Addressing the rising cost of biological medicines has become a priority for governments and healthcare systems around the globe. Biosimilar medicines are providing more cost-effective biological treatments, but what are biosimilar medicines, and how do they meet this challenge?
In the absence of competition, biological medicines place a huge financial burden on global healthcare systems.

The addressable* biosimilar medicines market in the US and the five largest European markets, 2016–2020:

**US biosimilars 10-year savings:** 12.6 billion USD in 2021 and biosimilars projected savings by 2025: 133 billion USD***

Potential combined savings of France, Germany, Italy, Spain and the UK: 50 billion USD**

Availability of biosimilar medicines offers an economic benefit to healthcare systems, thereby in part addressing the issue of new, innovative, high-priced medicines¹

Footnotes: *Addressable market is calculated based on projected growth of originator market without biosimilar entry. Growth rate is based on historical growth and analogue analysis.
**Conversion rate: Conversion rate: 1 EUR = 1.091 USD.
References: QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. ***IQVIA 2021
In many developed markets, the opportunity for biosimilar medicines by 2026 will continue to grow significantly

- In the next five years to 2026, biological medicines are expected to lose exclusivity and result in $70 billion lower brand spending, compared to an impact of $25 billion in the past five years.¹

The introduction of biosimilar frameworks is delivering tangible results for healthcare systems, with the next decade with biologic medicines representing close to half of total competition opportunity in the pharmaceutical market.

Europe was the first region in the world to develop a framework for biosimilar medicines

- A biosimilar medicine is a biological medicine that is developed to be highly similar to an existing biological medicine (the ‘reference product’)

- Biosimilar medicines can be marketed once all regulatory exclusivity and intellectual property right periods for the reference product have expired

- In 2004 and 2005, Europe was the first region in the world to develop a legal, regulatory, and scientific framework for approving biosimilar medicines

- Within 10 years, the EU framework moved from a science-driven, conceptual approach to a science-driven, knowledge-based approach

- Since 2006, EU-approved biosimilar medicines have already generated more than 2 billion cumulated patient treatment days of safe clinical experience

Scientific, regulatory, and legal frameworks have now been established around the world (1)

Europe
First legal framework for approving biosimilar medicines – directive 2001/83/EU¹

Japan
Guideline for the quality, safety and efficacy assurance of follow-on biologics²
Q&A regarding guidelines³

WHO
Guidelines on evaluation of SBPs⁴

Korea
Legislative basis for regulating biosimilar medicines established⁵
Guideline on evaluation of biosimilar products issued along with Q&A⁵

USA
BPICA signed as part of the Affordable Care Act⁶

Abbreviations: BPICA, Biologics Price Competition and Innovation Act; EMA, European Medicines Agency; MHLW, Ministry of Health, Labour and Welfare; SBP, similar biotherapeutic products; WHO, World Health Organisation.

Scientific, regulatory, and legal frameworks have now been established around the world (2)

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<th>2010</th>
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<td><strong>Canada</strong></td>
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<td>HC Guidance document: Information and submission requirements for biosimilar biologic drugs</td>
<td>TGA regulation for biosimilar medicines</td>
<td>Revision of EU biosimilar overarching guidelines</td>
<td>Guidelines revised to reflect current thinking of MFDS</td>
<td>Q&amp;A regarding guidelines</td>
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<td>Biosimilar guidelines released by ANVISA</td>
<td>Draft FDA guidelines released</td>
<td>Guideline including monoclonal antibodies and allowing extrapolation of indications</td>
<td>FDA release final guidances</td>
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Biosimilar medicines offer more cost-effective alternative options and thereby enhance competition in the marketplace

**Abbreviations:** ANVISA, The Brazilian Health Regulatory Agency; EMA, European Medicines Agency; FDA, Food and Drug Administration; HC, Health Canada; JGA, Japan Generic Medicines Association MFDS, Ministry of Food and Drug Safety; MCCZA, Medicines Control Council of South Africa; TGA, Therapeutic Goods Administration.

