

Chapter 3

Biosimilar medicines — rising to the cost challenge

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

- By introducing competition, the savings generated could be used to treat patients in need in Europe and the USA, who are currently denied access to biological medicines

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

US biosimilar savings totalled 2,2 billion USD in 2019 and 4,5, billion over the past 10 years***



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

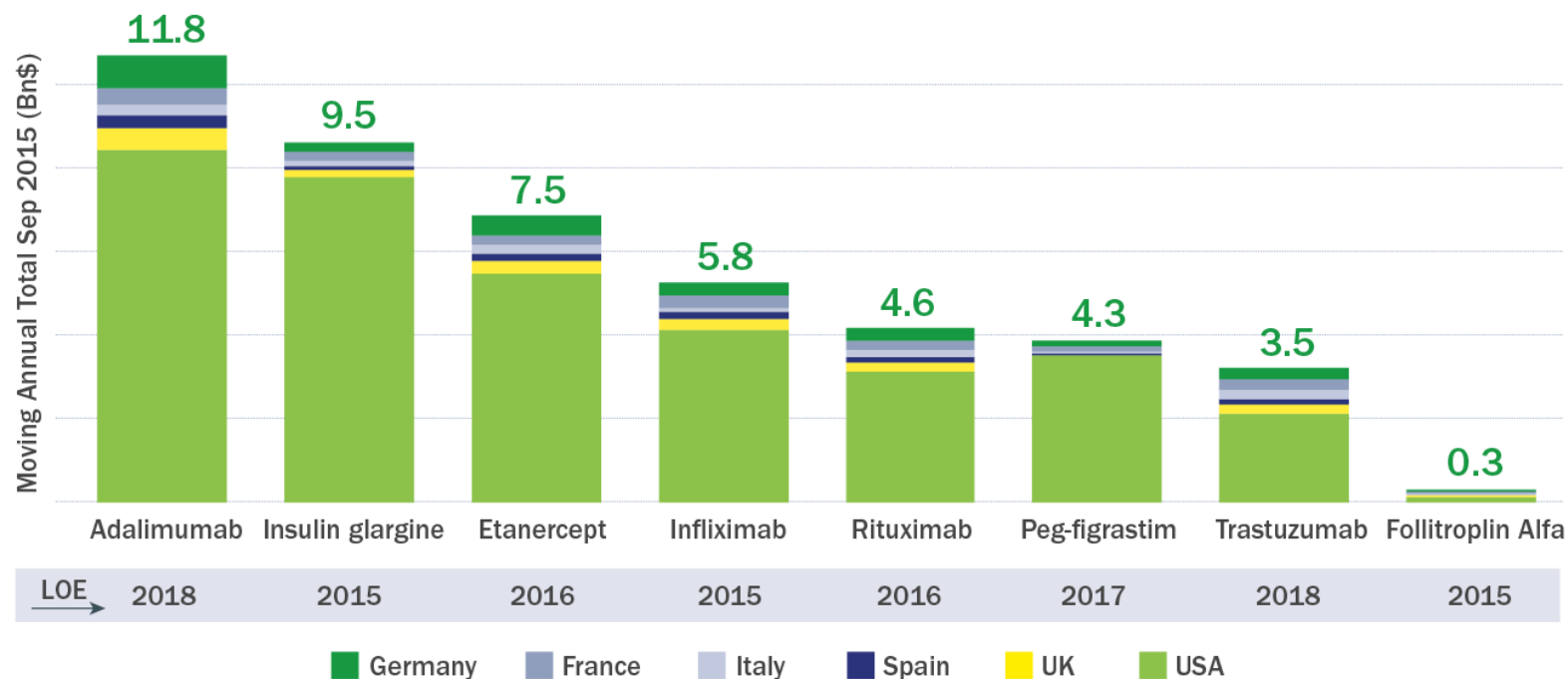
Footnotes: *Addressable market is calculated based on projected growth of originator market without biosimilar entry. Growth rate is based on historical growth and analogue analysis.

**Conversion rate: Conversion rate: 1 EUR = 1.091 USD.

References: QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. *** [IQVIA 2020 Report](#)

In many developed markets, eight prominent biological medicines came off patent between 2015 and 2020

- US and European* sales of key biological medicines have lost patent protection between 2015 and 2020:¹



The large number of biological medicines coming off patent presents a significant opportunity for the introduction of biosimilar medicines

Footnotes: *Values from five largest European markets. Conversion rate: 1 EUR = 1.091 USD.

