Transforming India's Biopharmaceutical Landscape: The Expanding Role Of Biosimilars In Cost-Effective Healthcare



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Abstract

The development of biological treatments has changed the treatment modality for chronic diseases and diseases that could be life-threatening, but the issue is the exorbitant cost, making them inaccessible, especially in underdeveloped and developing countries. Biosimilars present an effective solution that is equally safe, effective, and of equal quality compared to biologics, hence offering affordable healthcare. This article examines the movement from biologicals to biosimilars, highlighting the science behind them, their regulation, and validation. The article also notes the growing bioeconomy in India, involvement of local pharmaceutical companies, and initiatives by the Indian government to encourage the development of biosimilars and advances in drug delivery systems.

Keywords: Bioeconomy; Biosimilars; India's pharmaceutical industry

1. Introduction

Biologics are approved drug products that are manufactured using living organisms or components thereof, like cells, tissues, or microorganisms. They usually comprise large, complex biomolecules like proteins or nucleic acids and are manufactured using biotechnology techniques or cell culture methods, which greatly affect their properties due to their highly process-sensitive nature. Estimates indicate that the price of some high-molecular-weight biologics is set to become even more unaffordable in developing countries between 2030 and 2040 (1). Biosimilars, on the other hand, are drugs of biological origin that closely resemble a pre-existing drug referred to as the reference product and have no significant qualitative and quantitative (safety, purity/quality, or efficacy) differences compared to the reference product. Due to the inherent variability of the biological system, biosimilars are not exactly identical to reference products, like generics. Therefore, a comprehensive evaluation of the product is needed, taking into account analytical, non-clinical, and clinical assessments to determine the similarities (2). The introduction of biosimilars provides an economical option, allowing significant price cuts and encouraging

competition, thereby reducing medical expenses. This has been proven by experience in Australia (3) as well as other international studies. Further budget analyses indicate that biosimilars, such as adalimumab and tocilizumab, can save €187 million annually in major European countries, thereby expanding patient access to these treatments (4).

2. Indian Market Dynamics and Growth Trajectory

2.1 Growth of bioeconomy

The bio-economy of India has shown substantial growth, accounting for around 4.25% of its Gross Domestic Product (GDP) at present. In the past ten years, there have been significant gains made in this industry, as shown in Figure 1. This is made possible through infrastructure development via funding from organizations such as the Biotechnology Industry Research Assistance Council (BIRAC), which offers financial support to fund capital expenditure and operational expenditure needs to develop a comprehensive end-to-end biopharmaceutical research lab (5, 6).

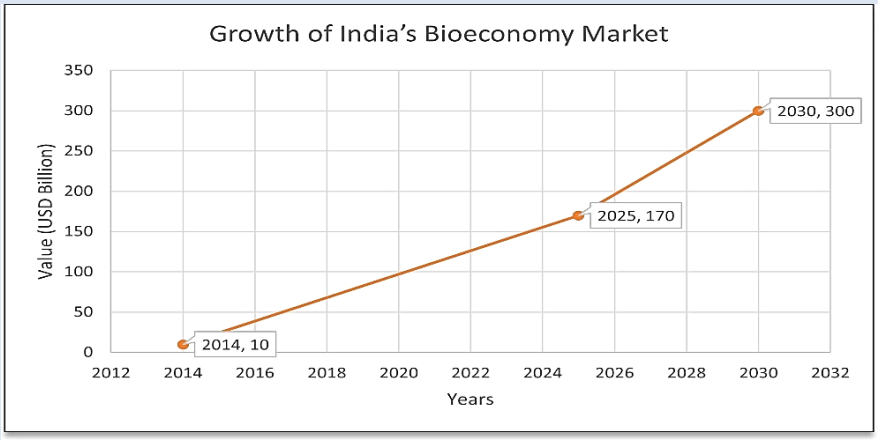

Figure 1. Growth trend of India's bioeconomy market from 2014 to 2030. By 2030, India's bioeconomy market is expected to hit $300 billion (5).

