JOURNAL OF SCIENTIFIC RESEARCH IN ALLIED SCIENCES
ISSN NO. 2455-5800
Contents available at www.jusres.com

Regulatory Requirements for Biosimilar Medicines: A Systematic Comparative Review of Global Frameworks and the 2022–2026 Shift Toward Tailored Clinical Development

Rita Mourya[1], Shweta Gogate[2], Murtuza Zaki[2], Neeraj Mourya[2]

1) *School of Pharmacy, Faculty of Medical and Paramedical Sciences, SAM Global University Raisen-(MadhyaPradesh) India- 464551*
2) *College of Pharmacy, Faculty of Medical and Paramedical Sciences, SAM Global University Raisen-(MadhyaPradesh) India- 464551*

ARTICLE INFO **ABSTRACT** **REVIEW ARTICLE**

Article History
Received: June 2025
Accepted: July 2025

Keywords: Biosimilar; similar biotherapeutic product; regulatory affairs; comparability; interchangeability; totality of evidence; FDA; EMA; WHO; CDSCO; pharmacovigilance.

Background. Biosimilars are biological medicines demonstrated to be highly similar to an already-licensed reference biologic, offering a route to lower-cost access to biologic therapy. Because these molecules are large, heterogeneous and manufactured in living systems, they cannot be shown to be identical to the originator; regulators therefore rely on a stepwise, comparability-based 'totality-of-evidence' paradigm rather than on the abbreviated bioequivalence pathway used for small-molecule generics.

Objective. To systematically compare the regulatory requirements for biosimilar approval across the principal frameworks—the US FDA, the European Medicines Agency (EMA), the World Health Organization (WHO) and India's CDSCO—and to characterise the convergent 2022–2026 shift toward reduced, analytically-driven ('tailored') clinical data packages.

Methods. A structured literature and regulatory-document search (PubMed, Scopus, Embase, Web of Science and the FDA, EMA, WHO and CDSCO repositories) was conducted following PRISMA 2020 principles. Guidance documents, primary regulatory texts and peer-reviewed analyses published up to mid-2026 were screened against pre-specified eligibility criteria and synthesised qualitatively across eight comparative domains.

Results. All four frameworks share a common scientific core—comparative analytical characterisation as the foundation, supported by in vitro pharmacology, comparative pharmacokinetics and case-by-case clinical evaluation—but differ in legal basis, terminology, reference-product sourcing, interchangeability policy and post-marketing obligations. As of December 2025 the FDA had approved roughly 90 biosimilars (18 in 2025 alone) and the EMA more than 85 since 2006. A marked regulatory convergence occurred in 2022–2026: WHO (2022), the EMA reflection paper (adopted March 2026), the FDA draft guidance (October 2025) and India's 2025 draft all move to make comparative efficacy studies the exception rather than the default, relying instead on state-of-the-art analytical comparability plus a comparative pharmacokinetic study.

Conclusion. Global biosimilar regulation is converging on a leaner, science-driven model that preserves rigorous quality and pharmacovigilance standards while lowering development cost and time. Remaining divergence—chiefly

Corresponding Author
***Rita Mourya**

around the US 'interchangeability' designation and national substitution rules—represents the principal frontier for further harmonisation.

1. INTRODUCTION

Biologic medicines—monoclonal antibodies, fusion proteins, hormones, growth factors and cytokines—are among the most clinically valuable and most expensive therapies in modern medicine. Although biologics accounted for only about 5% of prescriptions in the United States in 2024, they represented roughly 51% of total drug spending, underscoring the economic pressure that patent expiry of originator biologics creates and the opportunity that follow-on competition presents [2]. A biosimilar is a biological medicine that is highly similar to an already-approved reference product, with no clinically meaningful differences in safety, purity or potency [1,17].

Unlike small-molecule generics, which are chemically identical to their reference drug and can be approved on the basis of pharmaceutical and pharmacokinetic bioequivalence, biologics are large, structurally complex molecules produced in living cells. Inherent micro-heterogeneity and sensitivity to the manufacturing process mean an exact copy cannot be made or demonstrated. Regulators therefore evaluate biosimilars through a fundamentally different construct: a stepwise comparability exercise assessed under a 'totality-of-evidence' standard, in which extensive analytical and functional characterisation forms the foundation and clinical studies serve to confirm—rather than independently establish—efficacy and safety [10,11,19].

