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Jayalakshmi PUNCHAPARAMBAN JAYACHANDRAN

A handwritten signature in black ink, appearing to read 'P. Jayalakshmi', is written over a horizontal line. The signature is cursive and somewhat stylized.

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LIST OF ABBREVIATIONS

ACA	Affordable Care Act
CAGR	Compound Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
CQAs	Critical Quality Attributes
DCGI	Drug Controller General of India
EMA	European Medical Agency
ESA	Erythropoietin Stimulating Agents
FDA	Food and Drug Administration
G-CSF	Granulocyte Colony Stimulating Factor
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
WHO	World Health Organization
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
INN	International Nonproprietary Name
IP	Indian Pharmacopoeia
ISBs	Indian similar biologics
R&D	Research and Development
rhGH	Recombinant Human Growth Hormone

ABSTRACT

Challenges in the adoption of biosimilars in India.

Jayalakshmi PUNCHAPARAMBAN JAYACHANDRAN

The main aim of this research was to identify the main challenges faced by the pharmaceutical companies of India for the adoption of biosimilar drugs in the most recent scenario. Although there are several factors affecting the wide development and usage of biosimilars, in this study it was found that the lack of consumer or patient awareness followed by concerns on the safety and efficacy of biosimilars and lastly the lack of physician education and the inadequate regulatory framework for their development and approval. It was also noted that most of the study participants believe that India has a promising future for biosimilar drugs and the market is attractive for investment. The primary methodology of the study was quantitative survey which was carried out among 158 random pharmaceutical professionals of India to get their insights on the factors hindering on biosimilars. In addition, market analysis was carried out to provide comprehensive understanding of biosimilar landscape in India and a case study on a safety incident of biosimilar product approved in India showed how a more streamlined regulatory network could help in raising the quality of biosimilar drugs to other international standards. The multiple linear regression was carried out on the collected survey data and the findings showed there is no significant relationship between the experience of pharmaceutical professionals to the knowledge on biosimilar products and to the willingness to adopt a biosimilar product. In order to overcome the barriers, public education initiatives, trainings for healthcare professionals and conducting thorough pharmaceutical surveillance for analyzing the safety and efficacy of biosimilars can be carried out. Overall, by identifying and examining the key challenges, this research adds to the ongoing discussions about the adoption of biosimilars in India. The outcomes can guide future policy choices and strategic actions aimed at encouraging the widespread use of biosimilars, which will ultimately result in improved access to reasonably priced and high-quality biologic therapies in India.

1. INTRODUCTION

1.1. Background:

A biosimilar is a biological product that is extremely similar to an already-approved biological product (also referred to as the reference product or originator), in terms of safety, purity, and potency, with no clinically significant deviations. Due to the inherent diversity of biological systems, biosimilars are created using a different technique than the reference product and are not exact replicas of it. Nonetheless, thorough comparative tests have demonstrated that they share the same efficacy and safety profiles as of the reference product. (McCamish and Woollett, 2011) The concept of '*similar biologic drug product*' which later came to be known as the '*biosimilar*' was officially first used in the European Union in 2001. (de Mora, 2015)

Biosimilar is referred to as "*similar biologics*" by the Indian regulatory bodies. Even though India was one of the earliest nations to adopt it, there was no clear guideline for "similar biologics," and the authorization for these products is more complicated and requires more evidence compared to other generic medicines. (Meher et al., 2019) In 2000, the very first biosimilar was licensed and commercialized in India for the treatment of hepatitis B, even though there was no particular protocol for the production and commercialization of biosimilars in India at that point.

The development of biosimilars have already found its marketplace in the biopharmaceutical sector. The standard or reference pharmaceutical products introduced into the market after years of research and development for rare and other therapeutic indications might be non-affordable for all throughout the general populace. This is where the opportunities for the biological similar agents found its way. These are low-cost products producing the same quality of the reference product. These can be introduced into the market only after the patent expiration of the standard or reference product which is initially developed, authorized, and introduced for use. The field of biosimilar drugs in India presents a lot of challenges for its hassle-free implementation. Indian biotech product developers and manufacturers have shown technological proficiency. The biologic regulatory

licensing processes used in China and India are less strict, and several medications have either been commercialized or are currently being studied. These substances haven't undergone the stringent EMA standards-required testing necessary to be considered "biosimilars" to the medications they are meant to mimic. Another issue that comes up is whether the biotechnology companies will work in harmony or whether they would compete over the same items while ignoring others with cheaper prices. (Saddique, 2017). The growing market for biopharmaceuticals is densely occupied; emerging nations like China and India complicates this problem. Safety and pharmacological equivalency of biosimilars manufactured in such countries are still issues. Indian biotech enterprises must implement Good Manufacturing Practice (GMP) rules and worldwide regulatory requirements to fulfill developing countries' strict regulatory criteria for biosimilars. (Singh et al., 2021)

1.2. Current biosimilar market:

Notwithstanding the fact that Europe became the first region to develop a set of policies for the authorization of biological products, India licensed its first biosimilar far before the Americas or Europe. According to Informa's Pharma Intelligence report 2021, India is the nation with the highest count of approved biosimilars after Germany and the United States, with approximately 127 authorised biosimilars.(P. Tejaswi, 2022) In the next few years, the patents on a number of biologics will expire. This will give India's low-cost manufacturers a huge chance to make a lot of money. Ranibizumab from Genentech/Roche was set to lose its patent rights in the US in 2021. In 2023, Aflibercept from Regeneron Pharmaceuticals will lose its patent rights in the US, just to mention a few. In the same way, when biologics like Avastin, Humira, and Levemir lose their own patent protection, more Indian pharmaceuticals will work on making biosimilars to boost their market share worldwide in these therapeutic areas.

Currently Western Europe is the biggest biosimilar market shareholder. The development of biosimilar was a strategic diversion in the life science industry. Before 2012, India authorized over 30 medicines. (Kang et al., 2020) The opportunity for biosimilars in India is projected to expand at a 22 percent compound annual growth

rate (CAGR) to reach \$12 billion by 2025. This would constitute about 20% of the whole Indian pharma economy.(Dr Saritha R S, 2022). India's biosimilar industry is \$2.2 billion and growing forward at 30% CAGR to \$40 billion in 2030. Indian biotech enterprises must implement Good Manufacturing Practice (GMP) rules and worldwide regulatory requirements to fulfill developing countries' strict regulatory criteria for biosimilars. (Singh et al., 2021) In the country which has the largest population in the world, it's important to have significant exposure to the newest medicines at the lowest prices possible so that as many individuals as possible can get quality healthcare.

1.3. Significance of research:

Emerging in the pharmaceutical business, biosimilars are anticipated to have a substantial impact on healthcare costs and patient access to therapy. Therefore, it is crucial for the industry and policymakers to comprehend the obstacles to their implementation. The study might provide significant information to pharmaceutical companies wishing to enter the biosimilars market in India or enhance their biosimilars business. India is one of the world's major markets for biosimilars, and a comprehension of the adoption issues in this setting can provide insights applicable to other rising economies. The study can also inform policymakers on the regulatory and policy changes required to improve the adoption of biosimilars in India, resulting to possible cost savings and enhanced patient outcomes. Recently while the research and development is ongoing for development of drugs for a number of diseases like the genetic disorders, cancers, autoimmune diseases etc, as well as a number of drugs getting authorized for use after extensive research and development; the emerging markets of biosimilar products could give rise to a blue ocean strategic approach for the pharmaceutical companies to confirm its front-line leadership and value added innovation in the market by developing new technology platforms especially during this digital era maintaining a sustainable nature as well. This research will help us learn and assess the scenario of Biosimilar drugs in India and draw out some conclusions for the challenges faced for the same.

1.4. Aim and objectives:

- To identify the current barriers that are preventing the widespread use of biosimilars in India and to analyze the current competitive landscape of the emerging biosimilar markets.
- To evaluate the availability and accessibility of biosimilars in the Indian market.
- To analyze the current regulatory framework for biosimilars in India and identify areas for improvement.
- To investigate concerns about the quality and safety of biosimilars in India and assess the validity of these concerns.
- To develop recommendations for overcoming the barriers to the adoption of biosimilars in India and increasing the use of these products in the country.

1.5. Research Questions:

- Does the quality and safety of biosimilar drugs produced in India raise potential concerns for the consumers?
- Is Biosimilar medicines easily accessible in the Indian pharmaceutical market?
- Is the regulatory framework for biosimilar production and its approval competent enough to compare them with the European biosimilar products?
- What recommendations can help with the challenges in the adoption of biosimilars in India?

2. LITERATURE REVIEW

2.1. Biosimilars In India

The Europeans made the very initial draft guidelines to serve biosimilars. Since then, Japan and the United States of America have also formed rules and regulations. In June 2012, India put together a set of rules for biosimilars. India possesses a strong industry in pharmaceuticals for generic medicines, and it has the potential to emerge as a growing field for biopharmaceutical drugs. The various considerations and how biosimilars are regulated in India and the comparisons on the rules that India and the World Health Organization (WHO) have set up for the biosimilar agents are clearly defined in “Biosimilars: an Emerging Market Opportunities in India” by P. Rushvi and K. Charmi. (P and K, 2016)

“BIOSIMILARS” in Different parts of the World.	
India	Similar Biologics
WHO	Similar Bio therapeutic Product
Europe	Biosimilar
US	Follow on Biologics
Japan	Follow on Biologics
South Africa	Non- Comparable Biologics
Canada	Subsequent Entry Biologics
Brazil	Follow on Biologics

Figure 2. 1. "Biosimilars" in different parts of the world.

Compared to making regular generic medicines, making biosimilars is a lot harder in terms of development purposes, clinical enhancement, the manufacturing process, authorization, and selling them. India have grown into to be among the most important players in developing and making the biosimilar products because of how well it markets the pharmaceuticals. (P and K, 2016)

The Indian regulatory framework poses a big problem for Indian producers. It require to be updated as soon as possible. The rest of the world thinks that India has much of potential to establish itself as a major player in developing and selling biosimilars. An article ‘Biosimilars in India’ from Journal of Proteomics provides a brief content

on how strong India is in terms of the research and marketing of biosimilars, the biggest problems it encounters, as well as the key role that this spectral components can play in figuring out if biosimilar agents are the same in terms of how they work. (Rathore, 2015) Biosimilars pose a positive image within health care providers because they are affordable. Although biosimilar products are growing more prevalent nationwide as well as global economies, it is crucial to know that they aren't exactly the same as biological generic drugs.

Research undertaken in recent years has shown that the biological activity of biosimilars that are is different from that of the "innovator" medicinal product. There was a clear difference between biosimilars and innovator drug. For example, the amount of quality of G-CSF as well as erythropoietin bio equivalents from various manufacturers was found to be very different. In a different investigation, several individuals who were given recombinant interferons showed that they had antibodies with neutralizing properties that stopped their own generation. When a biosimilar drug is approved, there isn't a lot of clinical research evidence to go on, so strong pharmaceutical surveillance is needed. Biosimilars have a special safety problem called immunogenicity. But the lack of validation and uniformity of techniques for detecting immunogenicity is another sign that drug surveillance needs to be stronger. For most generic compounds, automated substitution is a good idea and can help save money. But the same replacement criteria should not be used for biosimilars because it could make treatments more hazardous or lead it to be unsuccessful. The FDA and a number of different regulatory organizations continue to engage in making rules for approving the biosimilars for sale. In India, there are no clear rules about how the biosimilar drugs should be approved. (Misra, 2012) The Indian government is trying to make sure that the drugs manufactured here meet a superior standard. The sixth Issue of the Indian Pharmacopoeia (IP) came out in August 2010 and has product-specific descriptions over five biologic medications. Right away when the patent expires, newer biotherapies to substitute with those were only in the market should be introduced so that patients with low incomes who are unable to pay the high price of the original compound can choose a less expensive replica. Getting medicines at a price less has become a top concern all over the world, and

not only in nations that are developing. (Malhotra, 2011) Both the biosimilar as well as the original medication must have similar dosages, routes of administration, and drug forms. When the original medication in question is used for a few different therapeutic indications, the safety and effectiveness of all those uses must be shown or explained. After receiving marketing authorization, it's clinical efficacy & safety must be checked on all the time. Immunogenetic effects is a problem that must constantly be talked about, and they need to be watched over time. The FDA is given the authority to manage an "abbreviated pathway" in the authorization of biological products which are "biosimilar" to drugs that have already received authorization under the Biologics Price Competition and Innovation Act of 2009. The "Draft Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India," as part of the New India Guidelines, were available in June 2012. (Kumar and Singh, 2014) Nearly one hundred pharma businesses in India are busy researching, developing, producing, and selling bio equivalent medical products.

Biopharmaceutical products are hard to make because they have to go through a lot of stages to separate and clean it. All of these processes belong to the company that made the original product, so even slight modifications during manufacturing may have big effects on the safety and effectiveness of the medication. (Misra, 2010) Most of the time, a product by-product method is used to judge how close a biosimilar product is. Whereas companies of generic medicine have only to show that their pharmacokinetics are the same as the reference product in order to get approval from regulators. There isn't an obligation to demonstrate the pharmacodynamic and clinical similarity. Privacy and Data protection will pose yet another big problem when biosimilar forms of monoclonal antibody therapies already in the market emerge. It is still uncertain if companies that make biosimilars may be able to utilize the clinical information of the original drug to market the utilization of biosimilar drugs in additional ways which are covered by patents. Due to the complications and risks of biosimilars, a full promotional campaign is needed to teach consumers and doctors about how these drugs can be used in practice as making biosimilars is complicated and includes real microbes, there is reason to

worry about each short- and long-lasting responses of the immune system. (Dranitsaris et al., 2011) Adverse drug reactions which are a normal consequence of taking any medicine can be observed even in the initial compounds. But the fact that clusters have been found in some lots of Razumab draws the difference between batches into the spotlight and raises questions about quality control. It was a chance for companies all over the world that make biologically similar eye drops for conducting proper pharmacovigilance and cautious decisions regarding immunogenicity monitoring assays before putting these drugs on the market to minimize the impact of the nocebo. (Sharma et al., 2019) The variables and procedures which go into constructing technological abilities at the company level in emerging nations have evolved because of how technology and businesses are transforming. It makes me wonder if companies in emerging nations can use their own ways of acquiring information to keep up to companies in developed nations, and if globalization and other additional means of information have been the main ways that companies in developing nations improve their technology. One excellent resource to investigate the matter is the 'Indian pharmaceutical business'. The Indian pharmaceutical sector became the "pharmacy of the world" within a span of thirty years. Innovative researchers who investigate the growth of scientific and technological strengths in emerging nations have put most of their attention to the upgrade of technology in the company stage. The legal structures, strict research protocols, and large amounts of scientific information needed for biosimilars make it hard to Indian companies to get the money and technology they need. The typical expense of research and development of a biosimilar is between forty million dollars to three hundred million dollars, and it may require as long as five years. On the other hand, the typical expense of research and development of a generic drug is between two million dollars and five million dollars, and typically requires two to three years. Indian companies used various approaches to make biosimilar products. These approaches can be categorized into three main groups: methods for acquiring technology, methods for getting to foreign economy, and methods for meeting the legal standards that are necessary for biosimilar drug authorization. (Kale, 2019) Indian companies that employed biotechnology experts from highly developed nations and put them in positions in India raised their spending on research and

development (R&D) and reorganized research and development to make it easier to take in expertise from other places.

