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"We are well-equipped to cater to the increased demand for rapid antibody test kits"

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Catering to the current COVID-19 pandemic, the Mumbai based Voxtur Bio became the first manufacturer in India to get approval from The Indian Council of Medical Research (ICMR) for the manufacturing of rapid anti-body testing kits. Based on the technology transfer from ICMR, the company has developed COVID IgG Elisa and has also developed viral transport media (VTM). Now as the deadly second wave is spreading across the country, Dr Veeraal Gandhi, Founder & Chairman, Voxtur Bio, Mumbai, spoke to BioSpectrum about his experience of tackling the pandemic, and much more.

When did you receive the licence from Indian Council of Medical Research (ICMR)?

It was April 7, 2020, the 14th day of the 21-day nationwide lockdown when we got the licence for manufacturing Immunoglobulin M (IgM) and Immunoglobulin G (IgG) rapid antibody test kits for detecting Covid-19 from Indian Council of Medical Research (ICMR). Thus, Voxtur Bio became the first in-vitro diagnostics (IVD) kit manufacturer in India to receive manufacturing licence from the apex medical research body of the country. However, more than a company milestone and a testimony to our manufacturing brilliance, it demonstrates the unwavering dedication of our teams of experts and researchers who raced against time to empower the country's healthcare eco-system in the fight against the deadly pandemic. Our efforts in those unprecedented times were acknowledged by Prime Minister's Office (PMO) as well. A PMO official called to congratulate us on achieving the feat in a record time and assured us assistance in accelerating the manufacturing process. It was a moment of great honour for all of us at Voxtur Bio.

What was the qualifying criterion for obtaining the licence?

Both Central Drugs Standard Control Organisation (CDSCO) and ICMR are involved in the process of granting licence. IVD kit manufacturers essentially go through two stages to get the approval for licence. In the first stage, physical verification of the manufacturing process from the designing of the kits to the final output including the documentation and related studies is carried out. In the second phase, evaluation and validation of the sample kits are performed. Initially, a test license is issued to the IVD kit manufacturer to produce kits for validation. Actual manufacturing licence is issued when both the bodies are convinced of the effectiveness and satisfied with the performance of the kits.

Which product categories do the manufacturing licence cover?

Manufacturing each type of test kit type requires separate license. Apart from obtaining manufacturing licence for IgG and IgM rapid antibody test kits for Covid-19, we got licence for manufacturing ELISA IgG test kits separately through technology transfer from ICMR. Voxtur Bio was one of the seven companies shortlisted by ICMR for the technology transfer. The third manufacturing licence granted was for viral transport media (VTM) which facilitates safe transportation of virus specimens from collection centres to the testing labs. Our teams worked truly hard to develop the three types of kits within a short span of time.

How many manufacturing facilities do you have and where are they located?

Our 40,000 sq. ft. state-of-the-art IVD manufacturing facility is located in Vasai near Mumbai. It's a world-class manufacturing set-up equipped with clean room facility and all the essential and technologically advanced capabilities. Voxtur Bio has got ISO 9001:2015 and ISO 13485:2016 accreditations, signifying our consistency in meeting client and applicable regulatory requirements and quality control protocols.

How has been the journey so far? Could you provide a rough count of the products manufactured as per the licence specifications?

Well, the journey was full of challenges, but it was extremely fulfilling. Because, we at Voxtur Bio came together for a much greater cause at a time when the country was going through the biggest healthcare crisis. Our aim was to play our part in containing the pandemic spread by making rapid antibody test kits available in adequate numbers. The mission still continues as the country is currently battling with the second wave of Covid. For us, nation comes first, always.

Our planning and preparation to manufacture the rapid antibody test kits began almost 25 days prior to the first 21-day lockdown announced on March 24, 2020. Restrictions on the regular moments during the lockdown made the scenario even more challenging for us. However, our determination to overcome challenges and zest to serve the nation scored over and never allowed us to deviate from our goal to obtain the licence and begin manufacturing the test kits in a shorter time-span.

