[I] FOCUS: Indian CDMO cos must level up for opportunity from US Biosecure Act

Companies	Topics	Countries	Other
PIRAPHAR.NS	222.89		-0.56 %
SYNGINTE.NS	882.85		0.67 %
LAURLABS.NS	451.70		2.83 %
DIVILABO.NS	5886		6.11 %
NEULLABO.NS	11834.80		1.16 %
JUBIPHAR.NS	1165.55		2.36 %
DRREDD.NS	6687.85		0.48 %
GLANPHAR.NS	1715		0.90 %
SUPRLIFE.NS	582.55		2.66 %

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By Apoorva Choubey and Narayana Krishna

MUMBAI/HYDERABAD - On paper, Indian contract research and drug manufacturing firms may be among the biggest beneficiaries of the proposed Biosecure Act in the US, but the industry has much ground to cover if it wants to seize meaningful market share arising out of this business opportunity. Domestic contract firms will need to work with the Indian government to not only enhance their technological and manufacturing capabilities further but also reduce their own supply chain dependence on China, according to industry experts.

In September, the House of Representatives in the US passed the Biosecure Act, which aims to prohibit federal agencies from procuring, purchasing, or obtaining biotechnology equipment or services from a biotechnology company that is controlled or operated on behalf of a foreign adversary, most notably China. The bill has now moved to the Senate, and if approved, it will become a law once the President signs it.

This development would effectively force big pharmaceutical giants in the world's largest drug market to diversify their supply chains and reduce dependence on China, though over a period of a few years. "This bill will gravely influence the ability of US companies to outsource business to CRO and CDMO players located in China, Russia, Iran, and North Korea," according to InCred Equities.

The equity market has already started assigning higher valuations to Indian contract research and drug development and manufacturing firms to factor in the possibility that India could emerge as one of the preferred cost-effective options for pharma giants looking to move supply chains out of China. Over the last two months, shares of Piramal Pharma Ltd., Jubilant Pharmova Ltd. and Divi's Laboratories Ltd. have gained 10-30%, outperforming the Nifty Pharma index which has risen over 4%. Some other CDMO stocks had gained last month, but have since fallen due to the recent risk aversion in the overall stock market.

"The Biosecure Act is focused on protecting various elements of the (US) biopharmaceutical supply chain--intellectual property, personal data in terms of genomics, etc," Saharsh Davuluri, vice chairman, and managing director of Neuland Laboratories Ltd. told Informist. Given the significant role played by Chinese contract firms in clinical development, there will be a significant impact as innovators search for options, he said. "Indian companies are in a good position to benefit, given the cost advantages along with significant pharmaceutical manufacturing experience," he said.

OUTSOURCING LANDSCAPE

The global contract development and manufacturing industry has been growing at a faster pace than the overall pharmaceutical industry over the last few years. That's because smaller biotechnology and drug companies outsource drug discovery, development and manufacturing to contract firms to save money. Larger pharma players have also resorted to the outsourcing route to accelerate product launches and reduce costs, especially in recent years due to price economics and policy changes in the US such as the Inflation Reduction Act.

China remains the biggest contract manufacturing and development partner for US companies over the past 15-odd years because of its massive scale, strong active pharmaceutical ingredient production chain, innovation capabilities and 25-30% lower operating costs, driven by liberal local government funding. However, China started losing market share to rivals such as India, Japan, and Europe since trade sanctions were imposed by then US President Donald Trump and when supply chains were massively disrupted during the COVID-19 pandemic.

Thus, the Biosecure Act is set to provide fuel for a fire started three-four years ago, industry experts said. Many estimate that more than 65% of the drugs being developed by public companies in the US, of which 60% are marketed or in late clinical stage, could be at risk because of the Biosecure Act.

The bill could impact as many as 120 biopharmaceutical drugs under development by companies that have partnered with Chinese contract developing and manufacturing firms, and biotechnology companies, InCred Equities said, citing GlobalData's Pharma Intelligence Center Deals Database. Approximately half of these drugs are in clinical stage development and a third are in early-stage discovery and preclinical trials, it said.

The brokerage also noted Thinktank Atlantic Council estimates that US imports of Chinese pharmaceuticals and related products grew to $10.3 billion in 2022, from $2.1 billion in 2020, nearly a fivefold increase. Wuxi Biologics, Complete Genomics, Wuxi AppTec, and BGI Genomics, which have all been listed as problematic companies by the US government, reportedly have existing licencing agreements, contract service agreements, or partnership deals with more than 45 companies headquartered in the US.