In order to demonstrate similarity between the drug products, it is very important to use the right tools for analysis which could meet this goal through analyzing the critical quality attributes (CQAs) associated with the medicinal products in qualitative terms and/or quantitatively. The in vitro growth of cell tests can be used to compare the relative effectiveness of different substances. The biosimilar business is growing at a rate that has never been seen before. This is because new medicines are getting more complicated as time passes. (Nupur et al., 2016) Particularly in highly monitored economies, reports have led authorities to maintain a further favorable view of biosimilars. This opens the door for biological alternatives to be used in cancer treatment in the years to come. To show bio-similarity, the WHO suggests doing development and similarity investigations on physical and chemical characteristics, biological function, operation- or product-related contamination, and quality assurance, as well as non-clinical investigations involving in-vitro and in-vivo biological action and experimental research on drug kinetics and pharmaceutical dynamics, effectiveness, and their safety. The economic benefits of biological alternatives will additionally rely on how much the reference biological product costs, how many people buy it, the level of competition there is etc. Subsequently it may be hard to come up for strong research studies with useful outcomes to evaluate equivalence. (Chopra and Lopes, 2017) Further issues consist of the lack of standards for extrapolating authorized therapeutic indications for biosimilars, the likelihood of immune response occurring in consumers when experimented, interchangeable nature with the original medication, making sure biosimilars are made the right way, and healthcare and other medical professionals not knowing enough about the safety and effectiveness of biosimilars agents. Biosimilar companies won't be able to find out how innovative goods are made, since it's confidential information. So, it will turn out difficult for companies that make biosimilars to make exact copies of any protein-based product. Product manufacturing companies and doctors will have a moral responsibility to disclose details regarding the risks of changing from a well-known medication to its

biosimilar with all those who matter, which includes consumers, pharmacy as well as other providers. In India, certain mishaps led to multiple lots of biosimilars to be taken off from circulation in over a decade. A customer protection filed in Maharashtra has granted a biosimilar Insulin incident's sufferer money and fined the company that made it. This makes it important for India to have strict laws about how Biosimilars are approved. Concerns about the health risks of biological proteins also have to do with the aspects of quality. (Joshi, 2011) India's rules on medicinal products were constantly shaped by the requirement for making sure consumers could get a hold of vital drugs. Accessibility includes being able to get it and being able to pay for it. It works for both small chemicals and biological drugs for both short-term and long-term illnesses. In order to contrast the original version along with the biosimilar version in the real world, a comparison of pharmacokinetic & dynamic analysis is needed. For useful assessment of information, nevertheless, the structure of a clinical study has to be selected with an in-depth knowledge of the limits selected for comparison. Most biosimilars that might be sold in India could be copies of medications for which patents had lapsed out and for which the "originator" drug compound might not be allowed in the nation in question. It is likewise probable that certain items in India don't have patents, so both the original along with comparable goods could be sold in the country. (Nellore, 2010)

Certain businesses have even set up factories to make biosimilars in other countries to expand their global reach and get more support around the world. International pharmaceutical firms have staked their hopes in the Asian biosimilar consumers, however small local businesses are also discovering methods to stake off gaps in this sector. Asia has many different types of economies and medical systems, involving different rules for biosimilar agents as well. (Tsai, 2017) India continues to prove that they can produce cheap, higher quality medicines for people all over worldwide, especially generic medications. This can be proven through evidence that the number of medicinal products produced in India which are sold in the United States keeps going higher. It is now over thirty percent. (Rathore et al., 2018)

2.2. Biosimilars in Europe

From 2005, the European Union has had a scientific system of regulation in place to make sure that biosimilars are of excellent quality. This framework remains continually tracked and revised. In the end, it implies the fact biosimilars are cheaper to make and buy when compared to originator drugs. This creates a competitive market that might break up monopolistic structures, give more people the opportunity for therapy, and free up money to invest in development and research. In 2006, the EMA gave the green light to the first biologically similar medication, Omnitrope which is used as a rhGH manufactured by Sandoz. Europe has approved more than 20 biosimilars after that were the drugs included in categories of hematopoietic growth factors, follitropin, monoclonal antibodies as well as insulin. The ICH "Q5E tripartite comparability guidelines", which are used in Europe and other countries including the US and Japan, say that the objective of comparability was to give proof to biologic drug possesses extremely equivalent quality characteristics prior to and following modifications to the method of manufacture. The main things that the European Medicines Agency (EMA) recommendations talk about are security, and safety, immunogenicity, therapeutic efficacy, and broadening uses. A key part of making biosimilars and getting them approved is making sure they can be used in place of the original drug of reference. The EMA is not allowed to say that a biosimilar is the same as original medication. Effective therapy equivalent could be shown by broad prior approval investigations or with methods such as scientific assessment, in comparison pharmacokinetics, and pharmacovigilance. However, as analytical techniques keep improving, it has been suggested that a mixture of all the above mentioned methods could offer additional evidence to support them. (Schiestl et al., 2017)

Multiple research investigations attempted to simulate the contest among biosimilar and generic drugs on the basis of the variations within the two types of drugs. Based on the results, the cost variation among the original cost and the generic cost should be smaller as compared to generics. Research points to a quite distinct industry scenario among generics and biosimilars, with greater expenditures in research, manufacturing, and training for doctors around biologic medications, and also

varying regulations with the supply part along with customer demand across the European Union. A number of variables are cited as possible reasons for the use of biosimilars. These variables might clarify the variations seen within the European Union, such as the realization that both doctors and patients use biosimilars and that each country's medical sector has its own price, remuneration and purchasing strategies; they have different laws about incentives for biosimilars as well. In the point for the study, fifty percent of the nations studied was said to have prescription funding. Biosimilars have been less likely to spread into nations where generic drugs are used a lot. (Rémuzat et al., 2017) According to the European drug regulations, the EU Directive 2001/83/EC, as changed by the Directives 2003/63/EC and 2004/27/EC, explains how biosimilars are regulated along with certain standards. The EU method for approving biosimilars pays special consideration to queries regarding a biosimilar agent's possible effect upon immune systems, as well as to screening and analysis done after it has been sold to find any safety problems. The utilization of the International Nonproprietary Name (INN) is an additional issue with biosimilars. It is a helpful tool; however, it shouldn't serve as the only way to identify biosimilar agents. The factors that define what makes a good drug surveillance or vigilance plan are still being worked out. A different crucial component of the biosimilars regulation process is setting the standards regarding the non-clinical and clinical evidence which is required and enough to show biosimilarity between the originator and the newly developed drug.(Zuñiga and Calvo, 2009)

The prescribers are unfamiliar with biologic and biosimilar product manufacture, authorization, and legislations. Different fields of medicine exhibit favorable views regarding biosimilars, however they tend to be uncertain for extrapolating signals and changing consumers using an original biological drug to its biosimilar drug.

The European biological guidelines of relevance for biosimilars.	
Reference number	Guideline
CHMP/437/04	Similar biological medicinal product
CPMP/BWP/3207/00	Comparability of medicinal products containing biotechnology derived proteins as active substance; Quality issues. Revised.
CHMP/49348/05	Similar biological medicinal products containing biotechnology derived proteins as active substance; Quality issues.
CHMP/31329/05	Annex to guideline on similar biological medicinal products containing biotechnology derived proteins as active substance: nonclinical and clinical issues- guidance on biosimilar medicinal products containing recombinant granulocyte colony stimulating factor
CHMP/94528/05	Annex to guideline on similar biological medicinal products containing biotechnology derived proteins as active substance: nonclinical and clinical issues- guidance on similar medicinal products containing somatropin.
CHMP/32775/05	Annex to guideline on similar biological medicinal products containing biotechnology derived proteins as active substance: nonclinical and clinical issues- guidance on similar medicinal products containing recombinant human insulin
CHMP/94526/05	Annex to guideline on similar biological medicinal products containing biotechnology derived proteins as active substance nonclinical and clinical issues- guidance on similar medicinal products containing recombinant erythropoietins
CHMP/BMWP/118264/07	Similar biological medicinal products containing low molecular weight heparins
CHMP/BMWP/102046/06	Similar medicinal products containing recombinant interferon alpha
CPMP/BWP/1113/98	Development of a CPMP guideline on comparability of biotechnology derived products
CHMP/BMWP/7241/2006	Similar biological medicinal products containing recombinant alpha interferon- annex to the guideline on similar biological medicinal products containing biotechnology derived proteins as active substance- nonclinical issues
CHMP/BMWP/496286/06	Similar biological medicinal products containing low molecular weight heparins- nonclinical issues
EMA/CHMP/BMWP/170734/08	Revision of the guidance on similar medicinal products containing recombinant erythropoietins
EMA/CHMP/114720/2009	Immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use
CPMP/ICH/5721/03	Note for guidance on biotechnological/ biological products subject to changes in their manufacturing process
CHMP/42832/05	Similar biological medicinal products containing biotechnology derived proteins as active substance: nonclinical and clinical issues
CHMP/BMWP/101695/06	Comparability of biotechnology derived medicinal products after a change in the manufacturing process: nonclinical and clinical issues
CHMP/BMWP/14327/06	Immunogenicity assessment and biotechnology derived therapeutic proteins

Figure 2. 2. EU biological guidelines of reference for biosimilars.

Around 55 biosimilar drugs were authorized during the years 2017 and 2019. Regarding the purposes of marketing, the European Commission approved one biosimilar drug with distinct trade names. Major biosimilar drug companies collaborate with other companies regionally and enter the EU distribution in various brands. (Allocati et al., 2020) Before, unlike the Food and Drug Administration (FDA), the European Medicines Agency (EMA) doesn't assess interchangeability, so member

nations decide pharmaceutical substitution. Biosimilar drug replacement is now prohibited in every member nation. An initial cost investigation shows biosimilar reductions are often below twenty-five percent. The reductions in expenses from biosimilar drugs in the EU nations examined were tempering with the actuality that there is market competition which is confined within the first-generational originator drugs (for example- ESA and G-CSF classe), while a longer-lasting the 2nd generation variants had continued with lead shares. Despite the EU holds an accepted biosimilar products approval framework, variations in remuneration standards, incentives, and healthcare procedures have contributed to varying outcomes throughout nation-states. Germany offers biosimilars agents the best advantages. (Grabowski et al., 2014) Clinical resemblance for a single purpose could be extrapolated to various standard drug applications. Extrapolating centered on "appropriate justifications", comprising clinical evidence, mechanisms, and "same receptors" involvement. Most biosimilars were peptide medicines created by modifying genes in prokaryotic cells as well as suitable eukaryotic cells. To detect safety issues, the original medication & the biosimilar medication need to have a longer-term post marketing evidence. These data help identify uncommon and unfavorable medication responses. (Tsiftoglou et al., 2014)

Biosimilar medicine reductions allow for the therapy of more individuals. Biosimilars could help 7–11% more rheumatoid arthritis patients, according to research. Biosimilar prices and institutions' IV capabilities shall decide biosimilar drug advantages. (Jang et al., 2021) In the EU, longer-acting insulin equivalents are used more to improve adherence while decreasing low blood glucose levels. Because of several issues, biosimilars of longer-acting insulin equivalents have been discontinued in several EU nations. This involves biosimilar cost cuts and originator marketing campaigns. To improve biosimilar use for all important stakeholders, such worries must be resolved.(Godman et al., 2021) In the pharmaceutical industry, particularly biological agents, are expensive, making medical budget control difficult. The Hatch-Waxman Act promotes competition in generics while rewarding medication innovators. Biologics and biosimilars are targeted under the Biologics Price Competition and Innovation Act. Biologics are made using organisms that live,

making their production more essential than with chemical drugs. Biosimilar industry entrance is harder from generic manufacturers introduction and like speciality injection manufacturer launch. Innovators' competing reactions may also matter. Biosimilars' investment expenses and risk create collaborative efforts probable. (Blackstone and Joseph, 2013)

Using the approach known as Delphi, an agreement regarding sustainability of the biosimilar drug business in EU was reached. The most significant factors as well as challenges to sustainability were also found. (Vulto et al., 2020) Authorities require to work with doctors along with other interested groups to come up with innovative methods to buy and pay for the patent expired biological drugs and biosimilar agents that encourage competitors in open market while making sure people have a range of goods. From the side of demand, a prescription or switch system for off-patented biological products and biosimilar drugs that needs to be made using the help of healthcare professionals, research, and consumers. The doctor recommends a biologic or biosimilar drug that is no longer under patent or changes within medications according to medical expertise and good research. (Simoens et al., 2018) Following this way, pharmacists working in hospitals are information idols on how both products are used across real-world settings and what proof there is to back that.

Scientists talk about medical advances within the emergence of biosimilar drugs in different fields of study including gastroenterology, endocrinology, rheumatology, oncology, hematology, and nephrology as well as considering the consumer's point of view. Furthermore, they talk about the necessity over continuing drug surveillance, strong competing clinical investigations, and everyday life information to figure out the long-range benefit vs risk ratio profile of biosimilar drugs. On concluding, biosimilar drugs have a lot of promise to change the way biological treatments is done by making it easier for patients to get treatment in all therapeutic domains. Potential savings in expenses from competitive prices (like with generics) could be eased by things like having the potential to effortlessly switch between goods. Clinicians in addition must be aware of legislative bodies regularly keep an eye on modifications of the manner in which biological products are made to make certain

these modifications are not contributing to deviations from the original drug substance. (Khraishi et al., 2016)

2.3. Biosimilars in US

Consumers and medical insurance plans will only save money when biosimilars are recommended. Even though doctors and patients in the United States are particularly keen on biologic products that cost less, a lot have expressed worry and doubt about how well this novel category of drugs will work. Several organizations of patients and doctors have said that similar medications must be easy to recognize to let consumers know right away which item they've been given. Associations of doctors who write prescriptions have said that the packaging and instruction notes must make it clear whether the item being sold is a biological similar as well as a substitutable medication. The Food and Drug Administration proposed label advice states that this data must appear on the box leaflet and gives an example of where it should go. Further advancements in essential research and clearer rules from regulators will make it easier for businesses to plan ahead. The more that healthcare professionals and patients use biosimilar agents in medical settings, the less they must worry. In the decade to come, many people will be able to get reliable and efficient biologically similar treatments for a broad spectrum of ailments and diseases. (Christl et al., 2017) Some of the techniques that we currently possess for accurately describing biological products aren't very good, particularly for proteins with complicated structures and a lot of sugars attached to them. Employing "similar" as opposed to "identical" proteins simultaneously causes worries in making the immune response stronger. The method for biosimilar drugs in the EU could be used as an example to predict and solve technical and social problems with those in the United States. (Gottlieb, 2008) Biosimilar products can be tested additionally to see if it is interchangeable with the original product being studied in the US. This is something that is only possible through the FDA approval route. In particular, steps to help maintain correct healthcare data in the case that an auto replacement (such as documentation standards, the utilization of integrated digital medical records, and/or doctor notice following that action) lay in the individual state's legislation, that establish this norm. The latest poll of over four hundred medical

professionals showed that the majority didn't know much about biosimilar drugs or the federal authorization process for them (such as the right way to plan clinical studies and what the outcomes should be). (Camacho et al., 2014)

Ten years ago, the EMA started putting out drafts of rules to develop biosimilar agents. Since then, it has authorized a number of the same product. The US FDA has put out initial guidance with step-by-step factors regarding the nonclinical and clinical research and developing of biosimilars, but they did not approve a biosimilar using that route. Experimental trials are meant to clear up any questions about how comparable the planned biosimilar is to the standard version which could persist after nonclinical research. (Alten and Cronstein, 2015) Some of the factors that make it hard to get into an industry are legal matters, like patents and proprietary information that come from the Affordable Care Act (ACA). An employee at an institution that makes biologics and biosimilar products said that the doubt makes it hard for businesses lacking "deep pockets" to get through the business. Biosimilars have had a hard time getting into the market because they can't be switched out and used with each other easily. Automated replacement at the drugstore levels helped generic medicines win a share of the market. (Blackstone and Joseph, 2013) Specialized practitioners value peer reviewed biosimilar publications to be the best towards further learning. These medical advocacy groups may need credible data to deal with their issues. Communicating post-approval drug surveillance safety information can help allay biosimilar hypersensitivity worries. In the European Union, in which biosimilars had been successfully used for over 400 million consumers without significant immunogenicity issues, this might be helpful to clarify information regarding safety. (Cohen et al., 2016)

The pharma sector of India currently produces roughly twenty percent of generic medicines and sixty-two percent of vaccines. This country stands in an ideal position to make biological products and biosimilars as well which might enhance medical care by lowering the price of treatments. Meanwhile, India has invested a lot of money into biosimilars. India's pharma sector has helped battle COVID-19 by making and providing medicines and vaccines that mitigate and treat the disease. Even though the logistics system had been poor and there had been

a lot of stress on the workers, productivity was increased so that over 133 countries could get pharmaceuticals of the highest quality at prices they could afford. (Panda et al., 2023) Majority of Asian consumers could not afford the excessive cost of biological agents, and this made it harder for Asian countries to pay for health care. Asian countries take proactive measures in this sector by making sure rules are followed, lowering taxes, and bringing in highly qualified individuals. After completing this study, we will be able to understand how different factors affect the biosimilar market in India and how these factors could be related.

