Comparative Review of Biosimilar Regulatory Frameworks in the United States, European Union, and India: Approval Pathways, Market Access, and Future Perspectives

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***Abstract*—Biosimilars are biologic medical products that are highly similar to approved reference biologics, with no clinically meaningful differences in safety, purity, or potency. They help reduce healthcare costs and improve patient access to expensive biologic therapies used in diseases such as cancer, autoimmune disorders, and diabetes. Regulatory frameworks for biosimilars differ across regions, where the United States, European Union, and India representing major markets with varying regulatory stringency, pricing policies, and market adoption. In India, the Central Drugs Standard Control Organization collaborates with the Department of Biotechnology to regulate biosimilars. The European Union has the most established framework under the European Medicines Agency, approving its first biosimilar, Omnitrope, in 2006, and achieving the highest market penetration, with biosimilars capturing 50–80% of therapeutic areas. The U.S. pathway, established under the Biologics Price Competition and Innovation Act, has led to increasing approvals, though overall adoption remains moderate. The study evaluates biosimilar approval pathways, clinical and analytical data requirements, review timelines, pricing structures, and market penetration trends. India has strong biosimilar manufacturing, but overall market uptake is limited by regulatory and access challenges. The global biosimilar market has grown rapidly over the past two decades, reflecting the need for cost-effective biologic alternatives and enhanced patient accessibility worldwide. Overall, the comparative analysis demonstrates that balanced regulatory oversight, efficient approval pathways, and supportive pricing policies are essential to enhance biosimilar accessibility, affordability, and global market growth.**

***Index Terms*—Biosimilars, Biologic therapies, Reference biologics, Regulatory frameworks, Market access, Pricing policies, United States, European Union, India, Healthcare costs, Regulatory Stringency.**

I. INTRODUCTION

Biologics are complex therapeutic products derived from living organisms and include recombinant proteins, monoclonal antibodies, vaccines, hormones, and cell-based therapies. These products are extensively used in the treatment of chronic and life-threatening diseases such as cancer, autoimmune disorders, diabetes mellitus, and inflammatory diseases. Due to their structural complexity, sensitivity to manufacturing conditions, and advanced production processes, biologics are associated with high development and treatment costs and therefore require stringent regulatory evaluation. Biosimilars are biological products that demonstrate a high degree of similarity to an already approved reference biologic, with no clinically meaningful differences in terms of safety, purity, and efficacy. Regulatory agencies such as the United States Food and Drug Administration and the European Medicines Agency require a stepwise comparability approach involving analytical characterization, non-clinical assessment, and clinical evaluation before granting approval for biosimilars [1,9].

The growing utilization of biologic therapies has contributed substantially to global healthcare expenditure. Although biologics account for less than 2% of total prescriptions worldwide, they contribute

approximately 35–40% of total pharmaceutical spending. Biosimilars have emerged as cost-effective alternatives that can significantly reduce treatment expenses and improve patient access to advanced biologic therapies. In many healthcare systems, biosimilars are introduced at prices approximately 15–35% lower than their reference biologics, thereby increasing market competition and reducing healthcare costs [4]. Economic analyses have estimated that biosimilars could generate healthcare savings ranging from USD 38 billion to USD 124 billion between 2021 and 2025. Furthermore, cumulative global healthcare savings associated with biosimilars are projected to exceed USD 150 billion by 2026, highlighting their importance in improving affordability and accessibility of biologic treatments [2,19].

The global biosimilar market has demonstrated rapid expansion over the past decade due to increasing demand for affordable biologic therapies and the expiration of patents for several blockbuster biologics. The global biosimilar market was valued at approximately USD 34.43 billion in 2024 and is projected to reach around USD 40.36 billion in 2025. Market forecasts further predict that the biosimilar sector may attain a value of nearly USD 175.99 billion by 2034, registering a compound annual growth rate (CAGR) of approximately 17–18% during the forecast period. Europe currently dominates the global biosimilar market, accounting for nearly 38% of the total market share, mainly due to early regulatory implementation and higher biosimilar adoption rates. In contrast, the Asia–Pacific region is expected to exhibit the fastest growth owing to expanding pharmaceutical manufacturing capabilities, supportive government initiatives, and favourable regulatory frameworks [3,17].

