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

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****

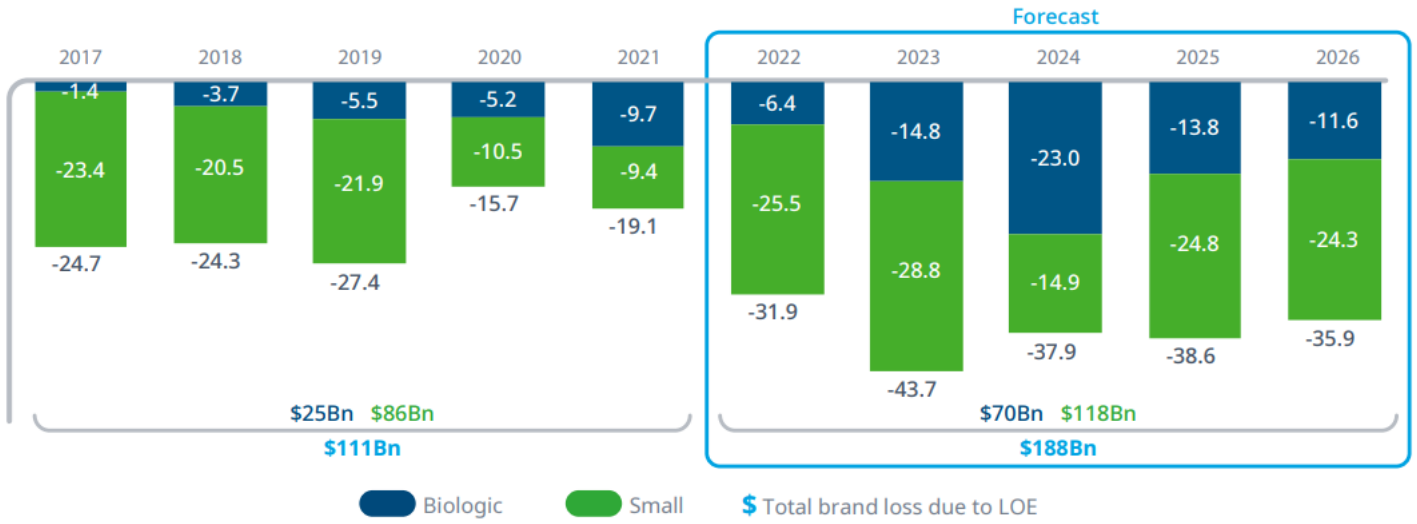
Availability of biosimilar medicines offers an economic benefit to healthcare systems, thereby in part adressing the issue of new, innovative, high-priced medicines[1]

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]

Exhibit 37: Developed markets impact of brand losses of exclusivity 2017–2026, US$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Nov 2021

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

References: 1. The Global Use of medicines – Outlook 2026. 2022. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022 . Accessed July 2022