Abbreviations: LOE, loss of exclusivity.

References: QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: <http://bit.ly/2es03mY>. Accessed July 2017.

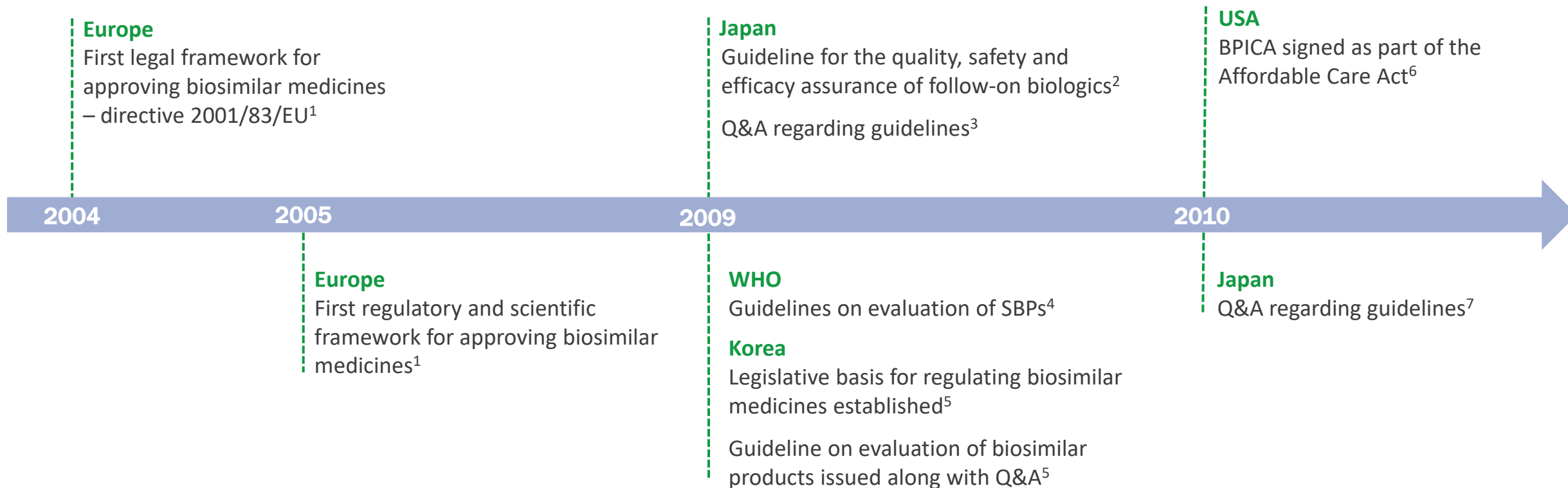
Europe was the first region in the world to develop a framework for biosimilar medicines

- A **biosimilar medicine** is a biological medicine that is developed to be **highly similar to an existing biological medicine** (the ‘reference product’)¹
- Biosimilar medicines can be marketed once all regulatory exclusivity and intellectual property right periods for the reference product have expired¹
- In 2004 and 2005, **Europe was the first region in the world** to develop a legal, regulatory, and scientific framework for approving biosimilar medicines²
- Within 10 years, the EU framework moved from a science-driven, conceptual approach to a science-driven, **knowledge-based approach**³
- Since 2006, EU-approved biosimilar medicines have already generated more than **2 billion** cumulated **patient treatment days of safe clinical experience**¹

Europe has pioneered the development, licensing, and marketing of biosimilar medicines²



