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Boost For India's Generic Pharma Majors

Biocon, Dr Reddy's and Mankind Pharma stress on development and manufacturing of biological drugs, look to cash in on a growing market. **By Joe C. Mathew**

WHEN BENGALURU-BASED Biocon Ltd. decided to focus on biosimilars — drugs and therapeutics that are similar to innovative biotech products already approved by the regulator — in the early 2000s, very few Indian firms were willing to take the plunge. An evolving regulatory landscape and substantial financial outlay for R&D and manufacturing infrastructure posed significant risks.

Biocon's biosimilar foray began with a partnership with U.S.-based Mylan (now Viatris) for biosimilar monoclonal antibodies (mAbs) in 2009, which subsequently expanded to insulin analogs in 2013. The partnership leveraged the strengths of both — R&D and manufacturing capabilities of Biocon, and regulatory and commercialisation of Mylan in global markets.

Almost a decade later, Biocon acquired the global biosimilar business of Viatris in November 2022, creating within Biocon Biologics a fully integrated 'lab to market' biosimilar enterprise with one of the strongest portfolios and pipelines in the industry. Though not many Indian players have gone that far, domestic pharma companies have still come a long way from being a marginal player in biosimilars to looking at the segment as an integral part of their future growth plans.

From Dr Reddy's to Zydus Lifesciences, and Lupin to Mankind, domestic drug firms are making major investments in the space, thanks to the savings potential that biosimilars offer, compared to biotech products.

One major trigger has been the change in mindset of global drug regulators to simplify the approval process and reduce both cost and time for biosimilar development. In the U.K., the Medicines and Healthcare products Regulatory Agency (MHRA) removed the need for Phase 3 clinical trials for certain biosimilars. The U.S. FDA has eliminated the requirement for Phase 3 trials to approve interchangeable insulins. Regulators are also increasingly receptive to reduce trial sizes and focus on non-clinical data to establish biosimilarity. Hence, the global biosimilar market today is worth $33 billion, with India having a 5-6% market share. According to the Indian Pharmaceutical Alliance (IPA), the global market is projected to grow at a 20% CAGR to $122 billion by 2031, an opportunity no pharmaceutical company wants to miss.

"India is rapidly establishing itself as a leading hub for biologics and biosimilars. The country's biopharma sector aims to replicate its global success in generic drugs and vaccines by focusing on biosimilars, emphasising affordable access through technological innovation and economies of scale. Over the past decade, India has seen the largest number of approved biosimilars, and several of these are now serving the needs of patients globally," says Kiran Mazumdar-Shaw, executive chairperson, Biocon and Biocon Biologics.

Who's Doing What

- **Biocon Biologics** has commercialised eight biosimilars in the U.S., Canada, Europe, Australia, and Japan. It has a portfolio of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, and other non-communicable diseases.
- **Dr Reddy's** has a fully integrated biosimilars business with six commercial products marketed in India, and some products marketed in more than 25 other countries. The company has a pipeline of products in oncology and auto-immune diseases, in various stages of development for global launches.
- **Zydus Life** has a portfolio of 13 biosimilars. The company eyes a portfolio of 25 products in the next three-four years.
- **Mankind Pharma** recently acquired Bharat Serums and Vaccines (BSV) for $1.64 billion. BSV has an established specialty R&D tech platform with complex portfolios across women's health, fertility, critical care and immunoglobulin segments.

The Indian drug regulator has also been proactive in ensuring that domestic companies get a conducive regulatory environment to develop and launch biosimilars. As a result, over the past decade, India has seen the largest number of approved biosimilars serving the needs of patients globally. "The introduction of the government's guidelines for biosimilars in 2012, revised later in 2016, has paved the way for increased investment in this sector. The guidelines established a regulatory framework for the development, evaluation, and approval of biosimilars, ensuring quality, safety, and efficacy of these products. Companies now look at strategic initiatives for vertical integration and scale for developing cost competitiveness," says Sudarshan Jain, secretary general, IPA.