3. RESEARCH METHODOLOGY

3.1. Conceptual framework:

The research problem addressed in this study is the various challenges faced by the Indian pharmaceutical industry in bringing up the biosimilar drugs into the industry. This may be due to different factors like perspectives of the people where people raises concerns on the quality and effectiveness of biosimilar drugs when compared to the original drugs that they have been using; the regulatory environment in conducting research and development of drugs, its approval and other necessary legislative concerns by the pharmaceutical companies; how is the biosimilar market prevailing in India and whether it has a good demand or not in the healthcare sector. However, that depends on the perspectives of the patients; the impact of pricing and reimbursement policies may also affect the demand for biosimilar drugs. The attitude of healthcare or pharmaceutical professionals could directly or indirectly affect the concept of biosimilars as well. It is important to be aware of what the biosimilars are and how they are different from their originator medication and the benefits associated by the health care professionals first and then pass it on to the next level of consumers.

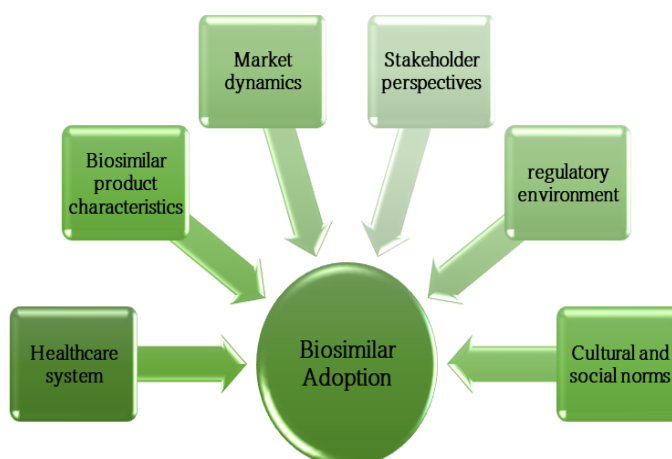


Figure 3. 1. Possible factors that affect biosimilar adoption.

Various existing literatures has brought the scenario of biosimilars especially the price policies and regulatory environments in India, Europe, and the United States. In this study, I am trying to focus and understand the most recent scenario of biosimilar drugs in India and which all factors mostly affect them, and the data collected for this

is from random population of pharmaceutical professionals itself. This might give us a real case scenario and what they go through.

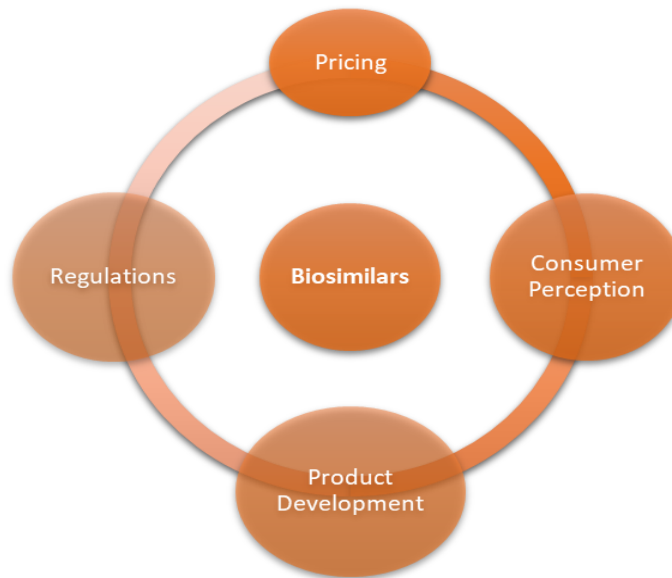


Figure 3. 2. Correlation of factors affecting biosimilar adoption.

3.2. **Research methodology:**

This research on challenges faced by the biosimilar drugs consider the ways in which social and political values can shape the research findings while the whole study is carried out to find a common acceptable knowledge. Thus, the research philosophy in this case is both epistemological (in terms of understanding how knowledge is constructed) and axiological (in terms of recognizing the role of values and ethics in research). In this study, a quantitative data collection method-‘surveys’ is used to gather and analyze objective data on the biosimilar market in India. Also based on the belief that reality is subjective and shaped by individual perspectives and experiences, using qualitative research methods, such as case studies, to gather and analyze subjective data on the experiences and perspectives of stakeholders in the biosimilar market in India incline the study partially towards a realistic approach. By adopting these primary research methods used in identifying the challenges in the adoption of biosimilars in India, this study can provide valuable insights into the complex and dynamic factors affecting the growth of the biosimilar market in India. A deductive approach is consistent in this research design where the research

question is formulated based on a theoretical framework and the survey data is used to test the hypotheses derived from that theory.

3.2.1. Surveys

Insights of the pharmaceutical professionals from the pharmaceutical businesses in India might be surveyed on biosimilar production and marketing challenges.

- **Evaluating the Impact of Pricing and Reimbursement Policies:** conducting surveys with stakeholders such as healthcare workers, and policymakers, to learn more about their perceptions of pricing and reimbursement policies, the cost and accessibility of biosimilars, and the effects of those policies on patient access.
- **Understanding the Level of Brand Loyalty:** Surveys can determine how loyal individuals are to the original biologics brand and why, as well as whether the respondents will prescribe or suggest the use of biosimilars to other people or consumers.
- **Assessing the impact of regulatory requirements:** Surveys can reveal how the development and approval procedure affects biosimilar use in India.
- **Evaluating Supply Chain and Distribution Challenges:** Surveys might reveal biosimilar availability, distribution, and supply chain issues in India or if they are hindering the adoption of these medications.

3.2.2. Market analysis

This technique would entail gathering and studying information on the market dynamics, regulatory landscape, and rivalry already present in the developing biosimilars industries. This information might be gathered from both primary and secondary sources, including news stories, industry reports, and government papers.

- **Assessing the market demand for biosimilars:** A market study may reveal if there is a demand for these biosimilar medications as well as how well healthcare professionals and patients understand and accept them.
- **Analyzing the Competitive Landscape:** A market study can reveal if consumers have strong brand loyalty to the original biologics and how

fiercely biosimilars compete with them. This also include the concerns over safety and efficacy of these medications.

- Identifying regulatory challenges: A market study may examine the licensing procedure and launch requirements for biosimilars in India, which may have an impact on how many people use them.
- Assessing intellectual property challenges: A market study can look at the original biologics' patent status and any issues that biosimilars could have in India, which may have an impact on how many people use them.
- Evaluating supply chain and distribution challenges: A market study may examine the accessibility and distribution of biosimilars in India as well as the issues with maintaining the supply chain's stability, which may have an impact on how many people use them.

3.2.3. Case studies

Case studies of safety and efficacy experiences with biosimilars can offer important insights into the difficulties and most effective methods for boosting the uptake of these drugs.

- Evaluating real-world experiences: Case studies can demonstrate how patients and healthcare professionals use biosimilars in practice as well as how they perceive and react to these drugs.
- Understanding the importance of pharmacovigilance: Case studies may be used to determine how continuous monitoring of developed and approved drugs help in improving the product and attitude of stakeholders and consumers towards the product.
- Evaluating Pricing and Reimbursement Issues: You may determine how much biosimilars and original biologics cost and are paid for in India using a market study, which may have an impact on how many people use them.

3.3. Research design

The research design for this study might include:

- Research question: What are the main challenges in the adoption of biosimilars in India?
- Population: Pharmaceutical professionals currently working or have experience working in India.
- Sample: A randomly selected group of pharmaceutical professionals from India.
- Data collection methods: Primary method-survey and Secondary data collection method- case studies, market analysis
- Data analysis techniques: Descriptive analysis, Statistical Multiple Linear Regression analysis
- Timeline: The study will take place over a three-month period.

Other experts in the field reviewed the research design for feedback and suggestions for enhancement. This made the study more thorough and compliant with the norms of the scientific community by pointing up any potential biases or flaws in the questionnaire design. The research data gathering techniques (survey) were also tested in a small-scale pilot study, which revealed a few problems with questionnaire-based data collection. The pilot study made it possible to improve the research design and make sure the study can be carried out as intended.

3.4. Subject population:

The sample subjects selected for this research will be those professionals who are able to provide useful insights on the topic. Here, a single cohort of participants will be involved who would be those working in the pharmaceutical sector of India. According to an estimate by Worldometer of the most recent statistics provided by the United Nations, the population of India as of Tuesday, May 2, 2023, was calculated to be 1,418,311,220 (approx. 1.42 billion) and is close to China, which is the most populated country in the world. Reports have shown it is expected to grow and beat China in terms of population any soon. Out of this population, 16,86342 pharmacy professionals have registered with the pharmacy council of India according to the Pharmacy notes on 'Total Registered Pharmacists in India- An Overview'. (ThePharmapedia, 2023) For this sample population, the study sample was calculated using the tool SurveyMonkey. The estimated sample size was 151 subjects calculated

with suitable parameters including the population size of 17,00,000 with 95% confidence interval and an 8% margin of error. These subjects will be contacted mostly through online platforms which include social medias like WhatsApp, LinkedIn, Facebook as well as via email or whichever that is convenient for the subjects to receive the survey forms and to complete them.

3.4.1. Inclusion criteria

Pharmaceutical industry experts including executives who manufacture and market biosimilars, decision makers from pharmaceutical company, patent experts, quality control and quality assurance professionals who ensure the safety and efficacy of drugs before they are released into the market. Market research and sales professionals analyze the market and promote the products to healthcare providers and patients. Supply chain and logistics professionals who manage the distribution of drug products to different regions in India. Research and development professionals who are involved in developing new drug products and improving existing ones. (All participants are professionals from India only).

3.4.2. Exclusion criteria

Clinical pharmacy professionals as they have less exposure towards the industrial or marketing sector of pharmaceutical industry, pharmaceutical teaching professionals, pharmaceutical internship students or trainees, Professionals who do not work in India or are not involved in the Indian market, Professionals who are not willing to participate in the survey or provide incomplete responses. Inability to read and comprehend English: Since the survey is done in English, those who do not speak the language well may find it difficult to comprehend and give correct answers. These exclusion requirements can ensure that survey respondents are pertinent to the study's topic and can offer important insights into the difficulties encountered in India while adopting biosimilars.

3.5. Data collection & analysis:

3.5.1. Questionnaire development:

As discussed earlier, the survey will be conducted among a single randomly selected cohort of pharmaceutical professionals in India. Using a questionnaire to collect reliable and valid data can aid in the process of informing policy decisions, developing strategies, and guiding future research on the usage of biosimilars in India. The questionnaire will contain only one section with 19 questions for the subjects to answer. This starts with their professional departments, years of experience and their knowledge on the biosimilar drugs. Later it is carried through their insights on the challenges their company faces and their thoughts or opinions on the adoption of biosimilars in India. It involves different type of questions including YES/NO, multiple choice questions, descriptive answer types. It is possible to conduct an analysis of the data gathered through the questionnaire by making use of various statistical tools and methods in order to detect patterns and trends in the responses. This can be helpful in identifying typical difficulties that pharmaceutical professionals confront and in prioritizing these challenges based on the frequency with which they occur and the severity of their impact. The questionnaire may contain open-ended questions that give respondents the opportunity to contribute their ideas and thoughts on the difficulties associated with the use of biosimilars in India. These insights have the ability to provide useful information that may be used to better understand the underlying causes of the difficulties as well as potential solutions to address those causes. The questionnaire can be of assistance in evaluating assumptions made regarding the difficulties encountered in the process of adopting biosimilars in India.

3.5.2. Analysis:

After completing the data collection accordingly to the planned research design, these data are sorted, and data cleaned for checking for missing values, outliers, and inconsistencies in the data using various software like MS Excel. It is then summarized using measures of descriptive statistics. This will give an overall understanding of the data followed by data summarization, testing the hypotheses, and drawing

conclusions about the population based on the sample data is carried out and the statistical method of regression analysis could be used for the same to find any correlations between the factors affecting the biosimilar adoption. the data is visualized to make it easier to interpret and to draw conclusions about the research questions. Finally, creating a report of the data analysis including the research question, approach, findings, interpretation, and conclusions.

3.6. Ethical issues

This research involve study into specific company activities that would be deemed sensitive or confidential. In this case, the name of company or trade name of medical product will not be mentioned but will be using the generic name of the product instead unless the matter isn't confidential. This study also involve research that might damage the reputation of companies or participants. Similarly, to the subject matters, the name of the pharmaceutical company or trade name of medical product will not be mentioned directly which might raise concern on the goodwill of the company but will be using the generic name of the product for reference instead. This survey is carried out online among different pharmaceutical professionals of India and the participation is voluntary. The participant data collected will have unified data protection as per the EU General Data Protection Regulation (GDPR) and all individuals have the right to withdraw from the research at any time.

4. FINDINGS AND ANALYSIS

4.1. SURVEY DATA ANALYSIS

As per the research design, a survey was carried out among the pharmaceutical professionals of India with the help of a questionnaire having 19 questions. A random 181 responses were collected which after data sorting finalized to 158 responses because there was pharmacy professors, students, clinical research trainee and clinical pharmacists which comes under the exclusion criteria.

Demographic data

In the survey, there were 54 professionals from pharmaceutical research & development, 32 from pharmaceutical marketing/sales, 21 from pharmaceutical manufacturing/supply chain/ logistics, 26 from pharmaceutical quality assurance, 10 from pharmaceutical regulatory affairs, 8 hospital/ community pharmacists, 6 from pharmacovigilance and 1 from pharmaceutical engineering/ consulting.