The first biosimilar framework was established by the EMA, which issued overarching guidance in 2005 and approved the world's first biosimilar, somatropin (Omnitrope), in 2006 [14,20]. The United States created its abbreviated 351(k) licensure pathway through the Biologics Price Competition and Innovation Act (BPCIA) of 2009, under which the FDA approved its first biosimilar, filgrastim-sndz (Zarxio), in 2015 [3,16]. The WHO issued guidelines on similar biotherapeutic products (SBPs) in 2009 to assist countries lacking their own legislation, and India's CDSCO and Department of Biotechnology first published 'Guidelines on Similar Biologics' in 2012, revised in 2016 [11,12]. Two decades of accumulated experience have now catalysed a coordinated re-examination of how much clinical data a biosimilar truly requires.

This review systematically compares the current regulatory requirements for biosimilar approval across these four principal frameworks and analyses the convergent 2022–2026 reforms that are reshaping the clinical evidence expectation. The objective is to provide regulatory-affairs professionals, developers and policymakers with a consolidated, evidence-based reference on where the frameworks agree, where they diverge, and where global harmonisation is heading.

2. METHODS

2.1 Design and reporting standard

This work was designed as a systematic comparative review of regulatory frameworks and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) statement, adapted for the synthesis of regulatory guidance rather than clinical outcome data. No meta-analysis was performed because the outcome of interest is qualitative regulatory requirement, not a pooled effect estimate.

2.2 Information sources and search strategy

Four bibliographic databases (PubMed/MEDLINE, Scopus, Embase and Web of Science) were searched together with the official repositories of the FDA, EMA, WHO and CDSCO. Grey-literature and reference-list ('snowball') searching supplemented the electronic search. The core search string combined the concepts shown in Table 1. Records were restricted to English-language documents published between January 2005 and June 2026.

Table 1. Search concepts and representative terms used to construct the Boolean search string

Concept block	Representative search terms (combined with OR; blocks combined with AND)
Population / product	biosimilar; "similar biotherapeutic product"; "similar biologic"; "follow-on biologic"; "subsequent entry biologic"
Regulatory focus	regulatory OR guideline OR guidance OR "approval pathway" OR "marketing authorization" OR licensure OR 351(k) OR BPCIA
Scientific requirement	comparability OR "analytical similarity" OR immunogenicity OR pharmacokinetic OR "comparative efficacy" OR interchangeability OR "totality of evidence"
Jurisdiction	FDA OR EMA OR WHO OR CDSCO OR "European Union" OR India OR global OR international

2.3 Eligibility criteria and study selection

Documents were eligible if they described, compared or analysed the regulatory requirements for biosimilar development or approval in one or more of the four target jurisdictions. Records were excluded if they addressed a single product without regulatory-framework content, contained no comparative or requirement-level data, or were non-regulatory clinical reports. Titles and abstracts were screened against these criteria, and full texts of potentially eligible records were assessed. The study-selection process is summarised in Figure 1.

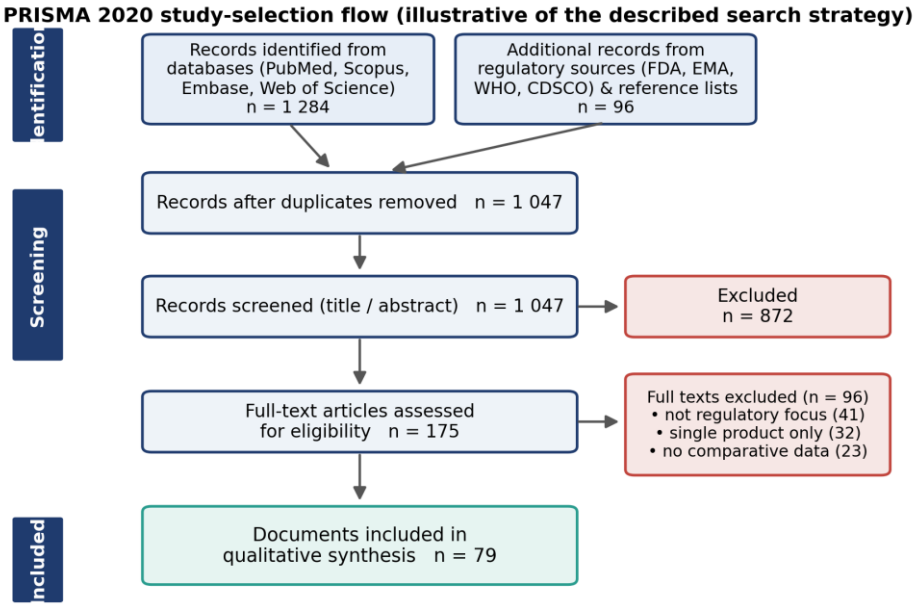

Figure 1. PRISMA 2020 flow of document identification, screening and inclusion. Counts are illustrative of the described search strategy and should be re-generated by authors upon executing the search prior to submission.