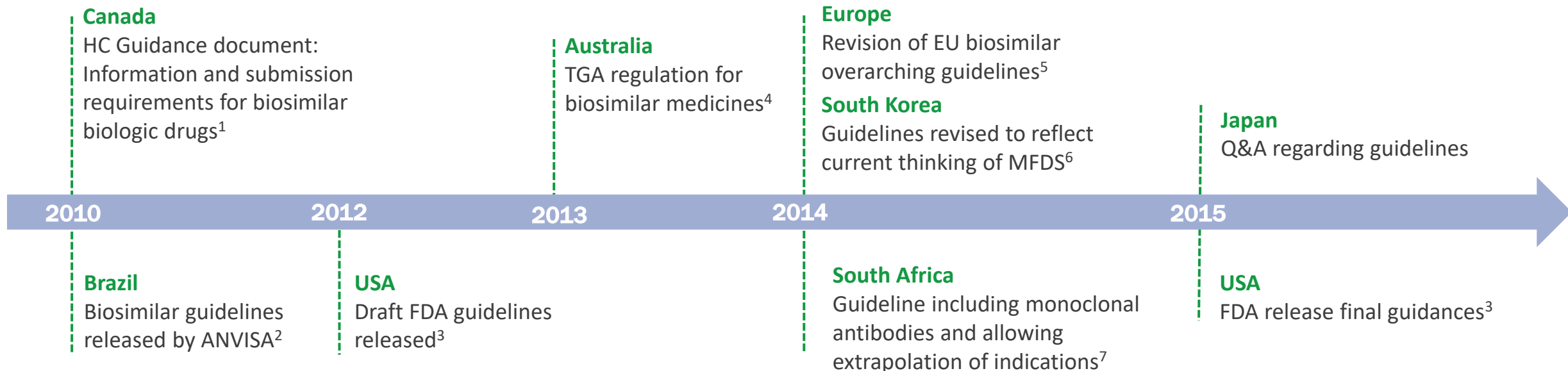
Scientific, regulatory, and legal frameworks have now been established around the world (1)



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.

References: **1.** EMA. [Biosimilar](#). Accessed March 2020; **2.** MHLW. [Guideline for the Quality, Safety, and Efficacy Assurance of Follow-on Biologics](#). Accessed March 2020; **3.** Yasuhiro Kishioka, Ph D [PMDA-Regulatory Framework for Biotherapeutic Products including Similar Biotherapeutic Products](#) Accessed October 2020; **4.** WHO. [Guidelines on evaluation of similar biotherapeutic products \(SBPs\)](#). Accessed March 2020; **5.** Park Y, et al. Presented at Biosimilars Medicines Group conference, London 2016; **6.** [Biologics Price Competition and Innovation Act \(BPICA\)](#). Accessed October 2020; **7.** [Yasuhiro Kishioka, Ph D PMDA-Regulatory Framework for Biotherapeutic Products including Similar Biotherapeutic Products](#). Accessed October 2020;

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



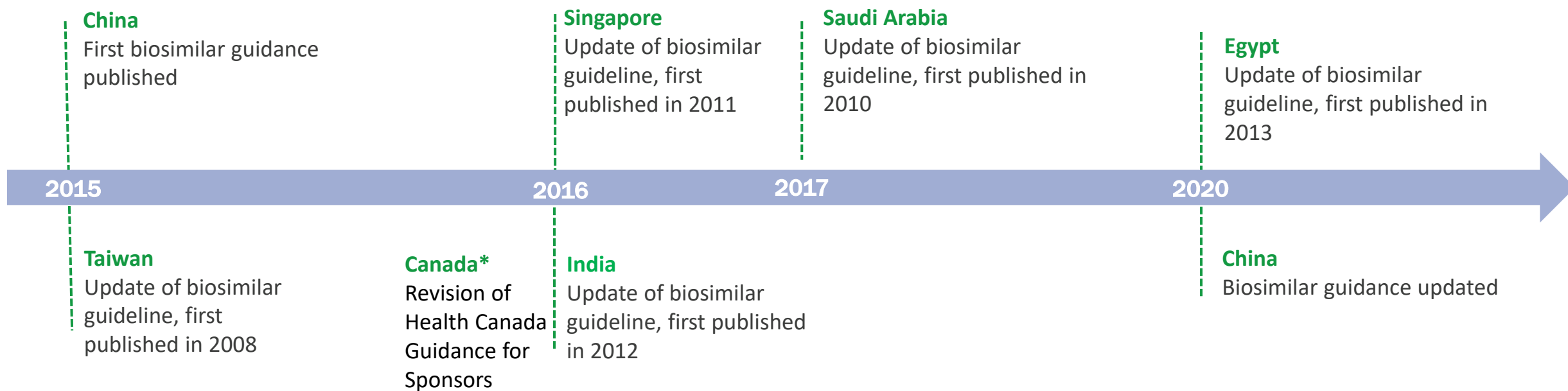
Biosimilar medicines offer more cost-effective alternative options and thereby enhance competition in the marketplace

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.