ADVANTAGE INDIA

In the last year or so, several pharmaceutical companies looking to reduce their reliance on China have started evaluating capabilities of Indian companies to explore new partnerships. India's thrust on local manufacturing, research and innovation, and adoption of advanced technologies, such as digitisation and automation, coupled with an established track record with the US drug regulator have put it on the radar of global pharma companies.

Companies like Syngene International Ltd. and Piramal Pharma Ltd. with contract research capabilities, which allow them to work on smaller projects and early-stage assets, will start to see the benefits before companies with large-scale manufacturing capacities, InCred Equities had said in a report earlier this year. Moreover, the Biosecure Act will benefit API and small molecule companies more than biologics players, it said. Rivals like Samsung Biologics and Lonza have Indian counterparts beat in the biologics space, it added.

"Being a strong pharma hub, India is home to a good talent pool and has a well-established network of manufacturing facilities compliant with international regulatory standards," said Akhil Ravi, chief executive officer of Aurigene Pharmaceutical Services Ltd., an arm of Dr. Reddy's Laboratories Ltd. These

advantages position India as a natural destination for biopharma outsourcing and will help it emerge as strong alternative to China, he said.

The Indian contract research, development and manufacturing market is expected to grow to a value of $44.69 billion in 2029, compared to $19.63 billion in 2023, led by active pharmaceutical ingredient and contract research opportunities, according to InCred Equities.

"The Biosecure Act will benefit many Indian players, but there is a leeway of five-six years for US companies to comply," said Vinay Paharia, chief investment officer at PGIM Mutual Fund. However, equity investors will start factoring in higher discounted cash flow for the coming years, even before actual business starts coming in, he said.

CHALLENGES

The change in timeline for the implementation of the Biosecure Act has lessened the urgency with which pharmaceutical companies need to find alternatives to Chinese partners. Indian contract firms will need to enhance their capabilities to offer cost-effective options and assure potential partners of their quality in order to stand out from the crowd.

"To take full advantage of the Biosecure Act, the Indian industry needs to be ready for expansion, not only in terms of infrastructure, but also in terms of development of talent," Sibaji Biswas, executive director and chief financial officer of Syngene International told Informist. India also needs to match the technological advancements of Chinese players, such as automation, and enhance productivity even more, he added.

Syngene International has already been awarded pilot projects from these companies it terms "China switchers", who are looking to evaluate the firm for a potential long-term partnership. It expects them to turn into meaningful revenues in the coming quarters.

Davuluri of Neuland Laboratories echoed the view that Indian companies will have to invest both in capacities and capabilities to fully capitalise on the opportunity. "Given the grandfathering clause and the timeline, the bigger commercial projects will take time and not move immediately," he said. "This is especially true in the newer modalities where the Chinese are significantly ahead. The Indian industry will have to pay close attention to trends in the innovation space at the global level and make investments ahead of time," he said.

Another big factor that could become a problem for Indian companies looking to attract contracts from global companies could be their own reliance on China. Indian companies still depend on Chinese suppliers for early-stage materials.

The industry recognises this problem and has started working together for certain molecules. Some companies, including Syngene, are offering the option of a China-independent supply chain to their clients, though at a higher price.

"If I look at the volume of raw materials that are imported from China that has significantly gone down, but still for many critical raw materials, particularly if it's related to rare earth or for many hazardous raw materials, we still depend on China," Biswas said. This is not going to happen overnight, but over the next five to seven years India must develop the ability to sustain an alternate ecosystem at the price point where China is at currently, he said.

GOVT SUPPORT

China also has vast capacities and government subsidies that create competitive pressure and allow them to offer discounts, said Krishna Raghunathan, chief financial officer of Supriya Lifescience Ltd. The Indian government is supporting the industry through production-linked incentive schemes, but there are areas that need improvement, he said.

"For instance, the PLI scheme for paracetamol was divided into too many small licences, which didn't suit the industry's needs. In contrast, China operates large factories with capacities of 40,000 to 50,000 tonnes," he said. Additionally, the new tax regime lacks research & development incentives, which were more favourable under the previous schemes, Raghunathan said.

Biswas, of Syngene, believes a concerted effort between companies and the government may be needed to help drive innovation and build an ecosystem less reliant on China. Production-linked incentives are a constructive initiative from the government for the pharma industry, but they aren't for the CDMO players because their manufacturing activities are driven by contracts with clients and not by 'own' products, Biswas said.

Thus, while the wind is blowing in their favour, Indian contract development and manufacturing firms will have to enhance their technological and manufacturing prowess in order to grab a sizeable share of the business arising out of the implementation of the Biosecure Act. End

US$1 = INR 83.97

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