Despite the application of similar scientific principles in biosimilar development, regulatory pathways and approval procedures differ considerably among global regulatory agencies. Authorities such as the Central Drugs Standard Control Organization, the United States Food and Drug Administration, and the European Medicines Agency have established distinct regulatory frameworks for biosimilar approval. The average biosimilar review timeline is approximately 10–12 months under the European Medicines Agency, 12–18 months under the United States Food and Drug Administration, and around 6–12 months under the Central Drugs Standard Control Organization, depending on the completeness of submitted data and clinical evidence requirements. Variations in analytical data requirements, clinical trial expectations, review procedures, and post-marketing surveillance obligations can significantly influence approval timelines and market entry. Therefore, comparative evaluation of regulatory approval timelines among these agencies is essential to understand global regulatory strategies, facilitate efficient biosimilar development, and improve timely patient access to biosimilar therapies [7,8].

Table-1: Overview of biosimilar regulatory frameworks [5,7]

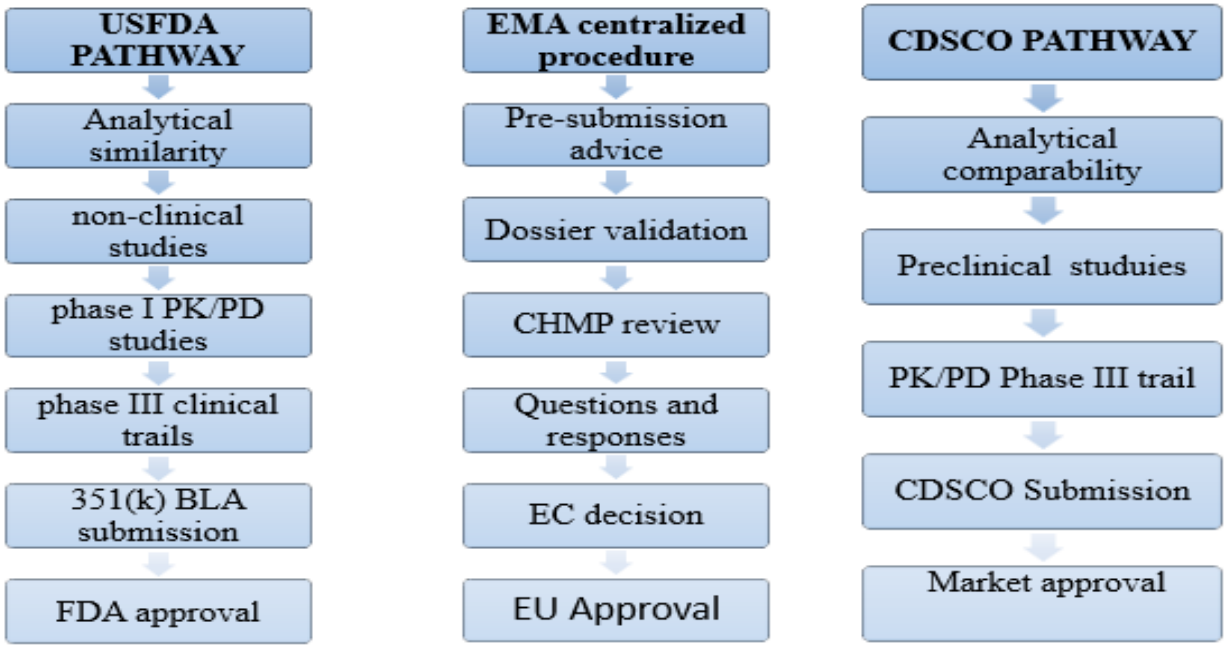
Region / Regulatory Authority	Regulatory Pathway	Key Data Requirements	Review Process
United States – U.S. Food and Drug Administration	Biosimilars are approved through the 351(k) Biologics License Application (BLA) pathway established under the Biologics Price Competition and Innovation Act (BPCIA) of 2009. This pathway allows manufacturers to rely partly on existing safety and efficacy data of the	Requires a stepwise approach including detailed analytical characterization, non-clinical studies, PK/PD studies, immunogenicity testing, and comparative clinical trials when necessary. Strong analytical similarity may reduce the need for extensive clinical studies [5].	Applications are evaluated based on the totality of evidence by scientific review divisions within the FDA. Biosimilars may also apply for interchangeability designation, allowing pharmacy-level substitution.