References: **1.** Health Canada. Information and Submission Requirements for Biosimilar Biologic Drugs. Available at: <http://bit.ly/2tJYGZJ>. Accessed March 2020; **2.** ANVISA. Resolution - RDC Nº 55. Available at: <http://bit.ly/2uPanhJ>. Accessed March 2020; **3.** FDA. Biosimilars; **4.** TGA. Regulation of biosimilar medicines. Available at: <http://bit.ly/2pquwpe>. Accessed March 2020; **5.** EMA. Biosimilar. Available at: <http://bit.ly/1trteeH>. Accessed March 2020; **6.** Park Y, *et al.* Presented at Biosimilars Medicines Group conference, London 2016; **7.** MCCZA. Biosimilar medicines quality, non-clinical and clinical requirements;



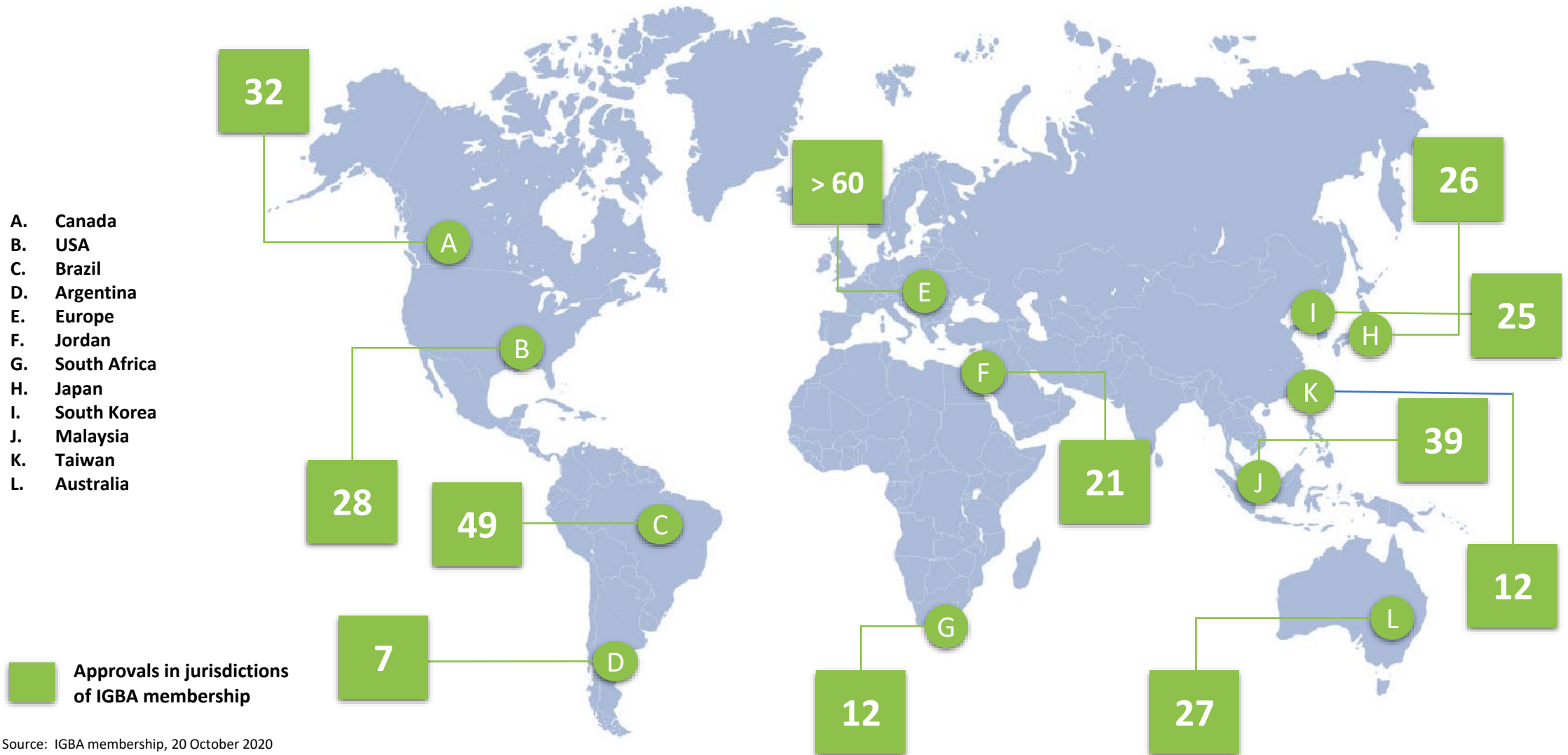
Scientific, regulatory, and legal frameworks have now been established around the world (3)



