

MARKET ACCESS AND COMMERCIALISATION STRATEGIES FOR BIOSIMILARS IN COMPETITIVE AND CONSTRAINED HEALTHCARE SYSTEMS

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Vikas Bhujbal¹

Ashish Das²

Author Affiliations

Vikas Bhujbal¹ and Ashish Das² are seasoned pharmaceutical professionals with more than 22 years of experience across pharmaceutical business development, sales, marketing, branding, go-to-market strategy and commercialization. Their extensive industry exposure provides a practical commercial perspective on the rapidly evolving landscape of biologics and biosimilars, including market access and opportunities in emerging markets.

This review has been developed in their independent professional capacity. It does not represent the views or positions of any current or former employer or affiliated organization.

Abstract

Background: Although biologics account for only a small proportion of prescription volumes, they represent a disproportionately large share of pharmaceutical expenditure. In the United States, biologics accounted for approximately 2% of prescription volume but 37% of net drug spending,[69] while specialty medicines are projected to account for approximately 43% of global pharmaceutical spending by 2028, [70] creating substantial financial pressures on healthcare systems.[70] Biological medications proven to be very similar to FDA-approved reference biologics in terms of structure, function, safety and effectiveness (called biosimilars) represent a proven way to reduce costs and increase patient access to treatment. The penetration of the market, however, is far from even across jurisdictions, and this has nothing to do with the quality of the product; it is related to the policy environments in which the product exists.

Objective: This review brings together evidence relating to the regulatory, economic and institutional factors affecting commercialisation of biosimilars, paying particular attention to strategies that can be adopted in both competitive and resource-limited healthcare systems.

Methods: A narrative synthesis was undertaken based on peer-reviewed literature and regulatory documents related to biosimilar approval pathways, biosimilar market penetration data, and real-world economic outcomes in Europe, the United States, the Asia-Pacific region, and Latin America.

Results: Biosimilars bring cost savings of 20-80% compared with the reference biologics in therapeutic areas such as oncology, rheumatology and endocrinology. [60, 61, 62, 63] The EU has one of the highest levels of biosimilar market penetration globally, with uptake exceeding 90% for certain molecules and therapeutic areas. Biosimilar competition has generated substantial savings in Europe, while global estimates projected biosimilar savings of up to approximately USD 124.5 billion during 2021–2025. [64, 65, 66, 67] The major obstacles to adoption include the threat of patent litigation, rebate exclusion of innovative drugs, physician reluctance and poor pharmacovigilance systems in emerging markets. Key strategies for successful commercialisation are national tender procurement, mandatory managed switching programmes, structured prescriber education and harmonised regulatory approval routes.

Conclusions: Market access for biosimilars is not a scientific issue only, but a policy issue related to the policy architecture of products. Economic and equitable potential of biosimilars can be realised only through coordinated action across regulatory, reimbursement and educational levels, especially in resource limited health care systems. If supportive policy and market conditions are implemented at scale, biosimilars have the potential to generate substantial global healthcare savings, with market analyses estimating cumulative savings of more than USD 290 billion globally through 2027.[68]

Keywords: Biosimilars; market access; commercialisation strategy; healthcare cost containment; regulatory pathway; biologics pricing; formulary policy; healthcare equity

Introduction

Biological therapeutics are a key driver of the financial sustainability challenge in modern healthcare systems. Biopharmaceuticals are produced using recombinant DNA and other genetic engineering technologies and have transformed the management of diseases including cancer, autoimmune disorders and metabolic diseases. [1]. Their economic impact is significant as they account for 43% of pharmaceutical expenditure and only treat less than 2% of patients in developed markets [69]. The high cost of biologic therapies has contributed to concerns regarding affordability and access, creating an important rationale for the development and adoption of biosimilars [3].

Biosimilars have been shown through detailed analytical and clinical comparability studies to be highly similar to an already-approved reference biologic in terms of structure, function, safety, and efficacy [4]. The challenge associated with biosimilars is that they can't be reverse-engineered to make an exact copy; the goal is to demonstrate that any structural differences that result are of no clinical significance with regard to safety, purity, or potency [5]. The difference is what it means for opportunity and complexity of biosimilars commercialisation.

The European Medicines Agency (EMA) gave its approval to Omnitrope (somatropin) in 2006, marking the first biosimilar product to be approved through a formally structured pathway. The worldwide biosimilar market has grown significantly since then. [6] As of December 2024, EMA has approved 115 biosimilars, whereas the U.S. Food and Drug Administration (FDA) has authorised 51 biosimilars, including six with interchangeability designations [7]. Notwithstanding this regulatory push, uptake rates are very uneven across therapeutic categories, ranging from under 20% in some United States markets to over 90% in Nordic markets for some molecules without being correlated with the differences in product quality [8, 50].

