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“India needs vaccines that are ‘Made for India’”

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With a legacy of over 75 years in pioneering advancements with their vaccines within the Indian pharmaceutical landscape, Mumbai-based Novo Medi Sciences (Novo Group) has been instrumental in introducing many first-of-its-kind vaccines in India, playing a vital role in public health and setting standards in healthcare quality and accessibility. The company is all set to launch new vaccines in the country, further strengthening the innovation landscape for vaccine R&D. Forum Bhagat, Managing Director of Novo Medi Sciences (Novo Group) spoke to BioSpectrum about the company’s present and future plans.

What were the key highlights of the company in 2024? What are the major plans in store for 2025?

In 2024, we continued to expand our mission, considering that we must cater to critical healthcare challenges with innovative solutions. One of our recent key achievements, guided by the principles of our founder and my grandfather, late Ramesh C Bhagat, was the reintroduction of NEXICLOX DS 250mg, a trusted Cloxacillin syrup formulation. This move addresses the dire need for effective treatments against critical infections like skin and soft tissue infections (SSTIs), osteomyelitis, respiratory tract infections (RTIs), and Endocarditis within the paediatric community. Initially launched in 1965, Cloxacillin is the gold-standard penicillin that was discontinued in the Indian pharmaceutical market for over 25 years. The rise of multi-drug resistance (MDR) has rendered many current combination molecules ineffective against susceptible Staphylococcus infections. Consequently, the medical fraternity emphasised the need for ‘old is gold’ standard molecules like Cloxacillin, which offers a lower likelihood of resistance due to its limited use in recent years.

By reintroducing NEXICLOX DS 250mg, we aim to provide healthcare professionals with a reliable and effective solution for treating critical infections in children, effective against MDR Methicillin-Susceptible Staphylococcus Aureus (MSSA) and has a

low resistance risk with a proven safety profile.

We also expanded our product portfolio with the launch of NEXI D3, an advanced Vitamin D3 60,000iu syrup, in first of its kind, easy-to-use pack and CEFZINEX, a next-generation injectable antibiotic combining Ceftazidime and Avibactam. Our vaccine pipeline saw two major candidates for Meningitis and Pneumonia entering Phase 3 clinical trials, underscoring our commitment to tackling critical diseases across all age groups. Additionally, we celebrated eight years of uninterrupted availability of NEXIPOX, our varicella vaccine, which has become a cornerstone of Paediatric immunisation against the chickenpox disease in India. We extended our presence to over 45 countries on the international front, adding new markets in Europe, Africa, Latin America, and North America.

Looking ahead to 2025, we aim to build on these successes by commercialising vaccines for Meningitis and Pneumonia. Furthermore, our research on the Shingles vaccine will progress with the completion of its clinical trial and commercialisation by mid-year, making it India's first Live Shingles vaccine with 1 dose, for 40 years age group and above, providing lifetime immunity. Apart from commercialising these three vaccines, our team has worked hard by advancing to initiate clinical trials for vaccines targeting Typhoid, Cervical cancer, and Hand, Foot, and Mouth Disease (HFMD). HFMD represents a particularly significant milestone, as it will be the first vaccine of its kind in India. We also plan to strengthen our global footprint by launching our own sales and marketing operation in nine African countries and three Latin American nations, alongside obtaining regulatory registrations in 15 additional markets. We are also expected to complete a site audit of our injectables plant by the Philippines FDA.

Are there any investments or collaborations planned in the coming times?

As a country, we have been very highly reliant on multinational corporations to provide vaccines for our country. However, this limits our scope for mass and affordable immunisation for critical diseases like Dengue, Malaria, and Chikungunya, vaccines for these diseases are yet not actively researched in India. With this in mind, we are in discussion with multiple European and Asian biotech research companies for developing niche vaccines along with the new advancement in vaccine development accessible to the Indian population. India needs vaccines that are 'Made for India'.

Are you collaborating with the government to enhance the country's healthcare delivery ecosystem?

In the past decade, India has improved the supply chain, but we still lack the infrastructure to ensure cold chain maintenance for the entire nation. WHO estimates that up to 50 per cent of vaccines are wasted each year globally due to a lack of temperature control and a broken cold chain. We recognise the importance of robust infrastructure to support vaccine efficacy and reduce wastage. Our research and technical team have been working on a device which can solve the biggest issue for vaccines and products that require cold chain maintenance throughout their shelf life. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and their providers if they require re-vaccination, as the vaccines they received may have been compromised. This upgradation of India's infrastructure cannot just be the government's responsibility; it must be an initiative taken by the people who have operated in such conditions and with our 77+ years of legacy, we have the experience and the technical knowledge to bridge this underlying gap effectively.

An effective cold chain relies on four main elements: 'well-trained staff', 'reliable storage', 'temperature monitoring equipment', and 'accurate vaccine inventory management.' What if we could do this with just one device that simplifies the entire process while requiring only renewable energy to keep it functional? To make the zero wastage dream a reality, we plan to work with the government to make this device accessible for India, enabling the cold chain products to maintain their potency thereby reducing wastage and proving to be an economic boon for the country.

What are your expectations from the government?

We hope the Health Ministry will keep updating the minimum threshold of India's quality standard to ensure that only quality care is acceptable. Like how the PLI scheme has put India on the path of developing its APIs, we hope similar initiatives are taken to enable investment in making only the highest quality vaccine manufacturing plants which can cater first to the nation and then to the world.

India being a vaccine manufacturing hub, how do you foresee the future of vaccine R&D in India? What are the current challenges facing vaccine R&D in the country?

India has firmly established itself as a global leader in vaccine manufacturing. However, the future of vaccine R&D in the country depends on overcoming key challenges such as limited infrastructure for advanced research, dependency on imported raw materials, and barriers to scaling innovative solutions as also pointed out above.

We as a nation can mass manufacture for the world the basic immunisation vaccines that are much needed for an infant. However, when it comes to tackling complex diseases, we cannot still develop our own. We believe the first step in India becoming an R&D centre for the world is to engage in strategic partnerships with the R&D centres in the developed nations and enable them to provide us with the technology for tackling critical diseases. Once we equip ourselves with the right technology at the right time, there is no stopping us.

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