Scientific, regulatory, and legal frameworks have now been established around the world (3)

Biosimilar medicines offer more cost-effective alternative options and thereby enhance competition in the marketplace

* Revision of Health Canada Guidance for Sponsors
Scientific and regulatory frameworks continue to evolve

This evolution is driven by the billions of patient treatment days of experience, as well as improvements in regulatory processes, analytical science and characterisation technology.

Opportunity to generate competition in the biologics space with 600 biosimilar approvals covering over 10 therapeutic areas

A. Canada
B. USA
C. Brazil
D. Argentina
E. European Union
F. Switzerland
G. Serbia
H. Montenegro
I. Jordan
J. South Africa
K. Japan
L. South Korea
M. Malaysia
N. Taiwan
O. Australia
P. Singapore

Source of data: IGBA membership, Swissmedic and HSA Singapore

2 November 2022
Savings produced by biosimilar medicines have contributed to the sustainability of healthcare systems

- Biosimilar medicines could produce cumulative savings of nearly 107 billion USD in Europe and the US combined, between 2015 and 2020*¹

Potential cumulative savings from eight key biosimilar medicines in France, Germany, Italy, Spain, the UK, and the US¹

Biosimilar medicines have already delivered savings of around 1.6 billion USD in the five largest European markets alone²

Footnotes: *Savings potential in five largest European markets plus US biosimilar accessible market dependent on change in price per treatment day. The accessible market analysis is based on adalimumab, insulin glargine, etanercept, infliximab, rituximab, peg-filgrastim, trastuzumab, and follitropin alpha. Savings potential in biosimilar accessible market at different price levels is calculated based on extrapolated size of the originator market between 2016 and 2020, and historic CAGR and analogues. Accumulation of savings potential between 2016–2020 is shown. Conversion rate: 1 EUR = 1.091 USD.

Globally, biosimilar medicines have the potential to offer healthcare systems huge savings for the same outcomes.

**Canada - $94 million CAD**
Combined savings from use of etanercept, filgrastim, infliximab and insulin glargine biosimilars in 2018.

**U.S.A – 12,6 billion USD**
Biosimilars 10-year system savings: 12,6 billion USD in 2021. Biosimilars projected system savings by 2025: 133 billion USD.

**Europe – 15 billion EUR**
between 2016 and 2020 based on a 30% price reduction across eight key reference products, driven by biosimilar competition.

**Japan – 46 billion JPY**
between 2017 and 2019 with CAGR 61%.

**South Africa – 6.4 million USD**
(84.5 million Rand) per annum.

A 50% price reduction following the introduction of the biosimilar trastuzumab would translate into 670 more patients being treated (2016).

Biosimilar medicines represent a cost-effective alternative to the reference products.

More people globally will access relevant biological medicines as biosimilar competition unfolds

- Key upcoming biosimilars are expected to reach patients throughout the next five years, particularly to treat patients living with cancer and autoimmune diseases

Cumulated global biosimilar savings estimated to 215 billion USD over 2021-2026\(^1\)

Global annual savings could exceed $100 billion in 2026 as some of the largest spending biologic molecules will face biosimilar competition during this period\(^1\)

Access to relevant biologic medicines will open up to more people globally, as costs of treating patients for cancer or autoimmune disorders are reduced to affordable levels for both patients and governments across all countries\(^1\)

Summary: Biosimilar medicines — rising to the cost challenge

In the absence of competition, biological medicines place a **huge financial burden** on global healthcare systems

In many developed markets, key biological medicines are **coming off patent**

Patent expiry presents a **significant and growing opportunity** for the introduction of biosimilar medicines

Around the globe, biosimilar medicines are being introduced, **enhancing competition** in the marketplace and **access for more patients**

In the five largest European markets alone, biosimilar medicines have saved **1.6 billion USD**

The **potential savings** offered by biosimilar medicines by **2025** could help support the **long-term sustainability** of healthcare systems