DUOPHARMA

A Quick Guide to Biosimilars

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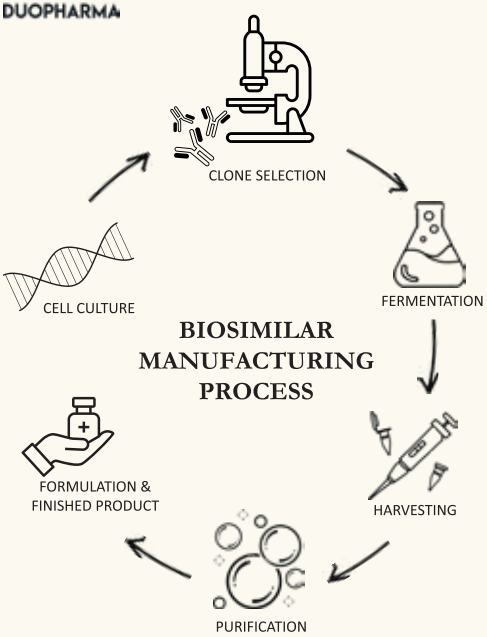
"Providing Smarter Solutions for Healthier Life"

The information contained on the booklet is not a substitute for medical advice or treatment. Please consult your physician for personalized medical advice.



What are biosimilars used to treat?

Biosimilars are used to treat a variety of medical conditions[1], which includes

1. Cancer
2. Arthritis
3. Diabetes
4. Kidney Disease

And many more.

What is a biosimilar?

A biosimilar is a type of a biologic drug, which is different from the traditional drugs that we normally consume. For instance, paracetamol that we consume are referred as small molecules made from chemicals, whereas biologic drugs or biosimilars are a type of protein from living organisms[1].

A biosimilar is an approved biotherapeutic product that is manufactured through a highly regulated and deliberated process[2]. A biosimilar is highly similar to a reference product, or products that were approved by health authorities. A biosimilar is a prescription drug that you can only get through a healthcare professional prescription.

Do biosimilar medicines represent generic versions of biological medicines?

Biosimilar medicines differ from generic medications, which precisely replicate existing non-biological drugs like aspirin. Unlike non-biological medications, biological medicines can't be replicated identically but are incredibly similar. Referring to a biosimilar as a generic biologic is scientifically inaccurate[4]. A biosimilar might not have the same exact structure as the original drug, while a generic small-molecule drug shares an identical active ingredient with the branded drug. It is important to note that while biosimilars may differ slightly in its chemical structure, they carry the same therapeutic efficacy as their reference product[4].

Why have biosimilar medicines been developed and approved?

Biological medicines used to treat diseases such as cancer and inflammatory diseases have a long, complex and time-consuming development process. Patient's access to such medicines is limited, and if available, will be costly. Biosimilar medicines can improve patient access to such treatments and are expected to be less costly[5], mainly because:

- The development process of biosimilars is based on the scientific knowledge obtained with the reference medicines. This saves time and cost on some clinical researches that may not be needed to repeat[3,5].
- Upon biosimilar introduction to the market, they need to compete with the reference medicine[4].

Biosimilars can be offered at a lower price, but quality is assured as they are manufactured following strict quality requirements, using state-of-the-art methods, and manufacturing facilities are subject to inspections like those of all other medicines[2,3,4].

Biosimilars go through a stringent regulatory approval process

Are biosimilars safe?

Biosimilars go through a stringent regulatory approval process prior to usage approval. Biosimilars undergo a comparability testing to ensure that it functions similarly to the reference product and undergoes clinical studies to evaluate the safety and efficacy levels. Manufacturing of biosimilars require strict quality control standards to ensure high consistent quality and safety[3,4].

The initial guidelines for reviewing and approving biosimilars were established by the European Medicines Agency in 2005. Subsequently, the World Health Organization (WHO) introduced its guidelines in 2010. Various global regulatory bodies have either developed or are in the process of refining approval protocols and pathways for biosimilars[2].

Compared to my usual treatment regime, what are the benefits of switching to biosimilar?

One of the primary advantages of using biosimilars is cost savings. Biosimilars are typically more affordable than their reference biologic counterparts, which can make them a more cost-effective option for both patients and healthcare systems. The price of biosimilars in the US is 10-45% lower than their reference products, while biosimilars are up to 35% cheaper in Germany[7]. The continued advancement of biosimilars is aimed at reducing the high costs associated with brand-name biologics and enhancing patient access to effective treatments at a more affordable price.

Lower costs associated with biosimilars can lead to improved access to biologic treatments for a broader patient population[3]. This is particularly important for individuals who may have been previously unable to afford or access these therapies.

Are biosimilars used in other countries?

The success of biosimilar use in Europe has been attributed to several contributing factors. This success can be linked to educational programs aimed at increasing knowledge of biosimilars among providers and patients. Additionally, the government's role as a central purchaser often offers health care at minimal or no cost to patients[6].

Is it safe to transition to a biosimilar after starting treatment with the reference product first?

All biosimilars registered in Malaysia exhibit safety profiles similar to their reference products and are interchangeable with those reference products[4]. However, the decision of switching from a reference product to a biosimilar should be determined by the prescribing physician in consultation with the patient. Cost, efficacy and safety are all valid concerns and the transition should be done with the patient's best interest in mind[5].

Most importantly, consult with healthcare providers on the best option suitable for your needs.

Sources:
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