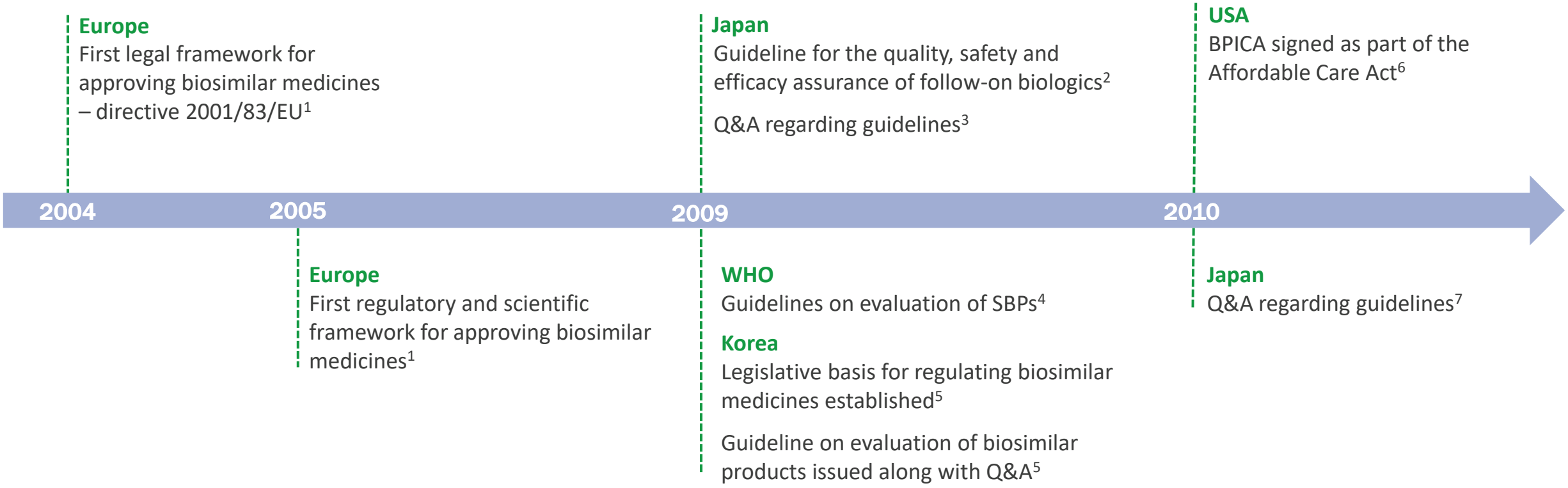
Europe was the first region in the world to develop a framework for biosimilar medicines

- 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 expired[1]
- In 2004 and 2005**, Europe was the first region in the world** to develop a legal, regulatory, and scientific framework for approving biosimilar medicines[2]
- 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 pioneeed the development, licensing, and marketing of biosimilar medicines[2]

References: 1. MIDAS MAT Q2 2020 data; rituximab and trastuzumab DDDs calculated via IQVIA Real World Data, Oncology Dynamics physician surveys on average cycles; pre-2009 analysis includes extrapolated treatment days for biosimilars launched between 2005 – 2008; country cohort includes 30 countries within Europe Economic Area; **2.** EMA Biosimilar Guidelines. Available at https://bit.ly/34iUkJY : Accessed October 2020; **3.** Weise M. Evolving landscape on data requirements to demonstrate biosimilarity – The EU perspective. Presented at 14th Biosimilar Medicines Group Conference, London 2016.

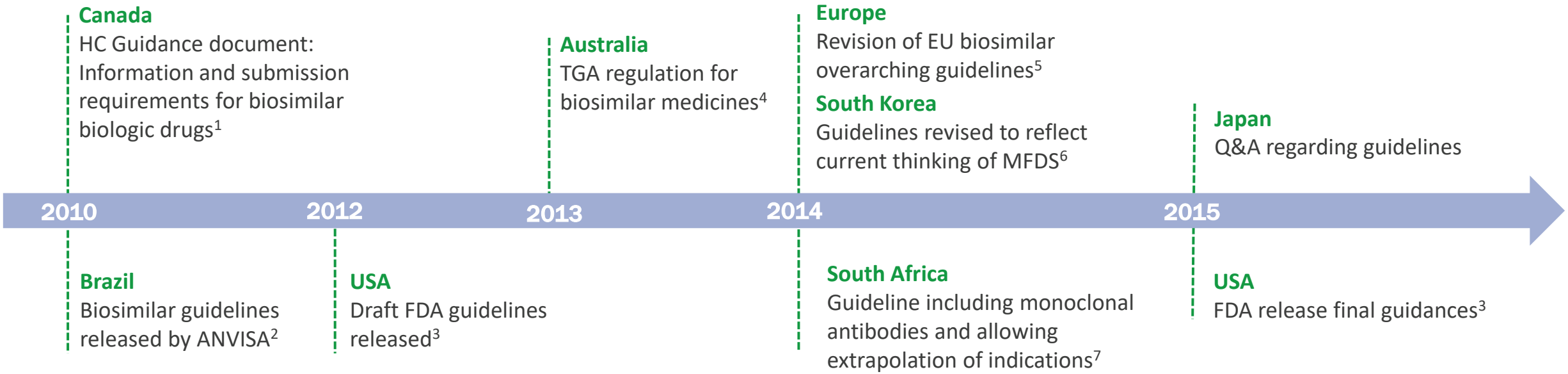
Scientific, regulatory, and legal frameworks have now been established around the world (1)



