

**REGULATORY REQUIREMENTS FOR BIOSIMILARS AS PER CDSCO IN INDIA IN
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ABSTRACT

This review examines the regulatory requirements for biosimilars in India and Canada, comparing the frameworks of the Central Drugs Standard Control Organization (CDSCO) and Health Canada. Biosimilars are biological medicines that are highly similar to an already-licensed reference biologic and offer a cost-effective alternative for the treatment of cancer, autoimmune disorders, diabetes and other chronic diseases. This comparative analysis reviews the manufacturing process, stepwise approval pathway, WHO guidelines, and the regulatory requirements followed by CDSCO in India and by Health Canada, including pre-licensing, licensing, manufacturing, pharmacovigilance, labelling, importation, marketing authorization, post-marketing surveillance, renewal and inspection requirements. Both CDSCO and Health Canada require a totality-of-evidence, comparability-based approach to demonstrate biosimilarity, but the two frameworks differ in their legal basis, reference-product requirements, registration fees, review timelines, and the extent to which comparative clinical efficacy studies may be waived. CDSCO has a dedicated Guideline on Similar Biologics and an abbreviated pathway relative to new biologics, whereas Health Canada authorizes biosimilars through a New Drug Submission supported by an eCTD dossier. The review also compares the biosimilar markets of the two countries, in which India has emerged as one of the largest biosimilar manufacturing and export hubs globally while Canada is one of the fastest-growing adopters of biosimilars in North America. The findings can inform regulatory agencies, manufacturers and researchers seeking to navigate biosimilar development and commercialization in these two markets.

KEYWORDS: Biosimilars, Regulatory requirements, Health Canada, CDSCO, Clinical trials, Approval process.**1. INTRODUCTION**

Biological medicines, commonly called biologics, are therapeutic products manufactured from living organisms using biotechnology. This category includes monoclonal antibodies, recombinant proteins, vaccines, hormones and blood components, and it has substantially improved the treatment of chronic and life-threatening diseases such as cancer, diabetes, rheumatoid arthritis and inflammatory bowel disease. Because biologics are complex and require advanced production processes, strict quality control and specialized storage, their development and manufacturing costs – and consequently their price to patients – remain high.

The expiry of patents on several innovator biologics has led to the development of biosimilars, which the World Health Organization (WHO) defines as a biotherapeutic product that is highly similar in quality, safety and efficacy to an already-licensed reference biotherapeutic product. Unlike small-molecule generics, biosimilars cannot be exact copies of the originator because biological products are produced in living systems, where even minor manufacturing changes can alter the final product's characteristics. Biosimilar development therefore relies on an extensive, stepwise comparability exercise – analytical characterization, non-clinical evaluation, clinical pharmacokinetic/ pharmacodynamics (PK/PD) studies and, where necessary, comparative

efficacy and immunogenicity studies – before a regulator will authorize the product.^[4,5]

Regulatory agencies worldwide, including WHO, the US FDA, the European Medicines Agency (EMA), India's Central Drugs Standard Control Organization (CDSCO) and Health Canada, have each developed frameworks for biosimilar evaluation and approval. While all of these agencies share the same underlying scientific principle – demonstrating no clinically meaningful difference from the reference biologic – they differ in their legal basis, documentation requirements, extrapolation policies, review timelines and post-marketing surveillance obligations. Understanding these differences is important for manufacturers, regulatory professionals and healthcare providers involved in the development and commercialization of biosimilars in more than one market.^[1,2]

1.1 BACKGROUND AND OBJECTIVES

This review compares the regulatory requirements for biosimilars in India, governed by CDSCO under the Ministry of Health and Family Welfare, with those in Canada, governed by Health Canada. The objectives of this review are: to summarize the concept, classification and manufacturing of biosimilars; to describe the CDSCO and Health Canada regulatory pathways for biosimilars, including pre-licensing, licensing, manufacturing, pharmacovigilance, labelling, importation, marketing authorization, post-marketing surveillance, renewal and inspection requirements; to compare the two frameworks directly; to summarize clinical trial requirements and illustrative case studies of approved biosimilars; and to compare the biosimilar markets of India and Canada, including their current size, growth drivers and challenges.

