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From Approval To Affordability: Biosimilar Regulation And Pricing In India And Australia

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Abstract

Background: Biosimilars can improve access to biological medicines by increasing competition and reducing treatment expenditure. Their real-world impact depends on regulatory requirements, pricing policies, reimbursement arrangements, substitution practices, and market sustainability.

Objective: To compare the regulatory pathways, pricing and reimbursement mechanisms, market-access conditions, and selected approval-timing differences for biosimilars in India and Australia.

Methods: We conducted a structured comparative policy review using regulatory guidance, government documents, reimbursement materials, and peer-reviewed literature on biosimilars in both countries. We organised evidence by regulatory authority, legal framework, comparability requirements, clinical evidence, extrapolation, pharmacovigilance, pricing, reimbursement, substitution, and market access. An access–affordability–availability framework and a documentary SWOT analysis were used to synthesise the findings. Approval-year differences for selected trastuzumab and rituximab biosimilars were also examined descriptively.

Results: India and Australia apply broadly comparable scientific principles based on analytical, functional, non-clinical, and clinical comparability. However, India relies more strongly on domestic manufacturing, market competition, public procurement, and selective price regulation, whereas Australia uses a structured system linking TGA registration with PBS reimbursement, price management, and substitution policies. India's major advantages include production capacity and competitive potential, while Australia demonstrates greater regulatory and reimbursement standardisation. The selected biosimilars showed earlier approval in India, although the observed intervals may reflect submission and commercial factors as well as regulatory processes.

Conclusion: Biosimilar access requires more than regulatory approval. Clear substitution principles, effective pharmacovigilance, sustainable pricing, supplier diversity, reimbursement, and reliable supply are essential for long-term affordability and availability in both countries.....

Keywords : Biosimilars; similar biologics; regulatory science; pricing policy; reimbursement; market access...

INTRODUCTION

Biologic medicines are large, complex molecules derived from living organisms and have transformed the management of various chronic and life-threatening diseases, including autoimmune diseases, cancers, and diabetes. These drugs, commonly referred to as biologics, are vastly different from conventional small-molecule drugs in terms of their chemical, manufacturing, and assessment processes. Due to their complex nature, biosimilars cannot be viewed as simple generics; instead, they are highly similar versions of already approved biologic drugs that depend on a strict proof of comparability in terms of quality, safety, and efficacy to the original biologic drug. Biosimilars have immense potential for reducing costs and improving accessibility to biologic treatments, especially in low- and middle-income countries where cost is a significant hindrance to treatment.[1]

The World Health Organisation has been actively advocating biosimilars as a crucial part of a sustainable healthcare system, advising policies that encourage the early inclusion of quality-assured biosimilars to improve accessibility and affordability. As per WHO guidelines, biosimilars must be strictly assessed through legislative

and administrative procedures to guarantee safety and efficacy while ensuring easy market access within a short timeframe. Harmonization of regulations and education of healthcare professionals are also highlighted in efforts to enhance the adoption of biosimilars across the globe.[2]

The biosimilar regulatory environment is quite diverse across different countries. Although some countries have a rigorous and well-established regulatory process that conforms to international standards, others are still in the process of formulating their regulatory policies. Cross-national comparisons indicate that the regulatory bodies in different countries have published guidelines on biosimilars that define the requirements for demonstrating similarity to a reference product. The regulatory environments may vary in relation to clinical requirements, extrapolation of indications, and post-market surveillance approaches, among others.[3]

In this rapidly changing global scenario, India and Australia are two different regulatory systems with their own set of approaches to biosimilars. India has become a leading global manufacturer of biosimilars, capitalizing on its robust biotechnology industry and large population base. The regulatory framework for biosimilars in India, termed "similar biologics," was first established with the launch of the Guidelines on Similar Biologics by the Central Drugs Standard Control Organization (CDSCO) in partnership with the Department of Biotechnology (DBT) in 2012 and was later amended in 2016 to make it more congruent with international scientific norms. According to these guidelines, similar biologics are defined as products that are similar in quality, safety, and efficacy to an already approved reference biological in terms of comprehensive comparability studies, including analytical, preclinical, and clinical assessments.[4,5]

Despite the rapid expansion in the number of biosimilar approvals and production, the regulatory framework in India is still faces challenges of clarity in interchangeability standards, implementation of guidelines, and biosimilar market adoption. It is pertinent to note that, although the guidelines offer a clear regulatory framework for approval, they are not binding laws but rather guidelines.[6]

The regulation of biosimilars in Australia is firmly established through the Therapeutic Goods Administration (TGA) within the framework of the Therapeutic Goods Act 1989, which regulates the regulation of therapeutic products, including biologics and biosimilars. Biosimilars in Australia are required to undergo a rigorous assessment process to establish similarity with an existing approved product on the Australian Register of Therapeutic Goods (ARTG). The TGA regulatory framework is based on similar principles to those of the European Medicines Agency (EMA), with a focus on analytical similarity, as demonstrated by nonclinical and targeted clinical studies, to establish safety and efficacy.[7,8]