2.2 Role of Indian pharma companies

Indian pharmaceutical companies are currently gaining more prominence globally, not only by securing more drug approvals (more than 100) but also by succeeding in entering markets that have stringent regulations (7). For instance, the Biocon-Mylan alliance secured United States Food and Drug Administration (USFDA) approval of their biosimilars Ogivri (trastuzumab), Fulphila (pegfilgrastim), and Semglee (insulin glargine) in the United States(US) (7).

2.3 Global position of India

India is among the top countries globally for the pharmaceutical sector owing to its robust production capacity, cost-effectiveness, and high-quality standards. India enjoys a considerable stake in global pharmaceutical regulations through production in developed economies such as the US and Europe. India's participation in the global pharmaceutical industry can be summed up in three categories: generics, vaccines, and US prescriptions (8), as shown in Figure 2.

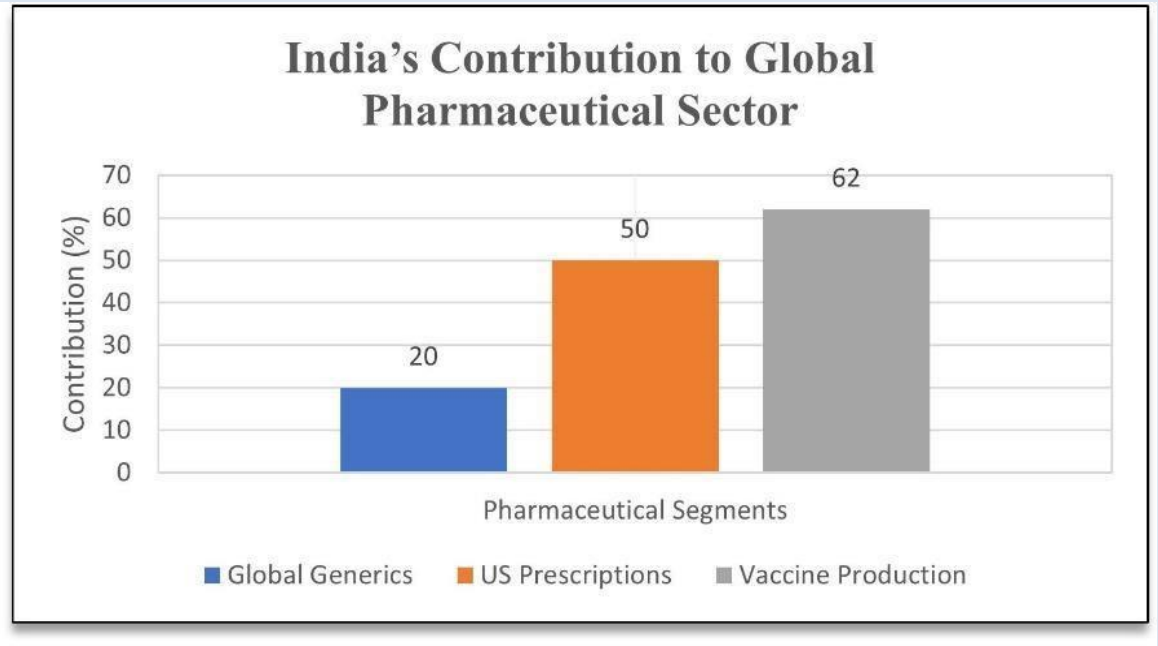

Figure 2. Comparative illustration of India's performance in various sectors of the global pharmaceutical industry.

3. Economic & Healthcare Impact

Biosimilar drugs have led to reductions in drug prices of 20% to 70% in sectors like oncology and rheumatology, making these medicines more accessible. This enables funding for new drug research while offsetting the high costs of biologics despite their relatively low utilization (9).

