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REGULATORY REQUIREMENTS FOR BIOSIMILARS IN INDIA: A COMPREHENSIVE REVIEW

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ABSTRACT

Biosimilars are crucial to the pharmaceutical industry, offering cost-effective alternatives to reference biologics. India has emerged as a leader in biosimilar production, with a regulatory framework established in 2012 to ensure their quality and safety. This article covers an overview of the regulatory pathway for biosimilars in India. The regulatory framework, mirroring international standards, ensures biosimilar safety and efficacy. Key authorities, including CDSCO and DBT, play vital roles in the approval process. The process includes rigorous quality assessments, preclinical and clinical data requirements, and post-marketing surveillance. India has approved numerous biosimilars since 2000, showcasing its leadership in this field. The renewal process ensures ongoing safety and efficacy monitoring. The country's commitment to biosimilars is a significant step toward making essential biologic treatments more accessible and affordable. Holding the promise of making essential treatments more accessible globally. The robust regulatory framework and adherence to quality control ensure that biosimilars meet stringent standards. Continued collaboration between regulatory bodies,

pharmaceutical companies, and international players will be crucial as the field of biosimilars evolves. India is set to have a major impact in providing affordable and accessible biologic therapies worldwide.

Keywords: Biosimilars, regulatory framework, data requirements, CDSCO, similar biologic

INTRODUCTION

Biosimilars are pharmaceutical products that are highly similar to an FDA-authorized biologic drug, known as the reference biologic. According to the Central Drug Standard Control Organization (CDSCO), biosimilars are defined as "similar biologic products that are similar in terms of quality, safety, and efficacy to an approved reference biologic product based on comparability" **[1]**. They are manufactured using the same or similar technology as the reference biologic, found to have comparable safety and effectiveness profiles, and can offer several advantages over reference biologics, including lower cost and increased availability. **[2]**.

Biologics are produced using a variety of biotechnology techniques, including recombinant deoxyribonucleic acid technology, regulated gene expression, and antibody technology, from natural resources like human, animal, or microbe cells **[3]**. By stopping the progression of the disease, easing the symptoms, and improving the quality of life, biologics have benefited patients with various conditions. These biologics are among the most popularly purchased medications globally and in the United States. Still, their high price has made them inaccessible to many patients and unaffordable for many, particularly in developing nations where the concept of health insurance is still in its early stages and most of the population lives in poverty **[4]**.

Biosimilars naturally differ from generic drugs in terms of their molecular structure, size, complexity, and cost of production. In addition to being more expensive, riskier, and difficult to manufacture than small-molecule generics, biosimilars have higher research and development costs **[5]**. While there were no clear guidelines available at the time for the development and marketing of biosimilar in India, the first biosimilar was approved and commercialized there in 2000 for Hepatitis B Vaccine. Despite India being one of the first nations in the world to adopt the term "biosimilars or similar biologics", their approval processes are more demanding and call for more information than those for other generic medications. Since then, other biopharmaceutical companies have created and launched biosimilars in India **[6]**.

India is a significant market for biologics, and the demand for biosimilars is expected to grow in the coming years as there's a potential solution on the horizon when the original company's patent protection expires. Other companies can step in to

create comparable versions of these biologics, known as biosimilars **[7]**. In order to guarantee the safety and effectiveness of biosimilars, the Indian government has put in place a regulatory framework for their development and approval **[8]**.

In 2012, India introduced regulations concerning biosimilars. Since then, approximately 50 biotechnology treatments have received official approval in the country, with over half being biosimilars. It was projected that the Indian market for biosimilars will witness remarkable growth, from $4 billion in 2015 to surpass $70 billion by 2025, indicating a significant expansion **[9]**. There have been more than 100 Indian Biopharmaceutical organizations and major collaborations reflect a strategic approach to leverage collective expertise and resources in the development, manufacturing, and commercialization of biosimilar products. Domestic and International players have been joining forces to navigate the intricate regulatory landscape, pool their research capabilities, and tap into each other's specialized knowledge **[10]**.

As these alliances continue to shape the industry, the Indian biosimilar sector stands poised to contribute significantly to affordable and accessible biologic therapies worldwide. Despite concerted efforts, a series of regulatory hurdles continue to persist in the landscape **[11]**. An examination conducted earlier, back in 2010, brought to light three primary challenges that were prevalent at the time, such as lack of recommended comparability studies, inadequate conduct of Comparability studies, and a complex situation unfolded where the term 'biogeneric products' were commonly utilized alongside the misapplication of the term 'biosimilar' in certain countries **[12]**.