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

* [Revision of Health Canada Guidance for Sponsors](#)

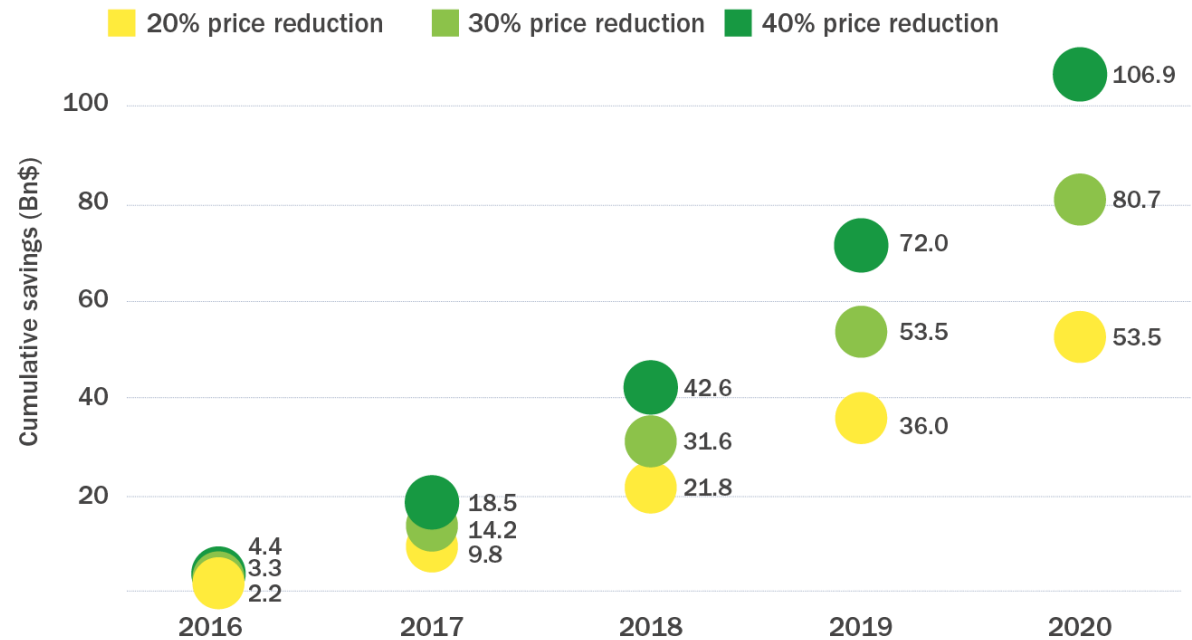
Building on the experience and success of over 300 biosimilar medicines approvals, covering over 10 therapeutic areas



Savings produced by biosimilar medicines contribute 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.

References: 1. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016.; 2. Lynch C. *Pharma Horizon* 2016;1:2–3.



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 2018⁵

U.S.A - 2,2 billion USD (2019)

Biosimilar savings totalled 2,2 billion USD in 2019 and 4,5 billion over the past 10 years⁴

Europe - 15 billion EUR

between 2016 and 2020

based on a 30% price reduction across eight key reference products, driven by biosimilar competition¹

Japan - 46 billion JPY

between 2017 and 2019 with CAGR 61%²

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)³

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

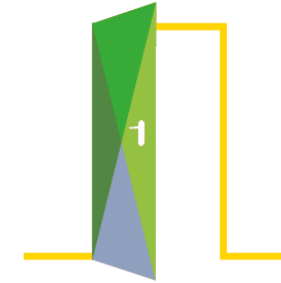
Summary: Biosimilar medicines — rising to the cost challenge



In the absence of competition, biological medicines place a **huge financial burden** on global healthcare systems¹



In many developed markets, key biological medicines are **coming off patent**¹



Patent expiry presents a **significant opportunity** for the introduction of biosimilar medicines¹



Around the globe, biosimilar medicines are being introduced, **enhancing competition** in the marketplace¹



In the five largest European markets alone, biosimilar medicines have saved **1.6 billion USD**²



The **potential savings** offered by biosimilar medicines could help support the **long-term sustainability** of healthcare systems¹