2.4 Data extraction and synthesis

Data were charted against eight pre-specified comparative domains: (i) definition and legal basis; (ii) reference-product requirements; (iii) analytical/quality comparability; (iv) non-clinical requirements; (v) clinical pharmacology (PK/PD); (vi) comparative efficacy and immunogenicity; (vii) interchangeability, substitution and switching; and (viii) pharmacovigilance, naming and traceability. Findings were ynthesized narratively and tabulated to expose points of convergence and divergence across frameworks.

3. RESULTS AND DISCUSSION

3.1 The scientific foundation: comparability and the totality of evidence

Across every framework examined, biosimilar development rests on the same conceptual architecture, formalised internationally in ICH Q5E and reflected in agency guidance [10,11,19]. Approval does not require re-establishing the clinical benefit of the molecule—already proven for the reference product—but rather demonstrating that the biosimilar is comparable to that reference. Evidence is assembled in a hierarchy of decreasing sensitivity (Figure 2): state-of-the-art physicochemical and functional characterisation constitutes the foundation and is the most sensitive tool for detecting differences; in vitro pharmacology, comparative pharmacokinetics (with or without pharmacodynamics), and—where residual uncertainty remains—a comparative clinical study, sit above it. Immunogenicity assessment and lifecycle pharmacovigilance run throughout.

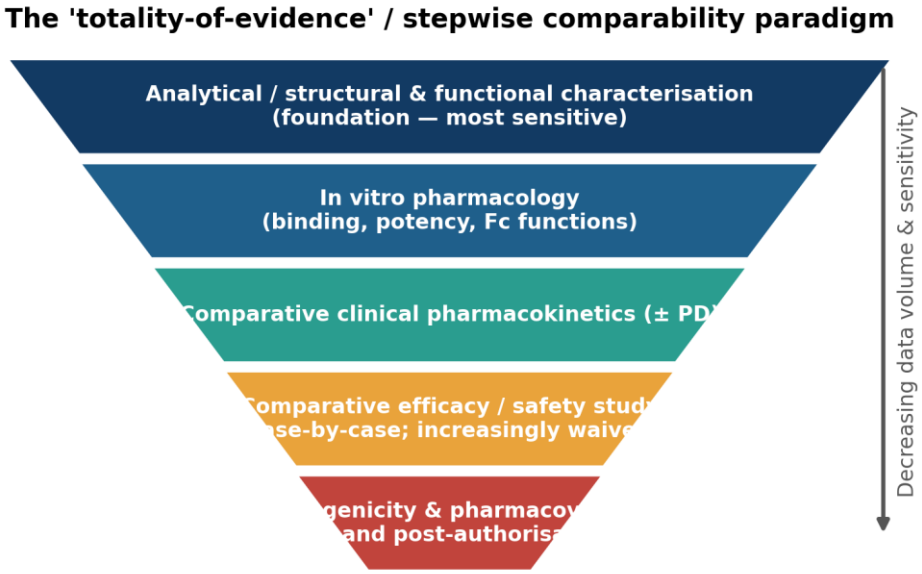

Figure 2. The stepwise 'totality-of-evidence' comparability paradigm shared by the FDA, EMA, WHO and CDSCO. Analytical characterisation is the foundation; the volume and sensitivity of confirmatory clinical data decrease as analytical resolution increases.

The practical consequence of this inversion—where analytical science, not the clinical trial, is the primary comparator—is central to the recent reforms discussed in Section 3.6. Comparative efficacy trials in biosimilar development are typically large equivalence or non-inferiority Phase III studies that, per FDA analysis, take one to three years and cost on average about USD 24 million, yet generally carry lower sensitivity to detect product differences than modern analytical assays [2].

3.2 Data requirements across the development programme

Table 2 charts the requirements at each stage of a comparability programme and how they are expressed in the four frameworks. The

quality/analytical package is uniformly the most demanding element and is non-negotiable in all jurisdictions; it is the clinical tier where requirements have historically differed and are now being harmonised downward.

