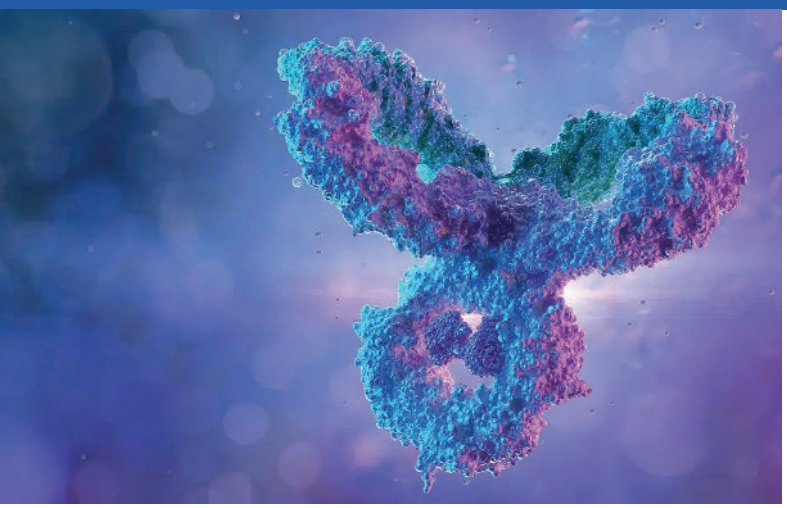
WHAT IS A BIOSIMILAR ?



RECOMBINANT TECHNOLOGY

"Bio" has its roots in the Greek language and means "life"; a biopharmaceutical is therefore a medicine that has been produced by living organisms or that has been derived from living organisms1. These biopharmaceuticals are also called biologics. Biologics are complex medicines with heterogeneous structures produced during complex and technologically advanced manufacturing processes with the help of what is called recombinant technology[2,3].

Biosimilars are complex medicines made from living cells or organisms

RECOMBINANT TECHNOLOGY

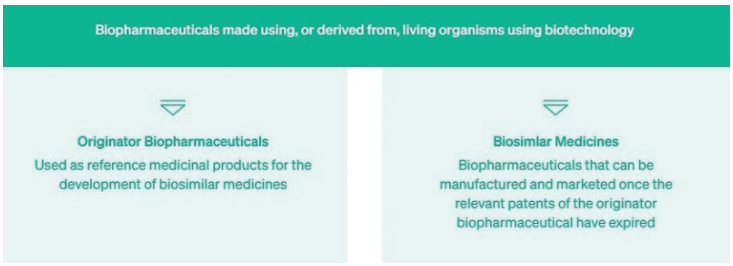
Biologics were first introduced in the 1980's. Examples include hormones such as insulin for diabetes as well as growth hormone.[4] Today biologics are one of the fastest growing segments of the pharmaceutical industry – in 2014, 7 out of 10 of the most sold medicines in Europe were biologics.[1] Biologics are also the fastest growing class of therapeutic products in the United States of America (USA) where they account for a substantial and increasing proportion of healthcare costs.[2] Today, biopharmaceuticals have become indispensable components of the clinician's armamentarium for the treatment of serious and chronic conditions such as diabetes, autoimmune diseases, and cancers.[3]

As with other inventions, original biologics are patent protected, meaning that copies or duplications of such a product cannot be made until the patent has expired. Once the relevant patents have expired, biologics can be manufactured and marketed by companies other than the company that originally introduced the biologic to the market. This has given rise to a novel subclass of biologics or biopharmaceuticals known as biosimilar medicines or biosimilars for short.[1, 4]

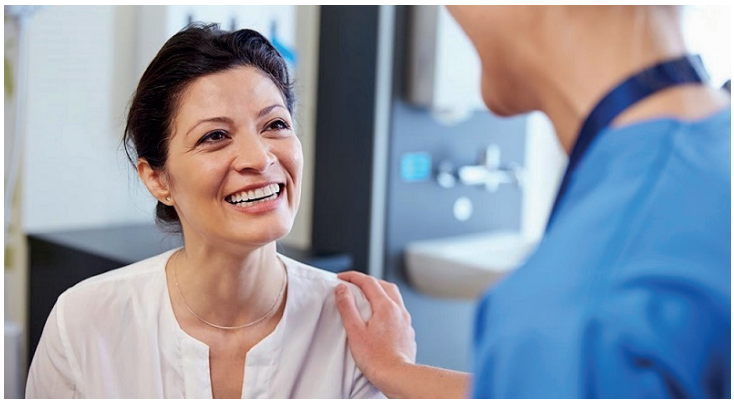
HIGHLY SIMILAR

The Biosimilar Medicines Group in Europe defines biosimilar medicines as versions of existing biopharmaceuticals, for which marketing exclusivity rights have expired, with proven comparable quality, efficacy, and safety to that of the originator reference medicinal products (in other words the originator biologic).[1] In the US, the Food & Drug Administration (FDA), defines a biosimilar as a biological product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components.[2] In other words, biosimilar medicines are highly similar in all essential aspects to an already approved biologic.[3,4]

From these definitions it can be seen that biosimilars are as effective and safe and of similar quality as the original product. One can therefore expect that, when using a biosimilar to treat a specific disease or condition, the clinical outcome will be similar to that obtained with the biologic. In fact, there are no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency.[2,4]



To demonstrate biosimilarity, the manufacturer must provide sufficient data and information to the FDA to prove that there are no clinically meaningful differences between the reference product and the proposed biosimilar.



BENEFITS OF BIOSIMILARS

Reduced Costs

On a clinician level, this may enable clinicians to initiate treatment earlier (because it is now more affordable), whereas on a collective (or medical scheme) level, it means that more patients can be treated within the same budget.[1] Due to the reduced costs, doctors are now in a position to prescribe high-quality, safe and efficacious medicines allowing more of their patients access to state-of-the-art treatment at earlier stages of diseases that are, in their course, disabling and/or life-threatening.

VALUE-ADDED SERVICES FOR PATIENT SUPPORT

In addition, the availability of biosimilars drives competition and this in turn produces increased treatment options and value-added services to support patient care.[5]

A further benefit of biosimilar products is that their development may use the latest state-of-the-art analytical and biotechnology methods, which may include some that might not have been available when the originator (or reference) product was first approved.[1]

Potential of biosimilars for patients, payers and providers

Additional treatment choices at potentially lower cost	May increase access to biologics, which may lead to better health outcomes overall
Possible savings and efficiencies	Offer a variety of therapeutic options