As of recent information, the TGA has approved more than 65 biosimilars across therapeutic areas such as human growth hormone, granulocyte-stimulating factors, insulin, and monoclonal antibodies.[9]

One of the key considerations in biosimilar regulatory frameworks relates to the issue of interchangeability, which refers to the ability of a biosimilar to be substituted for the reference biologic without the need for prescriber approval. Although the issue of interchangeability is being addressed by various regulatory authorities around the world, the regulatory and policy frameworks that govern substitution differ, which can have a major impact on biosimilar acceptance by healthcare providers and patients. Apart from the regulatory framework, pricing and reimbursement policies also play a crucial role in determining the acceptance of biosimilars. Biosimilars are expected to lower healthcare costs by offering competitive pricing alternatives to expensive originator biologic therapies. However, pricing policies and healthcare system reimbursement structures differ from country to country. While in some countries biosimilars offer a substantial price reduction, in other countries the price reduction is minimal.[10]

The increasing relevance of biosimilars in the current healthcare landscape thus highlights the importance of comparative analyses of frameworks related to regulation and pricing. These analyses can facilitate the identification of strengths, weaknesses, and areas of potential harmonization, thus facilitating not only better access to essential biologic therapies but also better affordability and sustainability of healthcare systems. Existing literature has examined biosimilar regulation, pricing, and uptake in individual jurisdictions, but fewer studies have considered these elements together in a focused comparison of India and Australia. A comparison is particularly relevant because the two countries differ in regulatory institutions, healthcare financing, domestic manufacturing capacity, reimbursement arrangements, and approaches to substitution. This study therefore examines how regulatory and market-access policies interact across the biosimilar product lifecycle, from development and marketing authorisation to reimbursement and use in clinical practice. The analysis does not attempt to determine which country has the universally superior system; rather, it identifies the policy mechanisms, trade-offs, and evidence gaps that may influence affordability, availability, and sustainable competition.[8,9,10]

MATERIALS AND METHODS

Study design

This study was designed as a structured comparative policy analysis. It examined publicly available regulatory documents, government policy materials, reimbursement information, and peer-reviewed literature concerning

biosimilars in India and Australia. The comparative analysis focused on four linked policy domains: regulatory approval, pricing and reimbursement, substitution and interchangeability, and post-marketing oversight. Because the study did not involve patient-level data, clinical intervention, or identifiable human participants, institutional ethics approval was not required. [11,12]

Information sources

Evidence was obtained from official sources, including the Central Drugs Standard Control Organisation, Department of Biotechnology, National Pharmaceutical Pricing Authority, Therapeutic Goods Administration, Australian Register of Therapeutic Goods, Pharmaceutical Benefits Scheme, Pharmaceutical Benefits Advisory Committee, World Health Organization, and European Medicines Agency. Peer-reviewed literature was identified through bibliographic databases and supplemented by reference-list screening. Secondary policy reports were used only when primary regulatory or reimbursement information was unavailable or when they provided contextual information.[9,10,12,13,14,15,16,18]

Eligibility criteria

Documents were eligible if they:

Described regulatory requirements or approval procedures for biosimilars in India or Australia;

Addressed pricing, reimbursement, procurement, substitution, interchangeability, or market access;

Reported approval dates, market-entry information, utilisation, or economic outcomes; were official regulatory or government documents, peer-reviewed publications, or clearly identified policy reports; and were available in English.

Documents were excluded if they:

Concerned only conventional generic medicines without relevance to biosimilars;

Lacked sufficient information to identify the jurisdiction or policy mechanism;

Consisted solely of promotional material without a transparent evidence base; or

Duplicated information already available in a more complete primary source.

Data extraction

Data were extracted into a structured evidence table. The extracted fields included country, regulatory authority, legal basis, terminology used for biosimilars, reference-product requirements, analytical comparability, non-clinical studies, clinical studies, indication extrapolation, interchangeability or substitution, naming and traceability, pharmacovigilance, pricing regulation, reimbursement, procurement, market uptake, and reported access or savings outcomes. For approval-timeline comparisons, the product name, manufacturer, reference product, jurisdiction, regulatory event, date, and source were recorded separately.[9,12,15,16]

Analytical framework

The findings were organised using an access–affordability–availability framework developed for this study. Access referred to the ability of a biosimilar to obtain regulatory authorisation and enter a reimbursement or procurement pathway. Affordability referred to the relationship between biosimilar prices, reimbursement arrangements, patient contributions, and reported payer expenditure. Availability referred to the number and diversity of suppliers, distribution through relevant healthcare channels, and evidence of continued supply. The framework was used as a qualitative organising tool and was not treated as a validated quantitative scale.