The factors that influence biosimilar market access and commercialisation success in competitive and constrained healthcare systems are explored. Particular attention is given regulatory policies, the economic and structural factors that hinder uptake, and policy approaches that have proven to have clear impact on advancing biosimilar uptake. A comparative regional perspective is utilized to look at the mature context of Europe compared with the maturing context of the United States, and the different paths of emerging markets, specifically India. The analysis is based on evidence derived from peer-reviewed literature and regulatory documents available up to early in 2026.

2. Economic Burden of Reference Biologics and the Biosimilar Rationale

2.1 Development and Manufacturing Costs of Reference Biologics

Biopharmaceuticals require substantially greater and more specialized resources than conventional pharmaceutical products. The process of developing a novel biologic usually takes 10–15 years and costs USD 1.2-2.5 billion per molecule [51]. The investment needed for manufacturing infrastructure is alone more than USD 500 million, accounting for the impressive specialized bioreactor systems, cold-chain logistics, and environmental controls which are required by modern Good Manufacturing Practice (cGMP) [10]. These structural cost drivers account for why prices of reference biologic drugs remain high and remain a major barrier to access, particularly in lower-income and emerging countries, where biologic utilization can be substantially lower than in high-income markets. [11].

2.2 Cost-Reduction Potential of Biosimilars

The development of biosimilars is a streamlined process that builds on the body of knowledge and evidence accumulated during development of the reference product, which significantly reduces time and cost. The cost of developing biosimilars is significantly lower than the cost of developing new biologic drugs, at USD 100–200 million and 6-8 years to clinical readiness [12]. These cost efficiencies contribute to the price reductions that typically follow biosimilar market entry.

Price reductions are usually 20-30% on initial market entry, and can be much greater in competitive multi-entry markets [13, 52]. The most comprehensive evidence base comes from European experience: national tender systems have led to price reductions for biosimilar infliximab of 69-83% in Norway, with average savings of 35% across all biosimilar categories in Germany, and with adalimumab's price reduced by 76% after biosimilar introduction in Denmark. [53, 54, 55] Overall, EUR 5.7 billion were reported as savings in the EU for the period by 2020, and for the US Healthcare system, savings of USD 104 billion were projected between 2020-2024 [15, 56].

Across European markets, biosimilar infliximab has been associated with price discounts relative to the reference product, with reported discounts varying by country. Budget-impact analyses have modelled discounts of 10–30% and demonstrated that greater price reductions can translate into substantial drug-cost savings for healthcare systems. [57, 58]

2.3 Resource Reallocation and Access Expansion

Biosimilar adoption can generate significant savings for healthcare systems through lower acquisition costs and increased price competition. These savings can create greater budget flexibility, allowing healthcare systems to expand access to biological therapies, extend reimbursement to additional patient groups, or consider biologic treatment at earlier stages of care. Evidence from European markets indicates that the benefits of biosimilars extend beyond direct cost reductions, with increased competition and affordability contributing to greater patient access and broader utilisation of biological medicines. Consequently, the economic value of biosimilars may extend beyond the immediate difference in acquisition costs by enabling health systems to treat more patients within available budgets and potentially improve the efficiency and sustainability of healthcare delivery. [17, 43, 56]

3. Regulatory Frameworks Governing Market Entry

3.1 The Scientific Foundation of Biosimilar Regulation

The comparability principle is the foundation for regulatory approval of a biosimilar, in that any differences between the biosimilar and reference product are not clinically meaningful in terms of safety, purity or potency [18]. This is done in a stepped approach and stratified by evidence starting with a broad physicochemical and analytical characterization, followed by non-clinical studies, and finally clinical pharmacokinetic and, if necessary, pharmacodynamic comparability studies. Extrapolation (approval of an indication that has not been researched in clinical trials, on the basis of the sum of comparative evidence) is a regulatory approach that is effective and science-based in decreasing development expenses where appropriate [19, 59].

3.2 European Medicines Agency Pathway

In 2004, the EMA created the first comprehensive regulatory pathway for biosimilars, which served as a template for the rest of the world. Comparative analytical studies, clinical efficacy assessment and pharmacovigilance after marketing are in focus when using a science-driven approval process. The regulatory clarity and the centralised approval leading to marketing authorisation in all EU member states has been a key factor in the number of approvals and the extent of market penetration that has been gained [20].

The EMA does not provide an official designation of interchangeability, interchangeability is left to the national authorities and is subject to member-state policy. This results in a union variation in switching policies, but does not thwart high uptake in jurisdictions that are proactively procuring [7, 71].

3.3 United States FDA Pathway

The FDA's approach to biosimilar regulation is based on the Biologics Price Competition and Innovation Act (BPCIA) of 2009, which provided an abbreviated licensing pathway similar in principle to the EU approach with added complexity [21]. An interesting aspect of the U.S. system is the interchangeability designation, which allows the substitution of a biosimilar product for its reference product at the pharmacy level without the prescriber's intervention, with important commercial consequences for the uptake of biosimilar products into the market [22].