Table 2. Data requirements across the biosimilar comparability programme

Development stage	What is assessed	Regulatory expectation (all frameworks unless noted)
Analytical / quality	Primary & higher-order structure, post-translational modifications, charge variants, glycosylation, purity, potency, stability	Extensive orthogonal, state-of-the-art characterisation vs. reference; must show no differences in critical quality attributes. Foundation of the dossier.
Non-clinical	In vitro target binding, potency, Fc-effector functions; in vivo studies	In vitro pharmacology emphasised. In vivo animal studies now only case-by-case (WHO 2022, CDSCO 2025, EMA/FDA reforms) applying 3Rs principles.
Clinical pharmacology	Comparative PK (Cmax, AUC) ± PD in a sensitive population	A comparative PK study is retained across frameworks as the pivotal in-human bridge; PD endpoints used where a sensitive marker exists.
Comparative efficacy	Equivalence/non-inferiority Phase III in a sensitive indication	Historically default; now required only where residual uncertainty remains after analytical + PK assessment (see §3.6).
Immunogenicity	Anti-drug & neutralising antibodies, incidence & consequences	Comparative assessment required; extent risk-based (e.g. reduced for insulin, filgrastim, somatropin; retained for higher-risk products).
Post-marketing	Safety, immunogenicity, effectiveness in real-world use	Risk-management plan / pharmacovigilance and traceability obligations in all frameworks.

3.3 Comparative regulatory frameworks: FDA, EMA, WHO and CDSCO

Figure 3 places the four frameworks on a common timeline, and Table 3 provides the detailed head-to-head comparison across the eight extraction domains. The EMA pioneered biosimilar regulation and remains the most mature system, with more than 85 biosimilars approved since 2006 [5]. The FDA's BPCIA pathway, though newer, has generated rapid growth. The WHO framework functions as a reference standard for countries building their own systems, while India's CDSCO/DBT guidelines align national requirements with international norms while retaining a mandatory comparative clinical component in most cases [12,24].

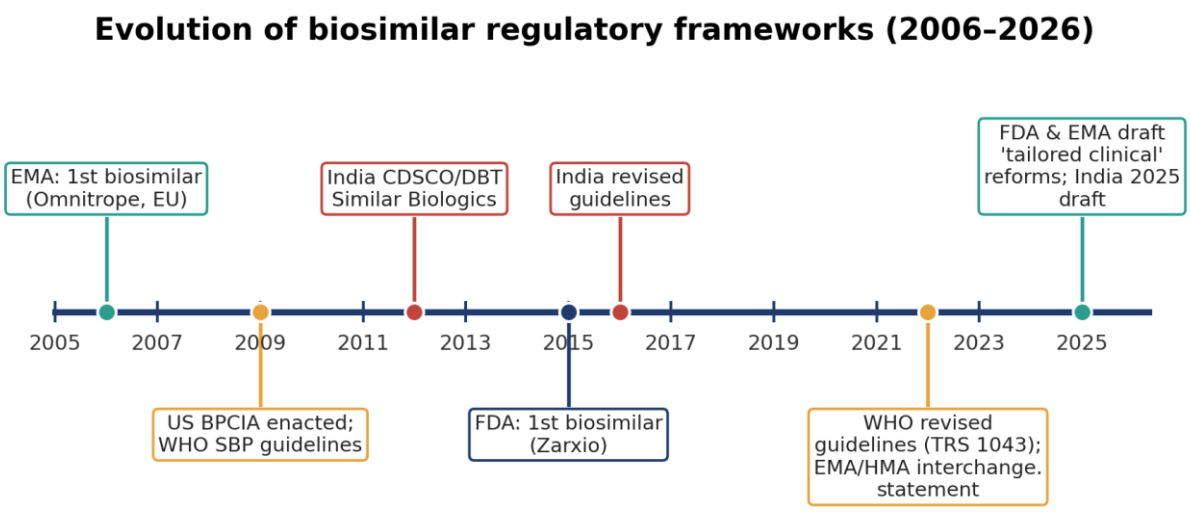

Figure 3. Evolution of the principal biosimilar regulatory frameworks, 2006–2026, showing foundational legislation and the recent wave of 'tailored clinical approach' reforms.

Table 3. Comparative regulatory requirements for biosimilar approval by agency

Domain	US FDA	EMA (EU)	WHO	CDSCO (India)
Term used	Biosimilar / interchangeable biosimilar	Biosimilar	Similar biotherapeutic product (SBP) / biosimilar	Similar biologic
Legal / guidance basis	BPCIA 2009; PHS Act §351(k); FDA guidances (2015 onward)	Directive 2001/83/EC; CHMP/437/04 Rev 1 (2014) + product-class guidelines	WHO SBP guidelines 2009; revised TRS 1043 (2022)	Guidelines on Similar Biologics 2016 (CDSCO/DBT); NDCT Rules 2019; 2025 draft
Reference product	Must be US-licensed; foreign comparator allowed with a scientific bridge	EEA-authorised; non-EEA comparator allowed with bridging	Nationally licensed or, since 2022, a suitable non-local comparator accepted	Reference authorised in India (or well-established regulated market with justification)
Analytical package	Extensive; foundation of 'totality of evidence'	Extensive; comparability exercise per ICH Q5E	Extensive; strengthened analytical focus (2022)	Extensive; 2025 draft strengthens orthogonal analytics
Clinical	Comparative	Comparative	Confirmatory	Comparative