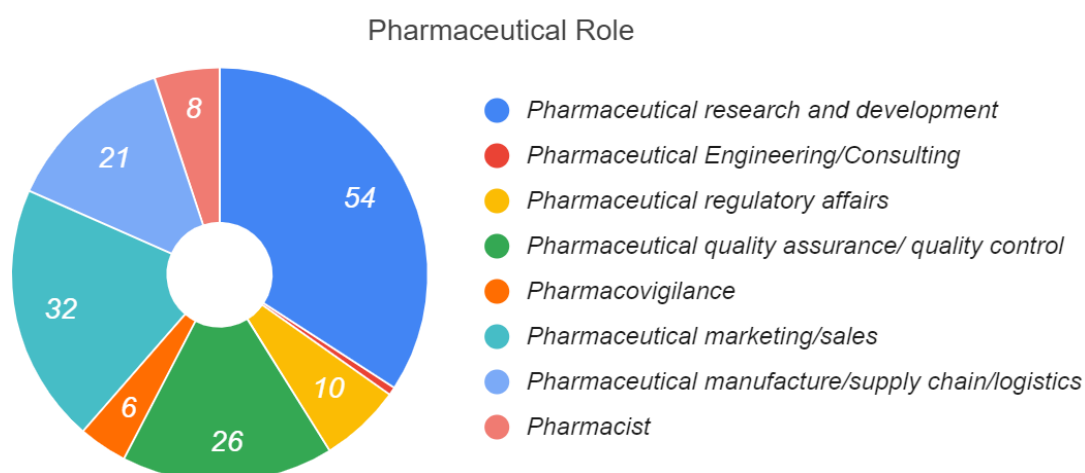


Figure 4. 1. Pharmaceutical roles of respondents.

94 survey participants had 0-2 years of experience, 29 individuals had 3-5 years experience, 17 individuals had 6-10 years of experience and 18 individuals had more than 10 years of experience in the pharmaceutical or life science sector.

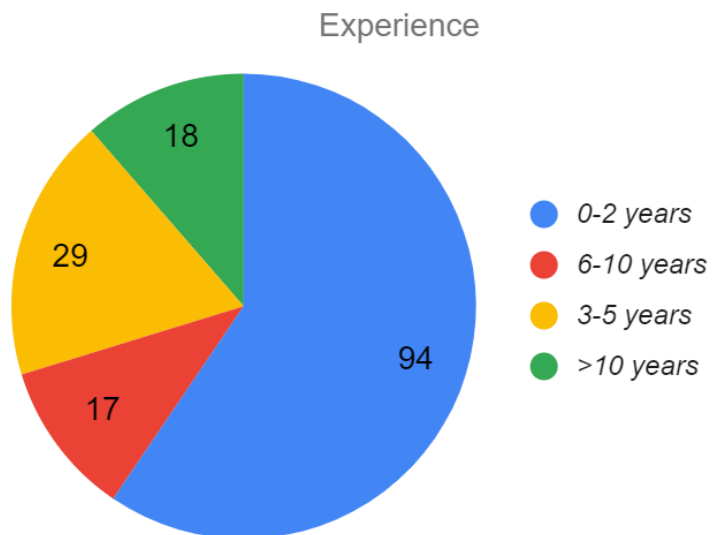


Figure 4. 2. Experience of respondents in pharmaceutical sector.

Familiarity of biosimilars

Professionals in India may or may not know much about biosimilars, based on their field and how long they have been working. 111 professionals participated in the survey where somewhat familiar with biosimilar drugs while 31 were very familiar and 16 of them not familiar at all.

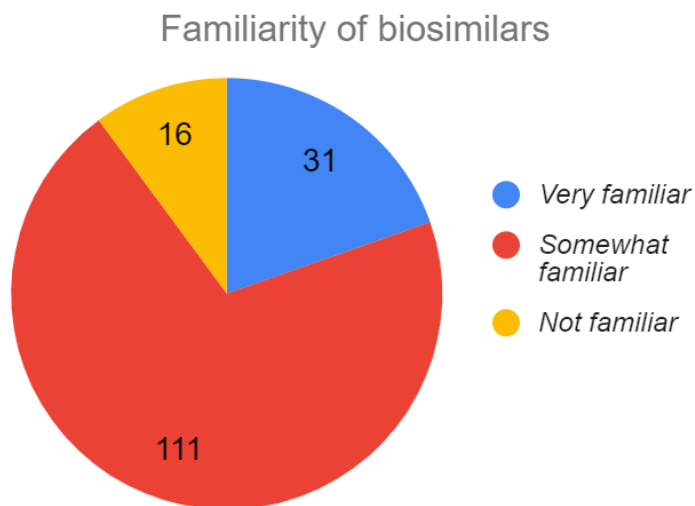


Figure 4. 3. Familiarity of respondents with biosimilars.

Price awareness of Biosimilars

Of the random 158 pharmaceutical professionals who had attended the survey, 27 did not know they were cheaper alternatives of the original biologic and 131 individuals responded that they knew the biosimilar drugs were cheaper alternatives.

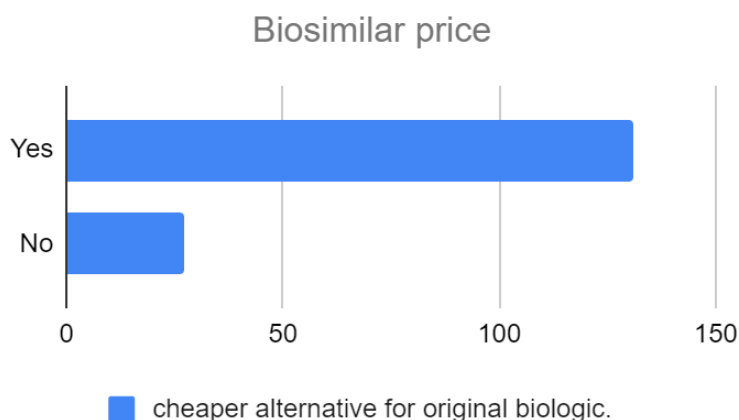


Figure 4. 4. Response rate about price awareness on biosimilars.

Safety & efficacy of biosimilars

A number of 113 participants believed that the biosimilars have the same safety and efficacy compared to their original biologic drug while 45 participants did not. The major reasons given by those who believed that they were safe and effective were no clinical meaningful differences compared to the original biologic, they have the same mechanism of action with similar active pharmaceutical ingredient, they are the duplicates of the original drugs with minor changes in structure of the drug molecule, identical copy of original product which is manufactured by a different company and it's cheaper, highly similar in terms of quality safety and efficacy, involves comprehensive comparison towards the original product during its regulatory process for approval, testing and evaluation carried out to meet exact manufacturing standards, all safety and efficacy quality tests recommended by regulatory authorities; One of them stated that he/she have compared the assay of a brand of biosimilar and the original biologic and found it to be similar as the person themselves work in a quality control department; They are similar in composition and methods of preparation; they are not identical to original biologics but only vary in

inactive ingredients and produce the same potential treatment. The marketing authorization from CDSCO comes only after the review of its clinical study report. Few people have suggested that they don't have any practical experience but rather noted through the referenced articles that there's only minor difference in the chemical product and this is very evident from the trial results and reports as well as high patient response rate to the use of these biosimilar products. While the others who contradict this states that for many biosimilar products the toxicity studies and the post marketing surveillance are not recorded, their elimination rates may differ from the original product, they have no specific guidelines for safety and efficacy compared to original medicines they are not interchangeable and may have very different efficacy from their original reference product, limited knowledge, their approval process is streamlined, there is potential risk of immune based adverse drug reactions, their quality can vary, usually the biological products are very hard to prepare as its protein structure is very complex so we might not expect that the biosimilar to have the same exact effect as original product. There will be minor difference in chemical products, the sensitivity of biosimilars is very high, the side effects are most identified during postmarketing stages of biosimilar drugs, regulatory and commercial requirements are different for the biosimilars.

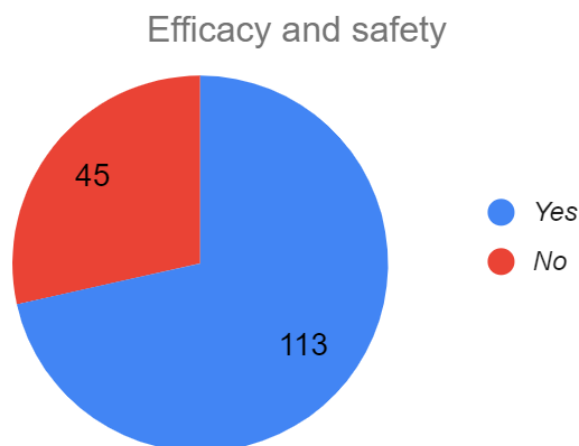


Figure 4. 5. Perspective on safety & efficacy of biosimilars.

Awareness among healthcare professionals & patients

128 participants think there is more awareness and education required among the healthcare professionals in India about the use of biosimilar drugs and 30 participants do not.

Awareness among healthcare professionals and patients

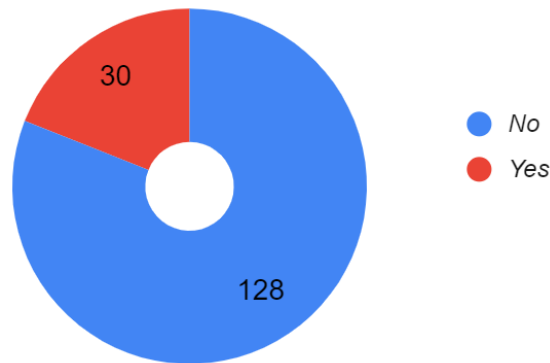


Figure 4. 6. Participant perspective on awareness of biosimilars among healthcare professionals & patients

Knowledge of any Biosimilar products in the market

85 participants were familiar with different biosimilar products in the market while 73 participants were not aware of any particular biosimilar. The most commonly mentioned biosimilar products by the professionals included Insulins namely insulin glargine, Injection Humalog, basalog and wosulin; monoclonal antibodies (Rituximab, Adalimumab, Trastuzumab, Bevacizumab, Infliximab, Razumab, Tocilizumab), Avsola, Herzuma (for treating breast cancer), Epoetin, Inflectra, Semglee, Amjevita, Idacio, Erbitux, Humatrope, Peg Filgrastim, Enbrel Adfrar, Imraldi, Hyrimoz, Bevacirel, Dapagliflozin, Glaritus, Maball, Zarzio, Reditux.

Familiar with any biosimilar products

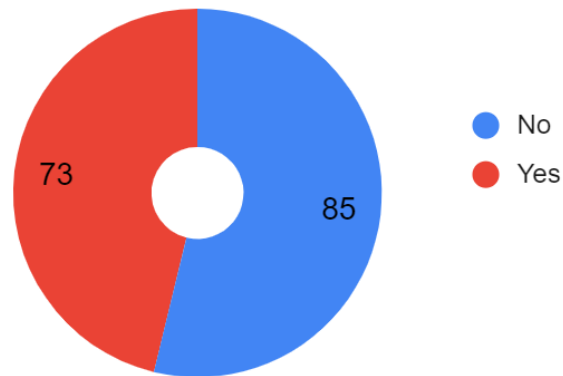


Figure 4. 7. Participant knowledge of any biosimilar products in market.

Challenges for not launching and launching biosimilars.

Of the 158 respondents, 25 have said that their company have launched a biosimilar product of their own; where these respondents may or may not belong to the same pharmaceutical/ life science company. A lot of factors were taken into concern and faced many challenges during the development and launch of these products as well as for not launching them as per the respondents.

The most mentioned challenges for launching the biosimilar products were lack of physician or patient awareness about the biosimilar products (20) and 18 participants voted for regulatory challenges, 17 voted for pricing pressures, 16 voted for competition from established brands the least were the distribution challenges by 9 participants. There was one response mentioning 'non surety' of the challenges faced. The challenges faced by the companies who haven't launched by a similar product included 46 words for lack of regulatory clarity 42 for limited market demand, 36 voted for difficulty in manufacturing for my 23 voted for intellectual property concerns, two people responded for non-surety and one response for cost concerns.

Launched any biosimilars in India

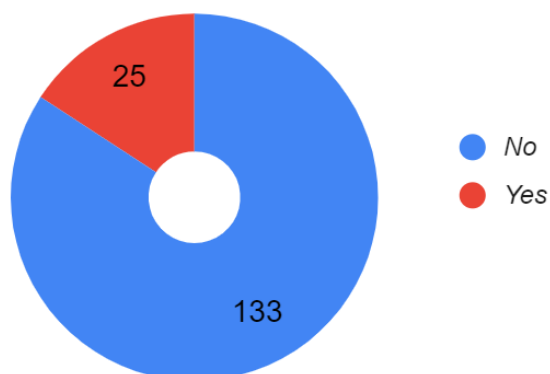


Figure 4. 8. Response rate over any biosimilars launched by own company of participants.

Factors to consider between biosimilars and reference products

For the question of what factors to consider between biosimilar and reference product, given the options of efficacy data safety data cost, availability, patient preference, and others; 117 people voted for efficacy data safety data and the cost, 85 people voted for availability, 59 voted for patient preference. There was one response for indication or interchangeability and immunogenicity of the biosimilars and one response for patient compliance.

Regulatory framework

Of the 158 responses, 82 people opinionated that there is no stringent regulation for the development and approval of biosimilars, 69 people had opinion on the presence of complex laws and six people were unsure about the regulatory framework for the development and approval of the biosimilar products in India. There was one response stating that there is right regulations for the development and approval of by similar products in India.

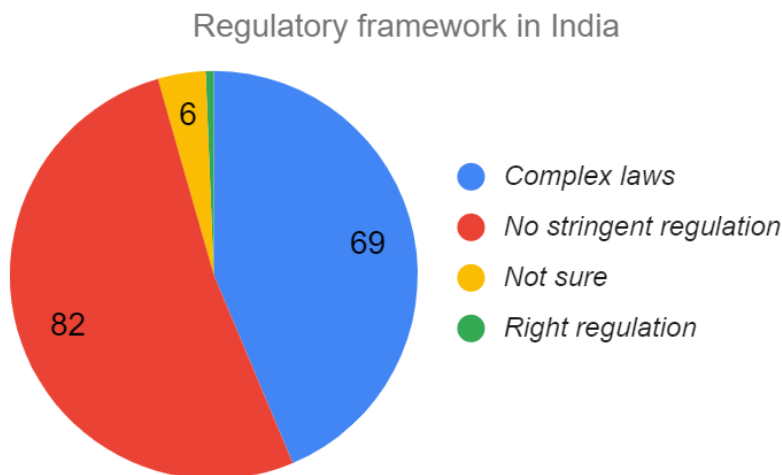


Figure 4. 9. Perspective of respondents on regulatory framework of biosimilars.

Necessity of more research and clinical trials

148 of the respondents believed it is necessary to carry out more research as well as clinical trials on the biosimilar products which are developed in India while the other 10 respondents believed it is not necessary.

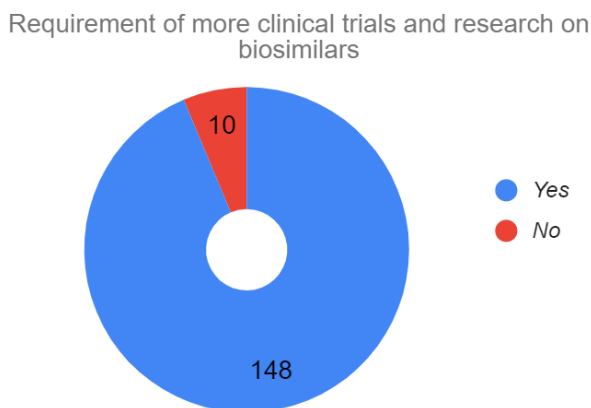


Figure 4. 10. Response rate on the necessity of more clinical trials & research on biosimilars

Major challenge in biosimilar adoption

Given the five options of different challenges in the adoption of biosimilars in India which include lack of physician education, inadequate regulatory frameworks, lack of patient awareness and acceptance, concerns about safety and efficacy, limited availability; 51 people voted for lack of patient awareness and acceptance of the biosimilar products which constitutes the majority of the responses followed by 43 voted for the concerns about safety and efficacy, 26 voted for lack of physician

education and 26 voted for inadequate regulatory framework and finally 12 people voted for limited availability of the biosimilar products in India which constitutes the least concerned challenge.

