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REVIEW: A REPORT ON BIOLOGICS AND BIOSIMILARS

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ABSTRACT

Biologics are a special kind of medicine that is made using living cells like bacteria, yeast, or animal cells. They are mainly used to treat serious diseases such as cancer, diabetes, and problems where the immune system attacks the body. Unlike normal medicines, biologics are more complicated to make because they involve advanced technology. That's why they are usually more expensive and harder to produce. But even though they are costly, they work very well and have helped treat many difficult diseases effectively. When the patents of these biologic medicines expire, similar medicines called Biosimilars are developed. Biosimilars are almost the same as the original biologics in terms of safety, quality, and effectiveness. However, they are not exactly identical because they are made from living systems. To ensure they work properly, Biosimilars go through strict testing and approval processes before they are available for use. In this project we talk about the challenges in making them, like keeping the quality high and making sure they don't cause unwanted reactions in the body. One of the biggest benefits of biosimilars is that they cost less than original biologics. Because of this, more patients can afford important treatments, especially in places where healthcare is expensive. Even though some healthcare professionals have concerns about their use, awareness and proper knowledge can improve trust in Biosimilars. In conclusion, biologics and Biosimilars are important in modern healthcare. They not only give effective treatment but also make advanced medicines easier to get and more affordable for patients.

KEYWORDS: Biologics, Biosimilars, Biotechnology, Drug Development, Reference Product, Immunogenicity, Monoclonal Antibodies, Healthcare Access, Chronic Diseases.

1. INTRODUCTION

1.1 Biologics

Biologics are a group of medicines that come from living sources such as cells, bacteria, or yeast. Unlike conventional drugs that are made using chemical methods in laboratories, biologics are developed using biotechnology. Because

living systems are involved, these medicines are usually more complex in structure and behavior. **(U.S. Food and Drug Administration *et al.,* 2024).**

They are widely used to manage and treat serious health conditions like cancer, diabetes, multiple sclerosis, and autoimmune diseases. Even though they are very useful, their production is quite difficult. The manufacturing process must be closely monitored, since even a slight change can influence the quality, safety, or effectiveness of the final product **(Wolff-Holz *et al.,* 2019)**

Common examples include insulin, vaccines, monoclonal antibodies, and products derived from blood. To make biologics, scientists put selected genes into living cells, and these cells then make the needed proteins. These proteins are carefully purified and processed before being used as medicines for patients. **(Mitra, S *et al.,* 2022, Mirjalili, S.Z. *et al.,* 2021)**

1.2 Biosimilars

A Biosimilars is a medicine that is very similar to an already approved biologic drug (called the reference product). It shows no clinically significant differences in safety or effectiveness, making it equally effective for treatment. Biosimilars are made from living cells, just like the original biologic drugs **(U.S. Food and Drug Administration *et al.,* 2024).**

The use of Biosimilars has increased a lot since the first one was approved in Europe in 2006 **(Millán-Martín *et al.,* 2024)** Today, many Biosimilars are available in both Europe and the United States, helping make treatments more accessible and affordable **(Ismail, S *et al.,* 2023).**

Before approval, Biosimilars go through strict testing to ensure they match the reference product in quality, safety, and effectiveness**.** Although small differences may exist because they are made from living organisms, these differences do not affect how the drug works **(Janjigian, Y *et al.,* 2018).**

It is important to note that Biosimilars are not the same as generic drugs **(Gamez-Belmonte, R *et al.,* 2018).** Generics are exact chemical copies of simple drugs, while Biosimilars are complex and produced using living cells, making them similar but not identical to the original biologic **(A Ismail, A. M *et al.,* 2020, Agbogbo, F.K., *et al.,* 2019)**

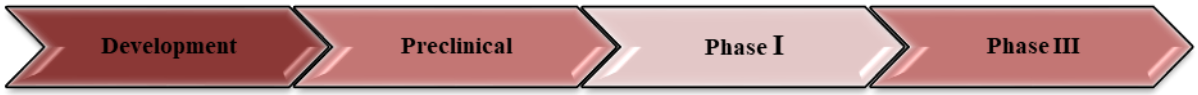
2. Comprehensive Study of Biosimilars and Biologics