4. Clinical Evidence & Regulatory Aspects of biosimilars

Despite the considerable economic value associated with reduced costs and improved availability of biosimilars, biosimilars require strong clinical evidence and rigorous regulatory evaluation to ensure safety, efficacy, and quality.

4.1 Comparable safety & efficacy

Backtracking the study of 38 biosimilar developments revealed similar efficacies for all products, thus validating the existing developmental methods, while in 95% of the cases, the clinical efficacy studies did not add any extra value apart from analytical and pharmacokinetic information. The observations indicate that clinical studies are less sensitive in comparison to physicochemical, functional, and pharmacokinetic assessments in picking up minute variations (10).

4.2 Role of regulatory bodies

Regulatory bodies are key stakeholders in ensuring biosimilar safety, efficacy, and quality. The roles of major regulatory agencies in biosimilar evaluation are outlined in Table 2 (11).

Table 1. Role of Major Regulatory Agencies in Biosimilar Evaluation

Regulatory Agency	Role
Food and Drug Administration (FDA)	Biosimilars are regulated using the "Totality of the evidence" approach, a unique three-tier statistical evaluation to rank critical quality attributes based on their impact on biological activity.
European Medicines Agency (EMA)	Analyzes products that consist of a particular variant of an active substance that has been authorized within the European Economic Area (EEA).
World Health Organization (WHO)	Provides global guidance to standardize the evaluation of biosimilars and promote international harmonization of regulations

4.3 Totality-of-evidence approach

This represents a step-wise approach that considers analytical, clinical, and non-clinical data. Aims to resolve any ambiguities that may exist concerning the similarities between the product and any other analytical uncertainties to guarantee human safety. It includes the evaluation of primary sequences, protein structure, glycosylation profile, and biological activities (12).

5. Technological Developments in Biologics and Their Impact on Biosimilars

Innovations in biologics have revolutionized the treatment methods due to improvements in drug delivery systems and molecular engineering techniques. Examples of such advances include liposomal nanoparticles, hydrogels, exosomes, and viral vectors, which can increase the stability, marketability, and efficacy of biologics.

Another result of such technological progress has been the development of "bio-betters," i.e., improved versions of biologics intended to produce better therapeutic results than those offered by the original drugs. Even though these innovations were developed with new biologics and "bio-betters" in mind, they can also be used to improve biosimilar drugs.

5.1 Liposomes and Lipid Nanoparticles (LNPs)

Liposomes are spherical vesicles with a phospholipid bilayer used to deliver hydrophilic and hydrophobic drugs. The application includes oncology, antibody, gene, and small interfering ribonucleic acid (siRNA) delivery. Characterized by size, polydispersity, zeta potential, efficiency of encapsulation, stability and release profile. Manufacturing challenges include scalability, batch consistency, aggregation, cost, and immune responses; advanced processes and material modifications are being developed (13).

5.2 Hydrogels and Nano-Particle-loaded Hydrogels

Hydrogels are hydrated polymer matrices with adjustable pore sizes, swelling, and degradation, enabling controlled delivery of proteins, cells, or nanoparticles through ocular, dermal, and parenteral routes, evaluated based on Porosity, swelling behaviour, degradation speed, and mechanical stability. Nanogel formulations require measuring particle size,

loading, and release profiles. Used for localized, sustained delivery of proteins, cells, and nanoparticles in medicines, oncology, ocular, and dermal indications. Main challenges are release control, shelf life, immunogenicity, need for a more standardised and quality-by-design approach (14).

5.3 Exosomes & exosome–liposome hybrids

Exosomes are natural nanovesicles with lipid bilayers that transport proteins, nucleic acids, and lipids between cells. This system is typically evaluated based on parameters such as size (NTA-Nanoparticle Tracking Analysis/ DLS-Dynamic Light Scattering), morphology (electron microscopy), surface markers, cargo loading, stability, and biodistribution. Used for Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) plasmid delivery to hard-to-transfect cells (e.g., mesenchymal stem cells); systemic RNA/protein delivery. Challenges include low/variable loading, stability issues (−80°C storage), rapid clearance, scalability, and regulatory hurdles (15).