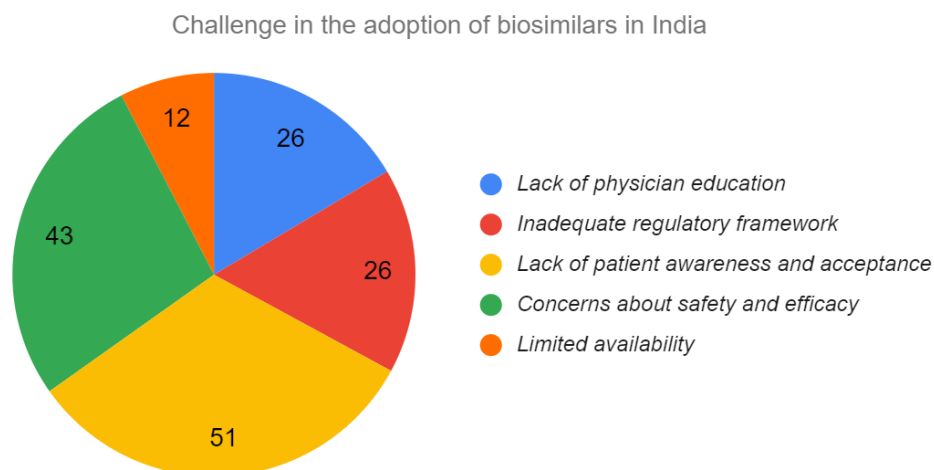


Figure 4. 11. Perspective of respondents on different challenges in the adoption of biosimilars.

Steps to improve biosimilar adoption in India

In order to improve the biosimilar adoption in India different steps can be taken like physician education on the biosimilars, patient education on biosimilars, improved regulatory framework for the biosimilars, increased availability of biosimilars, price controls for biosimilars. Given these steps, 97 of the respondents voted for physician education on biosimilars, 86 voted for patient education on biosimilars, 95 voted for improved regulatory framework for biosimilars, 66 voted for increased availability of the biosimilars and 61 voted for price control for the biosimilars. In this survey the most responses received were for the physician education on biosimilars as well as to improve the regulatory framework of the biosimilars while the least responses were for the price controls of the biosimilars.

Suggesting biosimilar products to be used

People's feelings about suggesting that biosimilar goods be used can vary based on what they know, have done, and think about biosimilars. Certain individuals could be welcoming of the notion of utilizing biosimilars as a safe and cost-effective option to reference biological products, whereas other individuals may be hesitant or doubtful about their safety and effectiveness. 85 of the pharmaceutical professionals who

participated in the survey responded that they were very likely to suggest the use of biosimilars to other people, 71 people responded that they were somewhat likely to suggest the biosimilars and two people responded that they will not suggest the biosimilar use.

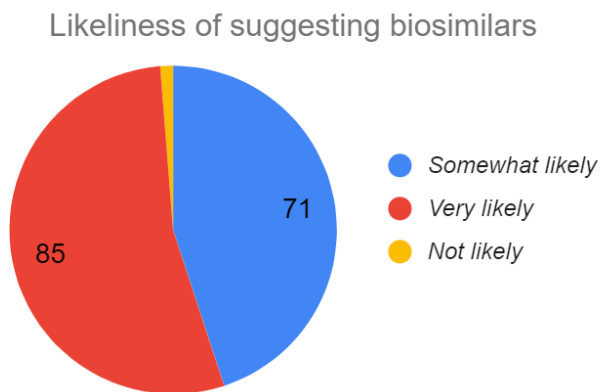


Figure 4. 12. Perspective of respondents in suggesting biosimilars.

Indian market for biosimilar investment

Being the pharmaceutical professionals of India, 86 of the respondents believe that the Indian market is attractive for investment in the biosimilar sector, 52 not sure of the Indian market for biosimilar investment and 20 people responded the Indian market is currently not attractive for biosimilar investment.

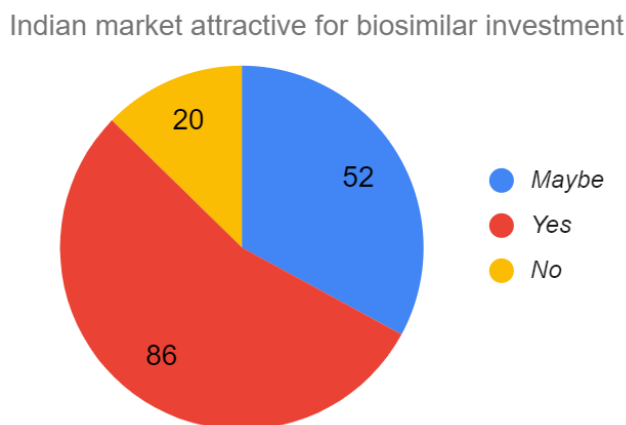


Figure 4. 13. Perspective of respondents on Indian market for biosimilar investment.

Steps by Indian government to encourage biosimilar adoption.

India's government has been diligently attempting to get biosimilars used so that more people can get the benefit of lifesaving therapies and healthcare prices go down. Also, biosimilars could offer many advantages over the original biologics, such as easier access for patients, enhanced safety accounts, and reduced costs. The Indian government can encourage the adoption of the biosimilar products enter the pharmaceutical market by taking some steps like to simplify the regulatory pathway for the biosimilars, increased the physician or patient awareness about the biosimilars, provide incentives for companies to invest in the biosimilar products development, promote the use of biosimilars in government run healthcare facilities. All of these 120 respondents voted to increase the awareness among the physician and patients about the biosimilar products which constitutes the major opinion followed by 80 responses for promoting the use of biosimilar products in the government run healthcare facilities, 93 responses for to simplify the regulatory pathway for biosimilar products and 62 responses to provide incentives for companies to invest in the biosimilar products which constituted the least responded step.

Future of biosimilars

The Indian market for biosimilars has been growing quickly, and it is likely to keep growing in the years to come. A study published by ResearchAndMarkets says that the Indian biosimilars industry will grow at a compound annual growth rate (CAGR) of 10.5% from 2021 to 2026 and hit USD 15.6 billion by 2026. This growth is caused by several things, like the rising number of people with persistent illnesses, the demand for inexpensive biological products, and the increasing number of biosimilars that are approved by regulatory authorities. When asked for the future of biosimilar products in India, 86 participants responded that it is very promising, and 72 participants responded that it is somewhat promising.

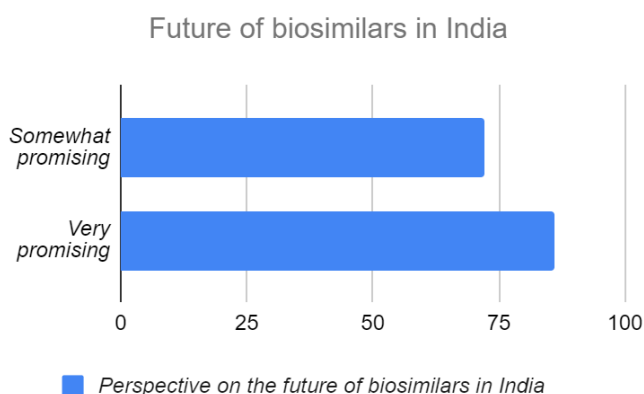


Figure 4. 14. Perspective of participants on the future of biosimilars in India.

4.2. Statistical analysis

In this research we have collected data on different variables which can be considered as challenges in the adoption of the biosimilar drugs in the Indian pharmaceutical market. With the help of multiple linear regression method, we can indicate if there is any significant relationships between different variables included in this study on biosimilars like the education level of the pharma professionals, the awareness among the pharma professionals and the willingness to adopt biosimilars. Multiple linear regression analysis was carried out considering the ‘pharmaceutical experience’ to be the dependent variable and the independent variables to be ‘level of awareness’ and the ‘willingness to adopt biosimilars’.

Respondent	Experience (scale: 1-4)	Familiarity (scale: 1-3)	Willingness to adopt (scale:1-3)
1	1	1	2
2	3	2	2
3	1	2	2
4	1	2	1
5	1	2	1
6	3	1	1
7	1	2	1
8	1	2	2
9	1	2	1
10	1	2	1
11	2	2	2
12	1	1	2
13	1	2	1
14	4	2	1
15	4	2	1

16	2	2	2
17	2	2	1
18	1	2	2
19	3	2	2
20	2	2	1
21	1	2	2
22	1	3	2
23	4	3	2
24	1	1	2
25	1	2	2
26	2	2	1
27	1	1	1
28	1	2	1
29	1	3	1
30	1	2	2
31	4	3	1
32	1	1	2
33	4	1	1
34	3	2	1
35	1	2	2
36	2	2	1
37	4	1	2
38	1	1	2
39	3	1	1
40	3	2	2
41	4	2	2
42	1	2	2
43	4	2	1
44	3	2	1
45	1	3	1
46	2	3	2
47	2	3	2
48	4	2	2
49	1	2	2
50	1	1	1
51	1	3	2
52	1	2	2
53	1	2	1
54	3	2	2
55	4	1	2
56	2	1	2
57	3	2	2
58	3	2	2
59	3	2	1
60	1	2	2
61	1	2	3

62	1	2	2
63	1	2	2
64	1	2	1
65	1	1	1
66	2	2	2
67	1	2	1
68	1	2	2
69	1	2	1
70	4	2	2
71	2	2	1
72	1	1	1
73	3	2	1
74	2	2	1
75	1	2	1
76	2	2	1
77	1	2	2
78	1	2	2
79	1	1	2
80	1	1	1
81	1	2	1
82	4	1	1
83	2	2	2
84	1	3	1
85	4	1	1
86	2	2	2
87	4	3	1
88	1	2	2
89	3	1	1
90	1	2	2
91	2	1	1
92	1	1	1
93	4	2	2
94	1	2	1
95	1	2	3
96	1	2	1
97	1	2	2
98	2	3	2
99	1	2	1
100	3	2	1
101	2	2	2
102	1	2	2
103	2	3	2
104	1	2	1
105	1	2	1
106	2	2	2
107	2	2	1

108	4	3	1
109	1	3	2
110	4	2	1
111	1	2	2
112	1	2	2
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115	1	2	2
116	2	2	1
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118	3	2	1
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121	1	2	1
122	1	2	1
123	3	1	1
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131	1	2	1
132	2	3	2
133	1	3	2
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143	1	2	2
144	1	2	2
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146	2	2	2
147	1	2	1
148	1	2	2
149	3	2	1
150	1	2	1
151	1	2	1
152	1	2	1
153	1	2	1

154	2	2	1
155	4	1	1
156	2	1	2
157	1	2	1
158	1	2	2

Table 4. 1. Data table for multiple regression analysis.

Parameters	Familiarity	Willingness to adopt
P- value	0.0846608	3.3662e-13
Average	1.905063	1.474684
n:	158	158
S:	0.538788	0.525761
Skewness	-0.0777198	0.368362
Normality	2.22e-16	4.441e-16

Table 4. 2. Data table for parameters in regression analysis.

Willingness to adopt = 1.218858 + 0.134287 Familiarity

Results of the multiple linear regression indicated that there was a very weak collective non-significant effect between the Experience, Familiarity, and Willingness to adopt, (F(1, 156) = 3.01, p = .085, R2 = 0.02, R2adj = 0.01).

Correlation matrix (pearson)

	Willingness to adopt	Experience	Familiarity
Willingness to adopt	1	-0.0755937	0.137614
Experience	-0.0755937	1	-0.0326341
Familiarity	0.137614	-0.0326341	1

Table 4. 3. Correlation matrix for variables.

The backward stepwise method is used to produce an initial screening of the predictors for multiple linear regression analysis of the data obtained.

1. Y and X relationship

R square (R²) equals 0.0189376. It means that the predictors (X_i) explain 1.9% of the variance of Y.

Adjusted R square equals 0.0126488.

The coefficient of multiple correlation (R) equals 0.137614. It means that there is a very weak correlation between the predicted data (\hat{y}) and the observed data (y).

2. Goodness of fit

Overall regression: right-tailed, $F(1,156) = 3.0113$, p-value = 0.0846608. Since p-value $\geq \alpha$ (0.05), we accept the H₀.

The linear regression model, $Y = b_0 + b_1X_1 + \dots + b_pX_p + \epsilon$, doesn't provide a better fit than the model without the independent variables resulting in, $Y = b_0 + \epsilon$.

The following independent variable is not significant as predictor for Y: **Experience**.

Therefore, it was excluded from the model.

The remaining variable: **Familiarity** is not significant.

The Y-intercept (b): two-tailed, $T = 7.957558$, p-value = 3.3662e-13. Hence b is significantly different from zero.

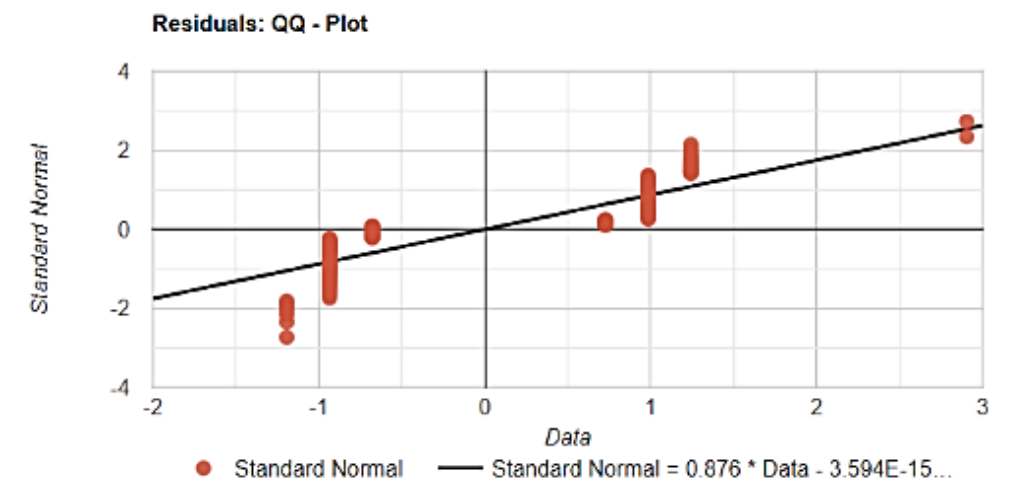


Figure 4. 15. Residuals: QQ Plot for Standard normal vs Data

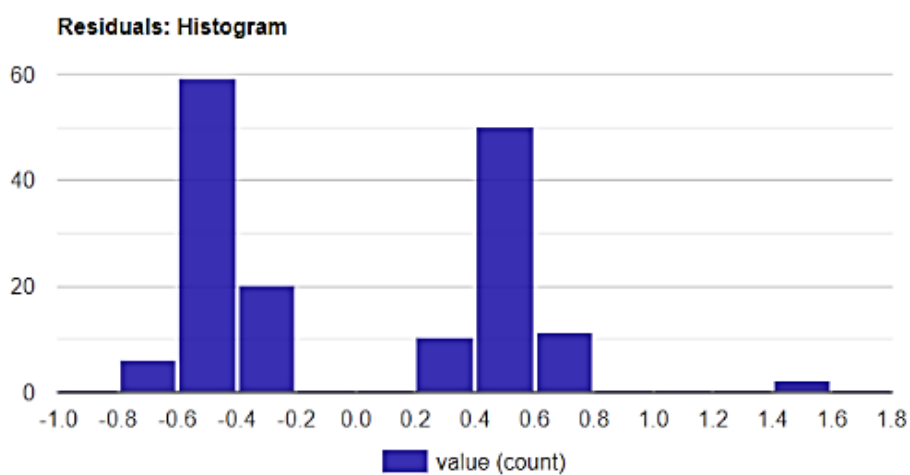


Figure 4. 16. Residuals: Histogram

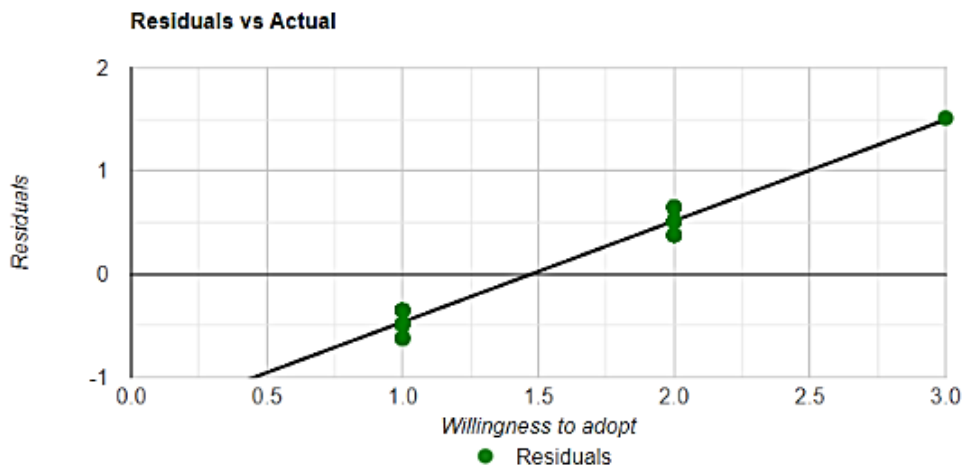


Figure 4. 17. Residuals vs Willingness to adopt Plot.

