About Biologics " >

Biologics have revolutionized the treatment and prevention of many disabling and life-threatening diseases. A biosimilar is a follow-on medicine of an existing biologic for which the patent has expired and exclusivity has been lost.

Biologics

Biologic medicines are developed using a complex process, as they are made by or extracted from living organisms, tissues, or cells.[1] These medicines have revolutionized the treatment and prevention of many disabling and life-threatening diseases in areas such as endocrinology, oncology, immunology, ophthalmology and dermatology.[1]

However, as developing and supplying these medicine is complex, biologics are driving the rising cost of healthcare, and this may restrict patient access to potentially life-saving treatments.[2]

The prospect of more affordable options that are as safe and efficacious as the references medicines, opens up opportunities for healthcare systems to expand access to biologics for more patients, free up resources for investment in new areas, and relieve pressured healthcare budgets.

Biosimilars

A biosimilar is a successor to a biologic medicine (also known as ‘reference medicine’) for which the patent has expired and exclusivity has been lost[3,4].

To be approved for use, a biosimilar has to match the reference medicine in terms of quality, safety and efficacy, demonstrating no clinically meaningful differences. This is based on the “totality of evidence” concept

using advanced analytical and clinical studies.[5,6] Find out more about the Development of Biosimilars here.

Depending on policies and systems implemented by countries' healthcare authorities, biosimilars have the potential to improve access challenges faced by patients, generate cost savings for healthcare systems and increase treatment options for healthcare professionals.

Benefit to patients	The introduction of affordable, high-quality biosimilars can expand access to potentially life-changing medicines for patients worldwide[7]	Biosimilars introduce competition, which leads to innovation such as enhancements of existing medicines and development of new treatments[8]
Benefit to payors	Biosimilars introduce competition, increasing affordability of biologics which delivers savings for healthcare systems, helping to liberate resources that can be used to improve care and fund next-generation medicines	It is estimated that biosimilars can lead to EUR 280 billion cumulative savings between 2021 and 2025 worldwide[9]
Benefit to Healthcare professionals	Introduction of biosimilars drives competition, resulting in increased treatment options and value-added services to support patient care and the healthcare community	Between 2021 and 2029, more than 120 biologic medicines will lose exclusivity – twice the number of biologics that have come off patent over the past decade.[10]

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