This inconsistency not only introduced confusion within the regulatory framework but also led to an inaccurate representation of the nature and attributes of these products. Though several of these initial challenges have been effectively addressed over time, the dynamic nature of the biosimilar landscape has ushered in new and ongoing challenges **[13]**. As an increasing array of biosimilars undergo evaluation and enter the market, novel hurdles have arisen, necessitating constant vigilance and adaptation within the regulatory framework. The continuous evolution of the biosimilar field demands a proactive approach to navigate these emerging challenges effectively **[4]**. The majority of formulation demands within India are met by domestic pharmaceutical companies, covering a wide spectrum of 60 therapeutic categories as they are an essential part of India's healthcare ecosystem. This industry also caters to approximately 70% of India's demand for bulk drugs, contributing

significantly to the pharmaceutical supply chain. Indian firms are responsible for the production of an impressive 60,000 generic brands, reflecting the industry's diversification and its ability to provide affordable healthcare solutions to a broad spectrum of patients **[14]**. A substantial portion of India's bulk drug production estimated at 60%, is exported to international markets and approximately 80% of the pharmaceutical industry's domestic production consists of more than 85% of these formulations being distributed within the country. This demonstrates the industry's commitment to addressing the healthcare needs of its citizens, and experts and healthcare providers are hopeful that biosimilars could lead to reduced costs for biologics, ultimately making these essential treatments more accessible for public health **[15]**. With the aim of enhancing affordability and accessibility to advanced treatments, the Indian government, in collaboration with regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT), has formulated comprehensive guidelines to regulate the development, approval, and commercialization of biosimilars. As a result, the realm of biosimilars in India is witnessing dynamic growth, underscored by regulatory advancements, technological breakthroughs, and an increased focus on post-marketing surveillance **[16]**.

This article delves into the status of biosimilars in India, shedding light on the regulatory framework, key players, market dynamics, challenges, and the broader impact of these biopharmaceutical products on patient care and the pharmaceutical industry.

DISCUSSION

Regulatory Framework of Biosimilars in India:

As per CDSCO, A similar biologic product is that which is similar in terms of quality, safety, and efficacy to an approved Reference Biological product based on comparability **[1]**.

The Indian regulatory requirements for comparable biologics encompass both pre- and post-marketing aspects, including a "comparability exercise" to assess similarity. The Drugs and Cosmetics Act of 1940, the Drugs and Cosmetics Rules of 1945 (as amended from time to time), and the Rules for the manufacture, use, import, export, and storage of hazardous microorganisms/ genetically engineered organisms or cells of 1989 (Rules, 1989) are the laws that apply to similar biologics **[17]**. These laws were notified under the Environment (Protection) Act of 1986. The following list of applicable rules is provided:

Guidelines for Recombinant DNA Safety, 1990.

• Guidelines for the collection of preclinical and clinical data for rDNA vaccines, diagnostics, and other biologicals, 1999. Recommendations By CDSCO Industry, 2008:

1. Submission of the Clinical Trial Application for Safety and Efficacy Assessment
2. Documents related to quality, safety, and efficacy for post-approval changes in biological products.
3. Requirement for approval of New Drugs
4. Creating Quality Information for New Drug Approval Submissions: Biotechnological/Biological Products
5. Handbook and Guidelines for Institutional Biosafety Committees (IBSCs), 2011.
6. Similar Biologics Guidelines: Regulations for India's 2012 Marketing Authorization **[18]**.

These regulations also address manufacturing processes and quality control. As a result, India's regulations for similar biologics share many similarities with the biosimilar regulations of the United States and the European Union **[19]**. India has adopted a "sequential strategy" for marketing biosimilar products, which bears resemblance to the "stepwise approach" followed by the US and the EU. This approach involves a systematic and phased introduction of biosimilars into the market. India's national regulatory body, CDSCO, assesses the quality, safety, and efficacy of pharmaceutical products. Preclinical testing of rDNA-derived products is supervised by DBT through the Review Committee on Genetic Manipulation (RCGM) **[20]**.

The following is the list of primary competent authorities responsible for biosimilar approval in India **(Figure 1)**:

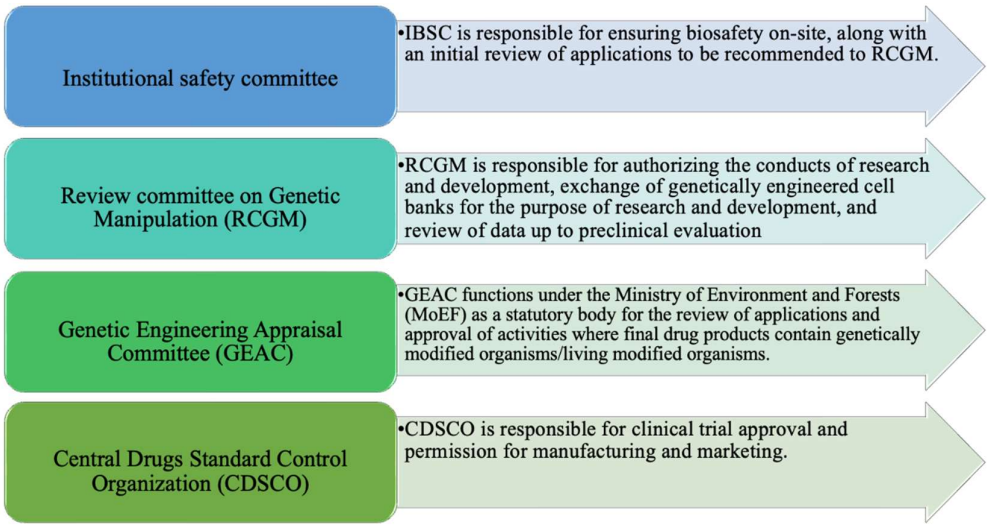

Figure 1: Major Regulatory authorities participating in the biosimilar approval process

1. **Central Drugs Standard Control Organisation (CDSCO):**

   CDSCO is an apex regulatory body, led by the Drugs Controller General of India (DCGI) and oversees the approval and regulations of pharmaceuticals, medical devices, and cosmetics. It functions as part of the Ministry of Health and Family Welfare and is essential to ensure the safety, efficacy, and quality of these goods. It is involved in various activities, including the evaluation of applications for new drug approvals, clinical trials, and import/export permission for drugs and medical devices. It formulates and updates regulations, guidelines, and standards to maintain quality control and adherence to good manufacturing practices. The organization also monitors adverse drug reactions and takes necessary actions to safeguard public health **[18]**.

2. **Department of Biotechnology (DBT):**

   DBT in India is a government agency responsible for promoting and coordinating biotechnology-related activities in the country. The DBT plays a significant in facilitating the development and manufacturing of biosimilars in India. One of the key initiatives by the DBT is the "National Biopharma Mission" (NBM), launched in 2017. The NBM aims to accelerate the development of affordable biopharmaceutical products, including biosimilars, and strengthen the biopharmaceutical ecosystem in India **[18, 21]**.

3. **Genetic Engineering Approval Committee (GEAC):**

   GEAC is a regulatory body in India responsible for the appraisal of activities involving the release of genetically engineered organisms and products into the environment, including biosimilars. It operates under the Ministry of Environment, Forest, and Climate Change (MoEF& CC) and plays a crucial role in ensuring the safety of genetically modified organisms (GMOs) and biotechnology-derived products in the country **[18, 22]**.

4. **Review Committee on Genetic Manipulation (RCGM):**

   RCGM is an important regulatory body in India that is responsible for evaluating and approving biosimilars, which are biological products that are highly like existing reference biologic drugs. The RCGM operates under the DBT within the Ministry of Science and Technology **[18]**.

5. **Institutional Biosafety Committee (IBSC):**

   IBSC in India plays a significant role in ensuring the safe handling, containment, and use of biosimilar products. An IBSC

is a committee established within an institution, such as a research facility or a biopharmaceutical company, to oversee and evaluate the biosafety practices and procedures implemented in various research and production activities involving biosimilars **[18, 23]**.

Approved Biosimilars in India:

As early as the year 2000, India granted approval for its initial biosimilar. Since then, India has observed with an emerging growth in the Biosimilar Industry corresponding with the India's increasing domestic demand, rising population and the possibility of expanding exports to advanced markets. India has achieved a remarkable milestone in the field of biosimilars, with a total of 98 biosimilars receiving approval in the country. Out of these, a minimum of 50 biosimilars are already available on the market, establishing India's position as the global leader in terms of biosimilar availability **[24]**.

Table 1: List of some approved biosimilar drugs in India [24]

Name of the product	Active Compound	Therapeutic Area	Approval/ Launch Date	Company
Biovac-B	Hepatitis B vaccine	Hepatitis	2000	Wockhardt
Basalog	Insulin Glargine	Diabetes	2000	Biocon
Erykine/Epofit	epoetin alfa	Cancer, Chronic Kidney failure, Anaemia	2005	Intas Pharmaceuticals
Filgrastim	filgrastim	Neutropenia	2013	Cadila Pharmaceutical
Cizumab	bevacizumab	Colorectal cancer	2016	Hetero
Krabeva	bevacizumab	Brain cancer, Metastatic colorectal cancer, lung cancer, cervical cancer, Kidney cancer, Ovarian cancer	2017	Biocon
Fesoteroterodine Fumarate Exteneded Release	fesoterodine fumarate	overactive bladder syndrome	2023	Dr. Reddy's Laboratories (UK) Ltd
Crisabrole Ointment 2%	crisaborole	atopic dermatitis	2023	Anacor Pharmaceuticals

The development process of Biosimilar:

1. **Reference Biologic selection**: Reference Biologic is the innovator product that has been authorized following review of the entire dossier and is utilized in the creation of the biosimilar product. Comparability testing for safety, effectiveness, and quality should be conducted using it. The important considerations for the selection of Biosimilars are as follows:
   - ❖ These products need to be approved/certified in India or any other country under the ICH Nation.
   - ❖ The selected route of administration, and dosage form for the follow-on biologics must

be like the reference biologic **[20]**.