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)

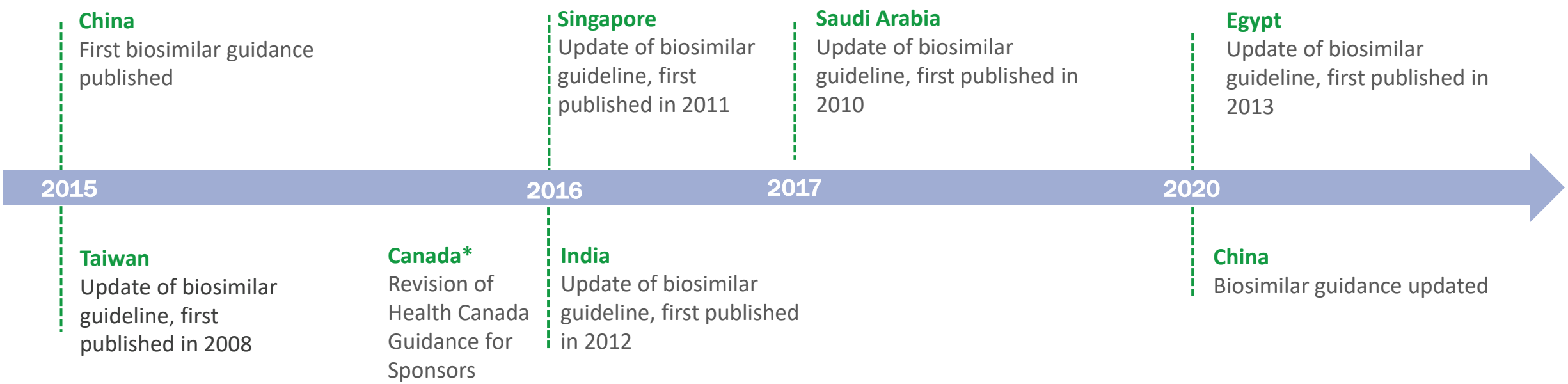


Biosimilar medicines offer more cost-effective alternative options and thereby enhance competition in the marketplace

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;

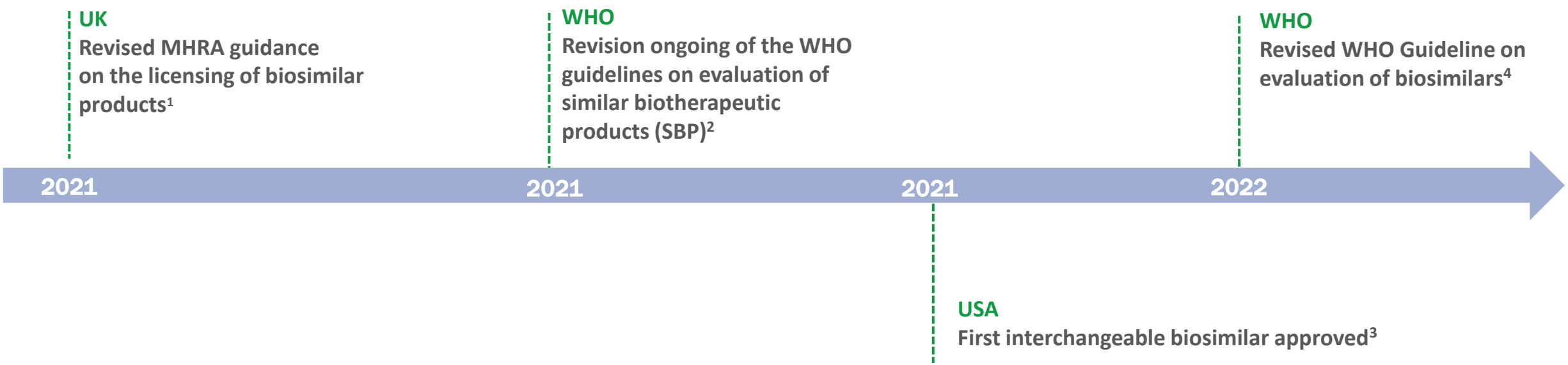
Scientific, regulatory, and legal frameworks have now been established around the world (3)