Domain	US FDA	EMA (EU)	WHO	CDSCO (India)
requirement	PK pivotal; comparative efficacy study now generally not recommended by default (2025 draft)	PK pivotal; efficacy study may be waived (reflection paper, 2026)	efficacy study case-by-case, often redundant (2022)	PK/PD; Phase III comparative efficacy generally required (few waivers, e.g. insulin)
Interchangeability	Distinct FDA designation; switching studies previously required, now generally not recommended	No separate designation; all biosimilars deemed interchangeable (EMA/HMA 2022); substitution set nationally	Not addressed as a formal designation; left to national authorities	No formal interchangeability designation; substitution governed nationally
Naming	Non-proprietary name + 4-letter random suffix	INN without suffix; brand-name traceability	INN-based; national discretion	Brand name + INN
Pharmacovigilance	Risk-management, adverse-event reporting, lifecycle monitoring	EU RMP, black-triangle additional monitoring, traceability by brand/batch	Pharmacovigilance plan recommended	Mandatory post-marketing / Phase IV pharmacovigilance

3.4 Interchangeability, substitution and switching

Interchangeability is the domain of greatest international divergence. In the EU, the EMA and the Heads of Medicines Agencies issued a joint statement in 2022 concluding that biosimilars approved in the EU are interchangeable with their reference product and with other biosimilars of the same reference, on the scientific rationale that they are comparable in efficacy, safety and immunogenicity; the actual act of substitution at pharmacy level remains a matter for individual Member States [5,6]. The EMA thus has no separate 'interchangeable' category—every approved biosimilar qualifies scientifically.

The United States is unique in maintaining a distinct statutory 'interchangeable' designation under the BPCIA, permitting pharmacy-level substitution without prescriber intervention where state law allows. FDA guidance finalised in 2019 originally expected dedicated switching studies to support this designation; draft guidance in 2024 and the October 2025 policy shift moved the agency toward relying on analytical data and generally not recommending switching studies, narrowing the practical distinction between 'biosimilar' and 'interchangeable' [4,14,18]. As of late 2025 the FDA had designated roughly two dozen products as interchangeable since 2020. WHO and CDSCO do not operate a formal interchangeability designation, leaving substitution to national policy. Table 4 summarises these positions.

Table 4. Approaches to interchangeability and substitution

Framework	Separate 'interchangeable' status?	Basis / evidence	Pharmacy-level substitution
FDA	Yes (statutory)	Analytical comparability; switching studies previously expected, now generally not recommended	Permitted for interchangeable products where state law allows
EMA	No — all biosimilars interchangeable (2022 statement)	Scientific rationale from 20 years of experience	Decided by individual EU Member States
WHO	No formal designation	Deferred to national authorities	National discretion
CDSCO	No formal designation	Comparability + post-marketing data	Governed by national/prescriber practice

3.5 Approval trends and market impact

The output of these frameworks has grown substantially. In the United States, biosimilar approvals accelerated from a single product in 2015 to a cumulative total of approximately 90 by the end of 2025, with a record 18 approvals in 2025 alone spanning oncology, ophthalmology, immunology, endocrinology and bone health (Figure 4) [3,4]. Counting conventions vary—the FDA's own tally of 76 as of October 2025 reflects 351(k) approvals, while inclusive counts that add certain follow-on biologics approach 96—but the growth trajectory is unambiguous.

