Expansion of Biosimilars in Indian Pharmaceutical Market

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ABSTRACT

The introduction of biosimilars into the Indian pharmaceutical sector has the potential to significantly transform the accessibility and cost of healthcare. A viable substitute for pricey original pharmaceuticals are biosimilars, which are extremely comparable copies of currently available biological medications. This is especially true for treating chronic and crippling illnesses. India is a major player in the global biosimilars market, thanks to its thriving pharmaceutical sector and increased emphasis on innovation and research. This review paper explores the factors—such as favourable regulatory frameworks, supportive government policies, and growing domestic demand for reasonably priced biologics—that are propelling the growth of biosimilars in India. It draws attention to the roles played by Indian pharmaceutical companies in the creation and production of superior biosimilars, demonstrating their proficiency with intricate manufacturing procedures and the management of clinical trials.

INTRODUCTION:

Among the first biotechnology products to hit the market at the start of the 1980s were recombinant insulin, human growth hormone (somatropin), granulocyte colony-stimulating factor (GCSF), and erythropoietin analytical procedures like mas. Since then, more than 150 biotechnology products have been approved for use in markets across Australia, Japan, Europe, and North America**(Datamonitor & Pavlou, 2004).** The biosimilar market in India is still in its early stages of development, but it is growing rapidly. There are currently over 95 approved biosimilars in the Indian market, and this number is expected to continue to grow in the coming years**(Simoens & Vulto, 2021).**

The Indian biosimilar market is dominated by domestic players, with over 85% of the market share held by Indian companies. However, there is also increasing interest from foreign companies, and several multinational pharmaceutical companies have partnered with Indian companies to develop and market biosimilars**(Chen et al., n.d.).**

REVIEW OF LITERATURE:

1. What Are Biosimilars

A biological product that closely resembles an already-approved, FDA-approved biological product in terms of structure, function, clinical safety, and efficacy is known as a biosimilar(What Is a Biosimilar Medicine)**.**

Biosimilars cannot be exact replicas of their reference items since biological products are inherently variable, in contrast to generic medications, which are identical replicas of their brand-name equivalents. Biosimilars, however, have to resemble the reference product so closely that any variations in safety, effectiveness, or immunogenicity cannot be clinically significant(McCamish & Woollett, 2011)**.**

2. Therapeutic Areas

Although biologics have significantly improved the treatment of many diseases, their sustainability and accessibility are impacted by the high cost of therapy. When many first-generation biologics patents expire, biosimilars provide a competitive substitute. anticipating a 20–30% variation. Budget impact is thought to be a significant factor influencing these products' ability to enter the market **(Al et al., n.d.).**

Example- Having access to life-saving insulin is especially important to avoid serious co-morbidities that can result in blindness, amputations, early death, and the associated costs of healthcare. By 2030, it is predicted that the annual cost of diabetes will reach 2.5 trillion dollars worldwide. Global expenses alone for all insulins are expected to increase to almost $30 billion USD **(Garg et al., 2018).**

The launch of biosimilar insulins is anticipated to boost market competition, provide access to insulin, and result in a 20–40% drop in US prices. According to a recent US cost-savings report, a 15% possible cost reduction using long-acting insulin analog biosimilars **(Joshi et al., 2023).**

Another example is that As of September 2021, the US had approved 15 biosimilars for the treatment of inflammatory arthritis. There are now just seven rheumatologic biosimilars on the market that patients can utilize. When comparing the cost of biosimilars to that of the reference medication, savings can range from 44% to 69% **(Kvien et al., 2022).**

According to estimates, moving RA patients to CT-P13 for five years will save the UK, Italy, France, and Germany's budgets by $233 million and $433.5 million, respectively, under 20 percent and 30 percent discount scenarios. 78 A thirty percent discount would allow these four countries to treat 7561 more patients **(Dorner T, n.d.).**

3. Market Trend

India is a prominent global contributor to the biosimilar business. The country of India has shown the highest level of biosimilar acceptance. which more than 50 biopharmaceutical brands reflect. Gaining approval for marketing. The biotechnology sector generated over $2 billion in revenue. billion in 2006, with biologics accounting for 70% of the total. Companies such as Biocon, Wockhardt, Cipla, Dr. Reddy's Lab, and Drug companies have already begun to use biosimilars **(Bhushan, 2014).** The 2016 ASSOCHAM-Sath guru research states that biosimilars offer the Indian biopharmaceutical industry a US$240 billion worldwide opportunity. Growth is anticipated in industry and the domestic market by $40 billion by 2030 **(Meher et al., 2019).**