2. Manufacturing of Biosimilars

Biosimilars are biological products that are highly similar to an already-approved reference biologic and show no clinically meaningful differences in quality, safety or efficacy. Unlike conventional generic drugs, they are produced using living cells and complex biotechnological processes, making manufacturing highly sophisticated and tightly controlled. Even minor changes in manufacturing conditions can affect the final product's quality, efficacy and immunogenicity, which is

why extensive analytical characterization and comparability studies are required throughout development.^[3]

The manufacturing process generally follows these stages:

- Gene identification and selection – the gene encoding the target therapeutic protein is identified and isolated.
- Vector construction – the gene is inserted into an expression vector (e.g., a plasmid) that carries it into host cells.
- Host cell development – the recombinant vector is introduced into host cells such as CHO, yeast or *E. coli*.
- Cell banking – a Master Cell Bank and Working Cell Bank are established to ensure consistency and traceability.
- Upstream processing – host cells are cultured and expanded in bioreactors under controlled conditions.
- Protein expression – the engineered cells synthesize the target therapeutic protein.
- Harvesting – the cell culture is collected and the target protein separated from other components.
- Purification – filtration, centrifugation and chromatography remove impurities and unwanted proteins.
- Characterization and comparability studies – advanced analytical techniques compare structure, purity, potency and biological activity against the reference product.
- Formulation development – the purified protein is combined with excipients, stabilizers and buffers.
- Fill and finish – the formulation is aseptically filled into vials, prefilled syringes or cartridges.
- Quality control and stability testing – identity, purity, potency, sterility and stability are verified.
- Regulatory submission and approval – analytical, non-clinical, clinical and manufacturing data are submitted to CDSCO, Health Canada or another regulator.
- Commercial production – large-scale GMP-compliant manufacturing follows approval.
- Post-marketing surveillance – safety, efficacy and immunogenicity are monitored during real-world use.

