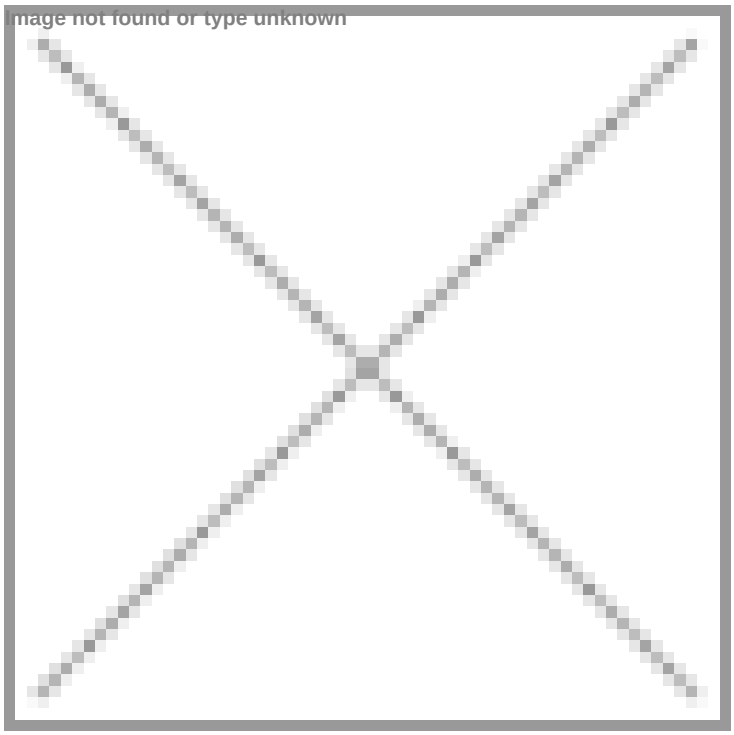

In the past few years, close on the lines of Indian pharma, which is investing heavily in novel drugs or better generics, the vaccine industry has been making concerted efforts to develop vaccines on not just tropical neglected diseases, but also affordable versions of vaccines already available in the West. The recently organized Vaccine World Summit 2013 in Pune proved to be a melting pot of not just the vaccine industry, but also clinicians, regulators, funding agencies and research scientists. What set apart the large number of foreign agencies looking to partner with Indian companies was the fact that a majority of them were for early stage technology platforms involved in the development of vaccines.

Dr Suresh Jadhav, executive director, Serum Institute of India, very simply put the importance of Indian companies in context when he said, "75-80 percent of vaccines developed and procured by UN agencies are from the developing world and almost 80 percent of these are from India."

Estimates for the entire industry have ranged from $260 million according to Dr TS Rao, Adviser, Department of Biotechnology (DBT) to $500 million as stated in a report by consultancy firm McKinsey. These facts only serve to reinstate the overall belief that the impact of the Indian vaccine industry on immunization around the world is undeniable, and will continue to be fundamental in the days for providing affordable quality vaccines to the world.

New vaccines on the horizon

The Rotavirus vaccine, a mammoth Public-Private Partnership (PPP) involving DBT, Gates Foundation, Program for

Appropriate Technologies in Health (PATH), Centers for Disease Control, USA, National Institutes of Health-National Institute of Allergy and Infectious Diseases (NIAID), USA, Society for Applied Studies, Translational Health Sciences Technology Institute, Indian Institute of Science, All India Institute of Medical Science, and Stanford University recently completed its Phase III trials in February 2013. These were conducted on 6800 subjects at three locations; SAS Delhi, CMC Vellore, and KEM Mumbai with the data currently being analyzed. Dr Krishna Ella, chairman and MD, Bharat Biotech had earlier announced that this vaccine would be made available at $1 only.

This has been the case with most ventures with a majority of the vaccines currently under development, a result of partnerships. One of those is Novavax and Cadila Pharmaceuticals, whose joint venture, CPL Biologics was created in 2009 to harness the innovation potential of a small biotech like Novavax and the advantage of scale and experience of Cadila Pharmaceuticals. Dr Sudeep Srivastava, Vice President, Biotech Manufacturing, Cadila Pharmaceutiacals, speaks of the progress made so far, "Moving ahead we have a very strong focus on developing vaccines using Novavax's platform technology. We have already completed Phase I and Phase II trials for a seasonal flu and a pandemic flu vaccine, based on based on Novavax's virus-like-particle (VLP) vaccine technology. Additionally,we are also in the midst of developing a rabies vaccine."

Indian companies are leading the way, when it comes to neglected diseases. Panacea Biotec is also in the early stages of development of a tetravalent dengue vaccine. Indian Immunologicals has also been pooling its efforts in developing vaccines for neglected tropical diseases such as chikungunya and kala azar. They are also concentrating efforts on an oral cervical cancer vaccine, a first from the developing world, thus alluding to its affordability for the masses. The DBT is closely monitoring the development of a cholera vaccine that is in Phase III trials.