	reference biologic.		
European Union – European Medicines Agency	Biosimilars are approved through the centralized marketing authorization procedure, which provides a single approval valid across all EU member states. The EU introduced the first biosimilar regulatory pathway in 2005[12].	Requires a comparability exercise involving quality studies, non-clinical evaluation, and clinical studies such as PK/PD and efficacy trials when required. Emphasis is placed on strong analytical characterization.	Scientific evaluation is performed by the Committee for Medicinal Products for Human Use (CHMP), which reviews biosimilar applications and provides recommendations for approval.
India – Central Drugs Standard Control Organization	Biosimilars are regulated under the Guidelines on Similar Biologics (2012, revised 2016) developed jointly by CDSCO and the Department of Biotechnology (DBT).	Requires comparability studies, analytical characterization, preclinical evaluation, PK/PD studies, and at least one comparative clinical trial to demonstrate safety, efficacy, and immunogenicity.	Regulatory review is conducted by CDSCO with scientific support from DBT. Approved biosimilars must undergo post-marketing surveillance and pharmacovigilance to monitor long-term safety and effectiveness.

Table-2: Comparison of biosimilar approval timelines in USFDA vs EMA vs CDSCO [6,10]

Regulatory Authority	Key Procedure Steps	Clinical Trial Requirements	Average Regulatory Review Time	Example Biosimilars
U.S. Food and Drug Administration (USFDA)	Analytical similarity → non-clinical evaluation → PK/PD studies → Clinical trials → BLA submission → FDA review and approval	Phase I PK/PD studies and Phase III comparative clinical trials when required	~10–12 months review after submission; total development ~6–8 years	Zarxio (filgrastim-sndz), Inflectra (infliximab-dyyb), Ogivri (trastuzumab-dkst)
European Medicines Agency (EMA)	Pre-submission advice → Validation (~30 days) → Scientific review by CHMP (~210 days) → Sponsor response → European Commission approval	PK/PD studies and comparative clinical trials depending on analytical evidence	~12–18 months review from submission to authorization	Omnitrope (somatropin), Benepali (etanercept), Herzuma (trastuzumab)
Central Drugs Standard Control	Analytical comparability → Preclini	Requires PK/PD studies and at least	~12–18 months depending on dossier	Exemptia (adalimumab), Razuma

Organization (CDSCO)	cal evaluation → PK/PD studies → Compar	one Phase III clinical trial	completeness	b (ranibizumab), Basalog (insulin glargine)
	ative clinical trial → CDSCO review and approval			



II. MARKET PENETRATION [7,20]

Table-3: Biosimilar Approval and Market Status [7,20]

Region	Regulatory Authority	Total Biosimilars Approved / Available
United States	U.S. Food and Drug Administration	~90 approved biosimilars, with approximately 67 currently marketed and available to patients as of early 2026 (totals include interchangeable products).
European Union	European Medicines Agency	~165 biosimilars approved including duplicates/withdrawn, with many commercially available across EU member states.
India	Central Drugs Standard Control Organization	~100 biosimilars approved (including many domestic products); around ~90 marketed and widely used.

In the United States, the FDA had approved 82 biosimilars by 2026, though not all may yet be commercially launched; approximately 67 of these are in active clinical use[7,14].

In the European Union, the EMA's biosimilar program has been active since 2006, resulting in between ~165 biosimilars approved (count varies slightly with reports) covering a wide range of biologics including monoclonal antibodies and growth factors[13,16].

India has one of the most active biosimilar landscapes globally, with nearly 90 biosimilars approved and many marketed domestically, driven by local biotech innovation and lower development costs[7,10].

- EMA (EU): ~165 biosimilars are approved and 86 are marketed
- FDA (USA): 90 biosimilars are approved and 67 are marketed
- CDSCO (India): ~100+ biosimilars are approved and ~90 are marketed

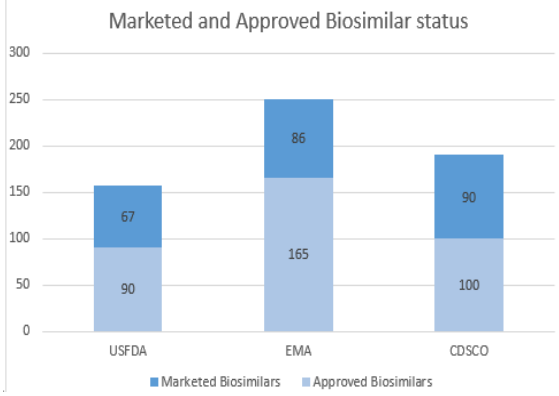


Table-4: Biosimilar Pricing and Regulatory Frameworks[14,15]