2. **Manufacturing Process:** The manufacturing or production process of a pharmaceutical product significantly influences the safety, efficacy, and quality of the final product, thus playing a crucial role in ensuring its reliability and high quality. The ICH guidelines, namely Q5A, Q5B, and Q5D provide guidance on quality testing during the development of biotechnological products. Hence, it is essential to understand the data regarding the reference biologic dosage form and method of administration as it is crucial in evaluating the analytical variances and their influence on the functionality of biosimilars during their development **[25]**.
3. **Quality aspects:** Stringent quality control measures must be implemented throughout the manufacturing process. It is mandatory to conduct a comprehensive exercise in comparison between the biosimilar and the reference biologic to establish similarity in terms of quality attributes. This involves extensive analytical and functional characterization **[25]**.
   - **3.1. Analytical characterization:** The strategies adopted for the comparability studies of Biosimilar and the reference Biologic should depend on the crucial product quality characteristics. The ICH quality guidelines, which are acknowledged by all the ICH member nations, should be followed when conducting analysis.
   - **3.2. Product characterization:** The product characterization involves factors that majorly represent biologics' quality, efficacy, and safety. These factors include immunological properties, Physicochemical properties, purity, strength, biological effect, contamination, and assays. The evaluation parameters should follow the ICH Q6B guidelines, whereas the criteria for active ingredients will be in accordance with the Indian Pharmacopeia monograph.
   - **3.3. Specifications:** Biosimilar drug product requires various specifications in terms of Clinical as well as nonclinical studies, to provide a comparative human investigation of pharmacokinetic and pharmacodynamic effects.
   - **3.4. Stability:** The stability requirements for the biosimilars must be performed and evaluated based on the ICH Q1A, and Q5C. There should be a similarity between the reference and the standard product in terms of the shelf-

life, storage conditions, and accelerated stability studies.

3.5. Quality comparability studies: Biosimilars are significantly more complex than small molecule drugs, making even minor changes potentially impactful on product quality and the risk of adverse effects. To mitigate these concerns, appropriate techniques and guidelines need to be employed during the entire production process. The safety, quality, and efficacy of biosimilars heavily rely on attention to manufacturing, purification, and formulation development. Ensuring structural integrity is essential, as any factors causing physical or stability issues may disrupt the three-dimensional structure and folding patterns, possibly triggering severe immunological reactions **[26]**.

4. **Animal Toxicology Data Requirements:** Submission of animal toxicology, reproductive, teratogenic, perinatal, mutagenic, and carcinogenicity tests is required as part of a new drug import or manufacturing application can be adjusted or eased for drugs that have been approved and available in other countries for over two years. These adjustments would be considered by the Competent Regulatory Authority (CLA) when they are convinced that there exists sufficient published evidence confirming the safety **[27]**.
5. **Clinical Data Requirements:** It is required for biosimilar regulations to demonstrate the safety and efficacy of the biosimilar comparison to the reference biologic, ensuring patient safety and therapeutic equivalence. The toxicity study data needed to be provided for the performance of CT are as follows:

5.1. For Phase I Clinical Trials (CT):

- Systemic Toxicity studies: Repeat-dose toxicity, Single-dose toxicity, Dose-ranging
- In-vitro genotoxicity studies.
- Male fertility study.
- Local toxicity tests for the application route that has been suggested.
- Allergenicity or Hypersensitivity tests are needed.
- A test for photo-toxicity or photo-allergy, if applicable.

5.2. For Phase II Clinical Trials (CT):

- Summarize non-clinical safety data from Phase I.
- Repeat-dose toxicity studies.
- In-vivo genotoxicity studies.
- Women of childbearing age segment II reproductive or developmental toxicity research

5.3. For Phase III Clinical Trials (CT):

- Summarize non-clinical safety data from Phase I and II.
- Repeat-dose toxicity studies.
- Reproductive or development toxicity studies.
- Segment I and Segment III reproductive studies if applicable.
- Carcinogenicity studies if required for longer drug use.

