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“The biosimilar developers are eagerly awaiting revised CDSCO regulations that might lead to simplification of the development pathway for biosimilars”

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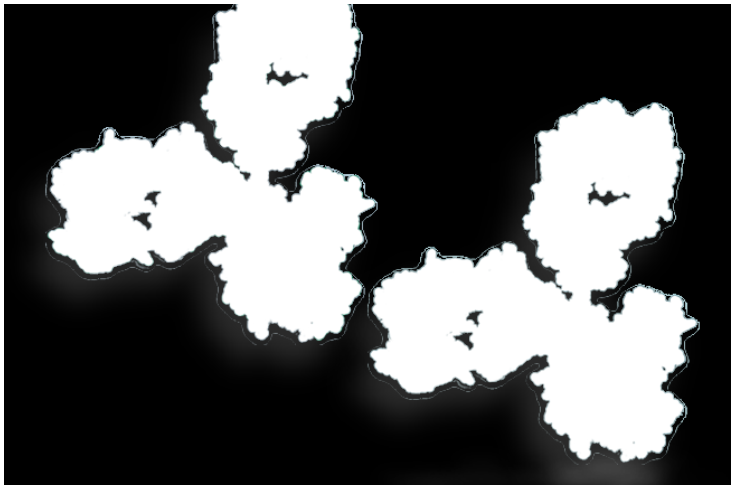
In an interaction with BioSpectrum, Dr Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC), reflects on the evolution of India’s biosimilars sector and shares his insights on the country’s growing role in the global biosimilars landscape over the next decade.



How has India's biosimilars landscape evolved over the past 25 years, and what have been the most significant milestones? Can you share insights into the number of biosimilars approved for domestic use vs. exports?

India approved its first biosimilar, Biovac-B for hepatitis B in 2000 which was launched by Wockhardt Limited. Since then, several biosimilars have been developed and marketed in India by various biopharmaceutical companies. Department of Biotechnology (DBT), India announced the release of regulatory guidelines for ‘similar biologics’ on 19 June 2012 and these guidelines were implemented on September 15, 2012. The guidelines outline a simple abridged procedure for evaluation of ‘similar biologics’ which have been approved and marketed in India, Europe or USA for more than four years. These guidelines were then revised and updated, with new guidelines, which came into effect in August 2016.

Apart from the streamlined regulations, DBT and its public sector enterprise Biotechnology Industry Research Assistance Council (BIRAC) have made sustained efforts through funding, policy advocacy, new initiatives, capacity building, and promoting innovation and infrastructure creation in research institutions, small and medium size companies, and large firms. The schemes of BIRAC like the Biotechnology Industry Partnership Program (BIPP), Small Business Innovation Research Initiative (SBIRI) and Promoting Academic Research Conversion to Enterprise (PACE) launched between 2008 and 2012 are to assist small and medium-sized biotech firms in the creation of biosimilars.

In 2017, the Government of India, DBT with co-funding from World Bank, launched the National Biopharma Mission (NBM), an Industry-Academia Collaborative Mission for accelerating discovery research to early development for Biopharmaceuticals, implemented by BIRAC. One of the focused mandates of the Mission is to accelerate the biosimilar development to bring them closer to market.

Under these schemes, BIRAC has supported several biosimilars including Trastuzumab, Insulin Glargine, Insulin Lispro, Bevacizumab, Ramicirumab, Liraglutide, Aflibercept, Pertuzumab, Romiplastim, Ustekinumab, Insulin Aspart,

Pembrolizumab, Golimumab, and Pegloticase. Many of these biosimilars are also developed by startups. Of these, Biosimilar Liraglutide for type 2 diabetes was developed by Levim Biotech LLP, and launched in the market by Glenmark (Levim's marketing partner) in January 2024 under the brand name "Lirafit", and is the first biosimilar of Liraglutide in market and introduced at ~65 per cent discount over the innovator's price. Many other biosimilars supported by NBM and BIPP and other schemes of BIRAC will be ready for market launch in the next 1-2 years.