A descriptive SWOT analysis was used only to summarise policy-relevant strengths, weaknesses, opportunities, and threats identified in the reviewed evidence. Each SWOT item was linked to at least one documentary or peer-reviewed source. The SWOT analysis was not used to rank the two countries or establish causal effects. [19,20]

A descriptive regulatory approval lag analysis was conducted for selected biosimilars approved in both India and Australia. The comparison was based on the date of Indian marketing authorisation and the date of Australian TGA/ARTG registration. Approval lag was calculated in months as the Australian registration date minus the Indian approval date. A positive value indicated earlier approval in India, whereas a negative value indicated earlier registration in Australia. Where exact dates were unavailable, the use of year-level data was recorded and interpreted as approximate. PBS listing, commercial launch, hospital procurement, and first patient use were not treated as equivalent to regulatory approval. Because the analysis included a limited number of products, the results were interpreted descriptively and were not generalised to all biosimilars. [12,15,19]

Data synthesis

Findings were synthesised narratively by country and then compared across the predefined policy domains. Differences in terminology, regulatory event definitions, product availability, reimbursement status, and data reporting were considered when interpreting cross-country comparisons. Price reductions and savings estimates were not pooled because the available studies used different price concepts, time periods, comparators, and populations.[1,2,11]

RESULTS

Global development of biosimilar

Over the past two decades, the biosimilar pharmaceutical sector has undergone remarkable expansion, driven by rising patient demand for biologic therapeutics and the imperative to enhance treatment affordability and accessibility. The biosimilar market is projected to reach USD 72.29 billion by 2035, growing from USD 35.04 billion in 2025 at a compound annual growth rate (CAGR) of 7.5 %. Alternative forecasts estimate the market will attain USD 112.93 billion by 2031, reflecting a CAGR of 17.95% from 2026.21,22. The World Health Organisation (WHO) has played a pivotal role in facilitating biosimilar development and regulatory standardisation through its "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs). These guidelines establish internationally accepted scientific principles for demonstrating bio-similarity through a systematic comparability exercise encompassing analytical, nonclinical and clinical studies. [19] The European Medicines Agency (EMA) pioneered biosimilar regulatory oversight by establishing the first dedicated biosimilar approval pathway, introducing comprehensive biosimilar guidelines in 2005. The EMA framework is founded on the totality of evidence approach, emphasising extensive analytical characterisation supported by targeted non-clinical and clinical studies.[19,20] In the United States, the Food and Drug Administration (FDA) regulates biosimilars under the Biologics Price Competition and Innovation Act (BPCIA) of 2009. The FDA employs a stepwise approach analogous to the EMA but includes a distinct regulatory designation for interchangeability, permitting pharmacy-level substitution under specific conditions. [19,20] The global biosimilar market has witnessed substantial growth, supported by patent expirations of several high-value biologic medicines and increasing healthcare expenditure. The Asia-Pacific biosimilar market is anticipated to register a significant CAGR of 19.84%, driven by the rising prevalence of diabetes, cancer, and autoimmune disorders. [23,24] Within the evolving global regulatory landscape, India and Australia represent valuable comparative case studies owing to their divergent healthcare systems, regulatory frameworks and pricing strategies. Comparative analysis of these jurisdictions provides insights into how different regulatory and pricing approaches influence biosimilar affordability, accessibility, market uptake and healthcare sustainability.[20]

Regulatory framework of biosimilars in India

India's regulatory framework for biosimilars, termed "similar biologics", operates under a structured system emphasising comparability to approved reference products.[11]

1. Regulatory authority

The Central Drugs Standard Control Organisation acts as the main authority for drug approvals, clinical trials, manufacturing licenses, and market authorisation, operating under the Ministry of Health and Family Welfare. It collaborates with the Department of Biotechnology (DBT) for technical guidance on development and with the Review Committee on Genetic Manipulation (RCGM) for biosafety assessments related to recombinant processes. [11,25]

2. Regulatory guidelines

Core legislation stems from the Drugs and Cosmetics Act, 1940, and rules 1945, with biosimilar-specific direction from the CDSCO-DBT joint "guidelines on similar biologics", originally released in 2012 and updated in 2016 to incorporate stepwise comparability principles aligned with the WHO standard. Supporting rules include the New Drugs and Clinical Trials (NDCT) Rules, 2019, which govern trial permissions and post-approval surveillance, plus ICH-aligned modules for quality and pharmacovigilance. A 2024 draft revision introduces enhanced analytical tools and potential waivers for certain nonclinical studies.[25,26]

3. Approval pathway

The Indian pathway for similar biologics follows a stepwise comparability approach. The central principle is to establish that the proposed product is highly similar to an appropriate reference biological product and that any remaining uncertainty does not result in clinically meaningful differences in quality, safety, or efficacy. The evaluation should therefore be understood as a totality-of-evidence assessment rather than as a fixed checklist requiring identical studies for every product.

The assessment generally begins with extensive physicochemical and functional characterisation, followed by consideration of non-clinical and clinical evidence according to the residual uncertainty identified during development. The clinical programme may include pharmacokinetic and/or pharmacodynamic comparisons and, where considered necessary, comparative clinical evidence addressing efficacy, safety, and immunogenicity. The extent of indication extrapolation and the need for additional studies should be justified using the totality of the comparability evidence and the characteristics of the reference product.