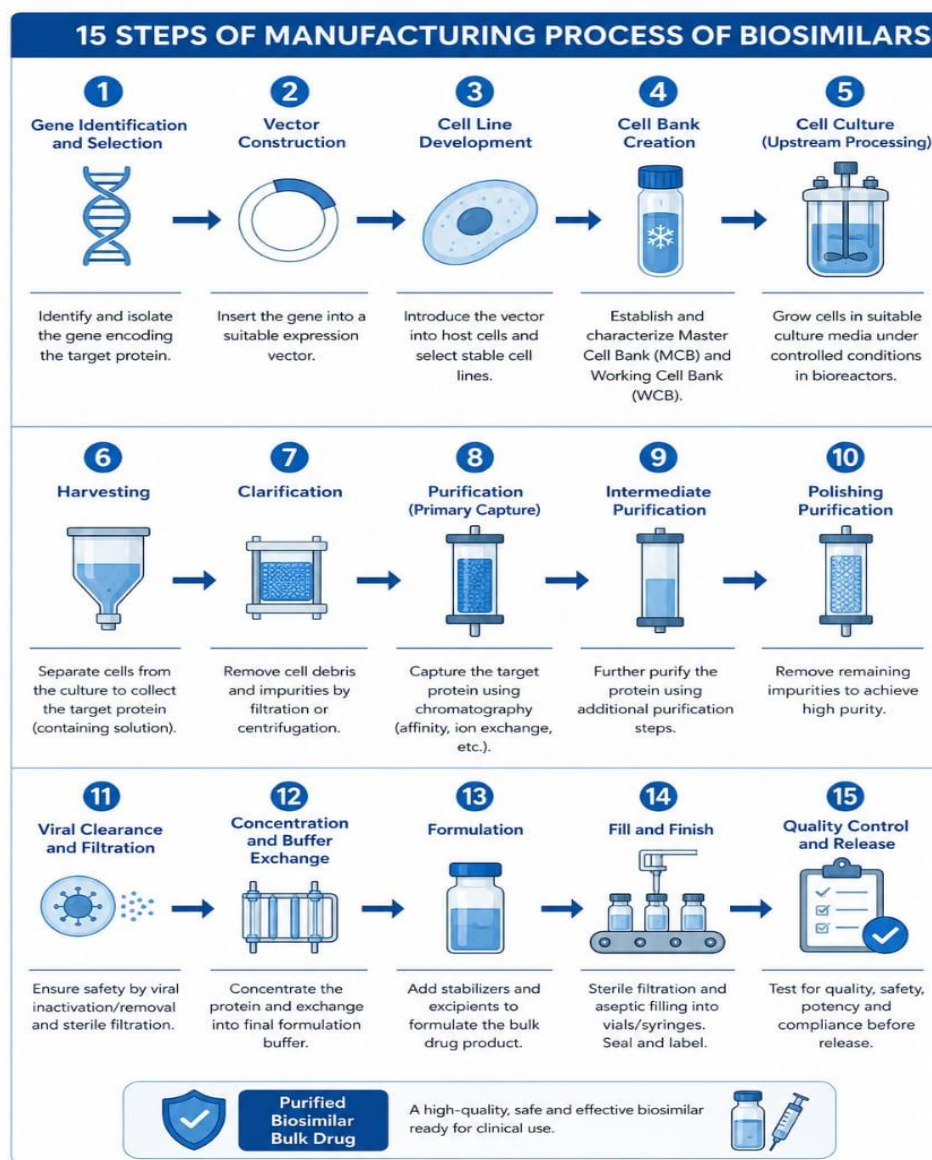


Figure No. 01: Steps Involved In the Manufacturing OF Biosimilars.

3. Approval Process of Biosimilars

Because biosimilars are produced in living cells, they cannot be identical to the reference product and therefore require a stepwise, evidence-based approval process. CDSCO in India and Health Canada in Canada both evaluate biosimilars through analytical, non-clinical and clinical studies, followed by regulatory review and post-marketing safety monitoring, so as to confirm that the biosimilar has no clinically meaningful differences from the reference biologic.

In India, biosimilars are regulated by CDSCO in collaboration with the Department of Biotechnology (DBT) under the Guidelines on Similar Biologics (2012, revised 2016), following a stepwise comparability approach across quality, non-clinical and clinical evaluation. In Canada, biosimilars are authorized through a New Drug Submission (NDS) reviewed by Health Canada's Health Products and Food Branch, supported by chemistry-manufacturing-and-controls (CMC), non-

clinical and clinical data submitted in electronic Common Technical Document (eCTD) format.^[12,13]

Both pathways broadly follow five stages:

- Development phase – preclinical (in vitro/in vivo, PK/PD, toxicology, immunogenicity) and clinical studies (Phase I safety/PK/PD; Phase II efficacy/dose-response; Phase III confirmatory comparative studies).
- Regulatory submission – a dossier covering quality, safety and efficacy modules (CTD for CDSCO; eCTD/NDS for Health Canada).
- Regulatory review – assessment of biosimilarity, safety, efficacy, quality/manufacturing and immunogenicity.
- Approval – marketing authorization, labelling and packaging approval (in Canada, a Notice of Compliance and Drug Identification Number).

- Post-approval – pharmacovigilance, periodic safety update reports, post-marketing surveillance and continuous quality monitoring.

Indicative timelines: development phase 2–5 years; regulatory submission 1–2 years; regulatory review and approval a further 1–2 years; post-approval monitoring is on going. Actual timelines vary by product and by regulatory agency.

