

'Preventive healthcare in India needs more investment'

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Interview

Dr Harish Iyer,
CEO, Shantha Biotechnics

Shantha Biotechnics was established in 1993 with the sole purpose of developing efficacious and cost-effective vaccines and therapeutics that are within the reach of the common man. In 2009, the company was acquired by Sanofi Pasteur, the vaccines division of Sanofi, that provides more than one billion doses of vaccine each year. In June 2011, Sanofi appointed Dr Harish Iyer as the chief executive officer of Shantha Biotechnics.

Dr Iyer, a graduate in chemical engineering from Indian Institute of Technology, Madras, and with a PhD from Rensselaer Polytechnic, New York, US, has over 15 years of experience in biotechnology and biopharmaceutical research and development. He has worked with Genentech, IDEC Pharmaceuticals and Biocon. Dr Iyer, who reports directly to Mr Olivier Charmeil, president and CEO of Sanofi Pasteur, and a member of the Sanofi Pasteur management committee, elaborates his vision for Shantha, plans of obtaining the pre-qualification status for Shan5, Shantha's pentavalent vaccine, and the company's exciting pipeline of other vaccines.

How has the shift been from being the head of R&D at a leading biotechnology company to being the CEO of a pioneering vaccine company?

Dr Iyer: I think it has been excellent. My previous role focused more on R&D, whereas now I have a very broad role that allows me to oversee finances and manufacturing along with commercial and regulatory aspects. Also, Shantha is a very exciting place to work, with great potential and a promising future. I work closely with Sanofi Pasteur and also interact with

World Health Organization (WHO), both of which have been very rewarding.

Has there been any change in the business model of Shantha since Sanofi acquired majority stakes in it?

Dr Iyer: The focus at Shantha was and continues to be on producing vaccines for the developing world. In the past, Shantha has dabbled in monoclonal antibodies and therapeutics. In more recent times, we have made a conscious effort to focus singularly on our area of strength, which is vaccines. Our aim is to make high quality affordable vaccines and get pre-qualified by WHO. Our primary markets are in developing countries of Asia, Latin America and Africa through Global Alliance for Vaccines and Immunization (GAVI), United Nations Children's Fund, because there is a very real need for vaccines in these countries.

Tell us about the product pipeline at Shantha?

Dr Iyer: Shantha has always emphasized on research and development and it continues to do so. Currently, we are in the midst of developing a rotavirus vaccine. Over 100,000 children die each year of rotavirus infection. There is a clear need and we want to fulfill it and so are developing a vaccine licensed from National Institutes of Health (NIH) with the goal of making it accessible to all developing countries. It is currently in clinical trials and we hope to get it approved by 2015.

We have also used innovative technology for the cholera vaccine, which was co-developed with the International Vaccine Institute. Earlier, the only available vaccine of cholera was primarily used in a travelers market with a high price. We have now introduced Shanchol, which is less than \$2 per dose and approved by the WHO. We are supplying it as and when required, especially in areas hit by flood or earthquake.

We are also doing a lot of research on a vaccine for Human papilloma virus (HPV) as the vaccines currently available for cervical cancer are very expensive. We hope to have an affordable vaccine in the market by 2018.

Another vaccine of exceptional interest to us are the hexavalent vaccine for hepatitis B, haemophilus influenzae, diphtheria, tetanus, pertussis and an inactivated polio vaccine (IPV). Studies have shown that once the number of cases go down to a certain level, IPV is a better choice for routine immunization against polio.

What is your opinion on the National Vaccine Policy in India? Do you think the inclusion of vaccines for neglected diseases in the National Immunization Program can help curb the fatalities?

Dr Iyer: The National Vaccine Policy published earlier this year looks very positive and is definitely a welcome start to initiate discussions and take concrete steps. There is a need for political will to back the National Vaccine Policy for the public to reap benefits. The provisions for incorporating vaccines in immunization programs that are relevant locally in the policy document are very sound. Almost 50 percent of the vaccines produced in the world are manufactured by the industry in India and, if given adequate support, they can make a huge difference on the healthcare scenario in our country.

Overall, healthcare, especially preventive healthcare in India needs much more investment. For me personally, preventive healthcare was one of the things that attracted me to Shantha, as it allows us to truly make a strong impact on public health in the developing world with affordable vaccines.

What has been the impact of a vaccine giant such as Sanofi acquiring Shantha Biotechnics?

Dr Iyer: The impact of Sanofi and its vaccine division Sanofi Pasteur has been huge. The technical expertise and experience that Sanofi Pasteur brings to vaccine development and manufacturing is very helpful. Additionally, they bring in global quality consciousness into our vaccine development space. Sanofi is also investing here, thus, enabling us to strengthen our R&D efforts.

What do you think of competition from other vaccine companies developing similar vaccines?

Dr Iyer: The markets that we are competing in are internationally funded markets, which work on competition based on tenders. So, one has to be efficient with an eye on costs. However, UNICEF generally seeks tenders from more than one vaccine manufacturer and hence there is room for all in this market.

What are your plans for Shantha Biotechnics?

Dr Iyer: We would like to complement the present portfolio of Sanofi Pasteur. In the long run, Sanofi plans to manufacture some of its products at the Shantha facility in Hyderabad, so that they can be more affordable in India and other countries in the southern hemisphere.

We are also looking forward to bringing Shan5 back into the market as it offers ease of administration by combining all the vaccines in one injection. Once we have Shan5 and these products on track, we will go ahead with more vaccines for diseases such as measles, rabies and hepatitis A. Also, we hope to introduce IPV before a hexavalent vaccine that is in the pipeline.

Additionally, we are in the process of building a very large plant in Shameerpet, a few kilometers from Hyderabad, for manufacturing the rotavirus and Shan5 vaccines.

Manasi Vaidya in Bangalore