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“In India, the anti-snake venom market has historically been unregulated and often grouped under vaccine guidelines”

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In India, around 50,000 deaths occur of an estimated 3-4 million snake bites annually which accounts for half of all snakebite deaths globally. Only a small proportion of snake bite victims across countries report to the clinics and hospitals and actual burden of snake bite is grossly underreported. As per the Central Bureau of Health Investigation (CBHI) reports (2016-2020), the average annual frequency of snakebite cases in India is around 3 lakhs and about 2000 deaths occur due to snakebite envenoming. BioSpectrum spoke to Siddarth Daga, Managing Director, Vins Bioproducts, a biotechnology company dedicated to developing life-saving antisera against snake bites since 1997 about the regulatory challenges and the growth and R&D plans of the company.

Could you please share the journey of Vins Bioproducts? How did it all begin, and what was your initial objective?

We started in 1997 with a small facility on the Bombay Highway in Erdanoor. Initially, our capacity was about 20,000 vials per annum. Over the past 27 years, we've expanded significantly. Today, our installed capacity has grown from 20,000 vials to nearly 5 million doses annually, specifically for antisera. Our objective was to address rural health issues, which many multinationals overlooked due to the complexities involved in handling biological products. Our chairman was always keen on developing niche products, and our first licensed product was Indian Anti Snake Venom Serum (ASVS). Currently, we have over 25 licensed products from the Drugs Controller General of India (DCGI).

Apart from Anti-Snake Venom Serum, what are your other major products and what are the international standards that you follow for your products?

In addition to Anti-Snake Venom Serum, our major products include Anti-Rabies Serum, Anti-Diphtheria Serum, and Anti-Scorpion Venom Serum. While our products don't have a significant market presence in the US or Europe, they are imported into these regions under special permits. Our facilities are approved by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and several Southeast Asian countries, such as Thailand, Indonesia, and the Philippines. We also have a strong presence in African markets, with around 15 to 20 registrations.

What are the key regulatory challenges you face in India?

In India, the anti-snake venom market has historically been unregulated and often grouped under vaccine guidelines, which isn't appropriate. Conducting clinical trials for anti-snake venom, as required for vaccines, presents practical challenges since we can't predict or control snake bites. Additionally, the efficacy of our products is region-specific, necessitating customisation for different snake species across various geographies. Another significant challenge is the availability of venom, which is critical for production but is controlled by strict regulations under the Ministry of Forest and Environment.

Tell us about your manufacturing facilities and the technologies you use.

We have two main plants in Hyderabad; one for animal handling and another for farming, 45 kilometres away. We manage the entire process from plasma extraction to the final product. Our facilities are equipped with advanced chromatography setups for additional purification, making our products comparable to human monoclonal antibodies. We collaborated with institutions like the Indian Council of Medical Research (ICMR) and the Centre for Cellular & Molecular Biology (CCMB) during COVID-19 to develop an indigenous antidote, demonstrating our technical capabilities.

How does Vins Bioproducts ensure ethical standards, particularly in animal handling?

We consider every equine (horse) a crucial part of our operations, so their health is paramount. We're regulated by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), ensuring compliance with animal welfare standards. Our processes, similar to human plasma donation, are designed to minimise harm and maximise care for the animals involved.

In fact at Vins Bioproducts, we adhere to rigorous ethical standards to ensure the welfare of our equines. We undergo frequent audits—at least two every month, each lasting three to four days—where auditors spend considerable time at our animal farms to inspect our practices. We grow our own fodder for about 2,000 horses using hydroponic farming techniques, which allows us to maintain a consistent and high-quality food supply. This practice also reduces our reliance on external suppliers who can be inconsistent. Additionally, we incorporate nutritious inputs such as ‘chana’ and barley to meet the protein requirements of our horses. Our focus is on minimising cruelty and enhancing the comfort of the animals through continuous technological advancements in their treatment.

How many animals do you have at your facilities?

We have around 650 animals at our main facility. At another location, about 40 kilometres from here, we have nearly 1,000 to 1,100 animals on a 100-acre farm.

Apart from equines, do you use any other animals for serum extraction?

No, we only use horses. Horses are easier to handle and are more human-friendly compared to larger animals like elephants, which are impractical to manage in large numbers.

Are you venturing into any new research areas? If so could you give us a brief on those developments and products in pipelines?

Yes, we are exploring several new research areas. During the COVID-19, we successfully developed a treatment platform, which we are now diversifying. We are currently focusing on treatments for Dengue and Gangrene. Our Dengue treatment is still in the proof-of-concept stage, but we are optimistic about its potential. We are also developing an anti-thymocyte product for aplastic anaemia and organ transplants.

How much investment have you made in these new research areas? Are you partnering with any academic institutions or organisations to take forward your healthcare solutions?

We are looking to collaborate rather than solely fund these initiatives. We have identified experienced scientists and partnered with companies like Sanofi and GSK. The investment required for moving a product from development to clinical trials can range from $5 to $10 million, given the high costs associated with clinical trials.

During COVID-19, we collaborated with CCMB and closely worked with them to develop an anti-dote for COVID. Though we could not complete our clinical trials, we gained significant knowledge and will definitely use it whenever a similar pandemic breaks in future. We had also collaborated with the University of Hyderabad.

Regarding snake bite treatments, how do you address the lack of awareness and the reporting of cases in India?

Currently, snake bite is not a notifiable disease in India, which means it is not officially tracked on health information portals. Some state governments are beginning to recognise it as a notifiable disease. In the meantime, we engage in community awareness programmes, especially in regions with high incidence rates, such as Mahabubnagar district in Telangana, collaborating with local authorities to raise awareness and improve reporting.

Do you have any plans of expanding and upgrading your company either in India or internationally? Who are your competitors, both in India and globally, particularly in your product domain?

Fortunately, we have ample land available here, so we're currently focused on upgrading and expanding our existing facilities. Since our inception almost reached a growth of 5 million doses capacity. We're enhancing our filling line facilities, purification labs, quality control, and small animal labs. While we are considering expansion beyond India, it's still in the preliminary stages. We need to assess feasibility and logistics before making any concrete plans.

In India, we face competition from both government and private entities. The Central Research Institute (CRI) Kasauli in Himachal Pradesh and Bharat Serums & Vaccines and Haffkine Bio- Pharmaceutical Corporation (both from Mumbai) are notable competitors. Globally, government organisations in countries like Thailand and Vietnam also pose competition, as they have their own labs focused on similar products.

Finally, how do you perceive the overall growth prospects for the biotechnology sector in India, particularly in Telangana? Can you provide an overview of your opinion on the Indian pharma sector?

The pharmaceutical sector in India has been experiencing significant growth, with record exports reaching $27 billion this year. There's a growing awareness about health post-COVID, leading to increased demand for diagnostic testing and subsequent treatments. This surge in demand is driving business growth, prompting companies to invest more in research and collaboration. Overall, the future looks promising, and the sector holds great potential for India's economy.

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