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India's Biosimilars Prowess: Transitioning to A Strategic Global Hub

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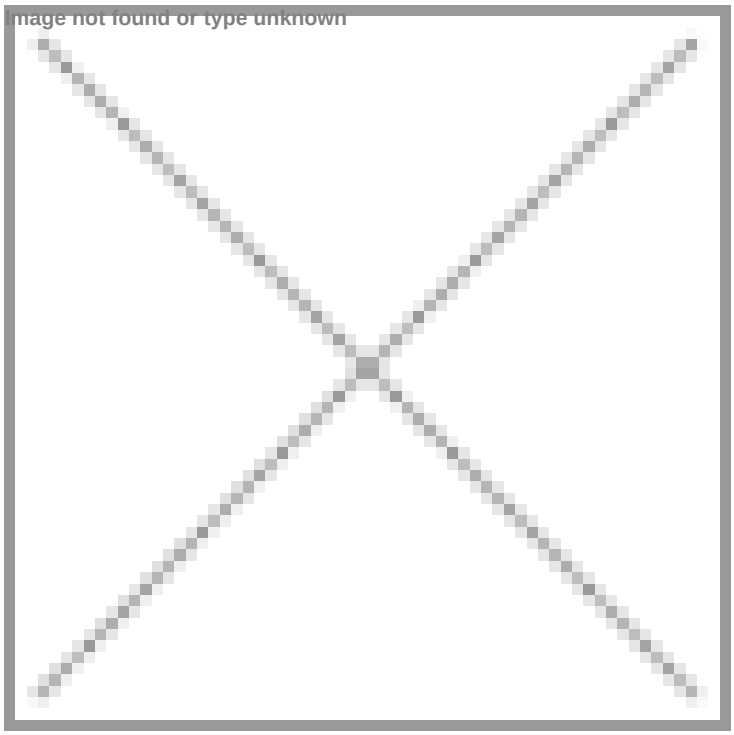
Biosimilars are an important part of modern therapeutics and a central component of India's shift beyond agenerics-led pharmaceutical model. As of December 2025, India has approved 146 biosimilars, giving it one of the largest and most diverse biosimilar portfolios globally. This portfolio has been built by around 33 companies actively engaged in biosimilar development and manufacturing. The Indian biosimilars market was valued at approximately Rs 4.37 billion in 2024 and is expected to grow at a compound annual growth rate of 14.2 per cent, reaching around Rs 16.49 billion by 2034, according to Expert Market Research. Policy initiatives, closer regulatory alignment with global standards, and a growing emphasis on exports are reinforcing biosimilars as a core pillar of India's evolving pharmaceutical landscape. Let's look at the current biosimilars landscape in India and how it is evolving.



Current Bisosimilars landscape in India

India's biosimilars landscape is at an advanced and rapidly scaling stage, with the country emerging as one of the world's most active biosimilar hubs. By December 2025, India had approved a total of 146 biosimilar (recombinant therapeutic products), including insulins, growth factors, peptide hormones, fusion proteins, and monoclonal antibodies.

India initiated the development and regulatory approval of recombinant therapeutics considerably earlier than many emerging markets, with the first approvals appearing as early as 2000. However, biosimilar activity remained limited during the initial decade, largely confined to relatively simple recombinant proteins such as erythropoietin, granulocyte colony-stimulating factors, insulin, and follicle-stimulating hormone.

A gradual transition toward more complex biologics began after 2013, marked by the approval of India's first biosimilar monoclonal antibodies, including rituximab, trastuzumab, and infliximab. From this point onward, the Indian biosimilar landscape expanded steadily, with increasing participation from domestic manufacturers and a diversification of therapeutic areas, particularly oncology, autoimmune disorders, and ophthalmology. The approval of biosimilars such as bevacizumab, ranibizumab, adalimumab, etanercept, and denosumab reflects a clear shift toward high-complexity antibody and fusion protein products.

Biosimilar approvals accelerated notably after 2018, coinciding with the maturation of India's regulatory guidelines for similar biologics and enhanced manufacturing and analytical capabilities within the domestic biopharmaceutical sector. Between 2020 and 2024, the approval volume increased substantially, driven by multiple approvals of monoclonal antibody biosimilars across oncology and immunology, as well as expanded approvals for insulin analogues and peptide hormones.

Based on the approvals from the regulatory agency, India's biosimilars approved between 2000 and December 2025 can be broadly classified into two major categories.

Peptide- and protein-based biosimilars form the foundational layer of India's biosimilar ecosystem and account for approximately 74 approvals during this period. These include insulins (regular, isophane, biphasic, and insulin analogs), erythropoietin and darbepoetin, filgrastim and pegfilgrastim, follicle-stimulating hormone, human chorionic gonadotropin, teriparatide, somatropin, interferons, romiplostim, tenecteplase, and streptokinase. This category dominates the early phase of biosimilar development in India and continues to contribute substantially to cumulative approvals through 2025, driven in particular by repeated approvals of insulin formulations and hematopoietic growth factors.

