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Can India Leverage US Biosecure Act to Strengthen CRDMOs?

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The United States of America (USA) is set to implement an Act that will impact the global biotechnology and pharmaceutical industries, potentially opening opportunities for India to dominate the landscape â?? the Biosecure Act. On September 9, 2024, the House of Representatives passed the Biosecure Act. The US Biosecure Act restricts US Federal agencies from contracting with or procuring services and equipment from Chinese â??biotechnology companies of concernâ?•, and will extend to companies that source or utilise equipment or services from five Chinese companies, namely WuXi Apptec, MGI, BGI, Complete Genomics, and WuXi Biologics.

With China as a leading destination for the USA for outsourcing contract manufacturing and research services in the biotech and pharmaceutical sectors, this Act can affect supply chain dynamics in these sectors and countries like India are positioned to be alternative destinations for the US for Contract Development and Manufacturing Organisations (CDMO)/ Contract Research Organisations (CRO) services and capitalise on this. Let's take a look at what its implications would be on the Indian CRDMO sector.

The US Biosecure Act aims to decouple its supply chains from China, presenting a huge opportunity for India's pharma industry. Experts predict that the US Biosecure Act is set to make a strong impact on the entire pharma and biotech sectors globally. The Act restricts US pharmaceutical and biotech companies from outsourcing their services to China-origin Contract Research Development and Manufacturing Organisations (CRDMOs). The Act aims to encourage US pharmaceutical companies to diversify their supply chains, and to shift their partnerships from China to neighbouring countries like India. This move will further boost the already global approach of the China + 1 strategy and help grow India-based CRDMOs who can offer competitive cost advantages along with a skilled labour force for the global pharmaceutical markets. With new developments happening around the US Biosecure Act, India with its strengths in CRDMOs space has been in the driver seat and can look up to capitalise on the opportunities that this Act will open up in the coming period.

The Biosecure Act, which mandates a phased reduction of dependency on China by 2032, underscores the need for global pharma companies to recalibrate their global supply chain strategies. “Over the past few quarters, we have seen a steady shift, presenting significant opportunities for Indian CRDMOs to leverage the evolving pharma ecosystem and the large skilled workforce to attract global pharma companies,” said **Sibaji Biswas, Chief Financial Officer and Executive Director, Syngene International Ltd.**

What India brings to the table

The Indian pharmaceutical sector, particularly the CDMO/CROs is experiencing a significant transformation driven by strategic investments and evolving market trends. According to a recent industry report by Mordor Intelligence, the pharmaceutical CDMO Market revenue in India was valued at $15.63 billion in 2023, and is expected to reach $26.73 billion by 2028, growing at a CAGR of 11.34 per cent during the forecast period of 2023-28. The report also highlights that the market is witnessing growth in clinical trials, driving the demand. For instance, according to ClinicalTrials.gov, the total number of registered clinical studies was 437.513 million in 2022, reaching 477.237 million in 2023.

Looking at the increase in novel biomolecules and biopharmaceuticals taking up a niche in India's burgeoning pharma market, the services sector, through advanced technology and specialised expertise, could be the highlight of the biopharma industry in the coming years. Owing to opportunities stemming from various novel biomolecules and biopharmaceuticals meeting with their patent expirations, multiple industry experts have estimated a significant growth of the Indian services market by the CDMO/CRO companies leveraging these.

Over the years, Indian CDMOs have invested in building state-of-the-art infrastructure. Reports and industry analysts are seeing the sector moving towards embracing advanced technologies, such as continuous manufacturing, and biomanufacturing capabilities, and also a focus on high-potency active pharmaceutical ingredients (HPAPIs) for instance. Experts state that India's ability to offer high-quality services at a lower cost compared to Western countries remains one of its biggest advantages. This cost-effective proposition has the potential to further attract more multinational pharmaceutical companies looking to outsource their R&D and manufacturing needs.

Even in terms of skilled workforce and expertise, India is host to strong scientific capabilities in terms of academia, and Indian CROs and CDMOs have also developed certain expertise in areas like analytical services, process development, etc. In addition, favourable government policies to support the pharmaceutical sector through initiatives like "Make in India" and Production-Linked Incentives (PLI) schemes for the biopharmaceutical sector further strengthen the competitive position of Indian CDMOs/CROs in the global market. The introduction of new forward-looking policies like the BioE3 policy for biomanufacturing, which aims to pave the way for India to become a leading global biomanufacturing hub, would potentially be another feather in the cap of India's able CDMO/CRO sector.

