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“Biosimilars in India are typically priced 60–80 per cent lower than originator biologics, significantly improving access for patients and public health programmes”

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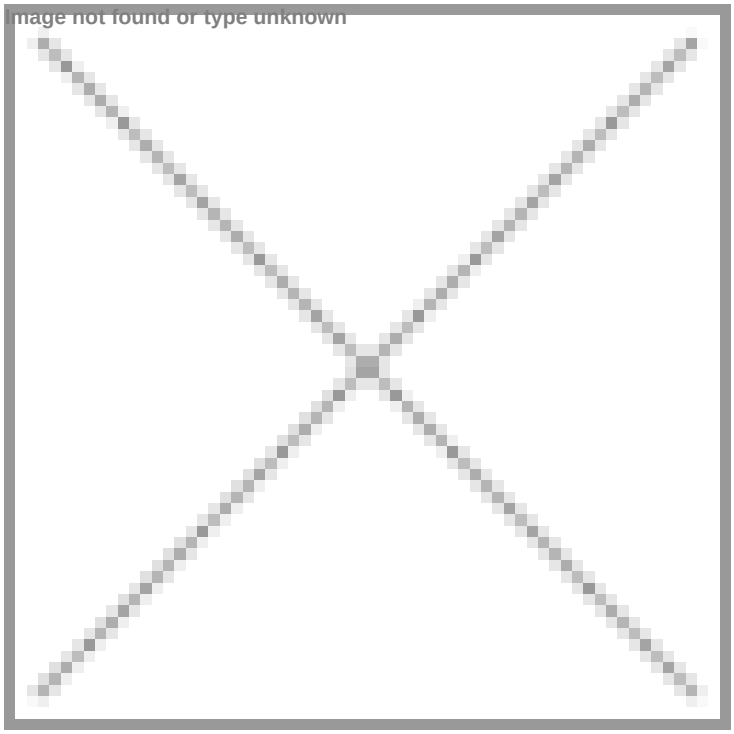
Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance, shares insights on India’s rapidly maturing biosimilars landscape, the shift from import dependence to export leadership, and the road ahead.



How is the biosimilars market shaping in India right now?

India’s biosimilars market is expanding rapidly and is a crucial pillar of India’s healthcare and pharmaceutical ecosystem. Multiple industry estimates indicate double-digit growth, with the market valued at around $ 1–1.3 billion in the mid-2020s and projected to reach $ 4–5 billion over the next decade, suggesting strong and sustained momentum. The biosimilars market in India was valued at approximately $ 1.3 million in 2025 and is expected to reach $ 5.9 million by 2033. A compound annual growth rate of 21.3per cent is expected for India biosimilars market from 2026 to 2033.

This growth is underpinned by strong biologics manufacturing capabilities, a skilled scientific workforce, and cost-efficient development models. These strengths have enabled Indian companies to launch biosimilars at significantly lower prices than innovator biologics, improving access to advanced therapies.

Domestically, biosimilars are seeing growing uptake across oncology, diabetes, nephrology, and autoimmune disorders, driven by affordability needs and increasing clinician experience. In a price-sensitive healthcare system like India's, biosimilars play a pivotal role in expanding access to life-saving biologic treatments beyond a limited urban or insured population.

From a regulatory perspective, India offers a competitive pathway with other countries for biosimilars. However, as highlighted in the *IGBA 2025 report on "Importance of Single Global Development of Generic and Biosimilar Medicines for Patient Access"*, Indian developers face challenges when scaling globally. Fragmented regulatory requirements, including duplicated clinical trials, local comparator mandates, and market-specific manufacturing standards, significantly increase development costs and timelines for exports to highly regulated markets.

Despite these constraints, India is well-positioned to benefit from the next major biologics patent cliff, with global biologic drugs worth over $ 200–250 billion in annual sales expected to lose exclusivity between 2024 and 2032. Greater global regulatory harmonisation and acceptance of single global development models could unlock India's full potential as a global biosimilars powerhouse while accelerating patient access worldwide

How would you describe the current Indian biosimilars landscape, and where do you see it heading next?

The Indian biosimilars landscape is steadily maturing, supported by a strong manufacturing base, scientific capability, and growing regulatory experience. India has positioned itself as a cost-efficient manufacturing and early-launch hub for biosimilars, enabling faster patient access to biologic therapies in a highly price-sensitive healthcare system.

Indian companies such as Biocon Biologics, Dr Reddy's, Zydus, Intas, and Lupin have built end-to-end capabilities spanning development, clinical trials, and large-scale manufacturing. As a result, biosimilars in India are typically priced 60–80 per cent lower than originator biologics, significantly improving access for patients and public health programmes.

Looking ahead, India's strengths in cost-efficient production, regulatory familiarity with emerging markets, and expanding global partnerships position it well to capture a larger share of the global biosimilars market. Going forward, success will depend on continued investment in complex biologics, regulatory harmonisation, pharmacovigilance and strengthening global trust in 'Made in India' biosimilars.

How do imports compare with exports in India's biosimilars market, and how is this balance changing?

India is rapidly shifting from a net importer to a leading global producer in the biosimilars market, with its industry poised to reach 1.5 billion by 2025. While India relies on imports for advanced biological products, it is now leveraging its cost-effective manufacturing, regulatory alignment with global standards, and a robust pipeline to increase exports to highly regulated markets like the US and Europe.

As of 2025, Indian companies have over 135 approved biosimilars domestically, with a growing number of approvals in the EU and the US. The export of similar biologics from India is growing rapidly, with major players like Biocon, Dr. Reddy's, and Cipla targeting the US market, which is expected to see a surge in biosimilar demand.

Requirements for market-specific reference products, duplicate clinical trials, and divergent manufacturing and quality standards significantly raise development costs and timelines for biosimilars intended for these regions.

As a result, many Indian biosimilars are commercialised domestically or in select international markets, while access to larger regulated markets remains selective. This balance is gradually evolving. With a growing number of biologics losing patent protection globally, Indian companies are increasingly investing in development strategies that are globally aligned.

The Indian biosimilars export sector is expected to grow from nearly $4.2 billion by 2030, and potentially up to $ 30-35 billion by 2047, driven by high-demand areas like oncology and diabetes. While India currently holds a small percentage of the total global market, it is on track to become a hub for biosimilar manufacturing and R&D.

Ayesha Siddiqui