Applications must also address manufacturing consistency, stability, immunogenicity, risk management, traceability, and post-marketing surveillance. Consequently, the regulatory assessment should not be reduced to the presence or absence of one particular clinical trial. The applicable requirements must be confirmed against the current Indian guidance and the product-specific advice available at the time of submission.[4,11,25,26]

Regulatory framework of biosimilars in Australia

Australia's regulatory framework for biosimilars adopts a comparability-based approach, ensuring high similarity to an approved reference biologic while meeting rigorous safety and efficacy standards.[27]

1. Regulatory authority

The Therapeutic Goods Administration (TGA), part of the Department of Health and Aged Care, acts as the central authority for evaluating and registering biosimilars on the Australian Register of Therapeutic Goods (ARTG), focusing on quality, safety and efficacy. The Pharmaceutical Benefits Advisory Committee (PBAC) advises on reimbursement through the Pharmaceutical Benefits Scheme (PBS), assessing cost-effectiveness post-TGA approval, without automatic interchangeability.[27,28,29]

2. Regulatory guidelines

Biosimilars are governed by the Therapeutic Goods Act 1989 and Therapeutic Goods Regulations 1990, with TGA adopting EMA's overarching and product-specific guidelines on similar biological medicinal products (eg, CHMP/437/04 rev 1 for quality/non-clinical/clinical issues). Key documents include the TGA's "Biosimilar medicines regulation" and ICH Q5E on biotechnological product comparability. Additional guidance covers immunogenicity, risk management plans, and post-market pharmacovigilance, with active ingredient naming using Australian Approved Names (AAN) or biological names (ABN).[30]

3. Approval pathway

In Australia, biosimilars are assessed by the Therapeutic Goods Administration through the prescription-medicine registration framework. The assessment is based on a comparative programme designed to determine whether the proposed product is highly similar to the Australian reference product and whether any identified differences are clinically meaningful. Analytical and functional characterisation forms the foundation of the assessment, with non-clinical and clinical evidence considered according to the uncertainty remaining after the quality comparison. Clinical evidence may include comparative pharmacokinetic and/or pharmacodynamic studies, together with additional efficacy, safety, or immunogenicity information where it is needed to address residual uncertainty. Indication extrapolation is not simply a consequence of similarity; it requires a scientific justification that considers the mechanism of action, pharmacological characteristics, clinical experience, and the evidence generated for the biosimilar.

Registration by the TGA and reimbursement through the Pharmaceutical Benefits Scheme are separate decisions. TGA registration establishes that the product meets the relevant regulatory requirements, whereas PBS listing involves a separate reimbursement assessment. Similarly, regulatory similarity, interchangeability, and pharmacist substitution should not be treated as identical concepts. Their practical consequences depend on the applicable Australian regulatory and reimbursement policies.[27,30]

Interchangeability, substitution, switching

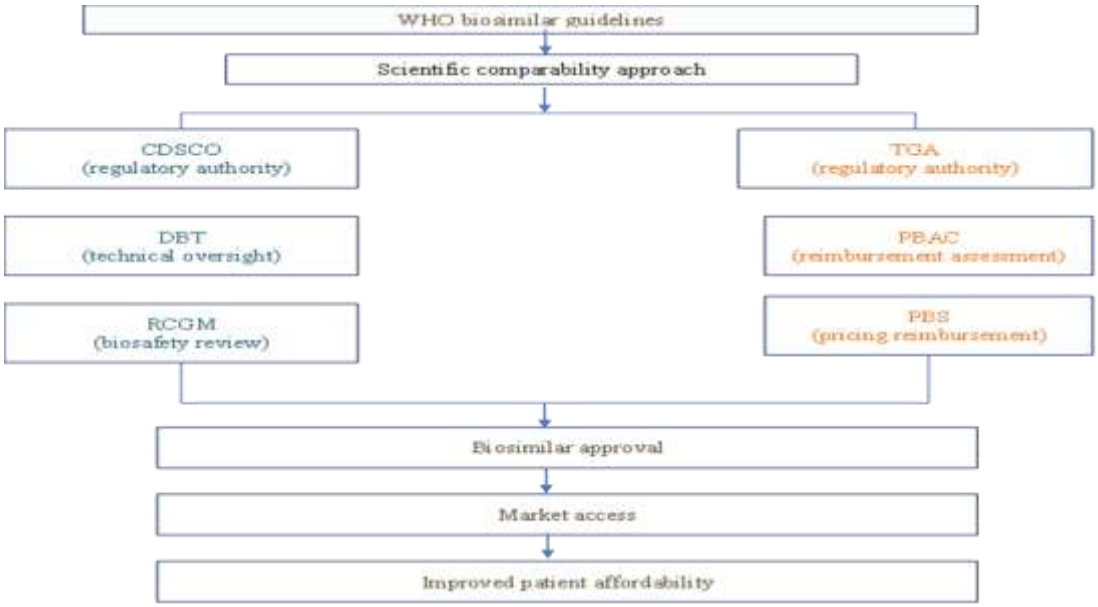
Interchangeability, pharmacist substitution, and clinical switching are related but distinct concepts. Interchangeability generally refers to a regulatory or clinical determination that a product may be used in place of another under specified conditions. Substitution refers to the dispensing decision made at the pharmacy or health-system level, while switching describes a change in treatment made for an individual patient. These concepts should therefore be reported separately.