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

*Revision of Health Canada Guidance for Sponsors

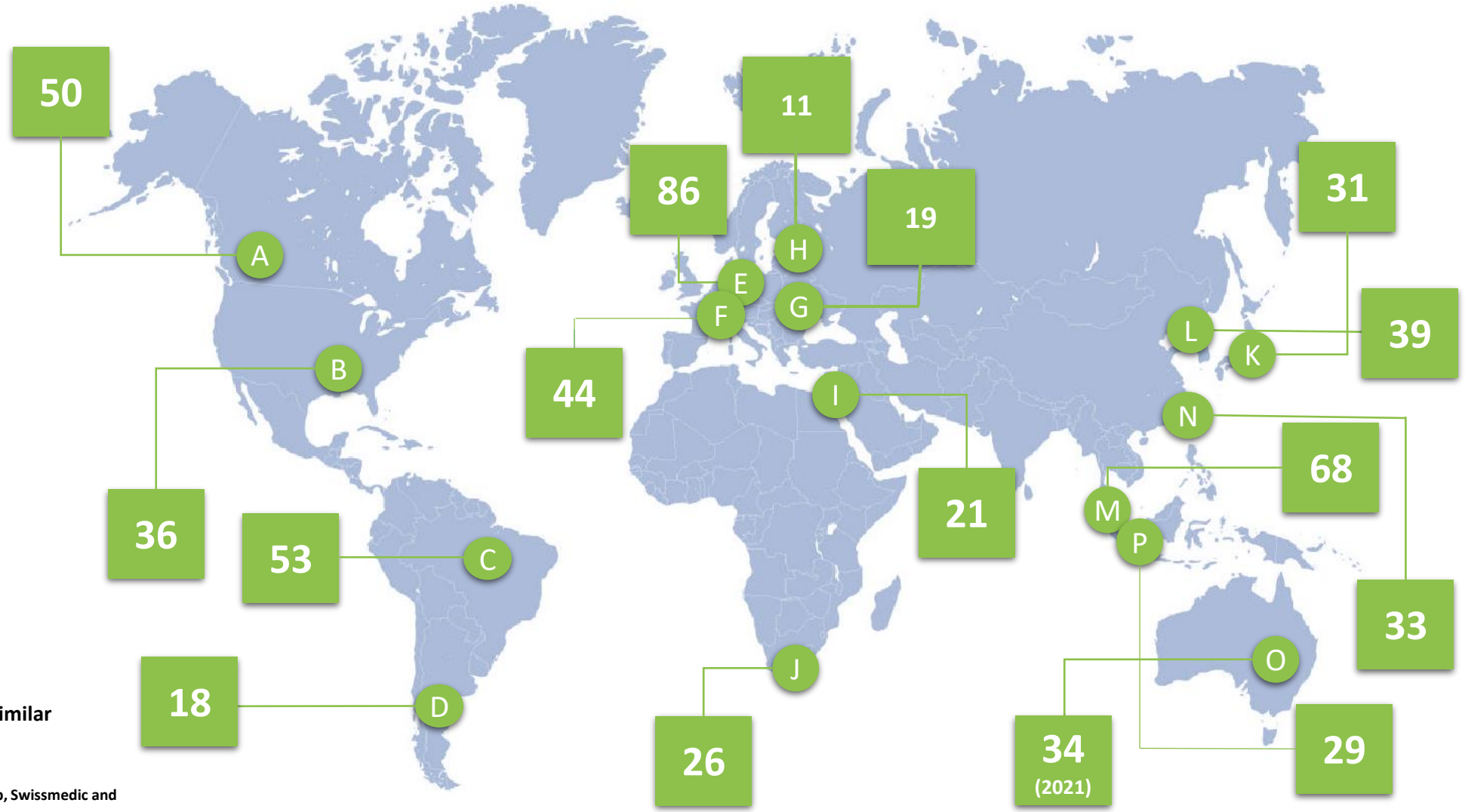
Scientific and regulatory frameworks continue to evolve



