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"Scientifically a nasal vaccine is much more effective than an injectable one"

11 April 2023 | Interviews | By Dr Manbeena Chawla

With another financial year coming to an end in March 2023, Serum Institute of India continues to shine as a leader in the biopharma sector. After generating a revenue of around Rs 25000 crore, owing to COVID-19 vaccine sales in FY 21-22, the company is now ready with new vaccine launches to stay ahead in the race. Adar Poonawalla, Chief Executive Officer, Serum Institute of India spoke in detail with BioSpectrum India about the companyâ??s plans in 2023 and beyond.

The industry is now shifting gears from vaccine manufacturing to vaccine R&D in India. How is Serum Institute leveraging this opportunity? What new launches are in the pipeline?

Traditionally the Indian vaccine industry has been mainly manufacturing but now we are seeing that certain companies are developing or co-developing their own vaccines which involves a lot of clinical trials expense and detailed work which takes at least 4 to 5 years. For example, our HPV vaccine which we are planning to launch soon, along with our malaria vaccine. We have developed the process for both these vaccines in India. The malaria vaccine is particularly for the African continent because it deals with the falciparum parasite, not the other one which is found in India which we would work upon after a couple of years. Then, we also have our dengue vaccine in the pipeline in partnership with the National Institutes of Health (NIH) in the US for which we are doing a lot of the development work in India. We also have our pneumococcal vaccine which we developed with NIH and we got our own patents for it. It is a ten-valent pneumonia vaccine for children since this disease is a major killer in children below the age of 5, and we are planning to make a higher valency of this vaccine i.e. 20 or 21.

The company had expanded its facilities for COVID-19 vaccine production. But now that the pandemic period is over, how do you plan to utilise that space for your new products?

Due to COVID-19, we had increased our capacity from 1.5 billion to 4 billion doses. So now we have a lot of idle capacity lying around which we just have to rejig, to be able to handle this situation. In fact, the space would be under utilised by a factor of almost 50 per cent. Even with the launch of our new vaccines, it will take time to further utilise this space. We have spent more than Rs 11,000 crore in the last two years in building capacity, and we have spent another Rs 10,000 crore over the last five years in other activities such as developing our new campus which is about 45-50 acres. So, we have been investing in setting up new equipment and other manufacturing purposes. We have also invested in partnership with Aspen, to have a hold and right to use facilities in South Africa to make some vaccines in Africa. We have also got a tie up in the UK with Oxford Biomedica to make up to 100-150 million doses there. So, we do not know what we are going to do with this space at the moment, as it is available. In addition, we have a plant in Europe. In different geographies, about 5-10 per cent of our capacity has been spread out, outside of India and 90 per cent is in India.

What are the company's revenue projections for FY 22-23?

Now that the COVID-19 sales have come down, we will be close to around $1 billion. During the COVID-19 period, we generated around $4 billion. So, this year, the non-COVID sales is around $900 million, and with these new launches coming up, we hope to add around $100 million with each vaccine to begin with. We hope to cross $1 billion in the non-COVID

vaccine revenue.

Is the company exploring new technologies for developing new vaccine products?

Yes, we are exploring some new areas of technology. Traditionally, it has been viral vectors or sub unit protein vaccines or live attenuated vaccines which have proven to be safe. We are now exploring CRISPR technology for HIV vaccine development. It is an early stage of phase 1 in the US. If it works out well in phase 2 and 3, we might have something that does not fully take care of HIV from one's system but does quite substantially. We are waiting to see how it works out in a larger study. Then, there is the mRNA technology for vaccine development which we are exploring in partnership with US-based GreenLight Biosciences. But, we still have to decide for which disease we should use the mRNA technology. Although mRNA as a therapeutic technology has been previously used for cancer, it has not been proven to be a stable option for vaccine development. Vaccines need to be stable for a period of two years in terms of shelf life. So, this area needs improvement.

Besides these two technologies, we are also developing hepatitis B vaccine in the patch format. But the patch technology also has limitations since it is difficult to figure out the actual dose that needs to be incorporated. It also requires a transformation in the way we manufacture vaccines. It requires bulk of the vaccines to be absorbed on patches. We would have to invest in new filling lines. So, technologies like patch or nasal might only be applicable to a few vaccines. But of course, scientifically a nasal vaccine is much more effective than an injectable one.

Serum Institute has forayed into the diagnostic testing space by investing in Pune-based Mylab Discovery Solutions? How do you plan to explore this space further?

Diagnostics has always been a weak spot where India has not been able to reach out quickly with accessibility and affordability. So, we are developing a lot of tests which were unavailable earlier. Also, most of the diagnostic tests require the presence of laboratories. Mylab is not only making a lot of kits, but also many compact machines which can be operated with 3-4 people and does not really require a full laboratory to perform the tests. With these machines, we are hoping to transform and change the way diagnostic tests are traditionally done. For instance, with these machines you can get the test results of an RT-PCR test in 2-3 hours. Hospitals and diagnostic service providers can simply buy such machines and perform multiple tests. And now we are developing diagnostic tests for a number of diseases, such as sexually transmitted diseases, HIV, HPV, and much more. Mylab has already become the largest RT-PCR and rapid antigen tests kit manufacturer in India. Simultaneously, we are also looking at bringing these Indian diagnostic tests onto the global market. We have been accredited by the European authorities and will be exporting these diagnostic kits very soon.

What role are you playing for enhancing tuberculosis (TB) diagnosis and elimination in India?

We have developed a Cy-Tb kit which helps detect latent TB with ease and accuracy. We also have our recombinant BCG vaccine which would be far more effective. We should launch that very soon. We hope to make a good headway in fighting TB this way.

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