2.1 Biosimilars development process

According Markus, R. the development of Biosimilars is different from creating a completely new biologic drug. Instead of starting from the beginning, scientists develop a product that is very similar to an already approved biologic medicine (called the reference product). The main aim is to show that the Biosimilars has the same quality, safety, and effectiveness as the original drug.**(Markus, R. *et al.,* 2017)**

According to Agbogbo, F.K. theDeveloping a brand-new biologic medicine is a long and complicated process. It usually takes about 10–12 years to bring a new drug to the market. This process includes discovering a new molecule, performing laboratory research, and going through several stages of clinical trials. All these steps are necessary to make sure the drug is safe and works properly before it is approved by regulatory authorities.**(Agbogbo, F.K. *et al.,* 2019)**

Reference biological product development



Pathway of Biosimilars development

Compared to original biologics, Biosimilars take less time to develop usually around 6–8 years. This is because researchers can use the existing knowledge of the reference product, so they do not need to repeat all the early research. Instead, they mainly focus on proving that the Biosimilars is highly similar to the original drug in terms of safety, quality, and effectiveness.**(Blackstone, E.A. *et al.,* 2013)**

The main purpose of developing a biosimilar is to prove that it performs in the same way as the original biological medicine and maintains comparable safety and effectiveness for patients **(Markus, R. *et al.,* 2017).**

Producing a biosimilar is still a complex and challenging task, even though it is based on an existing medicine **(Halimi, V. *et al.,* 2020).** The company that first developed the original biological drug usually keeps its manufacturing details confidential. Because of this, other manufacturers must carefully analyze the reference product and attempt to reproduce it using a scientific approach known as reverse engineering **(Socinski, M.A. *et al.,* 2015).**

During the development stage, researchers pay close attention to ensuring that the biosimilar closely matches the key quality characteristics of the original medicine. These characteristics include the drug's structure, how it functions, and its safety profile **(Markus, R. *et al.,* 2017).** Even very small variations can influence how the medicine behaves inside the human body, which is why strict control and detailed testing are required throughout the production process.**(Lee, S. J. *et al.,* 2021)**

3. Post-translational modifications (PTMs)

Post-translational modifications (PTMs) are chemical changes that take place in proteins after they are formed. In monoclonal antibodies, changes may occur during manufacturing, purification, and storage, which can influence their performance and stability.

Although the amino acid sequence determines the basic structure of a protein, PTMs play a major role in shaping its final structure, stability, and biological activity. Common PTMs include glycosylation, phosphorylation, and oxidation. **(Srivastava, A. *et al.,* 2022)** Among these, glycosylation is especially important because it significantly affects how the drug behaves in the body.**(Xie, H. *et al.,* 2010)**

Glycosylation is the process in which sugar molecules are attached to proteins. It mainly occurs in two forms: O-linked glycosylation, where sugars attach to serine or threonine residues, and N-linked glycosylation, where sugars bind to asparagine residues.**(Srivastava, A. *et al.,* 2022)** N-linked glycosylation is commonly found in antibody-based drugs and is critical for their therapeutic action.**(Xie, H. *et al.,* 2010)**

Because PTMs are complex, advanced analytical techniques such as mass spectrometry and chromatography are used to study them.**(Wang, T. *et al.*, 2024)** Peptide mapping is also applied to examine protein structure and detect any modifications or damage.**(Largy, E. *et al.*, 2017)**

Small variations in sample preparation or testing conditions can affect the results, so maintaining strict control during analysis is essential. **(Mouchahoir, T. *et al.*, 2018)**

Overall, careful analysis and monitoring of PTMs are necessary to ensure that biosimilars remain similar to their reference products in terms of safety, quality, and effectiveness.**(Millán-Martín, S. *et al.*, 2024)**

4. Demonstration of Analytical Similarity –Comparative Quality Studies

Analytical similarity studies are done to compare a biosimilar with its reference product (RP) to ensure both are highly similar in quality. These studies are repeated and use sensitive tests to detect even small differences.