5.4 Lentivirus-derived nanoparticles (LVNPs)

The LVNP system mimics viral delivery without replication; its characterization involves p24 particle quantification, electron microscopy (EM), ribonucleoprotein content analysis, and on/off-target editing via Next-Generation Sequencing (NGS). These systems have demonstrated utility in *in vitro* CRISPR editing, base/prime editing, and *in vivo* eye gene targeting and have the potential for donor-free precise editing. Challenges include manufacturing complexity, safety and regulatory classification concerns vs. classical lentiviral vectors, and scalability limitations (16).

6. Government Initiatives (India)

India has implemented several initiatives to strengthen the biosimilar sector, which are summarized in Table 3.

Table 2. Government initiatives supporting biosimilar development in India

Scheme	Year	Application Scope	Funding	Ref.
Biopharma SHAKTI	2026	Building capacity & enabling innovations	₹10,000 crore (5-year allocation).	(17)
BioE3 Policy	2024	Economy, Environment, and Employment. leveraging common infrastructure, such as bio-foundries. Supports India's net-zero goals.	Strategic policy framework with infrastructure support and innovation incentives	(18)
National Biopharma Mission (NBM)	2017	local development of innovative products related to vaccines (like Human Papillomavirus, Dengue), biologics, and advanced diagnostics.	₹1,500 crore (World Bank-supported program).	(19)

7. Manufacturing, Quality Considerations and Challenges in Biosimilars

In the absence of cell line and process information of the originator's biologic, companies are forced to perform lengthy reverse engineering and process development. With respect to the downstream process, the maintenance of critical quality attributes (CQAs) involves rigorous control over all steps of purification, from the protein step up to viral inactivation, to prevent aggregate formation due to immunogenicity (20). Immune response continues to be an important issue. It is necessary to carefully evaluate and benchmark the incidence of anti-drug antibodies (ADAs) and neutralizing antibodies (NAbs) against that of the reference biologic (21). Patent thicketing and Intellectual Property (IP) lawsuits remain a prominent challenge, leading to a delay in introducing inexpensive biosimilars into the market by an estimated one-and-a-half to two years (9). Pricing strategies and competition complicate matters further. Biosimilars often reduce costs by 20–70%. However, intellectual property issues could impede market entry by 12–18 months (9).

8. Case Studies / Real-World Evidence

The Ontario, Canada, case study is an example of the effect that a policy of compulsory use of approved biosimilars on patients can have, resulting in cost savings and optimal resource utilization. The fast adoption of the scheme made it possible for 96.5% adoption of biosimilars to be realized in a short period of time, hence enabling cost savings of above $65 million in the span of just 15 months, with more anticipated economic savings expected to total approximately $96 million in the second year (22). The case study for Aflibercept biosimilars involves a Randomized Controlled Trial (RCT) Phase 3 wherein the biosimilar products showed safety, efficacy, and immunogenicity comparable with the reference products in the treatment of nAMD(Neovascular (wet) age-Related Macular Degeneration)
(23). The real-world adoption has demonstrated significant cost savings and improved access

9. Conclusion

The use of biosimilars leads to cost reduction, as biosimilars provide 20-70% savings compared to expensive biologics. This leads to savings that can be used for the benefit of patients and allows for a wider reach of treatments. Also, their use allows for improvement in the capacity of healthcare systems due to the ability to invest in new innovations and diversification of manufacturing. The effectiveness of their usage, though, depends on the management of increased health care utilization due to switching programs. India has taken an impressive position in the field of biosimilars and bioeconomy. With an existing bioeconomy worth $195.3 billion that aims to reach up to $300 billion by 2030, India proves its strong position in the area.

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