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BIOSIMILARS REGULATORY STUDY – COMPRESSED THESIS

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ABSTRACT

This condensed thesis summarizes the regulatory framework, development challenges, pharmacovigilance requirements, market status, and future prospects of biosimilars in India, USA, and Europe. Biosimilars are highly similar biological products that demonstrate no clinically meaningful differences from approved reference products. They improve patient access by reducing treatment costs while maintaining quality, safety, and efficacy.
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INTRODUCTION

Biologics are complex medicines produced using living systems and are used to treat cancers, autoimmune disorders, diabetes, inflammatory bowel disease, rheumatoid arthritis, and other chronic diseases. Due to high development and manufacturing costs, biologics are expensive. Biosimilars provide a cost-effective alternative. Regulatory agencies such as CDSCO, FDA, and EMA have established pathways for biosimilar approval based on comparability exercises involving quality, non-clinical, and clinical studies.

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Literature Review

Published studies highlight the importance of analytical similarity, manufacturing consistency, pharmacovigilance, interchangeability, extrapolation of indications, and patent litigation. Researchers have demonstrated that biosimilars can achieve comparable efficacy and safety when supported by robust analytical and clinical evidence.

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Regulatory Framework in India

India regulates biosimilars through CDSCO and DBT. The approval pathway includes product characterization, comparability studies, preclinical evaluation, clinical studies, manufacturing validation, and post-marketing surveillance. Relevant authorities include IBSC, RCGM, GEAC, CDSCO, and DCGI.

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Regulatory Framework in USA

The Biologics Price Competition and Innovation Act (BPCIA) established the biosimilar pathway. FDA requires extensive analytical similarity data, animal studies where needed, clinical pharmacology, immunogenicity assessment, and comparative clinical studies. Interchangeability may require additional evidence.

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Regulatory Framework in Europe

EMA pioneered biosimilar regulation. Approval is based on a stepwise comparability approach. EMA emphasizes quality characterization, non-clinical evaluation, pharmacokinetics, pharmacodynamics, efficacy, safety, and risk management planning.

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Biosimilars vs Generics

Generics are identical copies of small-molecule drugs, whereas biosimilars are highly similar but not identical to biologics because biologics are produced using living systems. Biosimilars require more extensive development and regulatory evaluation.

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Manufacturing Challenges

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Structural and Functional Similarity

Developers must demonstrate similarity in primary structure, higher-order structure, purity, potency, biological activity, and stability. Advanced analytical methods are used to compare biosimilars with reference products.

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Interchangeability

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Extrapolation of Indications

A biosimilar approved for one indication may receive approval for additional indications of the reference product if scientific justification supports a common mechanism of action and comparable clinical performance.

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Nomenclature and Traceability

Distinct naming conventions improve product traceability and pharmacovigilance. Accurate identification of product name, manufacturer, and batch number is essential for monitoring adverse drug reactions.

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Harmonization of Regulations

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Pharmacovigilance

Post-marketing surveillance is essential because rare adverse events may not be detected during clinical trials. Pharmacovigilance systems collect, analyze, and report adverse drug reactions to ensure continued product safety.
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India Pharmacovigilance System

India operates through CDSCO and the Pharmacovigilance Programme of India (PvPI). Manufacturers are required to submit safety reports and maintain risk-management activities.
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European Pharmacovigilance

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FDA Action Plan

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Market Scenario

The biosimilar market continues to grow due to patent expirations, increasing healthcare costs, and broader acceptance among physicians and patients. Europe remains a leading market, followed by North America and Asia.
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Status in India, USA, and EU

India has approved numerous biosimilars across therapeutic categories. The USA and EU have also experienced substantial growth in approvals, particularly for monoclonal antibodies and supportive care biologics.

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Patent Litigation and the Patent Dance

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Recommendations

Improve regulatory harmonization, strengthen pharmacovigilance systems, increase physician and patient awareness, encourage transparent manufacturing practices, and streamline approval pathways.

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CONCLUSION

Biosimilars are transforming healthcare by expanding access to biological therapies. Strong regulatory oversight, robust analytical comparability, effective pharmacovigilance, and continued international cooperation will support future biosimilar growth.

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