Scientists perform tests like analytical characterization, bioassays, and receptor binding studies to check structure and function. Small differences (like glycosylation) are acceptable if they do not affect safety or effectiveness.. **(Declerck, P. *et al.*, 2017, Ishii-Watabe, A. *et al.*,2019)**

Techniques such as mass spectrometry, ELISA, and flow cytometry are used to compare properties like structure, activity, purity, and stability.**(Markus, R. *et al.*, 2017)** Pharmacokinetic (PK) studies also help understand how the drug behaves in the body.**(Declerck, P. *et al.*,2017)**

Purity and impurities must be carefully checked, as contaminants can cause immune reactions. Stability studies are also important to see how the product degrades over time.**(Markus, R. *et al.*, 2017)**

Biological functions like receptor binding, ADCC, and CDC are tested, especially for monoclonal antibodies. **(Ishii-Watabe, A. *et al.*, 2019)**Glycosylation is very important as it affects stability and activity, so it is considered a critical quality attributes (CQA).**(Markus, R. *et al.*, 2017)**

5. Post-Marketing Safety Monitoring of Biosimilars (Pharmacovigilance)

Pharmacovigilance (PV) is all about keeping medicines safe even after they are available in the market. It helps in identifying, evaluating, and preventing any risks linked to medicines so that patients stay protected.**(Beninger, P. *et al.*, 2018)** Since clinical trials are limited and may not detect rare side effects, continuous monitoring becomes very important. (**Blandizzi, C. *et al.*, 2017)** This is especially for biosimilars, which are developed in a shorter time than original products.**(Halimi, V. *et al.*, 2020)**

Once a biosimilar is approved, its safety is closely watched in real-life use.**(Markus, R. *et al.*, 2017)** This is important because these medicines can sometimes trigger immune reactions or other side effects. **(Singh, A. L. *et al.*, 2020)** Therefore, companies must have strong systems to track and study these issues over time.**(Beninger, P. *et al.*, 2018).**

Organizations like the European Medicines Agency play a key role in this process. They require companies to follow strict safety plans and report any side effects through systems like EudraVigilance.**(Ingrasciotta, Y. *et al.*, 2018)** However, it can sometimes be difficult to identify the exact cause of side effects, especially when patients are taking multiple medicines.**(Mellstedt, H. *et al.*, 2008)**

To improve safety monitoring, some medicines are marked with a black triangle symbol, which means they need extra observation.**(Kabir, E. R. *et al.*, 2019; Ascef, B. O. Lopes *et al.*, 2020)** Overall, biosimilars have shown good safety records so far, but ongoing monitoring—especially in children—is still very important. **(Ingrasciotta, Y. *et al.*, 2018)**

6. CONCLUSION

Biologics and Biosimilars are very important medicines in today's healthcare. Biologics are made from living cells and are used to treat serious diseases like cancer, diabetes, and immune system problems. They work very well, but they are expensive and difficult to make because their production needs advanced technology and careful control.

Biosimilars are made after the patent of the original biologic medicine ends. They are very similar to the original drugs in safety, quality, and effectiveness. Even though they are not exactly the same, they work in the same way in the body. Before coming to the market, biosimilars go through strict testing to make sure they are safe and effective.

One big advantage of biosimilars is that they are more affordable. This helps more patients get the treatment they need, especially in places where healthcare is costly. However, making biosimilars is still not easy. Scientists must carefully check their structure and quality to ensure they match the original product.

After approval, these medicines are continuously monitored through pharmacovigilance to track any side effects and ensure patient safety.

In conclusion, biologics and biosimilars are very useful in treating serious diseases. They not only provide effective treatment but also make medicines more affordable and accessible for people.

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