Antibody- and fusion protein–based biosimilars represent the most rapidly expanding segment since 2013 and account for approximately 72 approvals till December 2025. These include monoclonal antibodies and related biologics such as rituximab, trastuzumab, trastuzumab emtansine, bevvacizumab, ranibizumab, adalimumab, etanercept, infliximab, denosumab, cetuximab, nimotuzumab, tocilizumab, golimumab, ustekinumab, nivolumab, pertuzumab, omalizumab, aflibercept, and trinbelimab.

While oncology accounts for roughly 40 per cent of approved biosimilars, indications are increasingly expanding into immunology, ophthalmology, and metabolic disorders.

Key players such as Biocon, Intas Pharmaceuticals, Dr. Reddy's Laboratories, Zydus Lifesciences, Reliance Life Sciences, Hetero Biopharma, and Lupin hold multiple approvals across diverse therapeutic areas.

India's biosimilar manufacturing base has expanded steadily since 2000 and now comprises around 33 companies with focus on three areas: insulin and insulin analogues, oncology biologics, and immunology.

Insulins and insulin analogues form one of the most established segments, with around 10–11 companies producing human insulin, insulin glargine, biphasic insulin, and insulin aspart, reflecting strong domestic capability in high-volume, chronic therapies.

Oncology biosimilars, including monoclonal antibodies and supportive growth factors, represent the most developed and complex segment. Approximately 8–9 companies hold approvals for key reference products such as trastuzumab, rituximab, bevacizumab, filgrastim, pegfilgrastim, and darbepoetin, highlighting India's growing competence in advanced biologics manufacturing.

The immunology and autoimmune segment involves 6–7 companies active in TNF inhibitors and interleukin-targeting biologics, indicating expanding expertise in chronic inflammatory diseases. Ophthalmology biosimilars, largely centred on ranibizumab, are produced by 5–6 companies, while endocrinology and bone health products such as teriparatide, denosumab, and somatropin are manufactured by 4–5 companies.

In addition, fertility and hormone therapies involve 3–4 companies, and infectious disease and other biologics, including interferons, rabies monoclonal antibodies, and thrombolytics, are produced by 3–4 manufacturers. Taken together, this distribution illustrates a diversified biosimilar ecosystem, with multiple companies participating across therapeutic areas rather than concentration in a single segment.

Biosimilars in development

Industry and market reports indicate continued expansion in biosimilar development activity in India. According to Market Data Forecasts, biosimilar clinical trial activity increased by approximately 25 per cent in 2023, signalling a sustained build-up of the development pipeline compared with earlier years (BIRAC reported around 40 biosimilars in clinical development in 2019). Based on this trajectory and available forecasts, the current biosimilar pipeline is widely estimated to include around 50–70 biosimilars in clinical development.

Indian Biosimilars in Foreign Markets

India's biosimilars industry is increasingly shaped by exports, with international markets driving scale, investment, and strategic focus. Indian manufacturers have built on their strengths in cost-efficient production, regulatory compliance, and large-scale manufacturing to supply both regulated and emerging markets.

The US is the main market. Indian companies currently supply 47 per cent of all generic prescriptions filed in the U.S. and around 15 per cent of biosimilars by volume, according to IQVIA. While India's share of biosimilars volume is significant, its revenue contribution remains comparatively modest. In revenue terms, India accounted for approximately 3.2 per cent of the global biosimilars market in 2025, according to the Grand View Research report.

Indian biosimilar exports, currently valued at around $0.8 billion, are projected to grow to approximately $4.2 billion by 2030, accounting for about 4 per cent of the global biosimilars market.

Exports continue to dominate market dynamics. "Currently, India's biosimilars market is export-driven, with imports playing a relatively minor role. Imports are largely innovator biologics (reference products) used for clinical trials or niche therapies not yet produced locally. The share of imports in overall biologics consumption is declining, as several local biosimilar manufacturers have achieved strong market penetration," said **Dr Sridevi Khambhampaty, CEO, Shilpa Biologics**.

Sanjay Vyas, Managing Director, Parexel India agrees, "India has traditionally been export-oriented in biosimilars, supplying cost-effective products to both emerging and regulated markets. Exports continue to dominate, reflecting India's strength in large-scale manufacturing and biosimilar development. Imports, meanwhile, remain relatively limited and are typically focused on niche or highly specialised biologics."

He added, "That balance is gradually evolving. As India's regulatory environment becomes more accepting of global data and streamlined biosimilar pathways, the domestic market is also seeing faster access to biosimilars developed both locally and internationally. Over time, this is expected to create a more balanced ecosystem, one where India remains a global export powerhouse while also strengthening domestic availability and patient access through quicker biosimilar launches."

How India's Biosimilars Industry Is Evolving

India's biosimilars market is moving from early adoption to structural maturity. "For Indian pharma, biosimilars now represent a natural bridge between generics and innovation-led R&D. Firms with decades of manufacturing credibility are reinvesting that advantage into globally relevant biosimilar programs, particularly for regulated markets. Combined with India's strengths in contract manufacturing, digital enablement, and a high-quality scientific workforce, this positions the country not just as a low-cost producer, but as a strategic global hub for biosimilar development and supply," said Vyas.