4. Regulatory Framework

The scientific criteria for the biosimilar regulatory framework were initially released by the European Medicines Agency (EMA). This is regarded as a significant milestone in the advancement and assessment of innovative biopharmaceuticals' duplicate versions since it made the creation and evaluation of safe and efficient biosimilars for patient treatment **(Tsiftsoglou et al., 2013).** In June 2012, the Department of Health in India released the "Draft Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India." By Department of Biological Technology (DBT) **(Kumar & Singh, 2014).**

The approval process for biosimilar products involves multiple departments and committees. Four phases are involved in the creation of a biosimilar 1) Development of products and comparative evaluation; 2) Process creation, validation, and scale-up; 3) clinical studies; 4)FDA, WHO, and EMEA regulatory reviews and acceptance **(Undela, 2014).** Completed clinical study reports must be sent to DCGI after it is finished. The dossier needs to be approved by DCGI and should be in CTD format. Following the biosimilar's approval for post-marketing surveillance is necessary for the market for at least 4 months, with ongoing pharmacovigilance

oversight during the research. Furthermore, a periodic safety update report must to be submitted DCGI every six months for the initial two years. (**Malipatil et al., 2015**).

5. Challenges and Opportunities

Biotech therapeutic products are complex and heterogeneous, making a comprehensive analytical characterization impractical. This leads to a variety of issues that a manufacturer must deal with **(Rathore, 2015).** Biosimilars are linked to a number of problems, including rising treatment costs, accessibility, affordability, quality, safety, and intellectual property rights **(Singh, n.d.).**

Unlike generic medications, biosimilars are not generated from established chemical formulations, which raises serious concerns about their stability. When manufacturing, they use living cells. These might potentially bring in contaminants, for proteins, viruses, and impurities in DNA and RNA **(*Commentary: Use of Biosimilars for Retinal Diseases in India: Challenges and Concerns*, n.d.).**

With 30 out of 40 biological medicines on the market as biosimilars, India accounts for 75% of the global biosimilar market. In 2000, the first biosimilar treatment for hepatitis B was authorized and released on the Indian market. In recent years, the approval of more than 50 biopharmaceutical products with over half of them being biosimilar, for marketing in India **(P & K, 2016).** Given its enormous population, India has a great chance to become a major force in the production and distribution of biosimilars. Since a new regulatory policy went into effect, The domestic market is anticipated to expand due to improved affordability **(Bigoniya, 2017).**

6. Global Comparison

The market for biosimilars is predicted to increase at a compound annual growth rate (CAGR) of 23.1 percent from 2022 to 2030, from its estimated valuation of USD 11.1 billion in 2022 to USD 51.9 billion. The increasing incidence of chronic illnesses, the growing need for reasonably priced biologics, and favorable government regulations are some of the factors propelling the expansion of the worldwide biosimilar market **(Elvidge, S. (2013).**

In the global biosimilar market, Amgen, Celltrion, Pfizer, Sandoz, and Teva Pharmaceutical Industries are major companies. These businesses work on the creation, production, and distribution of biosimilars **(Malhotra et al., 2015).**

The Indian biosimilar sector is expanding quickly, despite being in its early stages. After the United States and Europe, India currently holds the third-largest global market for biosimilars **(Rahalkar et al., 2021).**

Region	Market share in 2022
Europe	45%
Asia Pacific	30%
North American	25%
Latin America	1%
Middle East and Africa	1%

(Alkhatib, n.d.).

