BioSpectrum the business of Bio & Health Sciences

“Made in India products need an ecosystem for commercialisation of innovations”

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Established in 1998, Ernakulam-based Agappe Diagnostics is one of the rapidly growing companies in the in vitro diagnostic (IVD) industry in India, having a wide range of products in the pre-analytical and analytical segment. Focused on research, design, and production of clinical chemistry reagents and instrument, Agappe has over 1000 distributors and holds a significant place in the global original equipment manufacturer (OEM) business.

The company currently has a workforce of more than 600 employees spread across sectors such as R&D, manufacturing, sales, support and operations. In conversation with BioSpectrum, Thomas John, Managing Director, Agappe Diagnostics, Ernakulam shares his strategies and plans for the company’s growth in the long run. Edited excerpts;

How has Agappe faced the challenges of COVID-19 in terms of production, technology and revenue?

In a highly import-dominated IVD sector, Agappe has always emphasised on the indigenous development of technology. Our far-sightedness for developing in-house manufacturing has enabled us to envisage products that are suitable for developing countries. In line with this thought, we have focused on our R & D division, with a committed expenditure of over 5 per cent of our revenues. The disruption of supplies caused by the pandemic and the lockdown did not deter us, as our products were already in the pipeline to be manufactured in India.

During this pandemic, we paced ourselves to commercially launch Mispa Count X, India's first indigenously built blood cell counter, in partnership with L&T Technology Services, a leading global pure-play engineering services company. We are the first Indian company to indigenously design, develop and commercialise the 3-part haematology analyser. Agappe also became the first Indian IVD company to launch IoT based semi-automated clinical chemistry analysers during the peak of the pandemic. In tune with the need of the hour, Agappe's R & D team has developed the RT LAMP technology-based COVID-19 test kits, Mispa LUME and Mispa Lume Screen nCov for the domestic market. These products are validated and approved by the Indian Council of Medical Research (ICMR) and Central Drugs Standard Control Organisation (CDSCO). The test kits have been approved by National Accreditation Board for Testing and Calibration Laboratories (NABL) for use by laboratories.

We were also able to quickly gather our resources to cater to the sudden demand for COVID-19 prognosis. The parameters of D-Dimer, Ferritin, CRP were identified for their benefits in prognosis and we had ramped up our production to meet the demand. Our team was able to roll out 1 million tests in 24 days and make them available for the end-users. Even as the lockdown crippled functionality to the bare minimum, we supported our employees and our employees had taken up this challenge to support our efforts in this fight against COVID-19.

What are the major plans in store for 2021?

For 2021 and beyond, we would like to be partners in the Atmanirbhar Bharat campaign to achieve full self-reliance in the manufacture of IVD devices and reagents. After launching the first semi-automated specific protein system in India in the year 2011, we control the protein estimation segment in India and the neighbouring market, making specific protein-based diagnosis and prognosis affordable to the masses. The first 'Made in India' 3-part haematology analyser, under the brand name Mispa Count X, is a testimony to our commitment to Aatmanirbhar Bharat. We intend to focus on molecular diagnostics. Molecular Diagnostics with its newfound prominence will be one of our major growth drivers and Agappe plans to make the process simplified so that mass screening of COVID-19 can be done with ease. We also plan to include more parameters in this segment. We will be increasing our product portfolio with improved and updated products in all major segments. Our aim is to become the number one IVD company in India by 2025.

How has the pandemic changed the face of the IVD sector? What trends do you foresee in this sector?

COVID-19 brought out the importance of molecular diagnostics in precisely diagnosing diseases. The pandemic exposed the big gap in the availability of reliable molecular diagnostic tools to carry out confirmatory tests and the need for affordable diagnostics technology with faster turnaround of results. The absence of a strong local IVD manufacturing sector could be felt during the pandemic as imports were disrupted. The Indian IVD sector will be technology-driven in the future, with the focus on indigenous development of devices that use high-end software. The focus will be on technology than products, with an effort to become self-reliant and self-sufficient. Technology adoption is likely to be faster owing to the changes in end-use. With molecular science dominating the clinical side, molecular diagnostic tools cannot be left behind. Pre-analytics and Post-COVID prognosis are also expected to be the main drivers for the industry. To facilitate R & D investments, technology development and adoption, the government should consider reforming the multiple regulatory and standardisation regime.

How do you plan to contribute to the growth of the IVD sector in the long run?

Agappe has a unique record of being an innovator in the IVD sector. Many of our products are revolutionary. Our success mantras are Innovation, Quality and Affordability. We have industry-industry collaborations and Industry- academic partnerships to enhance our product portfolio. We are planning to introduce compact and user-friendly systems in Haematology, Clinical chemistry, Immunology and Molecular Diagnosis. As part of the Atmanirbhar scheme, we propose to be at the forefront to provide affordable solutions in the IVD segment. Our compact user-friendly systems are the best to reach diagnostics solutions to the rural areas and to cater to the masses in India and nearby developing countries.

What are your views on the government's recent announcements on the Medical Device Park & PLI scheme for the manufacturing industries?

The IVD industry has generally welcomed the Government of India's medical devices policy and the PLI scheme. The medical devices parks scheme is also a good effort towards Atmanirbhar Bharat. However, we feel that the policy needs to be evaluated in the context of the lessons learnt during the pandemic and fine-tuned accordingly.

Given the fact that there are fewer home-grown units, the emphasis should be on quality and cost-effectiveness. 'Made in India' products need an ecosystem for commercialisation of innovations and incremental innovations into quality products because investments in the IVD industry comes in tandem with innovations and technology development. The medical parks will hopefully cater to the needs. However, companies that have invested time, energy and funds should be given recognition and rewards. We are of the firm opinion that the PLI scheme should reward domestic/homegrown IVD companies by factoring in the expenditure incurred by them in R & D. Multiple regulation and standardisation mechanisms should be reviewed.

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