Expressing his thoughts on India's strengths **Sanjay Vyas, President and Managing Director, Parexel India** said, "Strategically, Indian CROs possess several advantages, including cost-effectiveness, a skilled workforce, and existing infrastructure capable of supporting increased production and research activities. Therefore, analysts predict that this shift will lead to a notable increase in demand for Indian CROs and CDMOs, which are well-positioned to fill the gap left by Chinese suppliers. This will simulate increased business opportunities for India, which in turn will project a doubling in market growth in the next three years."

In the context of India positioning itself as an able competing market for the Chinese market, Sibaji Biswas said "India is becoming the preferred choice in the supply chain realignment due to its robust talent pool, infrastructure, and comprehensive capabilities. As clients seek to diversify and mitigate risks in their supply chains, the move towards India is further driven by the solutions and capabilities we offer. This is significant not only for our company but also reflects a wider industry movement. The "China plus one" strategy has been in discussion for some time and with the development around the Biosecure Act we are now seeing action on the ground and a definitive momentum to diversify away from China. Syngene is strategically poised to take advantage of this trend. We are experiencing a surge in activity, client engagement, and numerous pilot projects".

Sharing his thoughts **Dr Mahesh Bhalgat, Group CEO and Managing Director of Veeda Clinical Research Limited** said "India offers advantages coming from strong scientific capabilities with graduates from world-renowned institutions IITs and IISc, NIPER including others. Government interventions through incentives schemes such as Promotion of Research and Innovation in Pharma-MedTech sector (PRIPs) and PLI, help in building more capacity and skillsets."

Implications of the US Biosecure Act

The Biosecure Act, indeed, has the potential to transform India's CDMO sector. By fostering a more robust regulatory and operational framework, it can attract substantial investment in infrastructure and talent. This, in turn, positions India to manage a growing influx of global collaborations and; partnerships and enhance its standing in the global pharmaceutical industry.

Welcoming the move, **Dr Satinder Singh, Associate Director DMPK, Aragen Life Sciences, India** opined, "The USA Biosecure Act is expected to further boost the growth of the Indian pharmaceutical and biotechnology manufacturing sector. Additionally, this Act which prohibits US origin firms to source the services or equipment from prominent Chinese CDMOs and CROs like Complete Genomics, WuXi AppTec, or WuXi Biologics may fuel the growth and expansion of Indian preclinical CROs."

Sharing his thoughts on the US Biosecure Act, Dr Bhalgat said "The US Biosecure Act is likely to have a cascading impact in two directions. First, other countries would look to reduce dependency on the Chinese supply chain and second, is the reduction in Chinese sourcing of raw materials and manufacturing components. As we are seeing, the transition is easiest to be done for developmental programmes, such as those in phase II and phase III clinical trials, as the starting point for moving activities out of China. The other area of opportunity that we see is in preclinical research. Currently, there is a significant amount of preclinical research conducted in the Chinese CRO space and revaluating these programmes is an expected outcome. Notable increase in opportunities, particularly for products in phases II and III, driven by the passage of the US Biosecure Act has also been observed in recent times during our dialogues with clients. With strategic planning and execution, India will be able to capitalise on this opportunity and become a major player in the global pharmaceutical landscape."

"With the passage of this Act, more CROs in India will need to elevate their service offerings to meet the regulatory and quality expectations of US clients. To achieve this, they will likely invest in cutting-edge technologies and processes to enhance efficiency and ensure compliance with international standards. Consequently, the Act is expected to drive a significant increase in R&D investments among Indian CROs. There is also an anticipated increase in focus on biologics, biosimilars, Active Pharmaceutical Ingredients (APIs) and specialty drugs, areas where Indian firms can leverage their existing expertise. The demand for clinical trials in India is set to rise as US firms seek its diverse patient base and cost-effective services,

leading to more trials by Indian CROs. Increased regulatory complexities will also boost the need for consulting services, giving Indian CROs with expertise a significant advantage," said Sanjay Vyas.