While there have been 51 approvals by April 2025, strategies used by reference product manufacturers to use patents to delay uptake, rebate arrangements that provide financial incentives for payers to choose originator products and formulary placement barriers have significantly hindered uptake in the United States. [23]. These structural barriers are now being addressed in part through policy shifts and payer acceptance, and the rate of adoption, especially in oncology and immunology is increasing [8].

3.4 Indian Regulatory Framework (CDSCO)

The regulatory process in India, run by the Central Drugs Standard Control Organisation (CDSCO), is tailored to the specific needs of a large middle-income market. One of its most distinguishing characteristics is the need for local clinical trials, thereby proving the performance of biosimilar in the Indian population [24]. India approved its first biosimilar in the year 2000, and has approved drugs across a range of conditions including oncology, autoimmune disease, diabetes and haematological disease [25].

CDSCO released draft updates to its biosimilar guidelines in May 2025 to harmonize the guidelines with international standards and ease the approval process, showing a commitment to ongoing regulatory harmonisation [26, 72]. India has become an important player in providing biosimilar supply due to its manufacturing capability. Indian companies such as Biocon and Dr. Reddy's Laboratories have emerged as important players in the global biosimilar market, highlighting India's potential to combine cost-efficient manufacturing capabilities with the quality standards required for international regulatory approval. [27].

3.5 Comparative Regulatory Requirements

The summary of key approval parameters by jurisdiction are shown in **Table 1** below. Non-clinical data packages, clinical trial scope, interchangeability provisions and review time are scientific philosophy and market considerations, and have real-world consequences on the cost and time of global biosimilar development programmes.

Table 1. Comparative Regulatory Requirements for Biosimilar Approval Across Major Markets

Parameter	EMA (EU)	FDA (USA)	CDSCO (India)	NMPA (China)
Analytical Studies	Comprehensive	Comprehensive	Comprehensive with local standards	Comprehensive with local standards
Non-Clinical Studies	Abbreviated package	Abbreviated package	Full package required	Full package + local studies
Clinical Studies	Phase I PK/PD + Phase III (1 indication)	Phase I PK/PD + Phase III (1 indication)	Phase I & III with local population	Phase I & III with local population
Extrapolation	Permitted with justification	Permitted with justification	Limited permission	Case-by-case basis
Interchangeability	National-level decisions	Specific FDA designation	Not applicable	Not applicable
Review Timeline	Up to 210 days under centralised procedure, excluding clock stop	~10 months (Application- and user-fee-dependent)	~12 months (Regulatory pathway-dependent)	~12–18 months (Regulatory pathway-dependent)

Sources: Avhad & Patil (2025); CDSCO (2016); Rizwan et al. (2026); FDA BPCIA (2009).