7. Collaboration

The expansion of the biosimilar market in India is significantly attributed to collaboration. In order to create and sell biosimilars, Indian businesses are working with multinational corporations. This is assisting Indian

businesses in expanding their reach into international markets and developing their knowledge in the creation and production of biosimilars **(Volodin, A. G. (2023).**

Here are some examples,

1. In 2021, Biocon Biologics and Libbs Farmaceutica formed a collaboration to introduce a biosimilar form of adalimumab in Brazil.
2. In 2020, Dr. Reddy's Laboratories and Merck & Co. formed a collaboration to develop and commercialize biosimilars in emerging markets.
3. In 2019, Lupin and Mylan formed a collaboration to develop and commercialize biosimilars in India and other emerging markets.
4. In 2018, Zydus Cadila and Boehringer Ingelheim formed a collaboration to develop and commercialize biosimilars in India and other emerging markets **(Kshirsagar et al., 2023).**

In the biosimilar sector, the Indian government is also encouraging cooperation. One initiative the government has started is the National BioPharma Mission, which intends to support biosimilar development and production in India. Collaboration between Indian and international businesses is also supported by the mission **(Differding, n.d.).**

8. Stimulation of Innovation and Competition

Developing infrastructure and manufacturing skills is essential to participating in the biosimilar market. In order to secure the development of high-quality biosimilars, Indian firms have made significant investments in the establishment of cutting-edge manufacturing facilities and process optimization **(Iqbal & Sadaf, 2022).**

India's domestic biosimilars market has grown to accommodate the country's expanding healthcare needs. This growth has made room for competition among manufacturers, which has encouraged innovation and diversification in the range of biosimilar products available **(Paul et al., 2018).**

In the biosimilar market, maintaining a balance between competitiveness and intellectual property rights is a constant problem. Indian pharmaceutical firms have handled data exclusivity and patent conflicts with grace and respect for the intellectual property rights of pioneering businesses **(Kresse, 2009).**

Government programs that support competition and innovation, like research grants, incentives, and subsidies for biosimilars, have been essential. A portion of the upfront development and production expenses of biosimilars are mitigated by these incentives **(Sadek, 2020).**

9. Job creation

1. Research and Development (R&D): A lot of research is done in the process of developing biosimilars. Indian pharmaceutical corporations have formed teams and R&D departments dedicated to the development of biosimilars. Scientists, researchers, and analysts make up these teams, and they work on the difficult task of reverse engineering and creating biosimilars **(Rémuzat et al., 2017).**
2. Manufacturing: The production of biosimilars calls for a highly trained labor force and is a highly controlled process. There are several tiers of employment creation, such as supervisors of production, manufacturing engineers, technicians, and quality control specialists. Support personnel are also required by the manufacturing facilities for logistics, and maintenance **(Niosi, 2017)**.
3. Regulatory and Quality Assurance: Businesses hire specialists in regulatory affairs and quality assurance to help them meet the strict regulatory requirements for biosimilars. These experts make certain that the biosimilars adhere to all national and international regulatory standards **(Kushwaha et al., 2023).**
4. Sales and Marketing: To reach patients and healthcare professionals, biosimilars must be commercialized. This calls for marketing and sales initiatives. To distribute and market biosimilars,

pharmaceutical corporations use product managers, sales agents, and marketing experts. This helps to create jobs in the marketing and sales industry **(Sindkhedkar et al., 2020).**

10. Economic Growth

India's ability to produce biosimilars has given it a competitive edge in the world pharmaceutical industry. Since Indian businesses can produce biosimilars at a lesser cost, they are enticing choices for global markets. As a result, biosimilar exports have increased, boosting foreign exchange profits and general economic expansion **(P & K, 2016b).**

Generally speaking, biosimilars are less expensive than the original biologics. Governments, insurance companies, and healthcare systems all profit from this cost advantage in addition to patients. Lower healthcare expenses free up funds for investments in other economic areas, which stimulates growth in the economy **(Janjigian et al., 2018).**

By providing cheaper alternatives to pricy reference biologics, biosimilars have increased the size of the pharmaceutical market. A bigger market with more alternatives for treatments and products is the result of this expansion. Biosimilars support the expansion of the pharmaceutical industry overall as they become more widely accepted **(Bhattacharya, 2018).**

Due to the efficacy and promise of biosimilars in India, both local and foreign investors have expressed interest in making investments. The biosimilar sector is encouraged to grow and innovate by these investments. Furthermore, there has been an increase in the frequency of partnerships between pharmaceutical companies in India and foreign partners, which has stimulated economic growth and information **(Desai, 2018).**

The Indian pharmaceutical sector has witnessed substantial growth in employment and economic expansion due to the introduction of biosimilars. The industry is a significant contributor to India's pharmaceutical sector and the country's economy due to its potential for growth, cost-effectiveness, and the expanding global demand for biosimilars. To optimize the advantages, it is crucial to tackle regulatory obstacles, guarantee excellence, and surmount market entry obstacles **(Raveendrashenoy, 2020).**

