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Research Article

Growth of Biopharma, Biosimilars and Biotechnology in Healthcare in India

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Abstract: Biosimilars market in India has witnessed the rapid expansion by increasing demand in healthcare market to build a strong biopharmaceutical manufacturing ecosystem. Biosimilars are closely resambling biological products to reference biologics that act as cost effective alternatives for treatment of chronic diseases such as cancer, diabetes, autoimmune disorders and other non-communicable diseases. As India is having price-sensitive healthcare landscape biosimilars cost advantage has catalysed its increased adoption by healthcare providers. India has emerged as one of the active biosimilar hubs with over 140 biosimilars approved for use in multiple therapeutic classes including insulins, growth factors, monoclonal antibodies and peptide hormones. Increase in chronic disease prevalence and increasing budget allocation to biopharma and healthcare industry has underscored the robust trajectory of the biosimilars market in India positioning as a significant contributor to domestic healthcare.

Keywords: Biosimilars market (India), Biopharmaceutical manufacturing, Cost-effective biologics, Chronic diseases, Healthcare affordability.

INTRODUCTION

The pharma sector has seen the fastest transition from generics to biologics and eventually to biosimilars with the first approval in 2006 in Europe followed by US approval in 2015. Hepatitis B vaccine has been approved as first recombinant biologics in 2000. More than 20% of generic medicines along with 62% share of vaccine supply is by the Indian Pharmaceutical industry. This strong position of India in biologics and biosimilar production has led to improved healthcare with lower treatment cost. A significant increase for investing in the biosimilars have been witnessed for last few years. Several India based industries such as Enzene private Ltd. are positioning themselves alongside the established leaders such as Dr. Reddy's and Biocon. A significant enhancement to this Industry was with the remarkable success in production of vaccine by Bharat Biotech and Serum Institute of India against SARS-CoV2 virus during recent pandemic. Thus biopharmaceutical industry of India has played in manufacture and distribution of therapeutic products to fight against this virus that has affected global healthcare system. Despite of some constraints such as weaker supply chain along due to workforce demands the production was increased to provide high quality medication to more than 133 nations at a reasonable price.

Biosimilars being cost effective strategy over the expensive conventional therapies for treatment of many chronic ailments including diabetes, respiratory problems, cancer, connective tissue diseases. Many biologics and biosimilars have been tested and proved for managing the symptoms of COVID-19 characterized by inflammation and respiratory distress.

However, there are some gaps in effective translational research in India that needs to be addressed promptly. Innovative ideas demand strong and effective collaborations among various institutions, universities, research labs, techno-incubators and industries. Many successful research findings in academic institutions do not get translation opportunities due to less industrial collaboration, limited intellectual property knowledge and publication pressure with stringent timelines. This review evaluates the position of India in the biosimilar space, the gaps and areas for improvement addressing need for more

skilled workforce, industrial collaboration and effective business models.

New regulations have been implemented in response to the rising cost of biological medicines to promote the development of biosimilars with the objective to expand the treatment choices, improving patient accessibility and reducing the healthcare expenses. Biosimilars are the biological products that closely resamble the existing reference biologic in structure and are not exact copies. They demonstrate comparable clinical performance to the original product with respect to safety, efficacy and biological activity that are administered at equivalent therapeutic doses and strength. Manufacturers of biosimilars has to take the commercial authorization to market them as the drugs after their regulatory approvals and intellectual property issues. Due to increased prevalence of the autoimmune diseases and cancers there has been increasing demand for biologics and biosimilars.

Since there is an increasing demand for biosimilars and vaccines so huge potential and market opportunity is there for biopharmaceutical business. A clear stepwise plan assure the regulatory approval and optimal market access for biosimilar research and commercialization. With the growing competition from biosimilars, companies marketing branded biologic products are experiencing a decline in market share and focus. To sustain their growth, it is essential for these industries to adopt an integrated strategy that aligns development and commercialization efforts from the outset of biosimilar programs, ensuring their successful launch.

This comprehensive review examines Indian biotech and biopharmaceutical companies as emerging global players, highlighting their strengths, limitations, challenges and growth opportunities. Moreover, it adds light onto the history and scope along with the evolution of biotechnology companies in india. It put emphasis on the elevated Indian strategies and participation to lead and regulate the international biosimilars and vaccines market.