4. Regional Market Dynamics and Commercialisation Strategies

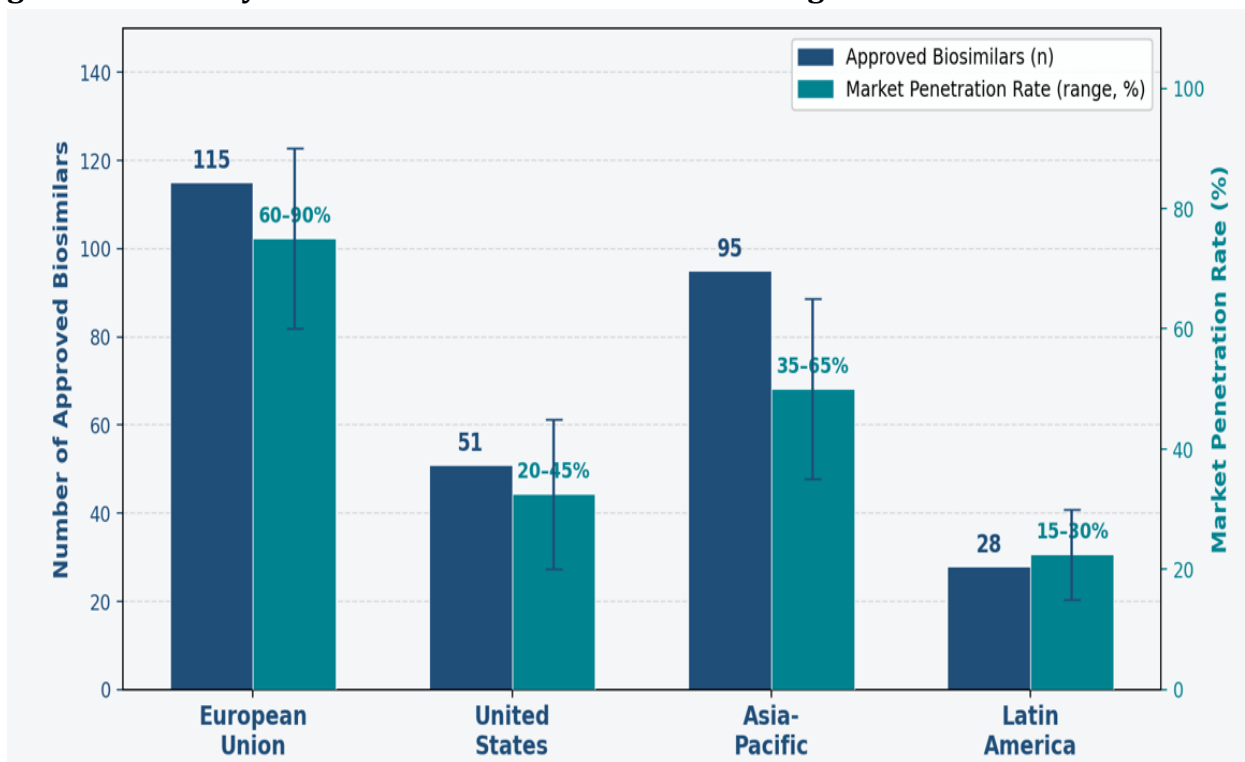


Figure 1. Global Biosimilar Market: Approved Products and Market Penetration by Region (2020–2024). Sources: Gunnam et al. (2025); Rizwan et al. (2026).

Sources: Gunnam et al. (2025) J Pharma Insights Res; Rizwan et al. (2026) J Pharm BioTech Ind.

4.1 European Union

The EU biosimilar market is the most developed worldwide experience and offers long-term evidence that competitive markets for biologics are sustainable. The number of biosimilars in active competition in the region was 84, which represented 60–90% market penetration across the oncology, immunology and endocrinology segments in 2020–2024 [28]. The highest uptake rates have been observed in the Nordic countries, both with over 90% uptake of key molecules in Norway and Denmark, which are both characterised by a centralised procurement process based on national tender systems that make biosimilar use the standard treatment for key molecules [14].

Germany provides an effective model of multi-stakeholder approach. In Germany, health systems obtained the highest market shares in the biosimilar market with a combination of prescription quota and evidence-based educational programs (65–85% for therapeutic categories) [29, 73, 74]. A combination of these three, regulatory clarity, procurement incentives and prescriber engagement, creates a framework that can be replicated in other markets looking to drive up uptake. One of the peculiar issues that confront the more developed markets in the EU is the viability of the strong price rivalry. By December 2024 there were 115 biosimilars approved, to the extent that some manufacturers face a future of commercial viability due to price erosion, the level of future competition is a concern, and there is potential for concentration of supply. The short-term cost savings versus long-term market sustainability is becoming a policy issue.

4.2 United States

The United States market is a curious one, where the regulatory landscape is highly developed and yet the uptake of the technology is not particularly significant. The structural constraints are primarily commercial, not scientific. Reference product manufacturers have large portfolios of overlapping patents which are used to achieve this objective, and litigation delays can take 12-18 months in major markets [30]. Rebate structures negotiated by originator manufacturers and Pharmacy Benefit Managers (PBMs) actually help to ensure that originator products remain in the best position even in the face of lower biosimilar list prices [23].

This is starting to change with recent regulatory and legislative actions. The rise in biosimilar uptake in oncology and immunology has been driven by a measurable increase in adoption owing to accelerated FDA review processes and growing acceptance by payers. The United States market is expected to play a significant role in the global savings curve; estimates of USD 133 billion in savings through 2025 have been made [31, 75].

4.3 Asia-Pacific and Emerging Markets

Cost effective manufacturing processes and conducive regulatory framework for product development have made India and South Korea as global manufacturing hubs for biosimilars. “Biosimilars in India are generally marketed at substantial discounts to reference biologics, with reported price reductions of approximately 30–70%, improving affordability and access to biologic therapies. India has also emerged as a major biosimilar development and manufacturing hub, with more than 95 biosimilars approved for domestic use and several products subsequently developed for regulated international markets.[28, 76, 77] Across the Asia-Pacific region, biosimilar development and adoption have expanded substantially, particularly in therapeutic areas such as oncology, immunology and diabetes.[78, 79 28].

China's biosimilar industry has seen tremendous changes since the regulatory reforms, particularly with the gradual convergence towards International Council for Harmonisation (ICH) guidelines, which has led to substantial investments in biosimilar facilities [32]. In Latin America, particularly in Brazil and Mexico, dedicated regulatory pathways for biosimilars have evolved alongside strong public-sector involvement in medicines procurement, supporting the development and uptake of locally manufactured biological products [33].

The global biosimilar market is projected to reach USD 116.90 billion by 2034 from USD 37.73 billion in 2025 [34]. Global savings of biosimilars are anticipated to be over USD 290 billion by 2030, with the highest savings anticipated to be in oncology, rheumatology, and endocrinology [35]. This pathway will continue until 2030 and is shown later in Figure 4.