According to Jain, a key driver for the market has been the loss of exclusivity for several patented biotech drugs in the U.S., the world's largest pharmaceutical market. "More than 55 blockbuster biotech drugs with projected $310 billion in sales are losing market exclusivity by 2032. At the same time, there is accelerated biosimilar adoption in major markets with over 80% for some molecules in the U.S. Although it varies by molecule, adoption is most notable for oncology therapies. Regulations now are more and more in favour of biosimilars," says Jain.

Recent announcements from leading domestic firms are testimony to the growing interest in biologics. In June, Aurigene Pharmaceutical Services (Aurigene), a global contract research, development, and manufacturing organisation set up by Dr. Reddy's inaugurated its 70,000 sq.ft. biologics facility in Genome Valley, a bio-cluster, in Hyderabad. The facility is designed to serve customers with process & analytical development and small-scale manufacturing of antibodies and other recombinant proteins for preclinical and early phase clinical requirements. Dr Reddy's already markets six commercial biosimilar products in India, with some products marketed globally in more than 25 countries. One of the products, Pegfilgrastim, has been commercialised in the U.S. and in Europe through a marketing partner. The company also has a pipeline of products in oncology and auto-immune diseases in various stages of development for global launches, including a biosimilar Abatacept candidate and a biosimilar Rituximab candidate.

In July, Delhi-based Mankind Pharma announced the acquisition of Bharat Serums and Vaccines for $1.64 billion to enhance its biopharmaceutical offerings. In August, Mumbai-based Lupin said it has received approval from Health Canada to market its biosimilar Pegfilgrastimin in the country. "Biosimilars play an important role in providing access to cancer treatment and supportive care. We are happy to receive our second biosimilar approval in Canada and look forward to maintaining this momentum with additional launches in regulated markets," says Cyrus Karkaria, president, biotech division, Lupin.

Zydus Life considers biosimilars as the only way to make biotechnology products affordable for patients in India and emerging markets. "Even in India, there are so many biotechnology products that are life saving, patented, but have access to only 5% of the required population. It is very disheartening to see that life-saving medicines are either not accessible, or are at a price point where a very small percentage of the deserving population can get it. That's why we decided to stick to India and other developing countries to create access for biosimilar products," says Sharvil P. Patel, MD, Zydus Lifesciences. The company offers its breast cancer drug Ujvira — an antibody drug conjugate biosimilar of Trastuzumab Emtansine highly effective for treating early and advanced HER2 positive breast cancer — at an 80% lower price than the currently available options, the company claims. On the global front, Biocon Biologics, the pioneer in the sector, says its biosimilar Pegfilgrastim, Trastuzumab and Insulin Glargine clocked around 20% market share in March 2024 in the U.S. In Europe, Biocon's biosimilars for Adalimumab and Trastuzumab have double-digit market shares in several countries, the company says. With eight biosimilars commercialised in global markets, Biocon touches the lives of nearly 5.5 million patients globally every year.

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Kiran Mazumdar-Shaw, executive chairperson, Biocon and Biocon Biologics

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Cyrus Karkaria, president, biotech division, Lupin

"India has over 100 approved biosimilars which shows the industry's commitment to advance public health," says IPA's Jain. "The recent approval of CAR T-Cell therapy and various platforms of vaccines is indicative of the sector's focus on moving up the value chain. The story of Indian entrepreneurship is driven by a commitment to providing quality and affordable medicines to patients around the world. Indian regulators are working to align with global best practices. We will see high thrust in the coming years."

Though not a leading player internationally, many Indian biosimilars are being supplied to highly regulated and advanced markets in North America, Europe, and Japan. The government's decision to deepen the penetration of health insurance, accelerated by the introduction of schemes such as Ayushman Bharat are resulting in the penetration of biosimilars into the Indian healthcare system like never before. Given the fact that these drugs address life-threatening conditions such as cancer, diabetes, and other immune-mediated diseases, Indian companies are finding market conditions ripe for both domestic business as well as international foray.

Biosimilars have the potential to fuel the Indian pharma industry and meet the unmet needs of patients globally, and there is a burgeoning market ahead.