HISTORY OF BIOTECHNOLOGY IN INDIA

Biotechnology is the production and development of products using the biological systems including the live cells from microbial, plant and animal origin as well as their derivatives and recombinant molecules to improve human life. Majorly it involves the modification of the conventional processes ranging from the old biotechnology to the modern biotechnological processes involving modified molecular processes. Genetic engineering has led to create the transgenics (genetically modified) organisms that can be used to prepare vaccines, drugs, diagnostic tools etc. Biosimilars and biologics provide the treatment for many chronic and fatal ailments.

Therefore, the Government of India is actively encouraging the growth of the biotechnology sector, recognising its role in building a sustainable future. The expansion of India's bio-based industries is being driven by financial backing from both public funding bodies and private investors including angel investors and venture capitalists. Many investments have been drawn for the development of high end innovative processes as start ups particularly by recent indian university graduates. Indian bioindustry can be classified into five main types viz. Biopharmaceuticals, agribiotech, bioinformatics, fermentation and bio-based sevices. Among the various segments the biopharmaceutical sector contributes the largest share of revenue. The agribiotechnology industry ranks third and focuses on transgenic crops, hybrid seeds, biofertilizers, biopesticides and related products. In recent years (2010-2011), the agribiotech segment accounted for approximately 14% of the overall bio-business revenue. Various products such as protein, natural amino acids and yeast, biofermentation produces chemicals that are generally produces chemicals that are used in many industrial applications ranging from leather to textile to healthcare industry. Bio services, on the other hand represent the bio industrial sector in India dealing with the services such as clinical trials, contract research, trading etc. rather than trading (https://www.indianmirror.com/indian-industries/biotechnology.html)

The expansion of the Indian biotechnology industry has been driven by multiple factors in the post-independence period. Key contributors include biotechnology enterprises founded by entrepreneurs from industrial and pharamaceutical backgrounds, as well as academic scientists with exposure to industry practices. Additionally, the return of Indian scientitsts, postdoctoral researchers and entrepreneurs with significant international academic and industrial experience has further strengthened the sector. New startups has been founded by extending the division from the existing drug industry diversifying it to multinational companies.

Biosimilars have the potential to change the quality of patient's life by reduction in the cos to treatment. Moreover the management of the chronic diseases has become easier with that of biosimilars. The guidelines related to the biosimilars were established by the Central Drug Standard Control Organisation (CDSCO) and the Department of Biotechnology (DBT). These guidelines on the production and approval of biosimilars were revised in 2016. In 2019, India had 98 approved biosimilars. Currently so many biosimilars are in the developmental stages.

Overview of the Market size and present landscape of Indian Biotech companies in the Biopharmaceutical sector

The bioindustry has significantly contributed to strenthening the Indian economy. Currently, India hosts over 2,500

biotechnology companies along with more than 2,700 start-ups. The Indian bioindustry was valued at approximately US$63 billion in 2019 and is expected to reach around US$102 billion by 2025, registering a CAGR of 10.9%. During this period, its share in the global market is projected to increase from about 3% to nearly 19%.

Within this sector, biopharmaceuticals accounted for nearly 62% of the market in 2020, followed by bioagriculture at around 16% and bioservices at about 15%. The industry is rapidly expanding and has emerged as a major hub for contract research, clinical trial execution and manufacturing support services. The Indian pharmaceutical sector is increasingly focused on the development and production of biologics and biosimilars. Research in biosimilars in India is expected to deliver affordable and effective therapeutic solutions, particularly in the post-COVID-19 recovery phase.

At present, India supplies nearly 20% of the world's generic drugs and around 62% of global vaccines, establishing itself as a leading pharmaceutical exporter worldwide. The sector demonstrated strong resilience and a proactive response during the recent pandemic.