5. Barriers to Market Access and Adoption

Healthcare Providers	Patients
▶ 35% report insufficient prescribing confidence	▶ Limited biosimilar conceptual understanding
▶ Immunogenicity & switching concerns	▶ Switching anxiety from established therapy
▶ Evidence extrapolation uncertainty	▶ Perception of inferiority to reference products
✓ Enabler: Peer education & clinical guidelines	✓ Enabler: Education → 80% higher acceptance rate
Payers & Formulary	Legal & Structural
▶ Rebate structures favouring originators	▶ Patent thickets: 12–18 month avg. delay
▶ Formulary exclusion: 40–60% uptake reduction	▶ Litigation costs added to development budget
▶ Step-therapy mandates without clinical basis	▶ Regulatory fragmentation across jurisdictions
✓ Enabler: Value-based contracting & risk-sharing	✓ Enabler: Harmonised regulatory pathways

Figure 2. Biosimilar Market Access Barriers and Enabling Factors by Stakeholder Domain. Sources:

Smeeding et al. (2019); Dylst et al. (2014); Jacobs et al. (2016); van Overbeeke et al. (2017).

Sources: Smeeding et al. (2019) P T; Dylst et al. (2014) Pharmacoeconomics; Jacobs et al. (2016) Patient Prefer Adherence; van Overbeeke et al. (2017) BioDrugs; Grabowski et al. (2015) Health Aff.

5.1 Intellectual Property and Patent Barriers

The most important structural obstacle to biosimilar market entry is patent thickets, clusters of multiple overlapping Intellectual Property rights around the reference biologics. These strategies result in effective market exclusivity far beyond the nominal period of patent protection, with litigation-induced delays of 12–18 months and the inclusion of high development costs for biosimilar programmes [30]. Within the U.S. context, patent litigation has been more widespread for high-value biologics, like adalimumab and etanercept, which has resulted in market competition being delayed by years since FDA approval.

5.2 Formulary and Reimbursement Barriers

Placing biologic products in a formulary makes all the difference in the game for biosimilar uptake. Manufacturers of originator drugs often implement systemically disadvantageous reimbursement arrangements, such as rebate schemes, and step therapy policies that require prescribers to show failure with the originator drug before switching to a biosimilar, regardless of regulatory approval [23].

In several market analyses performed in the United States, formulary restrictions have been correlated with between 40–60% reductions in uptake [23] comparable to the impact of patent litigation.

5.3 Healthcare Provider Hesitancy

Overall, confidence in biosimilar prescribing among physicians is inconsistent, with some specialties having greater confidence than others. However, roughly one-third of physicians say they lack confidence in the prescribing of biosimilars, with the greatest lack of confidence occurring in oncology and immunology, according to survey data [36]. Three primary concerns are raised with treatment switching, extrapolating from clinical data from other indications not specifically examined in comparative trials, and the lack of long-term data in patients switched from a well-established reference biologic therapy. These concerns remain even though there is a large amount of post-marketing surveillance data demonstrating that switching is therapeutic equivalent [37].

5.4 Patient-Level Barriers

Access to accurate information and the quality of communication by the prescriber and healthcare team influences patient acceptance. Research shows that poor knowledge of the technical differences between biosimilars and reference biologics, combined with concerns about switching treatment with biosimilars and perceptions of biosimilars as not being as effective as reference biologics, decreases acceptance of biosimilar treatment [38]. For acceptance, structured patient education and clear communication can play an important role in improving understanding and acceptance of biosimilar treatment. In a survey of Belgian patients with rheumatoid arthritis, patients generally trusted their physician's decision to initiate or switch to a biosimilar, although concerns about safety and differences from originator biologics remained. [39].

5.5 Infrastructure and Manufacturing Barriers

In emerging market manufacturers and health systems, obstacles are not just limited to production and distribution infrastructure. Bioreactor systems, validated cold chain logistics, and extensive quality control systems are required for biological manufacturing, and demand significant upfront investment [10, 80]. The increased cost of goods and potential delays in achieving competitive product pricing that can occur if there are quality issues, such as maintaining the critical glycosylation profile, when scaling up from bench to commercial production scale, are also a scale-up challenge. One of the most significant challenges of scale-up is the difficulty of maintaining the same critical quality attributes, such as glycosylation profile, during the transition from bench to commercial scale, which can lead to higher cost of goods and delays in achieving competitive product pricing [40]. Manufacturers operating in jurisdictions with less mature or less stringent biosimilar regulatory frameworks may face additional challenges when seeking approval in highly regulated markets such as the European Union and the United States, where regulatory authorities require comprehensive evidence of biosimilarity, including extensive analytical characterisation and, where applicable, clinical data. [41].

Table 2. Biosimilar Adoption Barriers by Stakeholder Category

Stakeholder	Primary Barriers	Enabling Factors	Implementation Responses
Healthcare Providers	Clinical uncertainty; limited prescribing experience	Evidence-based education; clinical guidelines	Peer education networks; practice protocols
Patients	Safety concerns; switching anxiety	Clear communication; support programmes	Tailored educational materials; advocacy engagement
Payers	Formulary exclusion; rebate-driven disincentives	Economic analyses; risk-sharing models	Value-based contracts; outcome monitoring
Healthcare Systems	Infrastructure limitations; process change burden	Systematic planning; resource allocation	Phased implementation; staff training
Manufacturers	Litigation costs; scale-up complexity	Streamlined pathways; QbD frameworks	Global partnerships; technology transfer

Sources: Gunnam et al. (2025) J Pharma Insights Res; Smeeding et al. (2019); Barbier et al. (2020) BioDrugs.