In the Indian context, the regulatory approval of a similar biologic should not automatically be interpreted as authorisation for unrestricted substitution. The practical use of a product may depend on prescriber decisions, institutional procurement rules, state-level implementation, product information, and pharmacovigilance arrangements. In Australia, TGA registration and PBS substitution policy should likewise be discussed as separate components of market access. A careful comparison should identify the authority responsible for each decision, the conditions under which substitution may occur, and the role of the prescriber and patient.

Clear terminology is important because conflating interchangeability with substitution may overstate the extent to which regulatory approval directly produces clinical switching.[2,4,6,7]

Comparative regulatory framework for biosimilars in India and Australia

Figure 1. Comparative regulatory pathways for biosimilars in India and Australia.



The figure highlights the key regulatory authorities, approval processes and reimbursement mechanisms that influence biosimilar market access and affordability in both countries under WHO-aligned scientific principles.[12,15]

Pricing of biosimilars in India

India's biosimilar pricing dynamics blend competitive market forces with targeted government interventions to promote affordability and access, particularly for essential therapies.[31,32]

Pricing control mechanism

The National Pharmaceutical Pricing Authority (NPPA) regulates prices via the drugs Price Control Order (DPCO) 2013, applying ceiling prices only to biosimilars listed in the National List of Essential Medicines (NLEM). As of March 2025, NPPA has set or adjusted ceilings for 764 NLEM formulations, using a simple average wholesale price (WPI) formula based on the six highest-selling/lowest-priced brands (excluding the outlier). Non-NLEM biosimilars operate under market-determined pricing, limited to a 10% annual maximum retail price (MRP) increase from the prior year's level, with NPPA monitoring for compliance.[31]

Impact of the biosimilar market

This dual system enables biosimilars to enter at 20-70% discounts compared to originator biologics, driven by India's low manufacturing costs, fostering market growth projected at 21% CAGR to $1.02 billion by 2035. However, NLEM ceilings can squeeze margins, leading to supply disruptions if deemed unviable, as manufacturers prioritise non-scheduled products. Public health schemes like Ayushman Bharat and central procurement favor the lowest bidders, amplifying price competition for NLEM items like erythropoietin or insulin analogues. [32,33]

Pricing of biosimilars in Australia

Australia's biosimilar pricing operates through a sophisticated reimbursement system that incentivises competition and automatic substitution to drive down costs for patients and payers.[34]

Pricing authority

The Pharmaceutical Benefits Advisory Committee (PBAC), within the Department of Health and Aged Care, evaluates biosimilars for listing on the Pharmaceutical Benefits Scheme (PBS), Australia's universal drug subsidy program covering approximately 90% of prescriptions. The Pharmaceutical Benefits Pricing Authority sets final prices post PBAC recommendations, while the Therapeutic Goods Administration (TGA) handles registration separately. Pricing decisions hinge on demonstrated cost effectiveness versus originators, with no direct NPPA equivalent but strong price disclosure mandates.[34,35]

Pricing framework

PBS listing triggers an immediate 16% price reduction for the originator upon first biosimilar entry, regardless of interchangeability, followed by ongoing reductions via the "price disclosure" mechanism. Suppliers must report actual pharmacy acquisition costs and market shares quarterly. After 6 months, PBPA adjusts the reimbursed price to the weighted average of disclosed prices across all flagged biosimilars in the group. Pharmacists dispense the

lowest-cost interchangeable option, capturing margins from the gap between PBS reimbursement and acquisition cost, fostering 30-70% cumulative originator discounts over 2-3 years.[36,37]

Pricing dynamics and market impact

This creates high-volume, low-margin dynamics. Biosimilars launch at 20-40% below originators, accelerating to 50-85% with competition. Biosimilars accounted for 8 of PBS's top expenditures pre-entry. Uptake policies mandate ≥5% originator-to-biosimilar switch rates for continued subsidy, yielding A$ 500M+ in annual savings by 2025. Hospital tenders amplify this, awarding contracts to the lowest bidders in oncology/nephrology, projecting market growth from A$906M (2025) to A$6.7B by 2034(21% CAGR).[36,38]

Comparative analytical assessment

a. Access-affordability-availability (AAA) framework

The Access- affordability-availability framework was applied to systematically evaluate how regulatory pathways and pricing policies influence patient access to biosimilars in India and Australia. Within this framework, access refers to how easily biosimilars obtain regulatory approval and integrate into healthcare systems. Affordability encompasses pricing controls, reimbursement mechanisms and cost savings achieved through biosimilar competition. Availability reflects the extent to which approved biosimilars are accessible to patients through market uptake, manufacturing capacity, and distribution networks.[19]

Table 1. AAA framework analysis

Domain	India	Australia
Access	CDSCO-DBT guidelines provide a structured approval pathway. However, implementation and interchangeability policies continue to evolve.[39]	TGA provides a well-established and highly standardized approval process aligned with EMA principles.[7]
Affordability	NPPA price controls and strong market competition enable significant price reductions and improved affordability. [40]	PBS reimbursement mechanisms, mandatory price reductions, and price disclosure policies improve affordability.[17]
Availability	Large domestic manufacturing capacity and increasing biosimilar production support broad product availability.[41]	Strong reimbursement support and substitution policies encourage biosimilar uptake and patient access.[12]