4. WHO Guidelines for Biosimilar Evaluation

The WHO first issued guidelines for biosimilar evaluation in 2009 and revised them in 2022 (WHO Technical Report Series No. 1043, Annex 3), promoting a stepwise, risk-based, evidence-based approach in which analytical characterization forms the foundation of the comparability exercise. Both CDSCO and Health Canada align broadly with WHO principles, including selection of an appropriate reference biologic, analytical and quality comparability, minimization of unnecessary animal studies in line with the 3Rs (Replacement, Reduction, Refinement), PK/PD-led clinical evaluation,

immunogenicity assessment, scientifically justified extrapolation of indications, and the ‘totality of evidence’ concept – in which the regulatory decision is based on the combined weight of analytical, non-clinical, clinical and post-marketing evidence rather than any single study.^[5,6]

5. Comparison of the regulatory requirements for biosimilars between CDSCO (India) and Health Canada

Table 1 compares the regulatory requirements for biosimilars administered by CDSCO in India and by Health Canada in Canada. Both agencies require a comparability exercise against a reference biologic, mandatory pharmacokinetic/pharmacodynamics and immunogenicity studies, and post-marketing pharmacovigilance, but they differ in legal basis, reference-product acceptance, registration fees, submission format, review timeline and the conditions under which comparative clinical efficacy studies may be waived.

Table no. 01: Comparative regulatory requirements for biosimilars – CDSCO (India) and Health Canada.

Feature	CDSCO (India)	Health Canada (Canada)
Regulatory authority	Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health & Family Welfare	Health Canada – Biologic and Radiopharmaceutical Drugs Directorate (BRDD)
Legal framework	Drugs and Cosmetics Act, 1940 & New Drugs and Clinical Trials (NDCT) Rules, 2019	Food and Drugs Act & Food and Drug Regulations
Regulatory guideline	Guidelines on Similar Biologics (2012, revised 2016)	Guidance Document for Biosimilar Biologic Drugs
Definition of biosimilar	Highly similar to the reference biologic, with no clinically meaningful differences	Highly similar to the Canadian Reference Biologic Drug (CRBD)
Reference product	Indian-approved or acceptable foreign reference product	Canadian Reference Biologic Drug (CRBD)
Registration fees	Approx. ₹50,000–₹15,00,000 (application-dependent)	Approx. CAD 400,000–600,000 (NDS fee)
Registration process	CTD submission → scientific review → GMP inspection → marketing authorization	eCTD/NDS submission → scientific review → GMP verification → Notice of Compliance (NOC) & DIN
GMP / Schedule M	Mandatory GMP under Schedule M	Mandatory Canadian GMP (GUI-0001); Schedule M not applicable
Quality / characterization	Comparative studies on structure, purity, potency, impurities, glycosylation, stability	Extensive characterization: structure, function, glycosylation, aggregates, impurities, stability, potency
Non-clinical studies	Comparative in vitro/in vivo studies if required	Comparative in vitro studies; animal studies only if justified
Clinical PK/PD studies	Mandatory	Mandatory
Clinical efficacy studies	Generally required	May be waived if analytical and PK/PD data are sufficient
Immunogenicity	Mandatory	Mandatory
Extrapolation of indications	Allowed with scientific justification	Allowed based on totality of evidence
Interchangeability	Not automatically designated	Determined by provincial/territorial authorities, not Health Canada
Pharmacovigilance	Risk Management Plan (RMP) and PSURs required	RMP and continuous post-market surveillance required
Submission format	Common Technical Document (CTD)	eCTD / New Drug Submission (NDS)
Review timeline	Approximately 12–18 months	Approximately 300 days

Key Differences Identified in the Comparison

- Reference product: CDSCO may accept foreign reference products more readily, while Health Canada generally requires a Canadian Reference Biologic Drug (CRBD).
- Clinical studies: CDSCO generally expects comparative Phase III efficacy studies, whereas Health Canada may waive these if analytical and PK/PD evidence is sufficient.
- Interchangeability: Health Canada does not itself determine interchangeability – that is a provincial decision – and CDSCO also does not automatically grant it.
- Submission pathway: India uses the CDSCO biosimilar pathway under the NDCT Rules, while Canada requires a New Drug Submission (NDS).

