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Indian pharma companies grows footprint in US cancer generics market

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Indian drug firms eye a larger share of the $145 billion US oncology market, which is growing at an 11 per cent compound annual growth rate (CAGR).

In the last few months, several Indian drug firms have received US Food and Drug Administration (USFDA) approvals for oncology generics, marking a steady rise in complex generic and biosimilar drug entries into the US market.

The US oncology market was valued at $145.52 billion in 2024 and is projected to hit around $416.93 billion by 2034, growing at a CAGR of 11.1 per cent over the forecast period 2025 to 2034.

Experts believe the approvals — including those for Cipla, Biocon Biologics, and Zydus Lifesciences — highlight the growing capabilities of Indian companies in the complex realm of cancer treatment and their increasing footprint in the lucrative US market. This signals a continuation of India's strategic shift from commoditised generics to specialty therapies like oncology.

Indian firms have been focusing on complex generics for some time now, which insulates them partially from pricing pressures in the generics space in the US. "The post-pandemic FDA process has normalised, and Indian firms are focusing on complex molecules like oncology drugs because the basic generics space has reached saturation," said Kinjal Shah, senior vice-president and co-group head at

ICRA.

On April 10, Biocon Biologics announced USFDA approval for Jobevne (bevacizumab-nwgd), a biosimilar to Avastin, used in treating various cancers including colorectal, lung, and glioblastoma. This is Biocon's seventh biosimilar approved in the US, further extending its oncology portfolio. The company also markets biosimilars such as Ogivri and Fulphila in the US, Europe, and Canada. A day later, Cipla secured FDA approval for its AB-rated generic version of Abraxane — paclitaxel protein-bound particles for injectable suspension (albumin-bound), 100 mg/vial. Indicated for metastatic breast cancer, non-small cell lung cancer (NSCLC), and pancreatic cancer, Cipla's version is expected to launch in H1FY26 in the US.

In March, Zydus received FDA approval for apalutamide tablets, 60 mg, a generic of Erleada, used to treat metastatic castration-sensitive prostate cancer. With this, Zydus now holds 420 abbreviated new drug application (ANDA) approvals, reflecting its ongoing focus on the US generics market.

The timing of these approvals is especially critical, as the US is currently grappling with persistent drug shortages, particularly in the oncology segment. According to the American Society of Health-System Pharmacists (ASHP), cancer drug shortages reached a 10-year high in 2023, impacting the availability of key medications for chemotherapy and supportive care. This ongoing crisis has created urgent demand for reliable, affordable sources — a gap that Indian companies are well-positioned to fill with their cost-efficient manufacturing capabilities and proven regulatory track record.

Indian players moving up the value chain assumes significance with the threat of tariffs looming on pharma exports from India. For limited-competition products, Indian-manufactured competitive pricing would be a key factor.

Nilaya Varma, group chief executive officer and co-founder of Primus Partners, stated that the demand environment in the US remains robust. "Yes, there's definitely a growing focus on affordable care in the US, especially with rising drug prices and more Americans struggling with medical debt," he said. "The Affordable Care Act has expanded access through insurance marketplaces and Medicaid eligibility. This has created strong demand for high-quality generics and biosimilars."

Affordability remains a core driver for the uptake of oncology generics and biosimilars in the US, where the focus on reducing healthcare costs continues. Oncology drugs — especially biosimilars — are gaining traction as payers and providers seek alternatives to high-cost brand-name treatments.

"The US aims to diversify supply chains and reduce dependence on China, creating opportunities for Indian firms. Leveraging their generics expertise, Indian companies have entered the biosimilars market, gaining FDA and European Union approvals through partnerships," Varma said.

However, risks persist. Indian companies entering the US oncology space face pricing pressure, regulatory scrutiny (such as FDA inspections), and potential patent litigation, similar to challenges in other therapeutic segments.

While India remains a dominant player in US generics, the country's continued dependence on China for active pharmaceutical ingredients (APIs) and intermediates limits its strategic autonomy, despite changing US–China trade dynamics. "There has been no meaningful change in sourcing patterns despite the geopolitical narrative," Shah added.

While the current trend suggests sustained opportunity in the US for Indian oncology products, analysts caution against reading too much into recent approvals. "This is more of a continuation than a consequence of any recent US policy. It reflects broader market dynamics and long-term strategies rather than short-term regulatory openings," Shah further added.