Interpretation of AAA framework

The AAA framework shows that both India and Australia have established effective mechanisms to improve patient access to biosimilars, though they use different policy approaches. In the Access domain, Australia demonstrates a more mature and standardised regulatory framework through the Therapeutic Goods Administration (TGA), which operates under WHO/EMA-aligned guidelines. In contrast, India continues to refine the implementation aspects of its CDSCO-DBT, similar to the biologic's guidelines established in 2016. Regarding affordability, both countries have successfully reduced treatment costs through distinct mechanisms. India relies primarily on competitive manufacturing and selective price regulation via the National Pharmaceutical Pricing Authority (NPPA), while Australia utilises reimbursement-based policies through the Pharmaceutical Benefits Scheme (PBS), with PBAC cost-effectiveness evaluation to generate cost savings. With respect to availability, India benefits from a robust domestic biotechnology industry capable of producing numerous biosimilars, positioning it as a major manufacturing hub. In contrast, Australia emphasizes structured reimbursement and regulatory maturity, while India leverages manufacturing capacity and market competition to enhance access and affordability.[7,12,41]

SWOT Analysis

A SWOT (strengths, weaknesses, Opportunities, and Threats) analysis was systematically conducted to evaluate internal and external factors influencing biosimilar development, regulation, pricing, and market adoption in India and Australia. This analytical framework provides insights into competitive advantages and policy challenges faced by each country while highlighting potential areas for future improvement in biosimilar ecosystems. A simple documentary scoring system was used to summarise the SWOT findings without relying on an expert panel. Each factor was assigned a score from 0 to 2 based on the strength and consistency of evidence identified in regulatory documents, government reports, and peer-reviewed literature. For strengths and opportunities, a score of 0 indicated that the factor was not demonstrated, 1 indicated limited or mixed evidence, and 2 indicated clear supporting evidence. For weaknesses and threats, a score of 0 indicated no substantial documented barrier, 1 indicated a limited or moderate barrier, and 2 indicated a substantial or clearly documented barrier. The same criteria were applied to both countries. Scores were summed and converted into descriptive percentages for

favourable factors and barriers. Because the coding was performed by the authors and was not independently validated or based on expert elicitation, the results were interpreted semiquantitatively and exploratorily rather than as an objective ranking. [20]

Table 2. SWOT analysis of India

Strengths	**Weaknesses**
Strong biotechnological manufacturing sector	Lack of explicit interchangeability framework
Lower production costs	Variability in implementation of regulations
Large domestic and export market	Limited awareness among some healthcare professionals
Competitive biosimilar pricing	Pharmacovigilance systems still evolving
Opportunities	**Threats**
Increasing global demand for biosimilars	Intense market competition
Patent expiry of major biologics	Margin pressure due to price controls
Expansion into international markets	Regulatory harmonization challenges
Growth of public healthcare schemes	Potential supply disruptions

Table 3. SWOT analysis of Australia

Strengths	**Weaknesses**
Mature regulatory framework	Smaller domestic manufacturing base
Strong pharmacovigilance systems	Dependence on imported biosimilars
Well-established PBS reimbursement mechanism	Limited market size compared to major regions
Structured substitution policies	High regulatory compliance costs
Opportunities	**Threats**
Increased biosimilar adoption	Market concentration among a few suppliers
Further healthcare cost savings	Reduced competition due to low margins
Expansion of automatic substitution policies	Supply chain vulnerabilities
Growth in biologic treatment demand	Resistance from prescribers in some therapeutic areas

Table 4. Comparative scoring table

Factor	**India**	**Australia**
Regulatory pathway	1	2
Manufacturing capacity	2	0
Reimbursement	1	2
Substitution clarity	0	1
Pharmacovigilance	1	2