5.4. For Phase IV Clinical Trials (CT):

- Summarize non-clinical safety data from Phases I, II, and III.
- Include necessary non-clinical safety data for Phase IV trial application.

5.5. Good Laboratory Practice application (GLP):

- Conduct In-Vivo studies in accredited laboratories.
- Safety pharmacology studies within toxicology studies should also be accredited **[27]**.

6. Post-market data requirements for Biosimilars:

6.1. Pharmacovigilance plan:

Rare adverse effects are less likely to be discovered because there have been few clinical studies on biologics with a comparable composition before market approval. Manufacturers must prepare a comprehensive pharmacovigilance plan to assess clinical safety post-marketing. This plan includes submitting periodic safety update reports (PSURs) every six months for the first two years after approval, and annually for the next two years, as per Schedule Y to the DCGI office **[20]**.

6.2. Adverse drug Reaction reporting (ADR):

Any major unexpected adverse reactions must be notified to the licensing authorities in accordance with Schedule Y **[26]**.

6.3. Post-Marketing Studies (Phase IV Study):

A scheduled single-arm trial with more than 200 evaluable patients should be used to gather further safety data after market clearance to reduce any residual risks linked to similar biologics. A comparison between this investigation and the reference biologic's historical data is necessary. Safety is the main goal of the post-marketing phase IV trial, with effectiveness and immunogenicity being secondary objectives. The marketing authorization application must be submitted alongside the phase IV protocol. Post-marketing studies are essential due to limited pre-approval clinical data. The plan for these studies should be included in the pharmacovigilance plan and updated reports should be submitted to CDSCO. On a case-by-case basis, a non-comparative post-marketing

clinical study emphasizing safety and immunogenicity must be necessary **[8]**.

Evaluation of the immunogenicity of similar biologics must be performed using validated methods assay methods to identify potentially impactful antibodies, such as neutralizing antibodies and those with cross-reactivity. Assessments should be made on their impact on safety and efficacy. In certain cases of evaluating Similar Biologics based on the rarity, severity, and limited availability of therapeutic options for the disease, the clinical trial population size for biologics for uncommon diseases can be decreased **[7]**.

6.4. Archival Data/Retention of Sample:

The manufacturer is required to establish a Standard Operating Procedure (SOP) for both data archiving and sample retention. The application should maintain a comprehensive archive of all data, including quality, preclinical, and clinical documentation. The archival period in India should last for at least five years after the relevant authority has granted marketing authorization **[28]**.

Crucial Samples, including the vehicle, tissues, test substances, plasma/serum, microscopic slides, paraffin blocks, and electronic items, should be stored until their expiration dates. The SOP for data archiving and sample retention should specify the designated authority responsible for overseeing this process. This authority can be contacted for inspections or retrieval purposes if the need arises **[1]**.

6.5. Renewal/Recall of Biosimilars:

The evaluation and endorsement of the Clinical Trial Application (CTA) are carried out by dedicated committees established by regulatory agencies. These committees include the Subject Expert Committee (CDSCO), and the Clinical Trials Committee (SAHPRA). An essential component of the CTA is the approval letter from the Ethics Committee (EC). This letter must be obtained from the Institutional Review Board of the relevant hospitals or institutions where the clinical trial is planned to be conducted. The validity of the registration provided through Rule 47 in form CT-09 will endure for five years starting from its issuance date unless the CLA decides to suspend or revoke it. The center responsible for Bioavailability or Bioequivalence studies must apply for registration renewal using form CT-08. This application must be supported by the required documents outlined in the Fourth Schedule, and it should be submitted at least 90 days before the current registration's expiration date **[27]**.

The approval process timeline involves multiple regulatory authorities, as detailed in the **Table 2** below.

Table 2: The Approval timeline for the Regulation of Biosimilars is as follows [29]

Procedure	Timeline
Approval for pre-clinical studies by RCGM	45 Days
Approval for Human CT protocol by DCGI	45 Days
CT data examination by DCGI	90 Days
GEAC and DCGI decisions	45 Days

In the following **Table 3**, you will find a comprehensive list of the various necessary forms that are essential components of the approval process.