11. Future Prospects

Biosimilars have a very bright future in the Indian market. Because they provide a more accessible and reasonably priced option to biologic medications, biosimilars are anticipated to play a bigger role in the Indian healthcare system **(Rudrapal et al., 2020).**

1. Developing biosimilars of complex molecules: As previously stated, producers of biosimilars are putting more of an emphasis on creating biosimilars for complicated compounds. This is a fantastic chance for manufacturers to set themselves apart from the competition and provide patients and healthcare professionals with something of value **(Hashida, n.d.).**
2. Entering the government procurement market: The Indian government purchases a significant amount of medical supplies and services. By taking part in government tenders, biosimilar producers can access this market.
3. Exporting biosimilars to developed markets: In developed markets, biosimilars are already heavily exported from India. **(Hashida, n.d.)**

METHODOLOGY:

An extensive literature study was carried out. The period covered by the literature search was from 2004 to 2023. Research databases at Academia, Research Gate, Elsevier, ScienceDirect, and Semantic Scholar were searched for articles using the terms “Therapeutic areas in Biosimilars ”, “Various Market Trends in Biosimilars”, “Regulatory Framework of Biosimilars”, “Challenges and Opportunities”, “Global Comparison”, “Economic Growth”, “Job Creation”, “Future Prospects in Biosimilars”.

Analysis

The Preferred Reporting Item for Systemic Reviews and Meta-Analysis (PRISMA) technique is the one that is employed. All publications that made it through the screening procedure were then examined and described based on goals, the year of publication, the frequency of citations, and the recommendations for additional study.

Inclusion & Exclusion Criteria

Studies must be fulfilled in order to be included in the present research.

(a) Studies have included some kind of selection criteria (Regulatory Framework, Market Trend, Collaboration, Stimulation and Innovation, Future Prospects). These criteria limited the number of studies.
(b) Accordingly excluded the studies in which it is based on irrelevant information, there is no proper Title, Abstract & Review.

Final data set

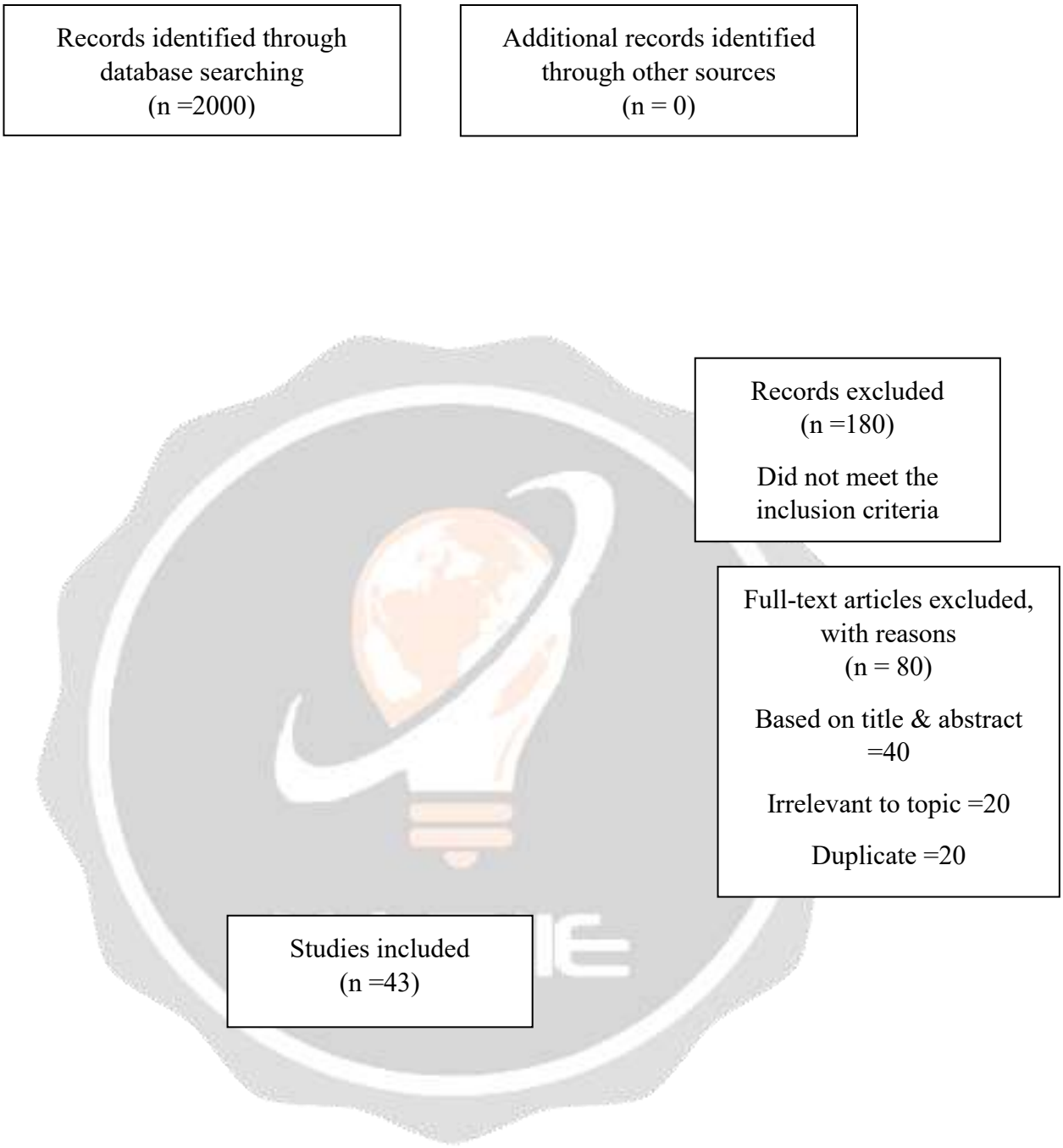
The research database search resulted in all keywords search results obtained 2000 research articles. After scanning the title, there was the same article in two different databases. The results after deducting the duplicates are 1550 articles. A total of 303 articles were screened. 180 Articles excluded that they not meet the inclusion criteria.