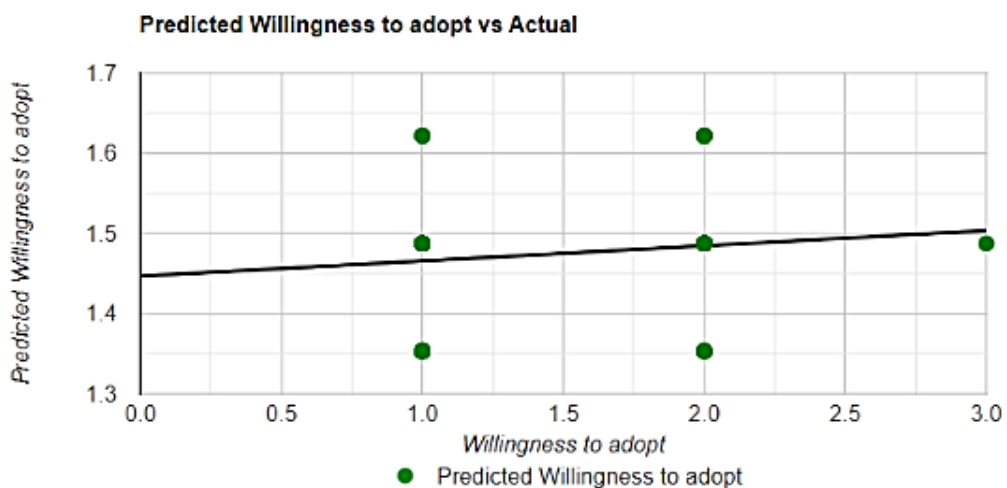


Figure 4. 18. Predicted willingness to adopt vs Actual Plot

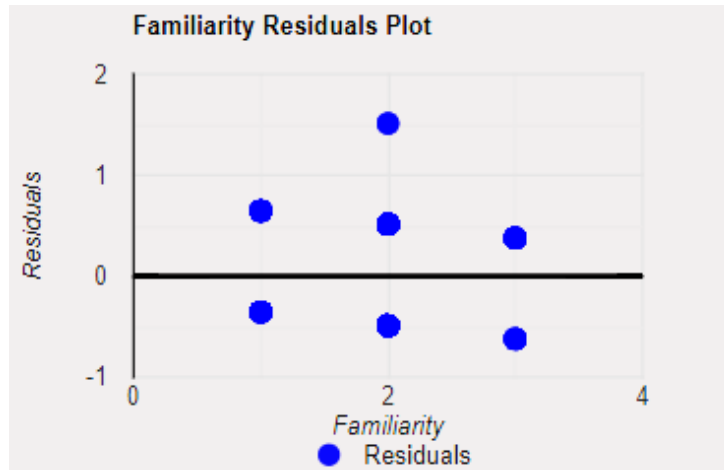


Figure 4. 19. Familiarity Residuals Plot

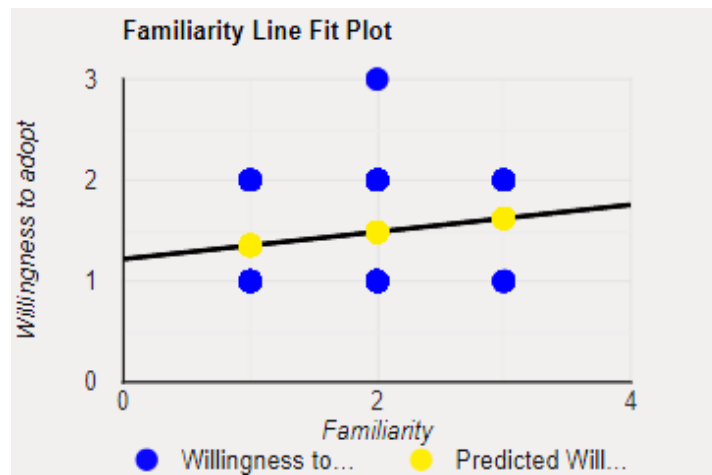


Figure 4. 20. Familiarity Line Fit Plot

4.3. Market analysis

Biosimilar milestones in India:

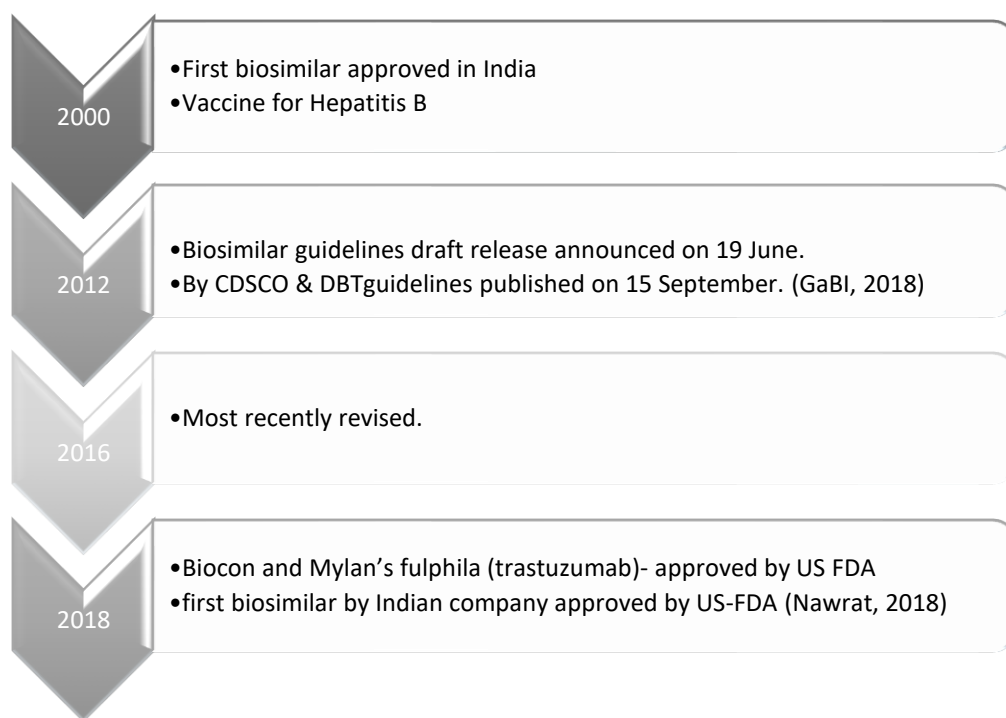


Figure 4. 21. Biosimilar milestones in India.

Year	No of biosimilars approved
2010	7
2011	7
2012	3
2013	12
2014	12
2015	15
2016	08
2017	05
2018	18
2019	03

Table 4. 4. Number of biosimilars approved in each year.

*“India has around **127 approved biosimilars**, propelled by companies like Reliance Life Sciences, Zydus Cadila, Intas, Biocon, Dr.Reddys, Sun Pharma, Lupin, etc. making it the country with the largest number of approved biosimilars after Germany and the US as per **Informa’s Pharma Intelligence report 2021**. The Indian biosimilar market was worth around \$300 million in 2015 and is expected to reach \$40 billion by 2030.” (P. Tejaswi, 2022).*

There are more than 2500 Indian biotechnology companies and more than 2700 start-ups. Biopharmaceuticals alone contributed about 62% in 2020.

Major biosimilar producing companies	Total approved biosimilars in India (till 2018)
Intas Biologicals	11
Biocon	9
Dr Reddy’s Laboratories	5
Zydus Cadila	7
Reliance Life Sciences	14
Lupin Pharma	5
Wockhardt	4

Table 4. 5. Major Pharmaceutical companies and their approved biosimilars.(Rupali Mukherjee/TNN, 2018)

Regulatory changes between India & other countries

India's legal requirements are still behind WHO norms. The Indian Parliamentary Standing Committee on Health and Family Welfare, which monitors the CDSCO, and the High Court of India criticized ISB legislation. In Europe, the typical clinically validating study for a trastuzumab biosimilar included at least 640 subjects, while ISBs typically had a maximum of 100 participants. After the revision of guidelines in order to address and improve the development and approval process of biosimilar products in India; it relieved manufacturers of having to conduct redundant studies; also there happened to be a necessity for phase IV post marketing surveillance with at least 200 participants within 2 years after market authorisation. Also, Indian companies can now create biosimilars based on EU, Japan, US, Canada, and Switzerland reference drugs which were not possible before. (Skylar Jeremias, 2020) After the US FDA approved biosimilar trastuzumab, we showed the product innovations require great dedication and large funds. (Nawrat, 2018) In Europe and America, for example, biosimilar officials usually look around 60 and 100

evaluations to make sure that a suggested biosimilar is the same as its reference medicine. They also watch the course of regulatory studies, make sure the drug is made and distributed according to standards, and keep an eye on pharmaceutical surveillance and modifications to the product over the life of the drug. For each biosimilar application, this takes well-resourced officials in Europe and America about a year, which is the same amount of time it takes to evaluate a new drug. (Paul Cornes, 2021) Indian medicines are now putting their best foot ahead because of the outbreak. The Indian authorities is telling Indian bioindustries that COVID-19 is a problem that can be turned into a chance to grow within the biosimilar sector. During the crisis, Indian stories about vaccines really stood out. Innovative business strategies and ways to make vaccines, generic drugs, and biosimilars that are made in the country were good. For example, Zydus Cadila worked on interferon -2b to be a therapy that could be sold as a biosimilar form. By the arrival of 2 more Indian industries to the international marketplace during the pandemic, Indian biopharma companies have changed the way vaccines and biosimilars are made. India also fights for a place in the international market through developing strategies that focus on the growing clinical trials and studies, making its workforce more skilled, using new production techniques, and so on. Because of all of these ground-breaking and multifaceted changes, India needs to change its rules for approving biosimilars.

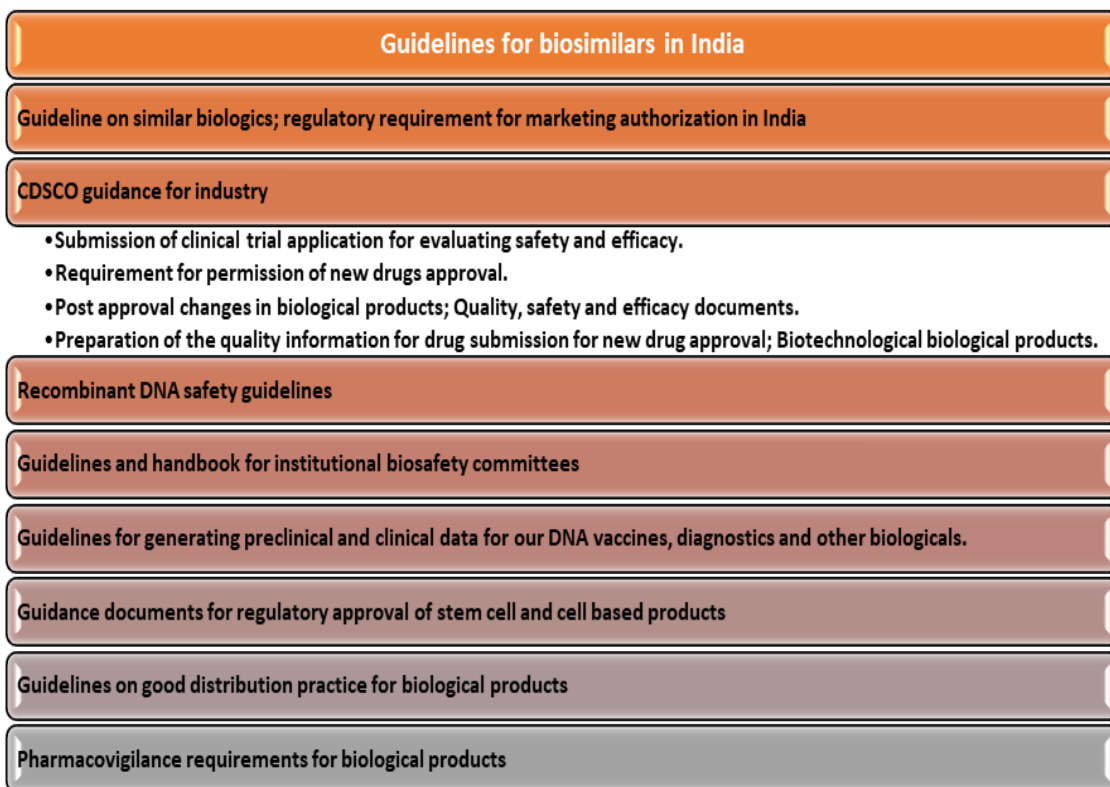


Figure 4. 22. Major guidelines for biosimilars in India.

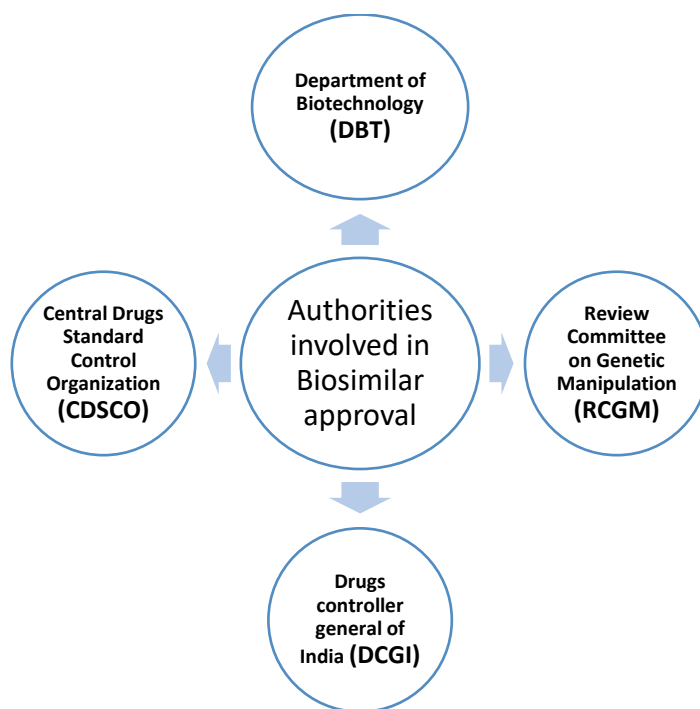


Figure 4. 23. Authorities involved in biosimilar approval.