Region	Regulatory Authority (Approval)[14]	Price Control Authority	Pricing Structure of Biosimilars [15]
United States	U.S. Food and Drug Administration	Centers for Medicare & Medicaid Services (CMS) and market-based pricing system	Competitive pricing through market competition and reimbursement negotiations
European Union	European Medicines Agency	National pricing agencies of EU member states (HTA bodies and national health systems)	Government-regulated tender systems and reference pricing
India	Central Drugs Standard Control Organization	National Pharmaceutical Pricing Authority (NPPA)	Government-regulated ceiling price and competitive generic market

III. MARKET OF BIOSIMILARS [3,17]

Biosimilars Market Summary

The global biosimilars market was valued at approximately USD 39.59 billion in 2025 and is anticipated to reach nearly USD 151.58 billion by 2033, registering a CAGR of 18.44% during the forecast period from 2026 to 2033. The increasing demand for cost-effective therapeutic alternatives and the rising global burden of chronic diseases are among the primary factors driving market expansion.

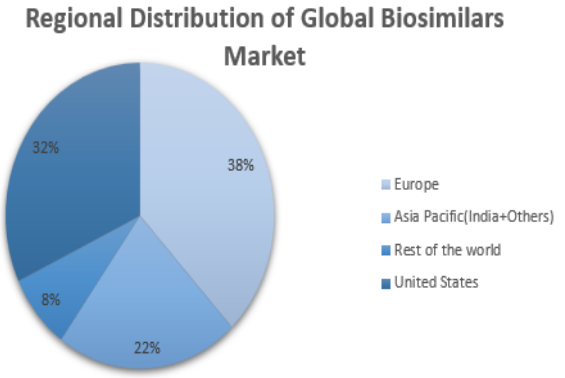
Key Market Trends & Insights

North America held the largest share of the global biosimilars market, contributing around 42.56% of total revenue in 2025. Meanwhile, the Asia Pacific region is projected to witness the fastest growth, with an expected CAGR of 19.84% over the forecast period.

Based on drug class, the monoclonal antibodies (mAbs) segment represented the highest market share of 44.90% in 2025 due to their extensive use in oncology and autoimmune disease treatment. By indication, autoimmune disorders, including rheumatoid arthritis (RA), inflammatory bowel disease (IBD), psoriasis, and ankylosing spondylitis, accounted for the largest revenue share of 39.90% in 2025. In terms of end use, hospitals dominated the market, contributing approximately 52.34% of the total revenue during the same year [17,20].

Regional Distribution of Global Biosimilars

The United States biosimilars market is projected to grow from approximately USD 22.6 billion in 2025 to USD 93.5 billion by 2034, driven by increasing adoption and competitive pricing mechanisms [17]. In contrast, the European Union accounts for nearly 38% of the global biosimilars market, largely due to early regulatory adoption and well-established tender-based procurement systems that encourage widespread uptake. India's biosimilars market is expanding rapidly due to lower production costs, government price controls, and strong domestic manufacturing capabilities, making it a key contributor to global biosimilar supply [20].



IV. OVERVIEW OF KEY INDUSTRY PARTICIPANTS

The global biosimilars market is characterized by a mix of established multinational pharmaceutical companies and emerging biopharmaceutical firms.

Leading companies such as Sandoz, Pfizer Inc., and Amgen Inc. dominate the market due to their early entry, extensive product portfolios, and strong regulatory expertise [21]. These organizations have leveraged their capabilities in biologics manufacturing and global distribution to maintain competitive advantages.

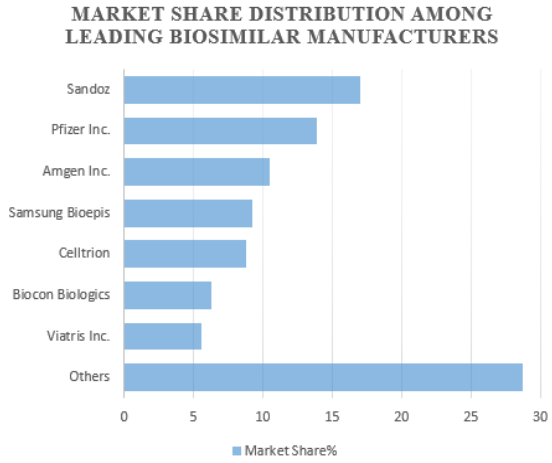
Companies such as Samsung Bioepis and Celltrion have emerged as significant competitors, particularly in regulated markets, through innovation and strategic partnerships [21].