6. Implementation Strategies for Constrained Healthcare Systems

6.1 Value-Based and Competitive Procurement

The most consistent evidence of effective biosimilar adoption at scale has been realized using centralised procurement systems. National tendering processes (where the payers invite competitive bids for supply contracts for biological products) establish price competition between the different biosimilar manufacturers and eliminate a decision-making blockage at the individual prescribers' level. The Norwegian national tender model is a prominent example of competitive biosimilar procurement. Following the introduction of biosimilar infliximab, competitive tendering resulted in substantial price reductions, with the biosimilar price reaching approximately 69% below that of the reference product in 2015. This approach was accompanied by rapid uptake of biosimilar infliximab while clinical evidence supported comparable efficacy and safety [81, 82] Multi-winner tender designs that split contracts between multiple suppliers have been proven to be effective in maintaining competitiveness and supply chain resilience [42].

This principle can be applied to outcome-based contracts, called value-based procurement arrangements. As payers and manufacturers are not at risk if new biosimilar products are not shown to be effective in the real world, agreements covering this can help speed the introduction of the new products into formularies. One way for adopting biosimilar is to be rewarded by gain-sharing mechanisms, which share savings resulting from biosimilar uptake with prescribers or health institutions, thus incentivizing institutional actions in line with policy goals [43].

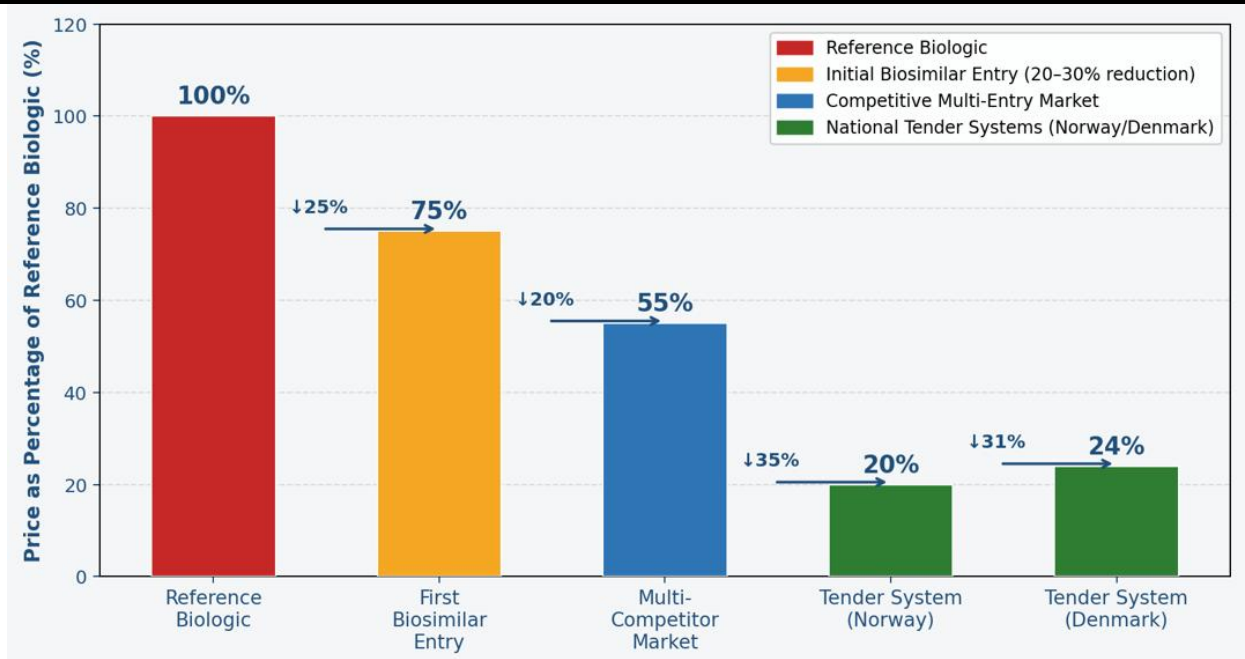


Figure 3. Biosimilar Price Reduction Cascade: From Initial Market Entry to Competitive Tender System Outcomes. Sources: Jensen et al. (2020) JAMA Intern Med; Moorkens et al. (2019) BioDrugs; Gunnam et al. (2025).