The healthy orders volume of our IgM and IgG rapid antibody test kits proved the usefulness and necessity of such solutions in the crisis situation. After that, we developed ELISA IgG test kits used for monitoring the development of herd immunity and VTM in quick succession. Our DSIR-certified in-house R&D centre played a key role in accelerating the development and manufacturing of those IVD test kits and solutions, enabling us to fulfill the growing demand in a timely manner.

What is the current capacity and how has the demand changed?

Our annual manufacturing capacity of rapid test kits is approximately 120 million tests. The demand for rapid antibody test kits surged last year during the pandemic outbreak. We have been witnessing a robust increase in demand following the roll-out of the vaccination drive as well. The availability of rapid antibody kits is essential for the healthcare service providers to monitor the levels of antibodies in the bloodstreams of the people in general and infants, individuals suffering from chronic diseases and senior citizens, in particular. In my opinion, the government should launch post-vaccination antibody testing

drive across the country to ascertain the herd immunity level and avoid hospitalization wherever possible to reduce the pressure on the healthcare infrastructure of the country. We have automated some of our critical processes to increase our productivity and for that we have made substantial investments in automation to develop advanced diagnostic tools and solutions.

What industry challenges have you seen so far and foresee while catering to an increase in demand for the products?

One of the key challenges for the industry has been the dependence on import for procuring raw materials and machinery for manufacturing. The Production Linked Incentive (PLI) scheme announced by the government for the healthcare industry will make the industry self-sufficient, as it will boost the manufacturing competencies of the diagnostics industry and promote localization of manufacturing supply chain and technology integration.

To answer the second part of the question, we are well-equipped to cater to the increased demand for rapid antibody test kits thanks to our fully backward-integrated manufacturing process. Each phase in the manufacturing process including the R&D is managed in-house. So, we are in a better position to ramp up production quickly whenever there is a rise in demand.

How do the manufactured products comply with global diagnostic standards?

The regulatory standards prescribed by CDSCO are on a par with the global standards. The stringent MDR 2017 involving process evaluation, infrastructure validation, product verification, etc. has ensured stricter compliance to quality and regulatory standards. The adherence to rigorous regulatory standards can open up the global market for the IVD kit manufacturers of our country. Since we at Voxtur Bio adhere to MDR 2017 compliance, our kits and solutions always excel in meeting the global standards.

What is the future plan of the company?

The IVD segment in India is growing at a faster pace thanks to growing health consciousness, increasing demand for point-of-care testing and personalized care. Banking on those growth drivers, we are strategizing our future business growth and expansion. We are planning to develop new IVD kits and solutions as well as foray into a new IVD segment as well.

What was your revenue during FY20-21?

We registered revenue growth of 400% in FY20-21 when compared with the revenue generated in FY19-20.

What is the growth expected this year?

With a spurt in pandemic caseloads driving the demand for diagnostic kits and solutions, we are expecting a substantial growth in business in the current financial year. We are ready to meet the growing demand for diagnostics kits in the country with our range of advanced solutions.

What are the future trends of the diagnostic market in India?

The global diagnostics market is set to grow at an exponential pace with an increasing number of people around the world becoming health conscious. In India, the approach to healthcare is transforming from curative to preventive with the concept of preventive healthcare gaining ground. More and more health conscious people are nowadays opting for wellness testing over illness testing. All these trends will drive the demand in the domestic diagnostics market, going forward.

On the manufacturing front, thanks to the introduction of the PLI scheme, a large number of manufacturers will be able to bolster their production capacity of diagnostic solutions. A robust diagnostics solutions manufacturing base will surely boost

the healthcare sector. The government is also setting up medical device parks in some states to incentivize and promote indigenous manufacturing of diagnostics products and machineries. This move will not only reduce dependence on imports and turn the dream of Atmanirbhar Bharat or self-reliant India into reality but also significantly enhance India's share in the global diagnostic device exports.

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