In India, Biocon Biologics and Dr. Reddy's Laboratories play a vital role in improving global access to biosimilars through cost-effective manufacturing and international collaborations [20]. Emerging firms such as Coherus BioSciences and Viatris Inc. are expanding their presence through specialized product pipelines and regional strategies [21].

V. COMPARATIVE MARKET SHARE DISTRIBUTION [20,22]

The biosimilars market demonstrates moderate consolidation, with leading firms holding significant shares due to early market entry, advanced technological capabilities, and regulatory expertise. However, increasing patent expirations and supportive regulatory frameworks are expected to drive further competition and diversification. Market share estimates are derived from global industry analyses and reflect ongoing expansion and competitive dynamics.

The market is moderately consolidated, with the top players accounting for approximately 80-85% of the global biosimilar market.



VI. REGULATORY CHALLENGES IN BIOSIMILAR APPROVAL [9,18]:

Biosimilar approval involves several regulatory challenges that can influence development timelines. One major challenge is obtaining interchangeability designation, which requires additional switching studies to demonstrate that the biosimilar can be substituted for the reference biologic without affecting safety or efficacy, particularly under the requirements of the U.S. Food and Drug Administration. Another important challenge is maintaining strong pharmacovigilance systems, as regulatory authorities such as the European Medicines Agency require continuous post-marketing surveillance to monitor long-term safety and adverse drug reactions. In addition, manufacturing and quality control complexities present significant challenges because biosimilars are produced using complex biological systems that require strict process control and analytical characterization. Therefore, regulatory bodies including the Central Drugs Standard Control Organization mandate rigorous quality evaluation and compliance with Good Manufacturing Practices to ensure consistent product quality and safety. "Another important challenge is maintaining effective pharmacovigilance systems and ensuring

manufacturing consistency because biosimilars are produced using highly complex biological processes requiring strict quality control and analytical characterization [9,18].

VII. FUTURE PROSPECTS [11,19]:

The future of biosimilars will be driven by evolving regulatory frameworks, pricing strategies, and the growing demand for affordable biologic therapies. Regulatory bodies such as the U.S. Food and Drug Administration, European Medicines Agency, and Central Drugs Standard Control Organization are improving approval pathways to speed up market entry while maintaining safety and efficacy. The United States is expected to see increased biosimilar approvals due to the patent expiry of major biologics, although legal and reimbursement challenges may affect market uptake. The European Union will likely continue leading in biosimilar adoption because of its well-established regulatory system and supportive pricing policies. Meanwhile, India is strengthening its regulatory guidelines and expanding biotechnology infrastructure, positioning itself as a key biosimilar manufacturing hub. Globally, initiatives from organizations like the World Health Organization are promoting regulatory harmonization, which may improve market access and reduce treatment costs, ultimately increasing the global use of biosimilars.

VIII. CONCLUSION

In conclusion, the comparative analysis of regulatory stringency and market access for biosimilars in the United States, European Union, and India demonstrates how differences in approval pathways, pricing regulations, and healthcare policies significantly influence biosimilar adoption. The U.S. Food and Drug Administration maintain a highly rigorous approval framework that ensures safety and efficacy but often results in slower market entry and moderate price reductions due to regulatory complexity and patent barriers. In contrast, the European Medicines Agency has established a well-structured and early regulatory pathway for biosimilars, enabling higher market penetration through supportive reimbursement systems and competitive procurement mechanisms. Meanwhile, India, regulated by the Central Drugs Standard Control Organization with guidance from the Department of Biotechnology, has developed a rapidly expanding biosimilar market driven by cost-effective manufacturing and increasing regulatory refinement, although challenges related to pharmacovigilance and global regulatory alignment persist. Overall, the findings suggest that while stringent regulatory oversight is essential for maintaining product quality and patient safety, balanced approval processes, effective pricing policies, and supportive healthcare frameworks are crucial to enhance biosimilar accessibility, affordability, and market growth across different regions.

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