Table 3: Various Forms required for the approval process [30] [31]

Stages	Regulatory Authority	Application Form	Approval
Manufacturing license for test, analysis, examination	State Licensing Authority	Form 30	Form 29
License for analysis, examination, or test	CDSCO Zonal Office	Form 12	Form 11
Import or export of Cell bank	RCGM	Form B1/B3/B5/B7	
Research and development	RCGM	Form C1	
Preclinical studies permission	RCGM	Form C3A	
Preclinical study submission	RCGM	Form C5A	
Conduction of CT	Central Licensing authority i.e., (CDSCO)	Form CT-04	Permission for Clinical trial
Import for manufacturing	Central Licensing Authority i.e., (CDSCO)	Form 44	Form 45A or 46A for API and Form 45 or 46 for Finished product
Manufacturing license	State and Central Licensing Authority	Form 27D	Form 28D
Import registration certification	Central Licensing authority i.e., (CDSCO)	Form 40 (with schedule DI and DII/ Form 44	Form 41 or Form 45
Imported product license	Central Licensing authority i.e., (CDSCO)	Form 8 & 9	Form 10

For the approval of biosimilars, CDSCO developed five different protocols:

Protocol I: Indigenous product development, manufacture, and marketing of pharmaceutical products derived from live-modified organisms (LMOs), where the final product is not an LMO **(Figure 2) [1]**.

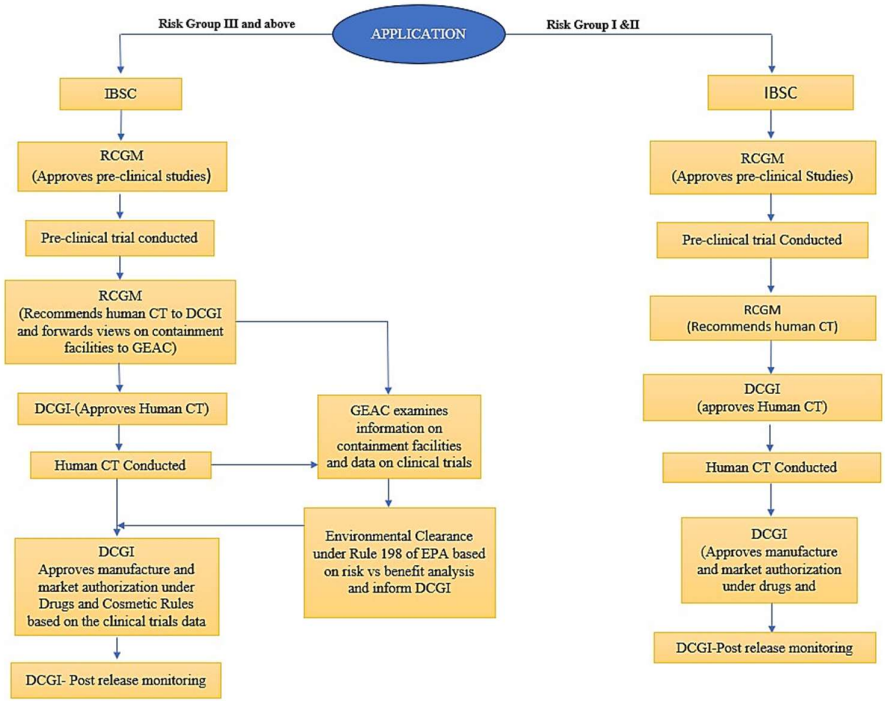

Figure 2: Biosimilars approval process under Protocol I [1]

Protocol II: Indigenous product development, and marketing pharmaceutical products when the final product is an LMO **(Figure 3) [1]**.

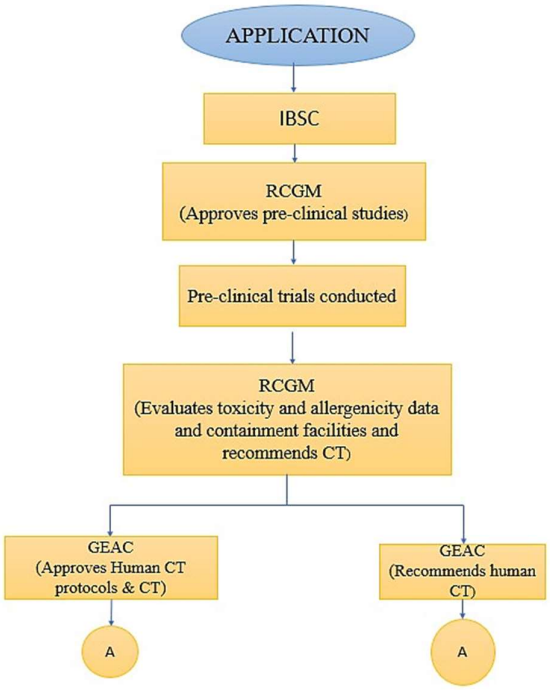

Figure 3: Biosimilars approval process under Protocol II [1]

Protocol III: Importing and marketing Pharma Products in Finished Formulations with an LMO as the final product **(Figure 4) [1]**