5.1 Biologics Versus Biosimilars**Table no 02: Difference between biologics and biosimilars.**

Feature	Biologics (originator)	Biosimilars
Definition	Therapeutic products developed in living organisms	Highly similar products, developed independently after the reference patent expires
Approval pathway	Full clinical trial package required	Abbreviated, comparability-based pathway
Development time	8–10 years	7–8 years
Cost to patient	Expensive	Typically 15–35% cheaper on average
Interchangeability	Reference standard	Designated ‘interchangeable’ only after additional studies, where applicable
Examples	Humira, Herceptin, Enbrel	Hadlima, Avsola, Ogivri

5.2 Examples of approved biosimilars**Biosimilars approved in India (Illustrative)****Table no 03: Examples of biosimilars approved in India.**

Product	Active substance	Therapeutic area	Launch date	Company
Biovac-B	Hepatitis B vaccine	Hepatitis B prevention	2000	Wockhardt
Wepox	Epoetin alfa	Anaemia (cancer/kidney failure)	Mar 2001	Wockhardt
Wosulin	Human insulin	Diabetes mellitus	Aug 2003	Wockhardt
Basalog	Insulin glargine	Diabetes mellitus	2009	Biocon

Biosimilars approved in Health Canada (illustrative)**Table no 04: Examples of biosimilars approved in Health Canada.**

Product	Active substance	Therapeutic area	Launch date	Company
Inflectra	Infliximab	Rheumatoid arthritis, Crohn's disease	2014	Celltrion Healthcare
Ogivri	Trastuzumab	Breast cancer, gastric cancer	2018	Biocon / Mylan
Truxima	Rituximab	Non-Hodgkin lymphoma, rheumatoid arthritis	2019	Celltrion Healthcare
Basaglar	Insulin glargine	Diabetes mellitus	2015	Eli Lilly Canada

6. Clinical Trial Requirements for Biosimilars

Clinical evaluation of biosimilars is designed to confirm biosimilarity rather than to re-establish the efficacy of the reference biologic, and it follows a stepwise, totality-of-evidence approach used by CDSCO, Health Canada, FDA, EMA and WHO alike. In practice this involves: (i) analytical and non-clinical evaluation of structure, purity and biological activity; (ii) submission of a Clinical Trial Application (CTA) with quality, non-clinical and protocol data; (iii) regulatory and Institutional Ethics Committee approval before trials begin; (iv) comparative PK and, where relevant, PD studies (C_{max}, AUC, T_{max} and biomarkers); (v) comparative efficacy and safety studies where necessary; (vi) immunogenicity assessment of anti-drug and neutralizing antibodies; (vii) compilation of a Clinical Study Report; (viii) regulatory review and marketing authorization on a totality-of-

evidence basis; and (ix) post-marketing pharmacovigilance.

7. Case Studies of Approved Biosimilars

Zarxio® (filgrastim-sndz), developed by Sandoz, was the first biosimilar approved by the US FDA (March 2015) and is a biosimilar of Neupogen® (filgrastim, Amgen), a recombinant G-CSF used for chemotherapy-induced neutropenia, bone-marrow transplantation, severe chronic neutropenia and stem-cell mobilization. Its development programme included physicochemical characterization, animal toxicity studies, human PK/PD studies, comparative efficacy trials and immunogenicity evaluation; clinical trials showed comparable increases in absolute neutrophil count, similar duration of severe neutropenia and a similar adverse-event profile to the

reference product, with no increase in immunogenicity. It has since been approved in the EU, the US and Canada.^[7]

Inflectra® (infliximab-dyyb), developed by Celltrion, is a biosimilar of Remicade® (infliximab, Janssen Biotech), a TNF- α -targeting monoclonal antibody used in rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. The PLANETRA trial (rheumatoid arthritis) and PLANETAS trial (ankylosing spondylitis) demonstrated equivalent efficacy, safety and comparable pharmacokinetics relative to Remicade®. Inflectra was approved by the EMA in 2013, the FDA in 2016 and by Health Canada, and it has meaningfully reduced treatment costs for autoimmune diseases while maintaining comparable therapeutic outcomes.^[8]