Echoing similar views, **Chandrachur Datta, Senior Partner with Vector Consulting Group** said, "Manufacturing expansion in biosimilars is both time- and investment-intensive. Once the decision is made to expand capacities, the actual augmentation may take anywhere from 2 to 3 years, depending on the availability of supplies, equipment, and process validation capacities. This situation creates a challenge in determining the lead indicator: whether to capture market share first or to augment capacities first. Regardless, any company making expansion decisions should prioritise adopting the latest technology in this constantly evolving space. Following the enactment of the Biosecure Act, regulatory standards for biosimilars are anticipated to tighten as existing supply chains are disrupted and new ones emerge. To effectively navigate these changes and instil confidence in regulatory bodies, companies must equip themselves with advanced technologies and streamlined processes that ensure operational transparency and uphold quality standards."

He further added, "When pursuing long-term growth through expansion, companies often concentrate solely on acquiring manufacturing equipment, overlooking essential areas like raw material storage, quality control (QC), and quality assurance (QA) capacities. If these aspects are not scaled alongside manufacturing capacity, they may create bottlenecks that restrict overall capacity increases and diminish the effectiveness of the investment."

Challenges

As the USA will aim to reorganise supply chains for pharma/biopharma outsourcing services, experts predict that shifting productions to other countries will involve challenges like high costs and higher capacities that will need to be built. According to a recent report, around 120 US biopharmaceutical drugs are currently being developed in partnership with Chinese CDMOs. Implications of the US Biosecure Act could mean extended development cycles and higher drug prices in the short term. Despite these challenges, analysts and industry experts predict that it could open up opportunities for Indian CDMOs that could offer competitive cost advantages along with a skilled labour force for the global pharmaceutical markets.

Analysts suggest that increased focus of Indian CRDMOs on compliance and regulatory frameworks, to optimise safety and efficacy of their products according to global standards, effective strategic planning along with investing in infrastructure comprising advanced technologies, expansion of facilities with specialised capabilities etc. could position India as a leading destination for US biotech companies in the coming years.

Talking about the strategies that will need to be implemented by Indian companies to stay globally competitive in this evolving landscape, Chandrachur Datta said, "To make significant leaps in the biosimilar space, the most important factor is technical know-how. For existing CDMOs that already possess a decent level of technical expertise for these molecules and have USFDA-approved facilities, scaling up is relatively straightforward. In contrast, CROs face significantly higher challenges related to technical know-how and clinical trials as they take on more projects. Improved technical expertise will enable firms to gain the confidence of innovators and regulatory authorities. For the long-term sustainability of this business, Indian CROs and CDMOs must prioritise investment in research and development. This commitment will enhance their expertise in biosimilar development and foster innovation, enabling them to create cutting-edge solutions. Additionally, forming strategic partnerships—an approach some companies have already adopted—with global biotech firms can provide access to advanced technologies, market insights, and collaborative research opportunities."

He further said that this implementation must go hand in hand with establishing robust quality assurance processes and strict adherence to Good Manufacturing Practices (GMP), as these are essential factors for building trust with both innovators and regulatory authorities, to ultimately position Indian companies as reliable players in the global biosimilars market.

Raising concern about India's established supply chain relationships with Chinese API manufacturers, Chandrachur Datta said, "As the new Act prevents involvement with the banned companies from China, even in the supply chain, steps must be taken immediately including Existing contracts should be evaluated and potentially terminated based on the likelihood of the firms being designated as "of concern." The associated risk of losing business is significantly higher than the risk of premature contract termination. As soon as possible, substitutes for the equipment or services provided by these companies should be explored to avoid disruptions in business."

"To fully seize this opportunity, India must prioritise effective strategic planning and execution. This involves not only investing in physical infrastructure but also developing a robust regulatory framework, nurturing a skilled workforce, and fostering an environment that promotes innovation and quality. India needs to improve to be competitive to Chinese output i.e. speed and efficiency of delivery. Indian CROs and CDMOs need to partner with US counterparts to bring in efficiency and delivery of

output. Indian firms do have other hurdles to clear like having advanced technology compared to their Chinese counterparts. Although the initial response has sparked greater investor interest in the US, it's important not to underestimate the resilience and adaptability of the Chinese biotech sector, " concludes Dr Mahesh Bhalgat.

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