The NBM has also contributed in establishing regulatory-compliant, accessible facilities to cater to services for bio-analytical and functional testing, immunogenicity testing and cGMP manufacturing of clinical trial lots, to support domestic industry and startups to accelerate the development of biosimilars to improve accessibility and affordability. In addition, NBM also supported indigenous production of raw materials such as culture media, resins and Single-Use Bioreactors which will further reduce the manufacturing costs of biosimilars and other biologics.

The biosimilar landscape in India is characterised by a multitude of bio-pharmaceutical entities actively involved in the production and distribution of biosimilar products. Prominent players include Intas Biologicals, Biocon, Dr. Reddy's Laboratories, Zydus Lifesciences, Reliance Life Sciences, Lupin Pharma, Cipla, Wockhardt Ltd. Apart from these, Gennova Biopharmaceuticals, Enzene Biosciences, Hetero Biopharma, Torrent Pharmaceuticals also have several approved biosimilar products for Indian and some for global markets. The startups who have ventured into biosimilars space include Levim Lifetech, Genext Genomics Pvt. Ltd, Lamark Biotech, Bycus Therapeutics, etc.

The biosimilar domestic market is projected to grow to ~$40 billion by 2030. Till date there are > 100 biosimilars for ~ 40 Reference Products (RP) approved from India, for oncology, hematological, immunological, toxicology, musculoskeletal and metabolic, hormonal, neurological disorders, ophthalmic diseases, infectious diseases, cardiovascular and respiratory diseases, and women health. Out of these ~ 20 (RP) biosimilars are exported to developed and emerging markets, mostly to USA, Europe, Brazil, Belgium, Netherlands, and Africa mostly by the Indian companies Biocon, Dr. Reddy's, Intas, Hetero and Lupin.

Which therapeutic areas have seen the most approvals?

Oncology has seen the most approvals, followed by haematological and immunological disorders.

How do you see India's role in the global biosimilars industry in the next 10–15 years?

Indian companies currently hold less than 5 per cent of the global biosimilars market, but with increasing R&D investments and an expanded product pipeline, biosimilar exports are expected to grow from $0.8 billion now, to $4.2 billion (£3.3 billion) by 2030, and $30-35 billion by 2047. Over the next seven years, about 100 drug patents valued at a total of $180 billion are expected to expire, creating a good opportunity for Indian companies.

As per the landscaping exercise done by BIRAC, large companies in India are trying to be vertically integrated in-house – i.e. Clone development to Manufacturing and aiming at the global markets from conceptualisation stage. The companies are also licensing tie-ups at an early stage or taking the co-development route. On August 31, 2024, Science &Technology Minister Dr Jitendra Singh released the BioE3 Policy. The policy, which is jointly implemented by DBT and BIRAC, aims to foster high-performance biomanufacturing in India. It seeks to develop and commercialise bio-based products through the establishment of BioEnablers like Bio-AI Hubs, Biofoundries, and Biomanufacturing Hubs, which will give a major boost to the biosimilars sector.

India's biotech ecosystem includes more than 800 core biotech companies, over 100 bio-incubators, and ~ 10,000 biotech startups. This investment, along with the focus on innovation, will encourage the growth of Indian biopharma capabilities. The 2024 Indian Bioeconomy Report prepared by the Make in India Facilitation Cell of BIRAC with research support from the Association of Biotechnology Led Enterprises (ABLE), highlights that India's BioEconomy achieved a landmark value of $151 billion in 2023, reflecting impressive double-digit growth. The report also gives hope that India is in the right direction to cross the $300 billion mark by 2030.

On the regulations side, on April 10, 2025, the FDA announced the plans to phase out animal testing requirements for monoclonal antibodies and other drugs. The biosimilar developers are eagerly awaiting revised CDSCO regulations which might lead to simplification of the development pathway for biosimilars with improved accessibility and affordability. The BioSecure Act is also expected to benefit India.

All of this will support the growth of smaller Indian companies into key players in the global biosimilar industry and help establish India as a leading contributor to the international biosimilar market over the next 10 to 15 years.

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