8. Comparative Market Analysis of Biosimilars in India and Health Canada

8.1 Indian Biosimilar Market

India is one of the world's leading biosimilar markets, supported by a strong pharmaceutical industry, a skilled biotechnology workforce, favourable government policy and cost-competitive manufacturing. Under the CDSCO/DBT Guidelines on Similar Biologics, the Indian biosimilar market is projected to grow at a CAGR of approximately 16–21%, driven by patent expiries of major biologics, improving healthcare access and rising awareness. India has approved biosimilars spanning oncology, diabetes, nephrology, haematology, endocrinology, ophthalmology and autoimmune disease,

and Indian manufacturers – including Biocon Biologics, Dr. Reddy's Laboratories, Intas Pharmaceuticals, Zydus Lifesciences, Reliance Life Sciences, Lupin, Sun Pharmaceutical Industries and Cipla – export biosimilars to more than 100 countries and increasingly hold approvals from the US FDA, EMA and Health Canada. Key challenges include high R&D and clinical-trial costs, manufacturing complexity, intellectual-property disputes, pricing competition and the need for continued physician and patient education.^[11]

8.2 Health Canada/Canadian Biosimilar Market

Canada's biosimilar market has grown rapidly – valued at approximately USD 1.4 billion in 2025 and projected to reach USD 5.7 billion by 2033 at a CAGR of about 19–20% – driven by rising healthcare expenditure, provincial biosimilar-switching policies (British Columbia, Alberta, Ontario, Quebec, Saskatchewan and others), patent expiries of major biologics, growing chronic-disease burden and an increasingly favourable regulatory and reimbursement environment. Monoclonal antibodies dominate the market given their use in oncology, rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis, and biosimilar insulin is also expected to grow significantly. Companies active in the Canadian market include Amgen, Sandoz, Pfizer, Celltrion, Samsung Bioepis, Viartis, Organon and Biocon Biologics. Reported challenges include high development costs, complex manufacturing, patent disputes, differences in provincial policy and residual concerns about switching.^[10]

8.3 Comparative Market Analysis.

Table no 05: Comparative market analysis of biosimilars in India and Health Canada.

Parameter	India (CDSCO)	Health Canada (Canada)
Market status	One of the largest biosimilar manufacturing and export hubs globally	One of the fastest-growing biosimilar markets in North America
Market growth	Expected CAGR of approximately 16–21%	Expected CAGR of approximately 19–20%
Manufacturing capacity	Strong biotechnology infrastructure; large-scale domestic manufacturing	Limited domestic manufacturing; largely supplied by multinational companies
Market objective	Affordable manufacturing, domestic availability and exports	Reduce healthcare costs and improve patient access to biologic therapies
Major market drivers	Patent expiry, chronic disease burden, government support, low production cost, export demand	Rising healthcare expenditure, provincial switching policies, reimbursement programmes, patent expiry
Government support	DBT, BIRAC, BioE3 Policy, biotechnology funding, innovation grants	Provincial biosimilar switching policies, public reimbursement programmes, physician education
Major companies	Biocon Biologics, Rd. Reddy's, Inters, Zeus Life sciences, Reliance Life Sciences, Lupine	Amgen, Sandoz, Pfizer, Celltrion, Samsung Bioepis, Viartis, Organon
Major therapeutic areas	Oncology, diabetes, rheumatology, nephrology, haematology, ophthalmology	Oncology, rheumatology, gastroenterology, endocrinology, dermatology, nephrology
Pricing	Generally 20–50% lower than originator biologics	Generally 15–50% lower than originator biologics
Export potential	Exports biosimilars to over 100 countries	Primarily serves the domestic Canadian market
Key challenges	High R&D costs, IP issues, physician awareness, manufacturing complexity	Provincial policy differences, switching concerns, high development costs, limited domestic manufacturing