6.2 Mandatory and Managed Switching Programmes

Switching programmes at the population level have helped to build significant amounts of real-world data demonstrating the therapeutic equivalence of the reference product and the biosimilar, and have helped to rapidly integrate biosimilars into the market in countries that have adopted them. The cost reduction in the managed adalimumab switching programme in Denmark with maintained clinical effectiveness [14] and the prospective finding of non-inferiority switching to biosimilar infliximab [44] in the NOR-SWITCH study are basic evidence for this.

To be effective, these should be based on a common switching protocol, linked to electronic health record systems, and have good pharmacovigilance facilities to follow up switched populations. High adoption rates have been consistently reported in healthcare systems that have switched to new systems using structured clinician communication before transition, such as patient-specific reasons for switching and documented monitoring plans [45].

6.3 Prescriber Education and Institutional Engagement

There are educational programmes available that have been evaluated for their impact on rates of biosimilar adoption and have proven to be effective in this area and have been used internationally. Programmes that are effective often have these characteristics: a presentation of comparative clinical data that is relevant to the prescriber's therapeutic area, peer-to-peer learning networks that take advantage of the influence of clinical opinion leaders, and useful information for managing treatment transitions [46]. Guidance from professional societies (such as those for rheumatology, oncology, and gastroenterology) that covers patient selection, switching schedules, and pharmacovigilance

requirements provides institutional approval needed by some prescribers for taking on new treatment strategies [47].

6.4 Regulatory Harmonisation

Regulatory fragmentation (biosimilar developers need to produce separate clinical data packages for each target market) will add to the cost of development and delay market introduction, thereby maintaining high prices. This duplication can be lessened by progressive convergence of national regulatory frameworks with ICH biosimilar guidelines, such as CDSCO's draft revisions of the draft guidelines and China's harmonisation of their regulatory framework with international standards, made in May 2025 [26]. Adaptive licensing pathways that involve collecting and incorporating real-world evidence into post-approval regulatory evaluations also decrease the amount of clinical data required in trials without sacrificing the scientific rigor of comparability assessments [48].

7. Ethical and Policy Dimensions

Beyond the economic aspects of drug pricing, commercialisation of biosimilars in competitive healthcare markets poses ethical questions. Doctors who work in reimbursement structures that financially incentivize originator biologic prescribing – such as higher reimbursement margins, reimbursement-linked formulary placement, or step therapy requirements – have a structural conflict between financial incentives and their ethical duty to deliver cost-effective treatment [41]. This imbalance is even stronger in health systems in which insurance companies mandate failure on originator therapy before approving biosimilar utilization—situations where there is no therapeutic need for this delay in access to affordable therapy.

A fair distribution of biosimilar benefits by income level and geographic location is a separate moral question. While the savings resulting from biosimilar uptake can benefit payers and health systems, in high-income markets these savings will not necessarily be shared with the patient who may still have to pay cost-sharing on products that are very much lower in cost than their reference products. This regulatory-to-patient gap in lower-income countries is due to an absence of policy support, including pharmacovigilance systems, cold-chain distribution systems, and prescriber education, and not to patients' lack of need for these products [49].

There is a need for coherent policy frameworks to ensure that all the incentives are aligned with the aim of equitable access to biosimilars. Such frameworks require fair reimbursements, with clear financial incentives for biosimilar use; interchangeability policies, which limit prescriber uncertainty; and coverage policies without cost-sharing requirements for biosimilar use, among key elements [41]. Policy is also needed to ensure the long-term commercial viability of the sector: When price competition is fierce, and the price of biosimilars is dropping to a level that threatens manufacturers' viability, the prospect of market exit and resulting concentration of supply may lead to a failure of competitive dynamics to keep biosimilar prices affordable [7, 8, 20, 29].

8. Discussion

The evidence presented in this review clearly indicates that the policy landscape around products, which encompasses aspects beyond scientific equivalence and product quality, is the key to biosimilar market access and commercialisation success. This is clearly reflected in the differences in penetration

between the EU markets with a high level of structured procurement and mandatory switching, and the United States market where the level of penetration is lower due to the complexity of the rebate structures and patent litigation [8,28].

The theoretical contribution of this analysis is that we consider commercialisation of biosimilars a multi-level challenge that needs coordinated action on regulatory, reimbursement, clinical and supply-chain levels. Single-lever interventions (regulatory only, or education programmes without formulation changes) have always been shown to perform worse than integrated interventions. All three models—Norway (tender), Germany (multi-stakeholder), and Denmark (managed switching)—were successful because they took multiple adoption barriers into account simultaneously [13,14,29].

The impact of devising a strategy that can be implemented in emerging market healthcare systems under fiscal constraint is stark. Procurement skills, pharmacovigilance systems, prescriber education and regulatory knowledge and capacity are also scarce resources to implement biosimilar savings. Implementing therapeutic areas where the clinical evidence for switching is clear, and where the cost burden for the system is greatest, helps to enable a gradual development of institutional capacity with early savings to support programme development [45].