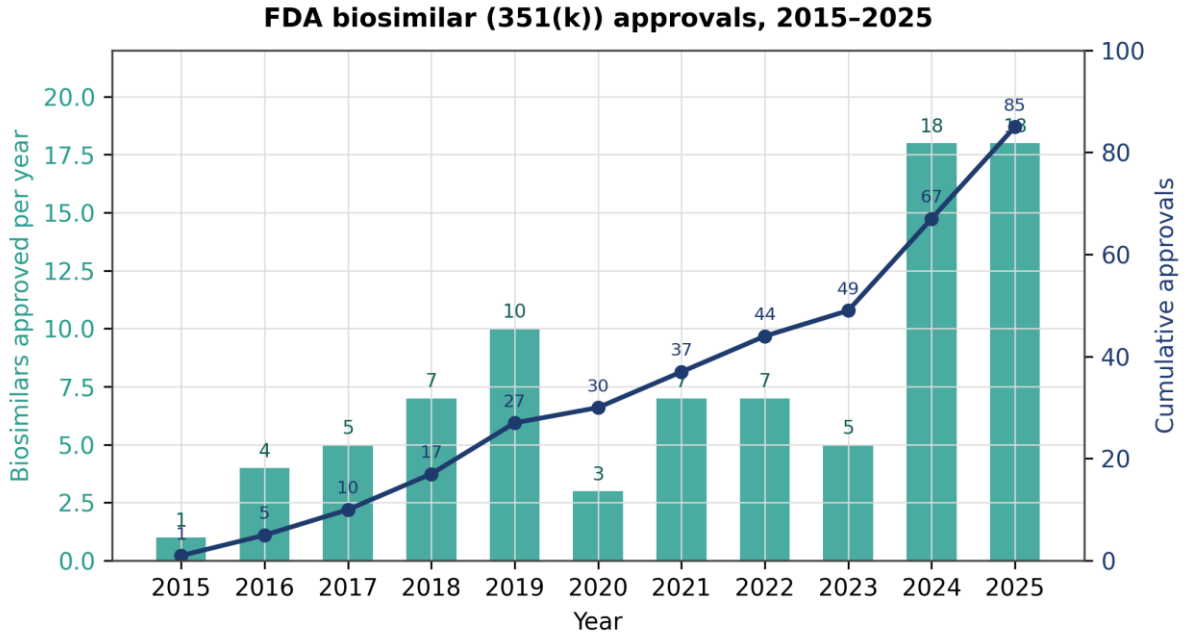

Figure 4. Annual and cumulative FDA biosimilar (351(k)) approvals, 2015–2025. Annual figures compiled from the FDA Purple Book and secondary trackers; year-end cumulative totals vary modestly by counting convention.

Regulatory approval, however, does not translate uniformly into market impact. Uptake and price erosion diverge sharply by therapeutic class (Figure 5). 'Fast-uptake' segments—oncology, ophthalmology and pegfilgrastim—reached an average biosimilar market share of about 81% within five years of launch, whereas 'slow-uptake' segments such as immunology, filgrastim and insulin glargine averaged only about 25% over the same period. By the third quarter of 2025, bevacizumab and trastuzumab biosimilars had captured roughly 92% and 88% of their markets respectively. Average sales prices fell by about 52% within five years of a class launch on average, and by as much as 77% in the most mature classes [4,10,22]. These economics—not the science of approval—now constitute the principal barrier to realising biosimilar savings, with pharmacy-benefit contracting structures frequently cited as the bottleneck [4].

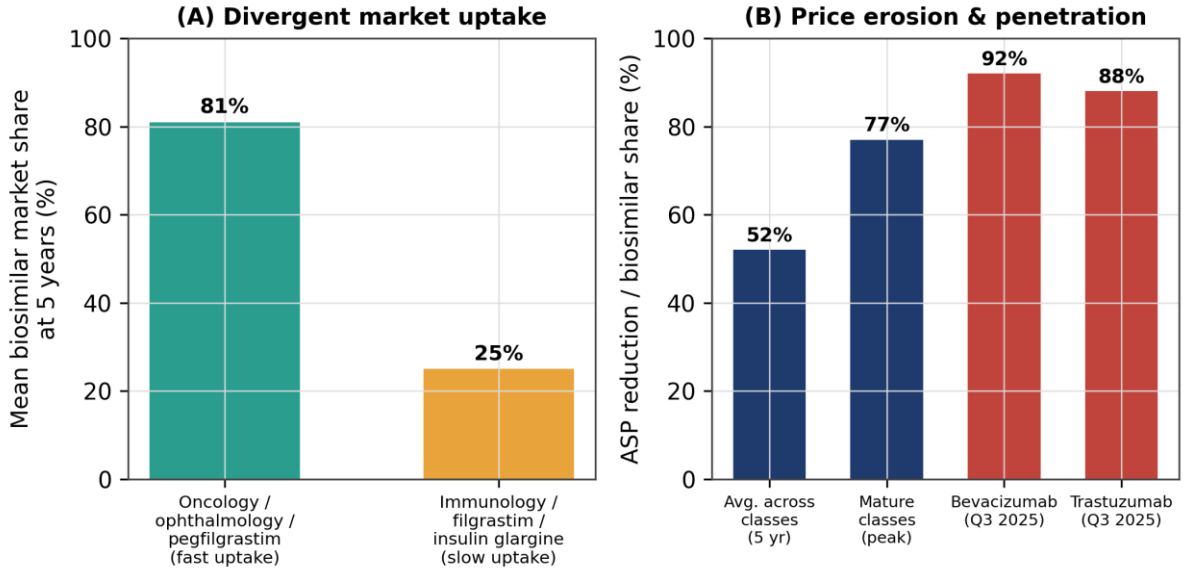

Figure 5. Divergent market uptake (A) and price erosion / penetration (B) for biosimilars by therapeutic segment. Data reflect US market analyses through Q3 2025.

