Awaken your mind to understand the value and potential of biosimilars

DISCOVER THE WORLD OF BIOSIMILARS
A biologic is a medicinal product that is derived from living organisms including humans, animals or microorganisms, and is used in treating many life-threatening and chronic diseases. However, the cost of biologics has often been high.\(^1,2\)

A biosimilar, falling under the category of biologics, is a biological medicinal product that is not identical, but highly similar to an already licensed biological medicinal product (reference product).\(^3,4\)

**From Biologic to Biosimilar**

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How are Biosimilars Different from Generics?

Unlike generics, biosimilars are large, highly complex molecules derived from living cells or organisms.

While producing generics is relatively simple, biosimilars require much more time and investment in the development process. If creating a generic drug is compared to designing a tricycle, developing a biosimilar medicine can be compared to building an airplane in terms of its complexity and size (Figure 1).5-7

**Figure 1.** The distinction between biosimilars and generic drugs is made from an important difference in their complexities: while generics can be fully characterised as identical to the originator product, biosimilars are highly similar with the originator product in terms of efficacy, safety, and quality.
The Value of Biosimilars

Cost Saving

Biosimilars can save more lives with less cost.

Biosimilars have the potential to offer cost savings for health services as they lower costs while offering highly similar efficacy and safety to that of the originator.

When a biosimilar is introduced to the market, price of the originator decreases due to competition. This leads to the overall decrease in treatment cost in the relevant category.

Increased Access

Such cost savings can consequently contribute to an increased access to biologics.

As healthcare costs continuously rise due to an aging population, today’s global healthcare systems carry the task in finding the solution. On that note, biosimilars are emerging as the best therapeutic option to reduce the healthcare costs.

With the expectation to play a major role in decreasing healthcare costs, biosimilars present an opportunity to alleviate pressure in the healthcare system. As a result, patients around the world will have greater access to effective biologic treatments.
Biosimilarity Based on Totality of Evidence

The development of biosimilars is based on a robust analytical comparability exercise which is aimed to establish the highly similar structural and functional features.

The U.S. Food and Drug Administration (FDA) recommends a totality of evidence approach for the development of biosimilars, which examines data from all aspects of the drug through comprehensive studies and pivotal clinical trials to evaluate the safety, efficacy, and immunogenicity (Figure 2).¹¹

Figure 2. The totality of evidence approach in biosimilar development programs recommended by the FDA.¹¹
Extrapolation of Indications

Extrapolation is the approval of a biosimilar for the treatment of all indications held by the originator even when therapeutic effects are not directly studied in a comparative clinical trial (Figure 3).

If a proposed biosimilar is truly highly similar to the reference product, it is expected that all aspects of its therapeutic effects would also be similar.

Extrapolation should be scientifically justified under the following conditions:12,13

- A step-wise approach with clinical trials that support similarity between the biosimilar and the originator in the most sensitive indication
- Same mechanism of action in all approved indications

Figure 3. Once extrapolation is granted, the clinical data from one indication can be extended and applied to other indications for which the reference product has been approved for.
Switching of Biosimilars

In order to switch from one drug to another, biosimilarity needs to be assessed based on criteria under a valid study design. The concept of switching includes both the narrow and the broad sense of switchability (Figure 4): \(^{14}\)

1) Switch from originator to biosimilar (O to B) and from biosimilar to originator (B to O)
2) Switch from originator to originator (O to O) and from biosimilar to biosimilar (B to B)

Switching should be acceptable and supported in accordance with regulatory frameworks (Figure 5). \(^{14}\)

The global experiences of switching from the reference product to a biosimilar have been positive and encouraging, suggesting no difference in efficacy, safety, and immunogenicity including antibody development. \(^{15}\)

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**Figure 4.** Concept of switching.

**Figure 5.** Switching requires biosimilars to go through regulatory pathways based on the totality of evidence approach in which high similarity to the originator product must be demonstrated.
1. How far are biosimilars known around the world?
Biosimilars are expanding into the global pharmaceutical market, and many international guidelines are also following this perceptual evolution towards the expanded biosimilar landscape. Results of a survey conducted among the members of the European Crohn’s Colitis Organization (ECCO) in 2015 show that 80.5% (compared to 39% in 2013) of prescribing physicians are confident that biosimilars are as safe as the reference biologic.17,18

2. What is the stance on biosimilars to payers, HCPs, and patients?
There has been a huge evolution in the perception of biosimilars amongst payers, HCPs (healthcare professionals), as well as patients. As payers are quite proactively promoting the uptake of biosimilars, HCPs’ perception has also changed positively in a very short timeframe. In turn, this has influenced the perception of patients. With the ever accumulating long-term data and clinical experience, it is anticipated that the confidence in biosimilars will continue to grow alongside with prescribing experience.19,20

3. Do biosimilars have the same safety and efficacy as their originators?
With their stepwise approach to establish biosimilarity, biosimilars are highly similar to their originators in physicochemical and biological terms. Robust physicochemical, biological, and non-clinical data ensure that the previously proven safety and efficacy of the originator can also be applied to the biosimilar.2-4

4. Why are biosimilars even more beneficial when planning long-term treatment of biologic therapy?
It is important to find ways to reduce healthcare budgets while providing high standards of care. Biosimilars have the potential to relieve pressure on healthcare costs and increase patient access to expensive biologic treatment. Healthcare system can achieve significant, sustained cost savings from the use of biosimilars.8-10

5. Who decides the prescription of biosimilars?
When switching to biosimilar from originator biologics, it is important that physicians and patients have a thorough discussion to set the best therapeutic goals together. Even when physicians are confident with the use of biosimilars, it is essential to carry out the discrete choice to switch and involve patients in the final decision.6
REFERENCES