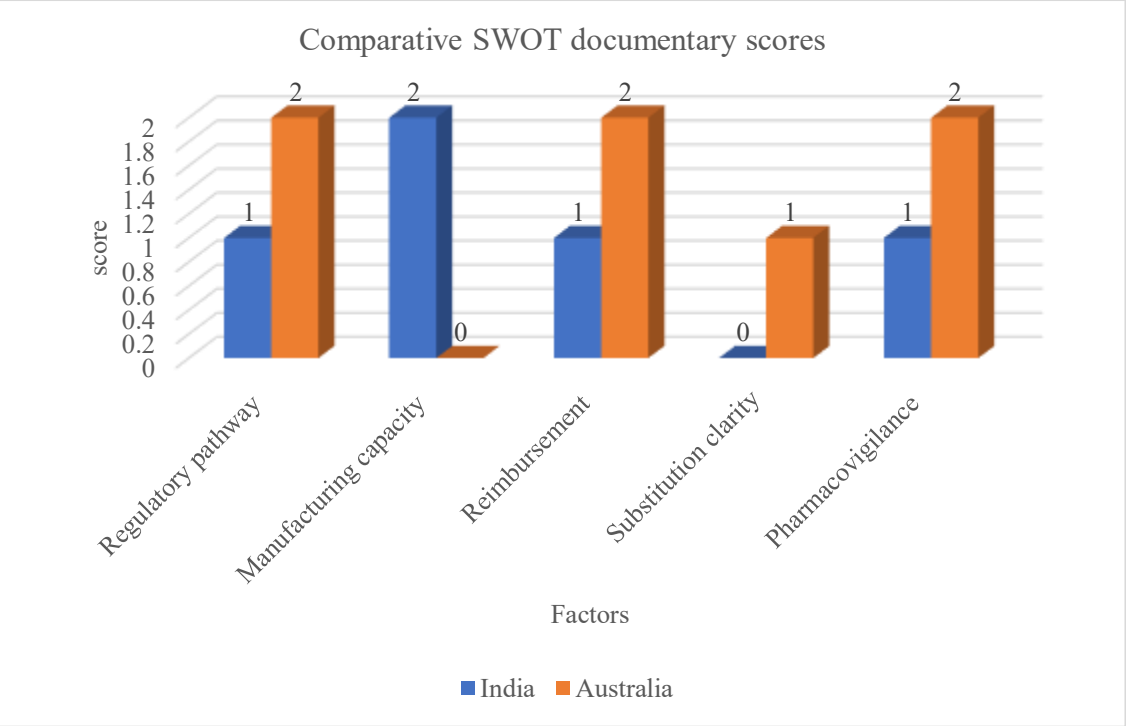


Figure 2. Comparative SWOT documentary scores for selected SWOT related factors in India and Australia

The documentary scoring indicated that the two countries had distinct policy profiles. India scored higher on manufacturing capacity and market production potential, whereas Australia scored higher on regulatory standardisation, reimbursement integration, and post-marketing oversight. India's main barriers were implementation variability, uncertainty about substitution or interchangeability, and the need to strengthen pharmacovigilance systems. Australia's principal barriers were market size, supplier dependence, and the risk that intense price competition could undermine long-term market sustainability. The scores summarised the evidence id entified in the review and were not intended as a validated measure of overall national performance.

The SWOT analysis shows that India and Australia have distinct strengths that support biosimilar adoption. India benefits from robust manufacturing capabilities, cost-efficient production, and an emerging role as a global biosimilar supplier, positioning it as the "Pharmacy of the World" with significant export capacity. However, challenges persist, including regulatory consistency under the CDSCO DBT three-tier system, the development of pharmacovigilance infrastructure, and the absence of explicit interchangeability policies. Australia, in contrast, has a highly mature regulatory framework through the TGA and a comprehensive reimbursement system via PBS, creating structured pathways that support biosimilar uptake and patient access. Nevertheless, Australia faces challenges related to a limited market size, dependence on imports, and long-term market sustainability concerns. [12,15,17,20,40,42] The analysis identifies significant opportunities for both countries. Patent expiries of major biologics, increasing healthcare expenditure, and growing acceptance of biosimilars across therapeutic areas are expected to support continued market growth, with the global biosimilar market projected to reach USD 72.29 billion by 2035. At the same time, both countries must address critical threats, including market concentration among a few suppliers, pricing pressures from regulatory price controls or PBAC cost-effectiveness evaluations, and supply chain risk, to ensure sustainable biosimilar competition and long-term affordability. [20,43,44]

Drug lag assessment

A drug lag assessment was conducted using trastuzumab and rituximab as representative biosimilars to compare regulatory approval timelines between India and Australia. These biosimilars were selected because they are among the earliest and most widely used monoclonal antibody biosimilars, have significant clinical relevance in oncology and autoimmune diseases, and have been approved in both countries through established regulatory pathways. Approval dates were obtained from publicly available regulatory sources, including the Central Drugs Standard Control Organization (CDSCO) for India and the Therapeutic Good Administration (TGA) for Australia. Drug lag was calculated as the difference between the year of biosimilar approval in Australia and the corresponding approval year in India using the following equation: [12]

Drug lag (year) = Approval year in Australia – Approval year in India [45]

A positive value indicates earlier approval in India, whereas a negative value indicates earlier approval in Australia. Average drug lag was subsequently calculated to assess differences in regulatory timelines and market access between the two countries.[45]

Table 5. Comparative Drug lag of India and Australia

Biosimilar	Approval year (India)	Approval year (Australia)	Drug lag years
Trastuzumab	2013[46]	2019[49]	+6 years
Rituximab	2007[47,48]	2017[50]	+10 years