The commercialisation aspect of manufacture must be kept an eye on. One of the most significant hurdles for smaller manufacturers is that of producing a consistent glycosylation profile across commercial-scale production necessary to ensure that biosimilar preparations have the same critical quality attributes as their reference product [40]. The use of Quality by Design (QbD) framework and Design of Experiments (DoE) methodology has proven to be beneficial in minimizing the manufacturing variability and the subsequent risk of regulatory delays and manufacturing costs [2, 12, 83, 84, 85]. Enhanced investment in manufacturing technology transfer, especially from established to emerging market manufacturers, could help to spur the growth of global biosimilar supply and drive price competition.

There are some constraints that accompany this synthesis. Published literature and regulatory documents have been used as the source for the information, and unpublished commercial information, such as confidential formulary negotiation results and rebate structures, are therefore necessarily excluded, potentially underestimating the magnitude of commercial barriers in some markets. Diffusion of regulatory definitions, data collection and healthcare financing in the region makes direct quantitative comparisons between markets difficult to interpret. This sector is experiencing rapid reforms at the regulatory and policy level, and particular provisions and approval numbers herein are as of early 2026.

9. Conclusions

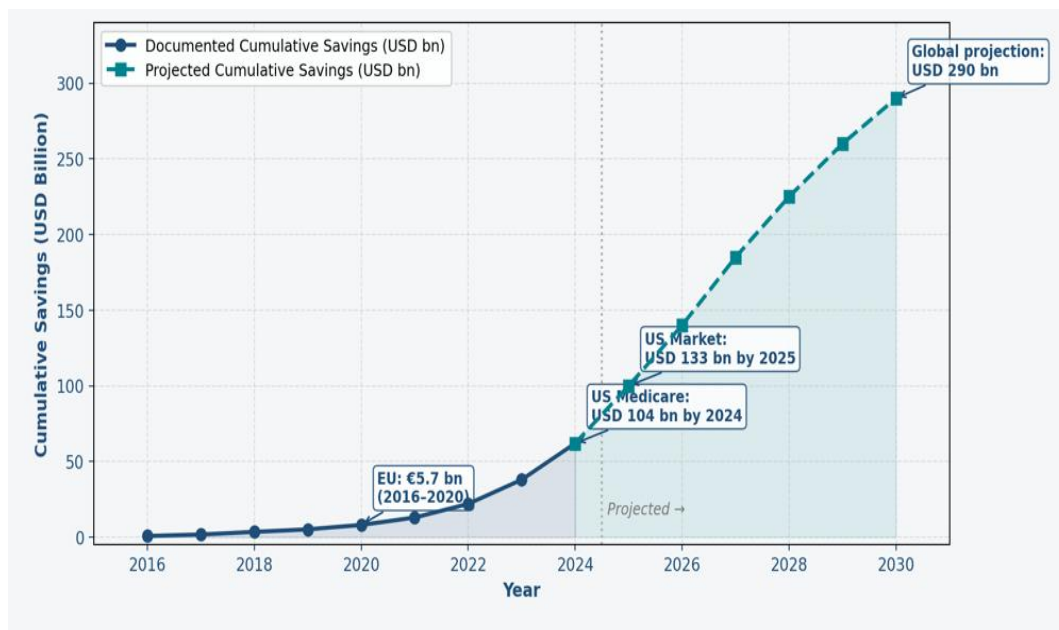


Figure 4. Global Biosimilar Cumulative Savings Trajectory: Documented (2016–2024) and Projected (2025–2030). Sources: IQVIA (2021); Mulcahy et al. (2020) RAND; Al Meslamani (2024); MedPAC (2019).

Biosimilars are a path to enhance access and cost-effectiveness of biological therapies in many health care systems and are supported by science. The evidence collected since the approval of biosimilars shows that regulated biosimilars continue to be therapeutically equivalent to the reference products, and published economic data demonstrate savings of 20–80% in almost every therapeutic category and country. The future cost savings will depend on the adoption of enabling policy conditions at scale, projected to total USD 290 billion globally by 2030.

It takes a trinity of activities to unlock that potential. Costs of development are lowered and the time between approval and patient access are shortened by regulatory harmonisation — aligning national approval processes with international standards and the increased use of adaptive licensing provisions. The incentives for biosimilar uptake, through procurement and reimbursement reform (termination of rebates that are tied to originators, competitive tendering systems, and value-based contracts) are needed for biosimilar uptake to take place on a mass scale. Hesitancy persists despite access to the formulary, and knowledge and confidence gaps that drive hesitancy can be addressed through stakeholder engagement which includes two aspects: structured prescriber education and patient communication programmes based on clear, transparent clinical evidence, and professional society guideline development.

If access to certain therapies is limited due to cost constraints, biosimilars are a way to increase access to the same therapy in a cost-saving way. The lessons from the successful markets are that this potential is real, but not inevitable, and the lessons from markets where adoption has been slow are that it is not inevitable. The question for health systems and policy makers is how to create institutional and policy environments where the science and economics of biosimilars are realized in a more equitable and sustainable patient benefit.

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