3.6 The 2022–2026 paradigm shift: the tailored clinical approach

The most consequential regulatory development in a decade is the coordinated move—across all four frameworks—to reduce or eliminate the default comparative efficacy study. Two decades of experience, together with advances in analytical science, have shown that for products that can be thoroughly characterised, a comparative efficacy trial rarely adds decision-relevant information beyond a rigorous analytical comparison plus a comparative pharmacokinetic study [7,9,10]. Table 5 traces this convergence.

Table 5. The 2022–2026 convergence toward reduced ('tailored') clinical requirements

Framework / instrument	Date	Core change
WHO — revised SBP guidelines (TRS 1043)	2022	Large confirmatory efficacy/safety studies considered redundant in most cases; reduced non-clinical & animal testing; acceptance of non-local reference comparators.
EMA/HMA — interchangeability statement	2022	EU-approved biosimilars declared interchangeable, harmonising the EU position

Framework / instrument	Date	Core change
		and reducing the need for additional switching data.
FDA — draft guidance on comparative efficacy studies	Oct 2025	Comparative efficacy studies no longer recommended by default; reliance on analytical testing; switching studies generally not recommended for interchangeability.
EMA — reflection paper on a tailored clinical approach	Draft Apr 2025; CHMP-adopted 16 Mar 2026	Biosimilarity may be established from analytical comparability + in vitro pharmacology + a comparative PK trial, potentially without a comparative efficacy study or even PD data.
CDSCO (India) — draft revised guidelines	Draft May 2025	Strengthened orthogonal analytics and in vitro studies; reduced reliance on animal testing (3Rs); alignment with WHO TRS 1043.

The direction of travel is unmistakable: the comparative efficacy trial is being repositioned from the default expectation to an exception invoked only when analytical or mechanistic uncertainty genuinely remains. This lowers development cost and time, potentially widens the range of biologics for which a biosimilar is commercially viable, and is expected to improve patient access—provided quality and pharmacovigilance standards are preserved, which every instrument explicitly reaffirms [7,9].

3.7 Pharmacovigilance, naming and traceability

Because immunogenicity and rare adverse events may only emerge in large real-world populations, all frameworks impose lifecycle pharmacovigilance obligations and require precise product identification so that any safety signal can be traced to the correct product and batch. The EU applies risk-management plans and additional 'black-triangle' monitoring with traceability by brand name and batch number; the FDA assigns a distinguishing four-letter suffix to the non-proprietary name; India mandates post-marketing (Phase IV) safety studies. These systems collectively ensure that the reduced pre-authorisation clinical burden of the tailored approach is counterbalanced by robust post-authorisation surveillance [11,12,23].

3.8 Convergence, remaining divergence and future directions

The frameworks are converging on a shared, science-led model: analytical comparability as the decisive evidence, a single comparative pharmacokinetic bridge, risk-based immunogenicity assessment, and robust pharmacovigilance. The principal residual divergences are (i) the US-specific interchangeability designation, now shrinking in practical significance; (ii) heterogeneous national substitution rules, especially within the EU; and (iii) differences in reference-product sourcing, partly eased by broader acceptance of non-local comparators. Continued reliance on ICH Q5E and WHO TRS 1043 as common anchors, mutual reliance and work-sharing between agencies, and adoption of the tailored clinical approach in emerging markets are the most promising routes to further harmonisation. The main unresolved challenge lies less in regulation than in market design—formulary and reimbursement structures that currently blunt the price competition biosimilars are intended to create [4].

4. CONCLUSION

Regulatory requirements for biosimilar medicines across the FDA, EMA, WHO and CDSCO share a common scientific foundation—stepwise comparability assessed under a totality-of-evidence standard—while differing in legal architecture, interchangeability policy and post-marketing detail. The defining trend of 2022–2026

is convergence toward a leaner, analytically-driven development model in which the comparative efficacy trial becomes the exception rather than the rule. This evolution, anchored by ICH Q5E and WHO TRS 1043 and reinforced by rigorous lifecycle pharmacovigilance, promises to reduce development cost and expand patient access without compromising quality or safety. The frontier for the next phase of harmonisation is the reconciliation of interchangeability and substitution frameworks and, beyond regulation, the reform of market and reimbursement structures that determine whether biosimilars' scientific success delivers its full public-health benefit.

DECLARATIONS

Funding: None declared.

Conflicts of interest: The authors declare no competing interests.