Articles accessed for eligibility are 123 articles. A Total number of 80 articles excluded based on title and abstract (40) Irrelevant to topic (20) Duplicate (20).

The final data set consists of 43 articles.

The oldest included study was published in the year 2004 and the most recent study was conducted on 2023.The Entire process is shown in figure

PRISMA Flow Diagram



DISCUSSION:

The emergence of biosimilars in the Indian pharmaceutical industry signifies a momentous transition, marked by developments in regulations, market forces propelled by the need for cost-effective treatment alternatives, and noteworthy financial factors. Biosimilars are less expensive than originator biologics, but they have interchangeability and immunogenicity issues that make focused efforts necessary before they can be widely used. It has a significant effect on healthcare access, lessening financial burdens and advancing more general inclusivity objectives. This growth has boosted international cooperation, promoted innovation, and established India as a major force in the biopharmaceutical industry. In order to take advantage of new opportunities, the industry's strategic outlook for the future calls for navigating trends like digital health integration and personalized medicine.

CONCLUSION:

A significant and expanding segment of the world's pharmaceutical market is made up of biosimilars. They can aid in expanding access to these crucial medications and provide a less expensive option to name-brand biologics. India is a major player in the development and marketing of biosimilars and is a manufacturer and exporter of these goods. In the biosimilar industry, the Indian government is also promoting cooperation between domestic and foreign businesses. Through this partnership, access to these medications will be increased in developing markets and new biosimilars will be introduced to the market. The pharmaceutical business is seeing an increase in innovation and competitiveness due to the introduction of biosimilars.

Biosimilars have made employment prospects possible in a number of industries, including manufacturing, sales and marketing, regulatory affairs, R&D, and manufacturing.

India's capacity to manufacture biosimilars has given it a financial advantage in the international pharmaceutical industry. Foreign investments and partnerships between Indian and foreign pharmaceutical companies have been stimulated by biosimilars.

Biosimilars have the enormous potential to completely transform the Indian healthcare system. Their accessibility and affordability are anticipated to be crucial in lowering healthcare expenditures, increasing the number of chronic illness treatment options, and improving patient outcomes.

With an emphasis on creating biosimilars of complicated compounds, breaking into the government procurement sector, and increasing exports to developed markets, biosimilars have a bright future in India.

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