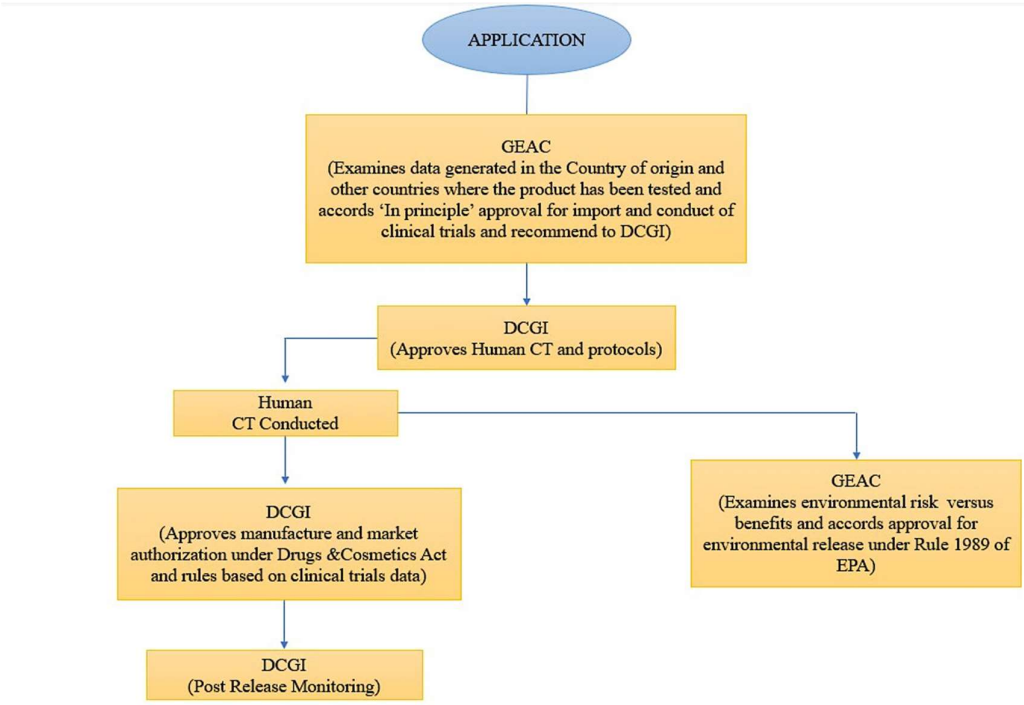

Figure 4: Biosimilars approval process under Protocol III [1]

Protocol IV: Importing and marketing finished formulations where the final pharmaceutical products in bulk to make product is an LMO **(Figure 5) [1]**.

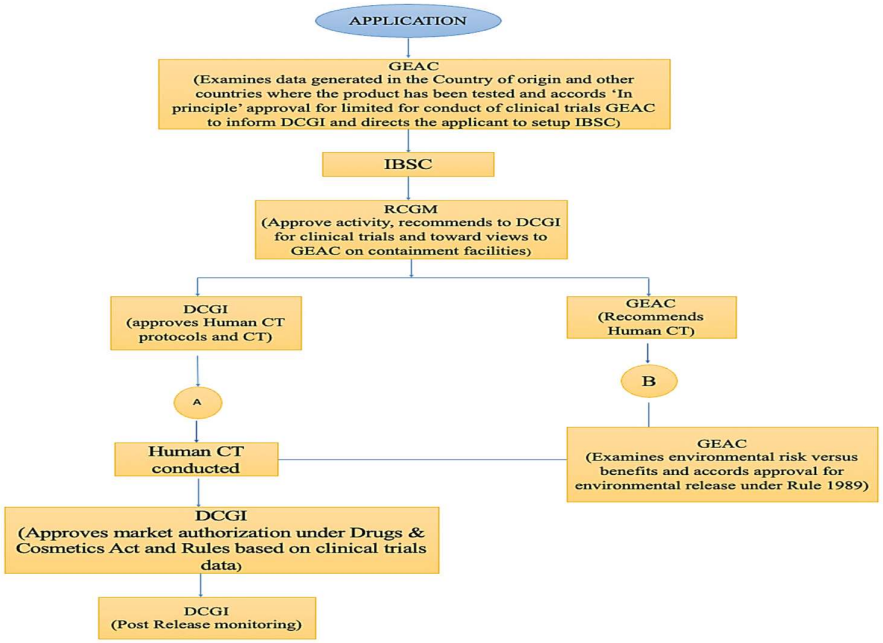

Figure 5: Biosimilars approval process under Protocol IV [1]

Protocol V: Importing and marketing pharmaceutical products made from LMOs in bulk and/or finished formulations where the end product is not an LMO **(Figure 6) [6]**.