4.4. Case study on safety & efficacy of biosimilars in India

A case study was carried out on the withdrawal of a biosimilar drug in 2014 by the DCGI of India. In 2014, one of the largest drug companies in India took its biosimilar drug trastuzumab off the Indian market because of worries about how safe and effective it was. Trastuzumab is a monoclonal antibody that is used to treat HER2+ breast cancer. The Drugs Controller General of India (DCGI) cleared this biosimilar in September 2013. It was the first biosimilar trastuzumab in the world. the monoclonal antibody trastuzumab, which is used to treat Metastatic Gastric Cancer (MGC), Early Breast Cancer (EBC), and Metastatic Breast Cancer (MBC), all of which overexpress the HER2 protein. It is a clean, clear to opalescent, colorless to slightly yellowish, no-preservative fluid that is given through an IV. The drug comes in a single-use bottle with 440 mg of trastuzumab in a 50 mL fluid. The drug is also sold in a 150 mg dose. The solution is meant to be diluted before it is given. The suggested amount is 6 mg/kg of body weight, given as an intravenous infusion once every three weeks. A lot of research and clinical tests, including a randomized, double-blind Phase III study in people with HER2-positive breast cancer, showed that this biosimilar was safe and worked well. The study showed that the biosimilar was not worse than Herceptin (the "originator drug") in terms of total response rate, progression-free survival, and overall survival. This biosimilar drug has side effects that are similar to those seen with Herceptin. These side effects may include response to the injection, cardiotoxicity, and pulmonary toxicity. During and after injection, patients should be closely watched for signs of infusion-related responses and cardiotoxicity, and their hearts should be checked regularly while they are taking this drug. It can't be given to people who are allergic to Trastuzumab, murine proteins, or any other part of the biosimilar product. It also can't be given to people who have severe shortness of breath at rest due to symptoms of advanced cancer and need extra oxygen treatment. As of September 2021, one dose of biosimilar Trastuzumab costs about INR 54,000-57,000, which is between \$730 and \$770. Roche's Herceptin (trastuzumab) costs about INR 120,000 (rupees) per 440mg dose in India. It's important to know that these prices can change based on things like dose, length of treatment, and area. (Tatum Anderson, 2017) The decision to take this biosimilar off the market was made after the Drug Controller General of India (DCGI) ordered a

national recall of the drug because some people who had taken it had bad reactions. The DCGI had looked at its manufacturing plant in Bangalore and found that the quality control method had some problems. Reports that biosimilar was less effective and potent than the reference product Herceptin led the government to take action. The Indian government did a study to compare the pharmacokinetic and pharmacodynamic qualities of biosimilar and Herceptin. They found that there were big changes between the two. The governing body also said that the product hadn't been tried enough for potency and immunogenicity, and there wasn't enough evidence to show that it was safe and worked. Later, after doing more research and getting permission from the government, the company put the biosimilar back on the Indian market.

The recall caused patients and health care workers in India to worry about how safe and effective biosimilars are. Some critics said that India's regulatory system for biosimilars wasn't strong enough to make sure that these drugs were safe and worked well. It showed that biosimilars in India need tighter rules and more control. The event made people think again about how important it is for biosimilars to have strong clinical trials and pharmacovigilance tools. The fact that the biosimilar trastuzumab was taken off the market showed how important strict regulatory monitoring and quality control are when making biosimilars. It also showed how important it is for patients, healthcare workers, and policymakers to learn more about the risks and benefits of biosimilars and be aware of them. In 2016, the Indian government made a new set of rules for biosimilars in reaction to the event. The framework has standards for clinical studies and pharmacovigilance, as well as rules for how biosimilars should be made and approved. The new system is meant to make sure that biosimilars are safe, work well, and meet the needed quality standards. It is also meant to encourage innovation and competition in the market.

4.5. Objective discussion

- To identify the current barriers that are preventing the widespread use of biosimilars in India and to analyze the current competitive landscape of the emerging biosimilar markets.

The major barrier in preventing the widespread use of biosimilars in India was found to be the lack of patient awareness and acceptance which is followed by concerns about safety and efficacy. When you look at the current competitive environment of India's new biosimilars market, you can see that both Indian and foreign companies are working hard to make and sell biosimilars there. Biocon, Dr. Reddy's Laboratories, Intas Pharmaceuticals, Lupin, Mylan, Pfizer, Roche, and Zydus Cadila are some of the big names. These businesses are working on making biosimilars for a variety of treatment areas, such as cancer, diabetes, and immunology. Most of the pharmaceutical professionals believe India has a promising future in the field of biosimilars and is attractive for investment.

- To evaluate the availability and accessibility of biosimilars in the Indian market.

The limited availability of biosimilars in India was seen to be the last concerned challenge the adoption of biosimilars. Biosimilars are becoming more and more common on the Indian market as more and more drug companies put money into developing and making them. But there are still a few problems with usability that need to be fixed. Biosimilars are often less expensive than their reference products, but many patients who need long-term care are still worried about their cost.

- To analyze the current regulatory framework for biosimilars in India and identify areas for improvement.

In India, the Central Drugs Standard Control Organization (CDSCO) works with the Ministry of Health and Family Welfare to make sure that biosimilars follow the rules. The method for approving biosimilars is built on steps, and the CDSCO sets out the requirements for each step. The regulatory system says that biosimilar makers must use a strict comparison exercise to show that the biosimilar is very similar to the reference product. This includes looking at a number of important quality factors, clinical and non-clinical data, and pharmacokinetic and pharmacodynamic research. The CDSCO looks at the data made by the maker to decide if the biosimilar meets the necessary standards. Even though the governing system is strong, there are still some things that could be done better. One of the biggest worries is that it's not clear whether biosimilars and their reference drugs can be used instead of each other.

There isn't a clear regulatory path for approving interchangeable biosimilars in India right now, which has made healthcare workers and customers confused. The amount of time it takes to approve biosimilars is another thing that could be made better. In India, it can take several years for a biosimilar to be cleared because it takes a long time to go through the legal process. This can make it hard for biosimilar drug makers to get into the market because the cost of research and approval can be high.

- To investigate concerns about the quality and safety of biosimilars in India and assess the validity of these concerns.

The concerns about the quality and safety of biosimilars in India was found to be one of the major challenges faced in the adoption of biosimilars in India. The worries that authorities and healthcare professionals throughout the world have regarding the efficacy and security of biosimilars are not specific to India. To guarantee that patients are receiving safe and effective care, it is crucial to determine if their concerns are legitimate. The possibility of manufacturing process variability, which can result in variations in the quality and effectiveness of the biosimilar compared to the reference product, is one of the key causes for worry. To address this issue, regulatory organizations have created stringent rules for the development and certification of biosimilars, including specifications for comparable analytical research and clinical trials. One such organization is the Central Drugs Standard Control Organization (CDSCO) in India. The possibility for immunogenicity, or the emergence of an immunological response to the biosimilar that might have negative consequences, is another matter of worry. Regulatory bodies demand thorough testing of biosimilars to make sure they have comparable levels of immunogenicity to the reference product in order to allay this worry. Regulatory authorities and manufacturers have taken action to address these issues and ensure that patients receive safe and effective therapy, despite the fact that worries regarding the quality and safety of biosimilars in India are legitimate. It's crucial to continuously monitor and keep an eye on biosimilars to make sure that any problems are found and taken care of right away.

- To develop recommendations for overcoming the barriers to the adoption of biosimilars in India and increasing the use of these products in the country.

To overcome the barriers in adoption of biosimilars in India, The following approaches could be taken into consideration like Public education initiatives because The adoption of biosimilars may be hampered by patients, medical professionals, and policymakers not being aware of their safety and effectiveness. Public education efforts can assist spread the word about the advantages of biosimilars and promote their use; Education and training on biosimilars In order for healthcare professionals to confidently prescribe and deliver these medications. Healthcare professionals can benefit from education and training programs that explain the similarities and differences between biosimilars and their reference products. The Indian government could take steps like the promotion of use of biosimilars in government run healthcare facilities to increase the adoption of biosimilars.

5. CONCLUSION

5.1. Summary of findings

The inferences from research showed 70% of the respondents were somewhat familiar with biosimilar products while approximately 80% of them knew that these were cheaper compared to their reference biologic medications. 71.5% believed that the similar biologic drugs had the same safety and efficacy compared to their originator product and this was mainly because they thought it involved comprehensive comparisons towards the original product during its regulatory process for approval testing and evaluation, there was no clinically meaningful differences and had minor changes in the structure of the drug molecule. The remaining individuals who stated that by a similar sword less safe and effective compared to the originator product Raised concerns over the regulatory network for safety and efficacy, interchangeability, potential risk of immune based adverse drug reactions and the complexity of biologic drugs. 81% responded that more education and awareness must be brought among healthcare professionals; 93.6% of the respondents stated more research and studies had to be carried out before implementing the biosimilar drugs in India; 51.8% had an opinion that there was no stringent regulatory network for the development and approval of biosimilar products in India. 32.2% said that the lack of patient awareness and acceptance was the major challenge in biosimilar adoption followed by 27.2% who stated that the concerns about safety and efficacy was the major challenge. The most suggested steps to improve the biosimilar adoption in India were providing physician education and providing patient education on biosimilars as well as improved regulatory framework for biosimilars. 53.7 % of the respondents were very likely to suggest or preferred the use of biosimilar products and 54.4% believe the Indian market had a great opportunity for biosimilar investments; 54.4% stated that the biosimilar products have a very promising future in India.

5.2. Conclusion

In conclusion, the study on challenges to biosimilar adoption in India shows a number of significant inferences. According to the survey, there are major challenges impeding the broad use of biosimilars in this country. These challenges include

doubts about their quality and safety, a lack of understanding and accessibility, and regulatory difficulties. These barriers prevent biosimilars from being widely used and reduce their ability to offer affordable therapeutic choices. The competitive environment of India's developing biosimilar sector offers encouraging growth prospects. The fact that numerous pharmaceutical firms are actively engaged in the creation and marketing of biosimilars suggests the possibility of greater competition in the market and increased accessibility to biologic medicines. There are few areas that could be improved in India's present regulatory environment for biosimilars. The confidence of healthcare professionals and patients in utilizing biosimilars can be further increased by streamlining the regulatory processes, increasing post-marketing surveillance, and making sure there are effective quality control methods. It is essential for biosimilars to be accepted more widely to address concerns about their reliability and safety. Comprehensive pharmacovigilance processes, adherence to high quality standards, and open sharing of data can all be used to identify and mitigate any potential hazards related to the use of biosimilars. It is crucial to concentrate on public awareness campaigns, healthcare provider education, regulatory incentives, supporting local manufacture, and building partnerships and collaborations in order to expand the usage of biosimilars in India. Together, these approaches may help to increase the availability of biologic medicines and encourage the use of biosimilars across the nation. Overall, the research offers insightful information about the prospects and problems facing the adoption of biosimilars in India today. India can fully utilize the benefits of biosimilars to improve patient access to life-saving medicines and support the sustainability of the healthcare system by addressing these problems and taking the necessary steps.

5.3. *Limitations & further research*

It is vital to recognize the research's limitations when discussing the challenges faced in the uptake of biosimilars in India. First off, as the study is based on survey data, it may be biased by responses or only reflect a portion of the pharmaceutical business as a whole. Although efforts were taken to guarantee a broad sample, it's possible that not all Indian pharmaceutical businesses will be able to fully apply the findings. The research may not adequately reflect the opinions and experiences of other

stakeholders, including patients, healthcare providers, and regulatory agencies, because it predominantly focuses on the viewpoint of pharmaceutical experts. A more thorough knowledge of the difficulties and prospects in the adoption of biosimilars might result from additional study involving a wider spectrum of individuals. Third, because the research was done at a certain period, it might not take into account potential changes and developments in the biosimilar market. To evaluate the long-term impact and address new difficulties, continual monitoring and research are required because the adoption of biosimilars is a dynamic process; Limited scope: The study might not have fully addressed all potential issues because it may have concentrated on a few particular aspects of the adoption of biosimilars. The generalizability of the results to the overall biosimilar landscape in India may be hampered by this restricted scope; Data availability: There may not be enough or inconsistent data on the use of biosimilars and other factors. As a result, the analysis may not be as thorough or accurate, and it may be difficult to draw firm conclusions from incomplete or fragmented data; External factors, such as socioeconomic, political, or cultural aspects that may have an impact on the adoption of biosimilars, may not have been taken into consideration in the research. These outside variables might affect the difficulties encountered and the approaches needed for a successful adoption; Lack of qualitative data: Depending on the research methodology, the emphasis may have been primarily on quantitative data, which may have restricted the exploration of complex influences or unique experiences relating to the adoption of biosimilars.

Despite these drawbacks, the report offers insightful strategic recommendations for overcoming the obstacles to the use of biosimilars in India. Stakeholders can create focused strategies and actions to encourage the widespread use of biosimilars and enhance patient access to reasonably priced biologic medicines by taking into account these constraints and building on the findings.

5.4. Applications

Our knowledge of the dynamics and processes involved in this complicated topic is deepened by the research on the challenges faced in the adoption of biosimilars in

India. The study throws light on the complex nature of biosimilar adoption in India by looking at many factors such as accessibility, availability, regulatory environment, quality, and safety. The study improves our comprehension of the barriers preventing the broad usage of biosimilars in India. It analyzes and investigates variables like patient and healthcare professional lack of understandings, difficulties with regulations, and market competition. This knowledge enables us to discern the intricate interactions between these variables and how they affect the adoption of biosimilars.

The study of challenges in the adoption of biosimilars in India adds various new insights and aspects compared to earlier research. Although several challenges and issues associated with the adoption of biosimilars have been discussed in earlier studies, this study offers a thorough and current overview of the situation in India right now.

5.5. Recommendations:

Although biosimilars go through stringent regulatory procedures and quality control checks, certain biosimilars have had quality problems and unfavorable side effects. These worries are principally brought on by variances in manufacturing procedures, potential deviations in efficacy and safety profiles from the reference biologics, and the requirement for continued post-marketing surveillance. To ensure the safety and efficacy of biosimilar medications in the Indian market, it is crucial to address these concerns through strong quality assurance systems, strict regulatory control, and ongoing monitoring. The availability of biosimilar medications is significantly influenced by elements including cost, accessibility in remote regions, and patient awareness and acceptance. By improving the networks of distribution, increasing affordability through controls on prices or other incentives, and improving healthcare infrastructure to provide fair access across the country, it is possible to increase the availability of biosimilars. The regulatory environment in India is developing and harmonizing with global norms, including standards established by regulatory bodies like the European Medicines Agency (EMA). However, there are several areas where the Indian regulatory structure should be improved, including the guideline clarity,

the approval process' transparency, and the standardized implementation of quality standards. By addressing these issues, India can improve the comparability of its biosimilar goods with European ones and further strengthen the regulatory framework's competency. In order to foster innovation and broaden the range of goods accessible, it is also important to support research and development in the field of biosimilars. creating a conducive environment for the use of biosimilars by working with industry stakeholders, healthcare providers, and patient advocacy organizations.