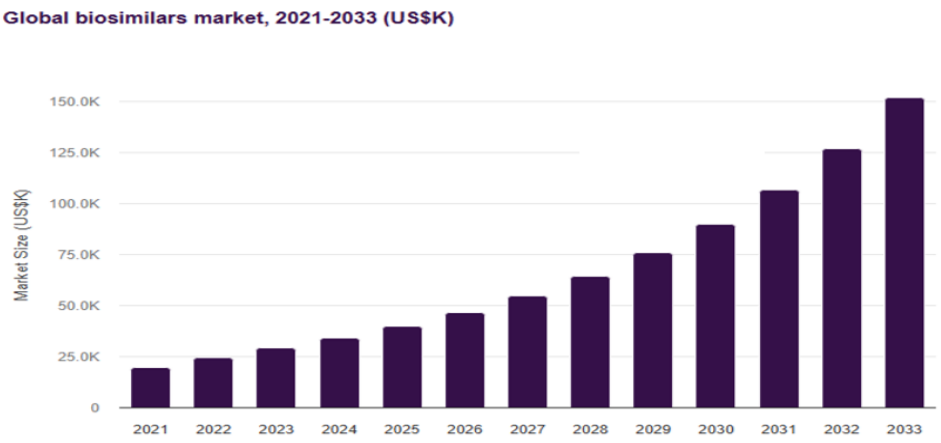
India's biopharma industry has been instrumental in dealing with the COVID-19 since the first reported case. Industries have provided the repurposed drugs, medicines at a reasonable price to 133 nations. At present, six Indian pharmaceutical companies are engaged in the production of the antiviral drug 'remdesivir' driven by its high global demand and distribution across 127 countries for managing the pandemic. In India, around 30 collaborative groups from industry and academic institutions are actively involved in the development of COVID-19 vaccines, many of which have received emergency use authorization. In addition, the country has made significant advancements in strengthening its nationwide immunization programme. There are still translational gaps to be appropriately covered. The adoption of good lab practices and good manufacturing practices (cGMP) for manufacturing ensured the participation of Indian producers of biosimilars to compete on the global market.

A short researched compilation of the state-of-art facts along with figures this provides an overview into the growth of the Indian biosimilars market and success of pharmagenerics at the global stage. Though there are some research gaps that limits the scope of this study. The primary focus is on evaluating the performance of emerging startup companies operating in the greenfield sector where data is often fragmented and not appropriately organised. Second factor is about the fine line of the difference between the new-age biosimilar products and the biologics thus making the picture somewhat blurred related to the financial projections that affect the global trends. Thirdly the understanding of the sectorial dynamics of the sector is not appropriate. A large proportion of biosimilars and vaccines in India are still in various stages of development, and their eventual influence on the global biosimilars landscape will become clearer over time. Furthermore, while India aims to extend its success in pharmaceutical generics to the more innovation and research driven domains of biosimilars and vaccines, it is likely to encounter significant competitions from countries such as the United States, China, South Korea, Japan and members of the European Union, with the full extent of these challenges emerging in the future.

GROWTH OF BIOSIMILAR GLOBAL AND INDIAN CONTEXT

Biosimilar have shown consistent growth globally, Fig 1 shows that markets have significantly generated revenue of USD 39,594.6 thousand in 2025 and the market is projected to be valued at approximately USD 151,575.3 thousand by 2033. It is anticipated to expand at a compound annual growth rate (CAGR) of 18.4% during the period from 2026 to 2033.

Fig – 1

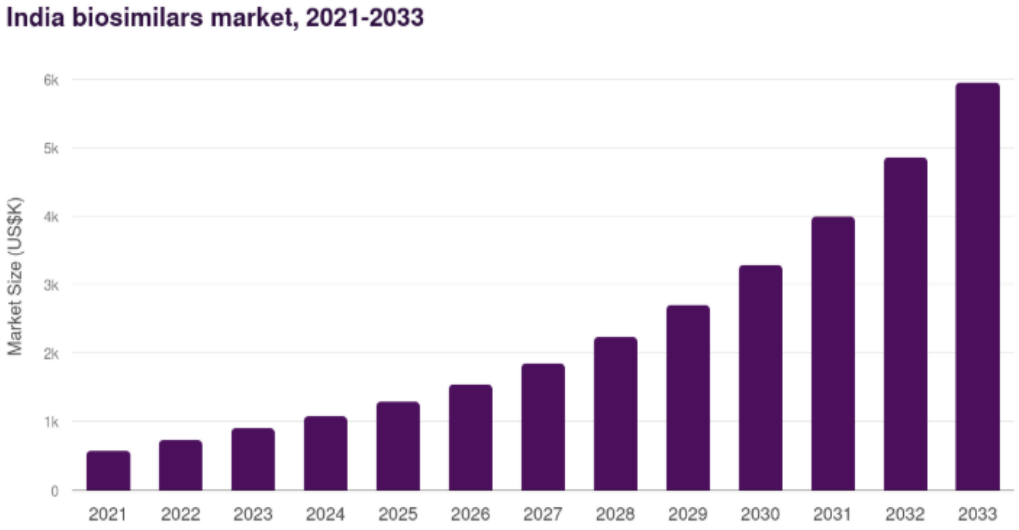


Source: https://www.grandviewresearch.com/horizon/outlook/biosimilars-market-size/global