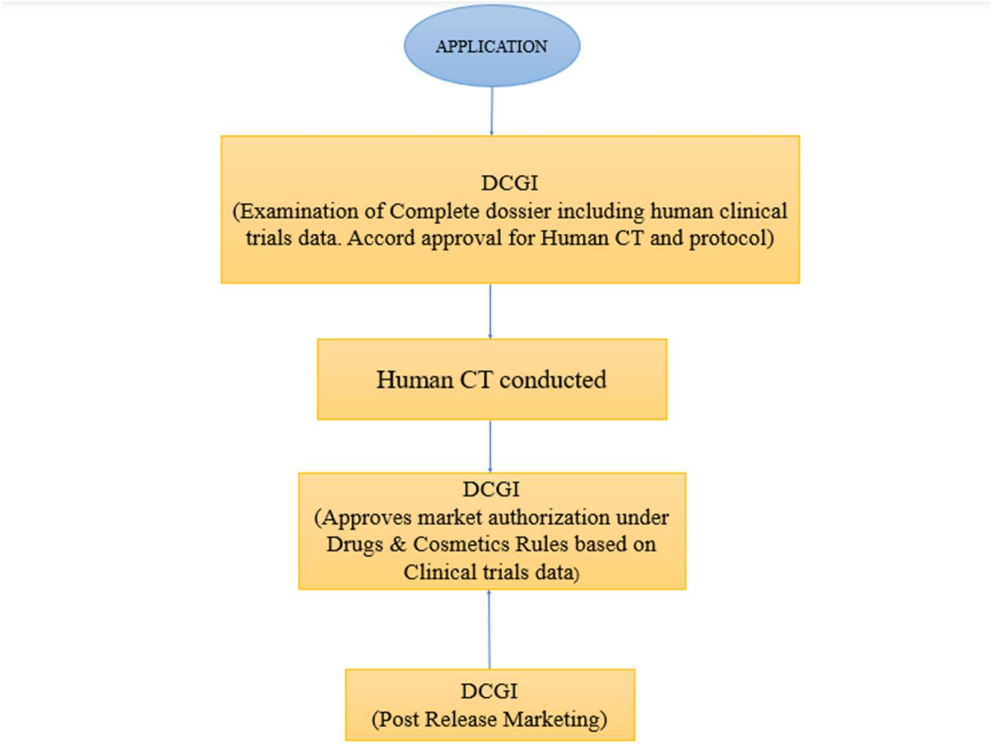

Figure 6: Biosimilars approval process under Protocol V [6]

FUTURE PERSPECTIVE

Due to the high incidence rates of chronic disease, the desire for biosimilar treatments for conditions like rheumatoid arthritis, blood disorder, cancer, etc., and the anticipated outcomes of clinical trials are some of the factors that have an impact on the global biopharmaceutical market's expansion. Future healthcare systems will increasingly rely on biotechnological medications. As innovator product patents expire, more biosimilars will be made available, therefore India has the potential to dominate the world market for biosimilar or comparable biologics. It is expected that the domestic market will rise by US$40 billion by 2030, while biosimilars create a US$240 billion global opportunity for the Indian biopharmaceutical industry, as per the analysis report published by ASSOCHAM-Sathguru in 2016. For correct prescription and the safety of the patients, it is crucial to understand the differences between biosimilars and the innovator product in terms of safety, efficacy, safety, and immunogenicity. Consequently, adhering to regulatory guidelines for producing biosimilars in India holds significant importance.

CONCLUSION

As an outcome of legislative developments, technological breakthroughs,

and a growing emphasis on lowering the cost and increasing the accessibility of key biologic medicines, the landscape of biosimilars in India is fast changing. India's biopharmaceutical sector has advanced significantly in the creation and marketing of biosimilars, establishing it as a world leader in this area. India ensures the quality, safety, and efficacy of biosimilars by maintaining a strong regulatory structure that includes important organizations like CDSCO, DBT, GEAC, RCGM, and IBSC. In India, preclinical and clinical research, analytical characterization, and post-market surveillance are all evaluated as part of the approval process for biosimilars. Like worldwide procedures, the sequential approach taken for releasing biosimilars into the market ensures a systematic and stepwise approach to safeguard patient safety while increasing competition. With multiple approved biosimilar drugs that cover a wide range of therapeutic categories, India's biosimilar journey has made impressive progress. These goods are anticipated to be crucial in meeting the growing demand for biologics, enhancing patient access, and strengthening India's biopharmaceutical sector. Despite the successes, the landscape of biosimilars still faces obstacles that call for ongoing regulatory framework adaption and attention in resolving new problems. However, with coordinated efforts from regulatory bodies, business stakeholders, and healthcare providers, India's biosimilar sector is positioned to significantly improve global public health by offering accessible and inexpensive biologic treatments. Future developments in the field of biosimilars are expected to be even more significant, with advantages for both public health and the pharmaceutical industry.

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