Author contributions: All authors contributed to conception, literature synthesis, drafting and critical revision, and approved the final manuscript.

Data availability: All data analysed derive from the publicly available regulatory documents and publications cited.

Author's note on methodology: *The document counts shown in Figure 1 are illustrative of the search strategy described in Section 2; before journal submission the authors should execute the pre-specified search, populate the actual PRISMA counts, and confirm all figures against the latest agency data, since biosimilar approval totals change monthly.*

REFERENCES

1. U.S. Food and Drug Administration. Biosimilar product information and the Purple Book database. FDA, Silver Spring, MD; accessed 2026. Available at: fda.gov/drugs/biosimilars.
2. U.S. Food and Drug Administration. FDA moves to accelerate biosimilar development and lower drug costs [press release]. 29 October 2025.
3. Generics and Biosimilars Initiative (GaBI). Biosimilars approved in the US. GaBI Online, Pro Pharma Communications International, Mol, Belgium; updated 2025–2026.
4. Center for Biosimilars. Milestone approvals and evolving PBM models may redefine the 2026 biosimilar landscape. 2025–2026; drawing on Samsung Bioepis US Biosimilar Market Report, 12th ed., Q1 2026.
5. European Medicines Agency. Biosimilar medicines can be interchanged [news]. EMA, Amsterdam; 19 September 2022 (updated 17 October 2022).
6. European Medicines Agency / Heads of Medicines Agencies. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. EMA/HMA; 2022–2023.
7. European Medicines Agency, Committee for Medicinal Products for Human Use. Reflection paper on a tailored clinical approach in biosimilar development. Draft 1 April 2025; adopted by CHMP 16 March 2026.
8. Generics and Biosimilars Initiative (GaBI). EMA adopts landmark reflection paper on tailored clinical approach for biosimilars. GaBI Online; 2026.
9. Wadhwa M, Kang H-N, Thorpe R, Knezevic I, et al. WHO informal consultation on revision of guidelines on evaluation of similar biotherapeutic products. Biologicals. 2022;76:1–9. doi:10.1016/j.biologicals.2022.03.001.
10. Kurki P, Barry S, Bourges I, et al. Regulatory evaluation of biosimilars: refinement of principles based on the scientific evidence and clinical experience. BioDrugs. 2022;36(3):359–371. doi:10.1007/s40259-022-00533-x.
11. World Health Organization. Guidelines on evaluation of biosimilars. WHO Technical Report Series No. 1043, Annex 3. Geneva: WHO; 2022.
12. Central Drugs Standard Control Organization & Department of Biotechnology. Guidelines on similar biologics: regulatory requirements for marketing authorization in India. New Delhi: CDSCO/DBT; 2016.
13. Central Drugs Standard Control Organization. Draft guidelines on similar biologics — regulatory requirements for marketing authorization in India, 2025. New Delhi: CDSCO; May 2025 (public consultation).
14. Regulatory requirements for interchangeable biosimilar designation: US trends 2019–2025.

Therapeutic Innovation & Regulatory Science. 2025. doi:10.1007/s43441-025-00897-6.
15. Biosimilars and interchangeability: regulatory, scientific, and global perspectives. Eur J Pharm Sci / ScienceDirect. 2025; S0928-0987(25)00223-4.
16. United States Congress. Biologics Price Competition and Innovation Act of 2009 (Public Health Service Act §351(k)). 2009/2010.
17. U.S. Food and Drug Administration. Scientific considerations in demonstrating biosimilarity to a reference product [guidance]. 2015; and Updated recommendations on comparative efficacy studies [draft]. 2025.
18. U.S. Food and Drug Administration. Considerations in demonstrating interchangeability with a reference product [guidance]. Final 2019; revised draft June 2024.
19. International Council for Harmonisation. ICH Q5E: comparability of biotechnological/biological products subject to changes in their manufacturing process. 2004.
20. European Medicines Agency. Guideline on similar biological medicinal products (overarching), CHMP/437/04 Rev 1. EMA; 2014.
21. European Parliament and Council. Directive 2001/83/EC on the Community code relating to medicinal products for human use. 2001 (as amended).
22. Samsung Bioepis. Biosimilar market report, 12th edition, Q1 2026. Incheon: Samsung Bioepis; January 2026.
23. U.S. Food and Drug Administration. Nonproprietary naming of biological products [guidance]. 2017.
24. Similar biologics in India: a story of access or potential for compromise? Indian J Med Res. 2021 (PMC8157901).
25. Examining the impact of the WHO 2022 guidelines on evaluation of biosimilars for non-local comparators. Pharmacy (Basel). 2024;12(4):94.