8.4 Estimated Global Market Size of Biosimilars

The global biosimilar market was estimated at approximately USD 20–42 billion in 2025 (estimates vary by source and market definition) and is projected to grow at a double-digit CAGR of roughly 17–19% in the coming years. Growth is driven by continued patent expiries of major biologics, cost pressures on healthcare systems, the rising burden of chronic disease, expanding regulatory pathways and increasing clinical confidence among prescribers and patients. Europe remains a leading region for biosimilar development and adoption; North America – including both the United States and Canada – is growing rapidly; and the Asia-Pacific region, led by India, is expected to be among the fastest-growing given its manufacturing capacity and rising healthcare expenditure. Oncology, autoimmune disease, diabetes, haematology, rheumatology and ophthalmology remain the leading therapeutic areas for biosimilar use worldwide.^[9]

9. Applications

- Oncology: biosimilar monoclonal antibodies such as trastuzumab, rituximab and bevacizumab are used in breast cancer, colorectal cancer and lymphoma, and biosimilar filgrastim and erythropoietin manage chemotherapy-related neutropenia and anaemia.
- Autoimmune and inflammatory disease: biosimilars of infliximab, adalimumab and etanercept are used in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and psoriasis, as well as Crohn's disease and ulcerative colitis.
- Endocrinology: insulin biosimilars provide a more affordable option for diabetes management, and biosimilar recombinant growth hormone treats growth hormone deficiency in children and adults.
- Haematology and nephrology: erythropoietin biosimilars are used for anaemia associated with cancer treatment and chronic kidney disease.
- Reproductive medicine: biosimilar follicle-stimulating hormone products support assisted reproductive technologies such as IVF.
- Ophthalmology: biosimilars of bevacizumab and ranibizumab are used for age-related macular degeneration and related retinal disorders.
- Transplant medicine: biological agents and their biosimilars help modulate immune responses to prevent organ rejection.
- Improving healthcare access: because biosimilars generally cost less than reference biologics, they reduce healthcare expenditure, encourage market competition and expand patient access to biologic therapy without compromising quality, safety or efficacy.

10. Future Perspectives and Recent Advancements

Biosimilar regulation continues to evolve toward greater reliance on advanced analytical characterization (mass spectrometry, advanced chromatography, glycan analysis) and a totality-of-evidence approach that can reduce unnecessary animal and comparative-efficacy

studies where scientifically justified, consistent with the 3Rs principle. CDSCO's more recent Guidelines on Similar Biologics and Health Canada's revised biosimilar guidance both reflect this shift, alongside growing interest in artificial intelligence and real-world evidence to support manufacturing-process monitoring and long-term pharmacovigilance. Extrapolation of indications, subject to scientific justification, continues to reduce duplication of clinical trials, while interchangeability and switching policies remain distinct issues – in Canada determined at the provincial/territorial level, and in India not automatically granted on approval. Greater international regulatory harmonization, particularly alignment with WHO principles, is expected to reduce duplication of studies and facilitate biosimilar development and approval across multiple markets.

11. CONCLUSION

The regulatory frameworks for biosimilars in India and Canada both aim to ensure the quality, safety and efficacy of biological products, and both rely on a comparability-based, totality-of-evidence approach. India regulates biosimilars through CDSCO and the DBT under the Guidelines on Similar Biologics, covering quality assessment, comparability studies, non-clinical and clinical evaluation and post-marketing surveillance. Canada regulates biosimilars through Health Canada using the New Drug Submission pathway, with an emphasis on comparative analytical and functional studies supported by appropriate non-clinical and clinical evidence.^[12,13]

The two frameworks differ mainly in legal basis, reference-product requirements, registration fees, review timelines and the extent to which comparative clinical efficacy studies can be waived in favour of analytical and PK/PD evidence. India has emerged as a major global manufacturing and export hub for biosimilars, while Canada's market is growing quickly through provincial switching policies and increasing physician confidence. Greater regulatory harmonization between CDSCO, Health Canada and WHO could reduce duplication of studies, improve accessibility and affordability, and support consistently high standards of quality, safety and patient protection in both countries.

Compliance with Ethical Standards

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