In terms of segment, monoclonal antibodies (mabs) accounted for a revenue of USD 20,771.6 thousand in 2025. The Insulin and analogues segment represents the most profitable drug class and is expected to record the fastest growth during the forecast period1. Regionally, North America emerged as the leading revenue-generating market in 2025. At the country level, India is projected to achieve the highest CAGR between 2026 and 2033.
https://www.marketsandata.com/industry-reports/india-biosimilars-market
https://www.marketsandmarkets.com/Market-Reports/biosimilars-40.html

The market is projected to reach approximately USD 5,947.2 thousand by 2033, with India expected to expand at a compound annual growth rate (CAGR) of 21.3% from 2026 to 2033. In terms of drug class, monoclonal antibodies (mAbs) accounted for the highest revenue share in 2025, making it the leading segment. Meanwhile, the Insulin and analogues category is anticipated to be the most rapidly growing segment over the forecast period due to strong demand and expanding applications. From a global perspective, India contributed around 3.2% of the global biosimilar market in 2025 and is recognized as the fastest-growing market within the Asia-Pacific region.

Fig – 2



Source: https://www.grandviewresearch.com/horizon/outlook/biosimilars-market-size/global

In terms of market segmentation - Monoclonal Antibodies (mAbs), Growth Factors & Hematopoietic Agents, Insulin & Analogues, Osteoporosis / Bone Metabolism Agents, Others Drug Class are playing significant role in growth. The key players in this space include Amgen Inc, Roche, Sandoz Group AG, Dr. Reddy's Laboratories, Teva Pharmaceutical Industries Ltd, Pfizer Inc, Samsung Bioepis, Biocon, Viatris Inc, Celltrion Healthcare and AbbeVie Inc.

Table 1: List of approved biosimilars in India

Sr. No.	Biosimilar Product	Therapeutic molecule	Therapeutic Use	Company
1.	Glaritus	Insulin glargine	Diabetic melitus	Wockhardt/Biocon
2.	Grafeel	Filgrastim	Neutropenia	Dr. Reddy's/Reliance
3.	Peggrafeel	Pegfilgrastim	Cancer associated neutropenia	Dr. Reddy's/Intas
4.	Epofer/Epofit	Epoetin alfa	Anaemia	Imcure/Intas
5.	Zyrop	Erythropoeitin	CKD Anaemia	Cadila
6.	Exemptia	Adalimumab	Rheumatoid Arthritis/Crohn's disease	Zydus/Torrent
7.	Krabeva	Bevacizumab	Colorectal cancer	Biocon/Reliance
8.	Canmab	Trastuzumab	Breast cancer	Biocon
9.	Intacept	Etanercept	Rheumatoid Arthritis	Intas

10.	Razumab	Ranibizumab	Wet AMD, macular degeneration	Intas
11.	Reditux	Rituzimab	Lymphoma, autoimmune disease	Dr. Reddy's/Intas
12.	Abcixirel	Abciximab	Angina/Cardiac ischemia	Reliance
13.	Zyvinex	Interferon alfa 2 b	Hepatitis b/c	Cadila
14.	FostiRel	Follitropin beta	Female infertility	Reliance
15.	Choriorel	r-hcg	Female infertility	Reliance

CHALLENGES IN THE PRODUCTION OF BIOSIMILARS

There are some of the major challenges that need to be met before going for the mass production of biosimilars. There is uncertainity in the regulations for biosimilars. As biosimilar act also known as Biologics Price competition and innovation act was passed in 2010 to establish the guidelines. Mandatory licensing, uniformity in sales and marketing along with the competitive market are some of the major challenges for production of biosimilars.

CONCLUSION

In conclusion the strategic allocation of a special budget to India's biopharma sector in 2026 marks a significant moment in the Nation's biotechnology journey. This targeted investment will not accelerate the growth of biosimilars and biopharmaceutical innovations but also stregthens India's position as a global leader in affordable, high-quality biologics. By empowering support this financial stimulator will catalyze robust ecosystem growth by creating high skilled employment opportunities and ensure greater access to lifesaving therapies for many. This will positively impact not only healthcare outcomes but also the economic resilience.

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