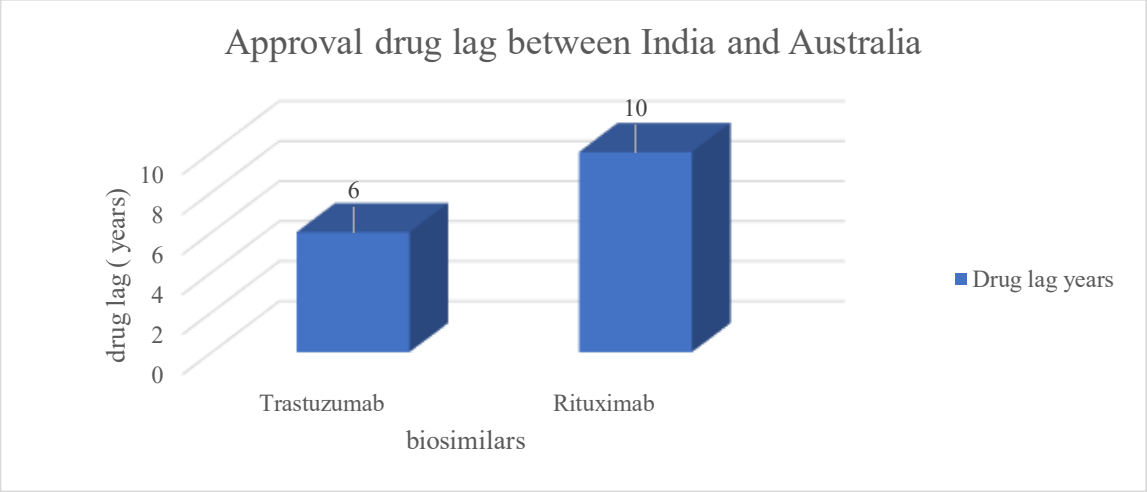


Figure 3. Drug lag for selected biosimilars based on approval year differences between Australia and India

Figure 3 compares the reported approval years of two selected biosimilars in India and Australia. Trastuzumab received approval in India in 2013 and in Australia in 2019, corresponding to an approximate six-year difference. Rituximab was approved in India in 2007 and in Australia in 2017, producing an approximate ten-year difference. The positive values indicate that the Indian approval preceded the corresponding Australian approval for both products. Thus, Figure 4 provides a comparative visual summary of the observed differences in regulatory approval timing between the two jurisdictions. Because the calculation is based on approval years rather than exact dates, the reported intervals should be interpreted as approximate rather than precise review durations.

DISCUSSION

This comparative analysis found that India and Australia use broadly similar comparability-based principles for biosimilar approval but differ in their regulatory implementation, pricing systems, reimbursement mechanisms, and market access policies. India's major strengths are its domestic manufacturing capacity, large potential market, and competitive pricing environment. However, regulatory implementation, interchangeability clarity, pharmacovigilance, and reimbursement consistency remain important challenges.

Australia has a more structured regulatory and reimbursement environment, with TGA registration operating separately from PBS listing and substitution policies. This may support more predictable market access and public payer savings. Nevertheless, Australia's smaller market, dependence on imported products, and potential supplier concentration may affect long term competition and supply sustainability. Biosimilar affordability in both countries should therefore be assessed using more than list price reductions; reimbursement, patient contributions, procurement prices, utilisation, and product availability are also important.

The AAA analysis suggests that India has stronger production and market competition advantages, whereas Australia has stronger regulatory standardization and reimbursement integration. The SWOT findings similarly indicate that both countries have significant opportunities arising from increasing biologics use and patent expiry, but face threats from excessive price pressures, limited supplier participation, prescriber hesitation, and supply chain disruption. These results should be interpreted as a structured qualitative comparison rather than as a validated ranking.

The drug lag analysis showed earlier approval in India for the selected trastuzumab and rituximab biosimilars. However, the observed differences represent approval year intervals and may reflects manufacturer submission

timing, development strategy, regulatory review or commercial decisions. They should not be interpreted as direct measures of regulatory efficiency or immediate patient access.

Overall, biosimilar policy must balance scientific assurance, affordability, clinical confidence and market sustainability. India may benefit from clearer implementation, stronger pharmacovigilance, and defined substitution principles, while Australia should continue monitoring price policies, supplier diversity and supply continuity. Further research using exact approval dates, net prices, reimbursement data, utilisation, and patient outcomes would enable more robust comparison between the two countries.

CONCLUSION

India and Australia have established biosimilar regulatory systems based on scientific comparability, but they differ in regulatory implementation, pricing, reimbursement, substitution, and market-access mechanisms. India benefits from strong manufacturing capacity and competitive potential, whereas Australia has a more structured regulatory and public-reimbursement framework.

The findings indicate that regulatory approval alone does not guarantee affordability or patient access. Sustainable biosimilar use also requires clear substitution policies, effective pharmacovigilance, reliable reimbursement, adequate supplier competition, and continuous product availability. India should prioritise regulatory clarity, traceability, and market sustainability, while Australia should maintain competition and supply resilience alongside expenditure reduction.

The observed approval differences for trastuzumab and rituximab suggest earlier approval in India for the selected products, but these findings are exploratory and should not be interpreted as a direct measure of regulatory efficiency. Overall, coordinated policy development and better product-level data on prices, utilisation, switching, and patient outcomes are needed to evaluate the long-term contribution of biosimilars to affordable and equitable access.

Conflict of Interest

The authors declare that there is no conflict of interest regarding with the publication of this review article. The authors have no financial, professional or personal relationships that could have influenced the work reported in this manuscript.

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