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 many developed markets, the opportunity for biosimilar medicines by 2027 will continue to grow significantly

- **Global biotech spending** is expected to exceed $660Bn by 2027 (35% of global medicines spending)\(^1\)
- In the next five years to 2027, biological medicines are expected to lose exclusivity and result in $65 billion lower spending\(^1\)

The introduction of biosimilar frameworks is delivering tangible results for healthcare systems which use them. The next decade offers massive opportunities 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 4.5 billion cumulated patient treatment days of safe clinical experience

Europe has pioneered the development, licensing, and marketing of biosimilar medicines

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

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

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

USA
BPICA signed as part of the Affordable Care Act

Europe
First regulatory and scientific framework for approving biosimilar medicines

WHO
Guidelines on evaluation of SBPs

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

Japan
Q&A regarding guidelines

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)

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

China
First biosimilar guidance published

Singapore
Update of biosimilar guideline, first published in 2011

Saudi Arabia
Update of biosimilar guideline, first published in 2010

Egypt
Update of biosimilar guideline, first published in 2013

Taiwan
Update of biosimilar guideline, first published in 2008

Canada*
Revision of Health Canada Guidance for Sponsors

India
Update of biosimilar guideline, first published in 2012

China
Biosimilar guidance updated

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

- UK: Revised MHRA guidance on the licensing of biosimilar products¹
- WHO: Revision ongoing of the WHO guidelines on evaluation of similar biotherapeutic products (SBP)²
- WHO: Revised WHO Guideline on evaluation of biosimilars⁴

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 more than 800 biosimilar medicines covering over 10 therapeutic areas

A. Canada  23
B. USA  51
C. Mexico  41
D. Brazil  81
E. Argentina  53
F. European Union  26 (2022)
G. UK  96
H. Switzerland  21 (2022)
I. Serbia  19
J. Turkey  62
K. Montenegro  37
L. Jordan  31
M. Saudi Arabia  24
N. Egypt  34
O. South Africa  38
P. Japan  40
Q. South Korea  31
R. Malaysia  29
S. Chinese Taipei  21
T. Australia  26 (2022)
U. Singapore

Source of data: IGBA membership and National Regulatory Authorities

19 October 2023
Savings derived from biosimilar medicines use have contributed to the sustainability of healthcare systems

- In 2012, estimates suggested savings could be in the range of €12–€34 billion by 2020\(^1\)
- As of 2022, the cumulative savings at list prices from the impact of biosimilar competition in Europe reached over €30 billion\(^1\)

References:

Biosimilar medicines have already delivered savings of over 30 billion EUR in Europe alone\(^2\)
Globally, biosimilar medicines have the potential to offer healthcare systems huge savings for the same or better 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 – >30 billion EUR**
between 2006 and 2022

**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 biosimilar medicines are expected to reach patients throughout the next five years, particularly to treat patients living with cancer and autoimmune diseases

**Incremental savings** from biosimilar medicines are expected to be a cumulative $383Bn globally from 2023 to 2027.¹

Global annual savings could exceed $100 billion in 2026 & 2027 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\(^1\)
- In many developed markets, key biological medicines are coming off patent\(^1\)
- Patent expiry presents a significant and growing opportunity for the introduction of biosimilar medicines\(^1,3\)

Around the globe, biosimilar medicines are being introduced, enhancing competition in the marketplace\(^1\) and access for more patients\(^3\)

European markets alone have cumulated over 30 billion EUR savings from biosimilar medicines competition since 2006\(^2\)

The potential savings offered by biosimilar medicines by 2027 could help support the long-term sustainability of healthcare systems\(^1\)