6. REFERENCE:

- Allocati, E. et al. (2020) 'Clinical Evidence Supporting the Marketing Authorization of Biosimilars in Europe'. *European Journal of Clinical Pharmacology*, 76(4), pp. 557–566. DOI: 10.1007/s00228-019-02805-y.
- Alten, R. and Cronstein, B.N. (2015) 'Clinical Trial Development for Biosimilars'. *Seminars in Arthritis and Rheumatism*, 44(6, Supplement), pp. S2–S8. DOI: 10.1016/j.semarthrit.2015.04.002.
- Blackstone, E.A. and Joseph, P.F. (2013) 'The Economics of Biosimilars'. *American Health & Drug Benefits*, 6(8), pp. 469–478.
- Camacho, L.H. et al. (2014) 'Biosimilars 101: Considerations for U.S. Oncologists in Clinical Practice'. *Cancer Medicine*, 3(4), pp. 889–899. DOI: 10.1002/cam4.258.
- Chopra, R. and Lopes, G. (2017) 'Improving Access to Cancer Treatments: The Role of Biosimilars'. *Journal of Global Oncology*, 3(5), pp. 596–610. DOI: 10.1200/JGO.2016.008607.
- Christl, L.A., Woodcock, J. and Kozlowski, S. (2017) 'Biosimilars: The US Regulatory Framework'. *Annual Review of Medicine*, 68(1), pp. 243–254. DOI: 10.1146/annurev-med-051215-031022.
- Cohen, H. et al. (2016) 'Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians'. *Advances in Therapy*, 33(12), pp. 2160–2172. DOI: 10.1007/s12325-016-0431-5.
- Dr Saritha R S (2022) *India's Growth in Biosimilars, Presence in Global Market*. Available at: <http://www.pharmabiz.com/ArticleDetails.aspx?aid=154337&sid=9> (Accessed: 25 March 2023).
- Dranitsaris, G., Amir, E. and Dorward, K. (2011) 'Biosimilars of Biological Drug Therapies'. *Drugs*, 71(12), pp. 1527–1536. DOI: 10.2165/11593730-000000000-00000.
- Godman, B. et al. (2021) 'Utilisation Trend of Long-Acting Insulin Analogues Including Biosimilars across Europe: Findings and Implications'. *BioMed Research International*, 2021, p. e9996193. DOI: 10.1155/2021/9996193.
- Gottlieb, S. (2008) 'Biosimilars: Policy, Clinical, and Regulatory Considerations'. *American Journal of Health-System Pharmacy*, 65(14_Supplement_6), pp. S2–S8. DOI: 10.2146/ajhp080210.
- Grabowski, H., Guha, R. and Salgado, M. (2014) (2) 'Biosimilar Competition: Lessons from Europe'. *Nature Reviews Drug Discovery*, 13(2), pp. 99–100. DOI: 10.1038/nrd4210.

Jang, M., Simoens, S. and Kwon, T. (2021) 'Budget Impact Analysis of the Introduction of Rituximab and Trastuzumab Intravenous Biosimilars to EU-5 Markets'. *BioDrugs*, 35(1), pp. 89–101. DOI: 10.1007/s40259-020-00461-8.

Joshi, S. (2011) 'Biosimilar Peptides: Need for Pharmacovigilance'. *The Journal of the Association of Physicians of India*, 59 Suppl, pp. 44–7.

Kale, D. (2019) 'From Small Molecule Generics to Biosimilars: Technological Upgrading and Patterns of Distinctive Learning Processes in the Indian Pharmaceutical Industry'. *Technological Forecasting and Social Change*, 145, pp. 370–383. DOI: 10.1016/j.techfore.2018.09.020.

Kang, H.-N. et al. (2020) 'The Regulatory Landscape of Biosimilars: WHO Efforts and Progress Made from 2009 to 2019'. *Biologicals*, 65, pp. 1–9. DOI: 10.1016/j.biologicals.2020.02.005.

Khraishi, M. et al. (2016) 'Biosimilars: A Multidisciplinary Perspective'. *Clinical Therapeutics*, 38(5), pp. 1238–1249. DOI: 10.1016/j.clinthera.2016.02.023.

Kumar, R. and Singh, J. (2014) 'Biosimilar Drugs: Current Status'. *International Journal of Applied and Basic Medical Research*, 4(2), pp. 63–66. DOI: 10.4103/2229-516X.136774.

Malhotra, H. (2011) 'Biosimilars and Non-Innovator Biotherapeutics in India: An Overview of the Current Situation'. *Biologicals*, 39(5), pp. 321–324. DOI: 10.1016/j.biologicals.2011.06.018.

McCamish, M. and Woollett, G. (2011) 'Worldwide Experience with Biosimilar Development'. *MAbs*, 3(2), pp. 209–217. DOI: 10.4161/mabs.3.2.15005.

Meher, B.R. et al. (2019) 'Biosimilars in India; Current Status and Future Perspectives'. *Journal of Pharmacy & Bioallied Sciences*, 11(1), pp. 12–15. DOI: 10.4103/jpbs.JPBS_167_18.

Misra, A. (2010) 'Are Biosimilars Really Generics?' *Expert Opinion on Biological Therapy*, 10(4), pp. 489–494. DOI: 10.1517/14712591003662615.

Misra, M. (2012) 'Biosimilars: Current Perspectives and Future Implications'. *Indian Journal of Pharmacology*, 44(1), pp. 12–14. DOI: 10.4103/0253-7613.91859.

de Mora, F. (2015) 'Biosimilar: What It Is Not'. *British Journal of Clinical Pharmacology*, 80(5), pp. 949–956. DOI: 10.1111/bcp.12656.

Nawrat, A. (2018) *Expanding from Generics to Biosimilars in India*. *Pharmaceutical Technology*. Available at: <https://www.pharmaceutical-technology.com/features/expanding-generics-biosimilars-in-india/> (Accessed: 7 May 2023).

Nellore, R. (2010) 'Regulatory Considerations for Biosimilars'. *Perspectives in Clinical Research*, 1(1), pp. 11–14.

Nupur, N. et al. (2016) 'Assessing Analytical Comparability of Biosimilars: GCSF as a Case Study'. *Journal of Chromatography B*, 1032, pp. 165–171. DOI: 10.1016/j.jchromb.2016.05.027.

P, R. and K, C. (2016) 'Biosimilars: An Emerging Market Opportunities in India'. *Pharmaceutical Regulatory Affairs: Open Access*, 05(01). DOI: 10.4172/2167-7689.1000165.

P. Tejaswi (2022) *Capitalising on Global Biosimilar Opportunity*. Available at: <https://www.biospectrumindia.com/views/17/20488/capitalising-on-global-biosimilar-opportunity.html> (Accessed: 26 March 2023).

Panda, S. et al. (2023) (1) 'Indian Biosimilars and Vaccines at Crossroads–Replicating the Success of Pharmagenerics'. *Vaccines*, 11(1), p. 110. DOI: 10.3390/vaccines11010110.

Paul Cornes (2021) *Column: India Struggles to Meet International Biologics Standards. Center for Biosimilars*. Available at: <https://www.centerforbiosimilars.com/view/column-india-struggles-to-meet-international-biologics-standards> (Accessed: 7 May 2023).

Rathore, A.S. (2015) 'Biosimilars in India'. *Journal of Proteomics*, 127, pp. 71–72. DOI: 10.1016/j.jprot.2015.08.005.

Rathore, A.S. et al. (2018) 'Development and Commercialization of Biosimilars in India: Current Regulatory and Clinical Experience'. In Gutka, H.J., Yang, H. and Kakar, S. (eds.) *Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development*. AAPS Advances in the Pharmaceutical Sciences Series. Cham: Springer International Publishing, pp. 653–674. DOI: 10.1007/978-3-319-99680-6_24.

Rémuzat, C. et al. (2017) 'Key Drivers for Market Penetration of Biosimilars in Europe'. *Journal of Market Access & Health Policy*, 5(1), p. 1272308. DOI: 10.1080/20016689.2016.1272308.

Rupali Mukherjee/TNN (2018) 'Desi Pharma Companies Top in Biosimilars Globally'. *The Times of India*, 29 October. Available at: <https://timesofindia.indiatimes.com/business/india-business/desi-pharma-cos-top-in-biosimilars-globally/articleshow/66407525.cms> (Accessed: 7 May 2023).

Saddique, A. (2017) 'Future of the Pharmaceutical Industry in the GCC Countries'. *Integrative Molecular Medicine*, 4, pp. 1–3. DOI: 10.15761/IMM.1000296.

Schiestl, M., Zabransky, M. and Sörgel, F. (2017) 'Ten Years of Biosimilars in Europe: Development and Evolution of the Regulatory Pathways'. *Drug Design, Development and Therapy*, 11, pp. 1509–1515. DOI: 10.2147/DDDT.S130318.

Sharma, A. et al. (2019) 'Ophthalmic Biosimilars: Lessons from India'. *Indian Journal of Ophthalmology*, 67(8), pp. 1384–1385. DOI: 10.4103/ijo.IJO_430_19.

Simoens, S. et al. (2018) 'How to Realize the Potential of Off-Patent Biologicals and Biosimilars in Europe? Guidance to Policymakers'. *Generics and Biosimilars Initiative Journal*, 7(2), pp. 70–75.

Singh, P., Desai, P. and Dutta, V. (2021) 'Rising Biosimilars in the Indian Biopharmaceutical Industry: Emerging Challenges and Way Forward'. *Technology Analysis and Strategic Management*, pp. 1–17. DOI: 10.1080/09537325.2021.1994139.

Skylar Jeremias (2020) Part 1: India Works on Guidelines for Biological Products. Center for Biosimilars. Available at: <https://www.centerforbiosimilars.com/view/india-works-on-its-guidelines-for-biological-products> (Accessed: 7 May 2023).

Tatum Anderson. (2017) Analysis: As Biosimilar of Key Cancer Drug Spreads, Where Is The Price Reduction? - *Health Policy Watch*. Available at: <https://healthpolicy-watch.news/analysis-biosimilar-key-cancer-drug-spreads-price-reduction/> (Accessed: 9 May 2023).

ThePharmapedia. (2023) Total Registered Pharmacist in India: An Overview | The Pharmapedia. Available at: <https://thepharmapedia.com/total-registered-pharmacist-in-india-an-overview-2022/news/> (Accessed: 2 May 2023).

Tsai, W.-C. (2017) 'Update on Biosimilars in Asia'. *Current Rheumatology Reports*, 19(8), p. 47. DOI: 10.1007/s11926-017-0677-1.

Tsiftoglou, A.S. et al. (2014) 'Demonstration of Biosimilarity, Extrapolation of Indications and Other Challenges Related to Biosimilars in Europe'. *BioDrugs*, 28(6), pp. 479–486. DOI: 10.1007/s40259-014-0109-y.

Vulto, A.G. et al. (2020) (11) 'Sustainability of Biosimilars in Europe: A Delphi Panel Consensus with Systematic Literature Review'. *Pharmaceuticals*, 13(11), p. 400. DOI: 10.3390/ph13110400.

Zuñiga, L. and Calvo, B. (2009) 'Regulatory Aspects of Biosimilars in Europe'. *Trends in Biotechnology*, 27(7), pp. 385–387. DOI: 10.1016/j.tibtech.2009.03.005.

7. APPENDIX

7.1. Questionnaire for survey

Dear Respondent,

This is a survey done in accordance with data collection for the research on “**Challenges in the adoption of Biosimilars in India**” as part of MSc Pharmaceutical Business & Technology degree, Griffith College, Dublin, Ireland.

Biosimilars are biological medicines closely similar to another approved medicine and can only be introduced to the market after the patent expiration of the standard medicinal product and the field of biosimilar drugs in India presents a lot of challenges for its hassle-free implementation. The purpose of this research include identifying various barriers to the widespread use of biosimilar drugs in India, evaluating their availability and accessibility, analyzing the current regulatory framework for biosimilar drugs, investigating quality and safety concerns, and developing recommendations for increasing the adoption of biosimilar agents in the country.

Hence this survey is carried out among different pharmaceutical professionals of India and the participation is voluntary. The participant data collected will have unified data protection as per the EU General Data Protection Regulation (GDPR) and all individuals have the right to withdraw from the research at any time. By participating in this survey, you may or may not benefit directly; but it will help us learn and assess the scenario of Biosimilar drugs in India and draw out some conclusions for the challenges faced for the same.

It will take only 5-6 minutes to complete this survey. Thanks a million for your participation.

For any queries, the participants can contact the researcher; Dr. Jayalakshmi P J (PharmD).

Email: jayalakshmipj@gmail.com

1. Which is your role in the Pharmaceutical/ Life science sector?
 - Pharmaceutical manufacture/supply chain/logistics
 - Pharmaceutical marketing/sales
 - Pharmaceutical research and development
 - Pharmaceutical quality assurance/ quality control
 - Pharmaceutical regulatory affairs
 - Others, specify:
2. How long is your experience in a life science/ pharmaceutical industry?
3. How familiar are you with biosimilars?
 - Not familiar

- Somewhat familiar
 - Very familiar
4. Are you aware of biosimilars as a cheaper alternative to original biologics?
- Yes
 - no
5. Do you think biosimilars have the same efficacy and safety as original biologics? Why or why not?
- Yes, reason:
 - No, reason:
6. Do you think there is enough awareness and education about biosimilars among healthcare professionals and patients in India?
- Yes
 - no
7. Are you familiar with any biosimilar products? If so, which ones?
- Yes (Can you specify:_____)
 - No
8. Have your company launched any biosimilars in India?
- Yes
 - No
9. If no, what are the reasons for not launching biosimilars in India? (Select all that apply)
- Lack of regulatory clarity
 - Limited market demand
 - Difficulty in manufacturing
 - Intellectual property concerns
 - Other (please specify)
10. If yes, what were the main challenges your company faced during the launch of biosimilars in India? (Select all that apply)
- Regulatory challenges
 - Pricing pressures
 - Lack of physician/patient awareness
 - Competition from established brands
 - Distribution challenges
 - Other (please specify)
11. What factors do you consider when choosing between a biosimilar and a reference biologic product? (Select all that apply)
- Efficacy data
 - Safety data
 - Cost

- Availability
 - Patient preference
 - Other (please specify)
12. What are your thoughts on the regulatory framework for biosimilars in India?
- Complex laws
 - No stringent regulation
 - Mention if anything particular that you have noticed:
13. Do you think there is a need for more clinical trials and research on biosimilars in India?
- Yes
 - No
14. What do you consider to be the biggest challenge in the adoption of biosimilars in India? (Select one)
- Lack of physician education on biosimilars
 - Lack of patient awareness and acceptance of biosimilars
 - Concerns about biosimilar safety and efficacy
 - Inadequate regulatory framework for biosimilars
 - Limited availability of biosimilars
 - Other (please specify)
15. What steps do you think can be taken to increase the adoption of biosimilars in India? (Select all that apply)
- Physician education on biosimilars
 - Patient education on biosimilars
 - Improved regulatory framework for biosimilars.
 - Increased availability of biosimilars
 - Price controls for biosimilars
 - Other (please specify)
16. How likely are you to prescribe or use a biosimilar product in the future?
- Very likely
 - Somewhat likely
 - Not likely
17. Do you think that the Indian market for biosimilars is currently attractive for investment?
- Yes
 - No
 - Not sure
18. What steps do you think the Indian government should take to encourage the adoption of biosimilars?
- Simplify the regulatory pathway for biosimilars

- Increase physician/patient awareness about biosimilars
- Provide incentives for companies to invest in biosimilars
- Promote the use of biosimilars in government-run healthcare facilities
- Other (please specify)

19. How do you see the future of biosimilars in India?

- Very promising
- Somewhat promising
- Not promising at all

Thank you for your participation!

Thank you for your time!