Malaria is another challenge that Indian companies have taken up in the recent past. A vaccine developed by ICGEB (International Centre for Genetic Engineering and Biotechnology) was initiated into clinical trials in late 2011, a project in which Bharat Biotech had manufactured the vaccine. Gennova Biopharmaceuticals too has been an active participant in the development of a malaria vaccine. Dr Sanjay Singh, CEO, Gennova Biopharmaceuticals says, "We have multiple projects targeting the different stages of the life cycle of the malarial parasite. The first candidate from Gennova will head for clinical trials soon. Another project initiated a year and a half back is studying people that have shown a natural immunity to the malarial parasite. By analyzing the monoclonal antibodies isolated from this population, we hope to gain further understanding in this field".

The launch of Biological E's indigenously developed Japanese Encephalitis vaccine too was the result of years of hard work as well as a successful collaboration with Intercell, a Vienna-based company who had done the early development work for the same vaccine.

Polio's success story

With sustained efforts from all quarters of society across the globe, we are now close to making polio, only the third infectious disease to be eliminated completely, after small pox and rinderpest. The Indian vaccine industry has played a major role in this initiative and continues to as well. As reported earlier in BioSpectrum, Panacea Biotec has been a major supplier of OPV (Oral Polio Vaccine). Recently after staying away from the crowded space of OPV suppliers in India, Serum Institute of India (SII) also finally joined the pack, by starting the production of its brand of the vaccine. While admitting that SII is a late entrant into this space, Dr Jadhav said that other events led them to take this step. "Since the supply from two other Indian suppliers for the OPV had to be stopped due to some regulatory issues, the UN agencies were facing a shortage of vaccines. We were then asked by the UN agencies to address this issue, and we have now risen to fill in the shortfall."

With no live case being reported in over two years in India, the OPV program will soon be phased out. Dr Jacob John, advisor, WHO committee on Global Polio Eradication and virologist at CMC, Vellore, and a renowned authority on the polio eradication effort in India explained the current scenario at length by saying, "Studies have shown that continued use of OPV will give rise to cases of Vaccine Derived Polio Virus, such as those that are emerging in some areas of Afghanistan. The strategic plan for 2013-2018 has already been drawn out. The general idea is that there will be a universal introduction of the IPV after 2015, along with a synchronized removal of OPV."

Currently one of the main challenges to using Injectible Polio Vaccine (IPV) is its cost which is approximately $2.66 per dose, as compared to $0.14 for OPV. Industry experts suggest that OPV production will not be stopped completely, but rather given along with IPV in a one out of three doses or one out of two dose scheme, in the beginning of the new effort. A number of manufacturers worldwide are working towards reducing the cost of a single dose of IPV to less than a dollar, so that the

transition is smooth and simultaneous around the world without cost being a barrier. At the same event, while receiving Lifetime Achievement Award for his contributions, Dr Cyrus Poonawalla, chairman, SII commented that SII would try to offer its own brand of IPV at $0.93 per dose.

The eventual introduction of IPV into the Universal Immunization Programme could also herald the popularity of hexavalent vaccines, something which a number of Indian companies including Shantha Biotechnics are working on. Global MNC, GSK (GlaxoSmithKline) recently initiated a joint venture with Hyderabad based Biological E for a hexavalent vaccine development for the developing world. This 50-50 joint venture will be focused on early stage R&D and will utilize GSK's brand of IPV. Biological E has already been one of the largest suppliers of DPT (Diptheria Pertussis and Tetanus) vaccines to the Indian government for their immunization programs.

The amazing work set aside, the dearth of a single window clearance was cited as one of the major challenges to the vaccine industry in India. The continued delays in procuring permission for trials has affected not only companies but also medical professionals who conduct trials for gaining a better understanding of the need and effect of vaccines for the Indian population. Mr Sai Prasad, vice president, business development, Bharat Biotech said, "The development of vaccines involves not one, but a number of government agencies. There are processes which need to be streamlined for developing newer vaccines so that simple yet important things such as importing specific cell lines is doable within a defined time limit."

Dr TS Rao, also commented on the same, by saying, "We realize that one of the challenges in the vaccine space is clinical trials of new vaccines. DBT is closely working with DCGI to solve this issue regarding clinical trials."
This has prompted all the major vaccine manufacturers in India to form a Developing Vaccine Manufacturers Network. This industry body is currently in the process of assimilating the necessary demands of the vaccine industry as a collective and not an individual company and then present it to various agencies such as Department of Biotechnology, Ministry of Health and Family Welfare and Indian Council of Medical Research and such.

However a lot remains to be done. Mr Ranga Iyer, advisor, India Health Progress says that despite the amazing progress by Indian individuals, "Two million vaccine preventable deaths still occur in India. India has huge capacities for vaccine production, with over 70 percent vaccines manufactured in India being exported, the per capita spend for vaccines for the Indian population is estimated to be US$0.01. When the pentavalent vaccines was included in the UIP last year the original plan was to expand it to other states, however, till date it remains restricted to the two states of Kerala and Tamil Nadu."

With an amazing pipeline in store, the next five years could put Indian manufacturers on the innovation map. For now, it would appear that the Indian population to reap the benefits of these efforts however will take a lot more than just technical ingenuity.