A key catalyst accelerating this transition has been the changing global and domestic regulatory environment. “Recent regulatory flexibility, particularly in the US and Europe has reduced the need for large, late-stage phase III clinical trials for biosimilars where sufficient analytical, PK (pharmacokinetic), and real-world evidence is available. This has significantly lowered development costs and timelines, making biosimilars a more attractive and viable pathway for Indian companies,” said Vyas.

Domestic regulatory reforms are further strengthening this trajectory. “Regulatory reforms by the CDSCO, including draft guidelines aligned with global standards and proposals to allow waivers for certain trials, may accelerate development and approvals,” said a spokesperson from Shilpa Biologicals.

These regulatory and market tailwinds have pushed the Indian biosimilars industry into a new phase of maturity. “India’s biosimilars industry is entering a decisive maturation phase. The early growth model anchored primarily in cost arbitrage, process efficiency, and fast-follow development has largely played out. Indian players have demonstrated that they can reliably develop and manufacture high-quality pharmaceuticals at scale. That credibility is now well established across regulated and semi-regulated markets,” said **Shreehas Tambe, CEO & Managing Director, Biocon Biologics Limited**.

Dr Cyrus Karkaria, President – Biotechnology, Lupin agrees, “Historically, India’s strength lay in affordability and scale. Today, that advantage is being reinforced by high-end biologics manufacturing know-how—from robust cell line development and process characterization to advanced upstream and downstream technologies such as perfusion-based manufacturing and continuous chromatography”

This evolution is increasingly evident in how Indian companies approach biosimilar development and regulatory strategy. “Indian companies are no longer approaching biosimilars purely as cost plays; instead, they are designing programmes with early engagement with regulators such as the US FDA and EMA, and with a clearer focus on global filings. This transition is supported by a steadily expanding innovation base: India’s pharma R&D pipeline has grown by roughly 1.5x over the past decade, underscoring a broader shift toward higher-value science, as highlighted by recent McKinsey & Company analyses,” said Vyas.

Despite persistent challenges, India’s direction is clear. “Despite high development costs and challenges such as patent litigation and limited penetration in regulated markets, India is positioning itself as a global biologics hub. Further, Indian companies like Shilpa Biologicals are foraying into complex biosimilars such as ADCs and are also opening up to work on novel biologicals, marking a shift away from traditional biosimilars,” said Dr Sridevi.

The Next Phase of India’s Biosimilars Market

Most experts agree that India’s biosimilars ecosystem is entering a new phase, shaped by regulatory evolution and more efficient development pathways. The focus is increasingly shifting toward interchangeability and global exports.

“Looking ahead, the next phase will be defined by smaller, more targeted studies, greater use of real-world and observational data, and closer regulatory dialogue. While clinical trials remain essential, they are becoming more focused and risk-based rather than expansive by default. This evolution positions India well to compete with other global biosimilars hubs, provided companies continue to strengthen regulatory strategy, data quality, and global execution capabilities,” said Vyas.

Strong regulatory support, expanding biologics expertise, and strategic partnerships are accelerating the momentum. These drivers are supporting both domestic uptake and export-led growth. “With multiple biosimilars approved or under review in highly regulated markets, Indian companies are strengthening global confidence in the country’s biosimilars capabilities. Players such as Biocon Biologics continue to reinforce India’s position as a reliable and increasingly sophisticated global supplier," said Tambe**.**

Indian companies are also working to improve biosimilar manufacturing robustness and scalability. “The industry is moving decisively towards smarter manufacturing robustness across scales including medium-scale perfusion systems, modular facilities, and flexible upstream–downstream integration. The shift will also be marked by the adoption of design processes that are economically sustainable, not just scientifically sound. These approaches allow manufacturers to increase yields dramatically while maintaining quality and regulatory confidence,” said Dr Karkaria.

Stronger global acceptance and more advanced manufacturing practices are reshaping India’s role in the international biosimilars market. “India’s biosimilars ecosystem is undergoing a quiet but significant rebalancing. India is increasingly becoming a net exporter of high-quality biosimilars, enabled by price competitiveness, process sophistication and manufacturing credibility. As manufacturers invest in high-yield cell lines, longer resin life cycles, and integrated modular

facilities, India’s role is evolving from a cost-efficient producer to a reliable global manufacturing hub for biosimilars,” said Dr Karkaria.

As over 55 blockbuster biologics lose patent exclusivity in the US and Europe by 2030, Indian players are perfectly positioned to capture the global patent cliff opportunity. Regulatory changes introduced in the United States in October 2025 are lowering development and approval barriers for biosimilars, supporting faster market entry. While the US remains a key market, trade uncertainty and the possibility of tariff actions are leading Indian companies to expand export strategies, with filings increasingly planned across Europe and other regions. All this is expected to define the next phase of India’s biosimilars industry.

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