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

References: **1**. Guidance on the licensing of biosimilar products - GOV.UK (www.gov.uk); **2**. https://bit.ly/2YQdRkK; **3** https://bit.ly/3DLjsIc; 4. WHO Guideline on evaluation of biosimilars.2022. Accessed July 2022

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

Number of biosimilar approvals

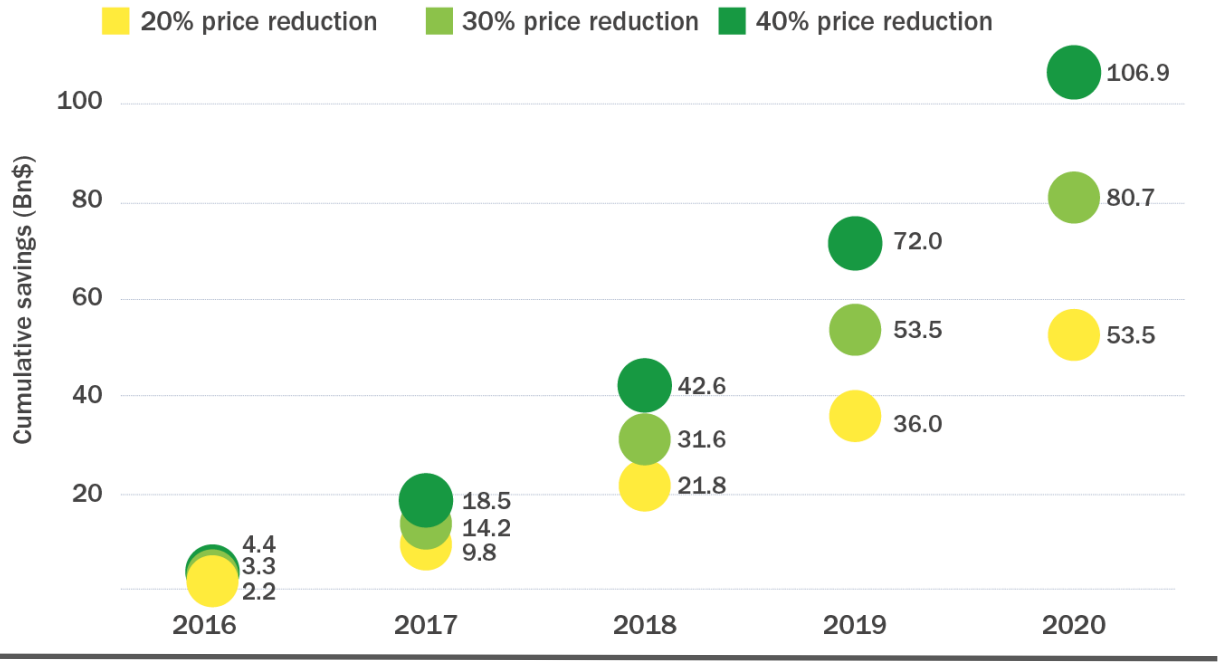
Source of data: **IGBA membership, Swissmedic and HSA Singapore**

IGBA
INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

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 US[1]

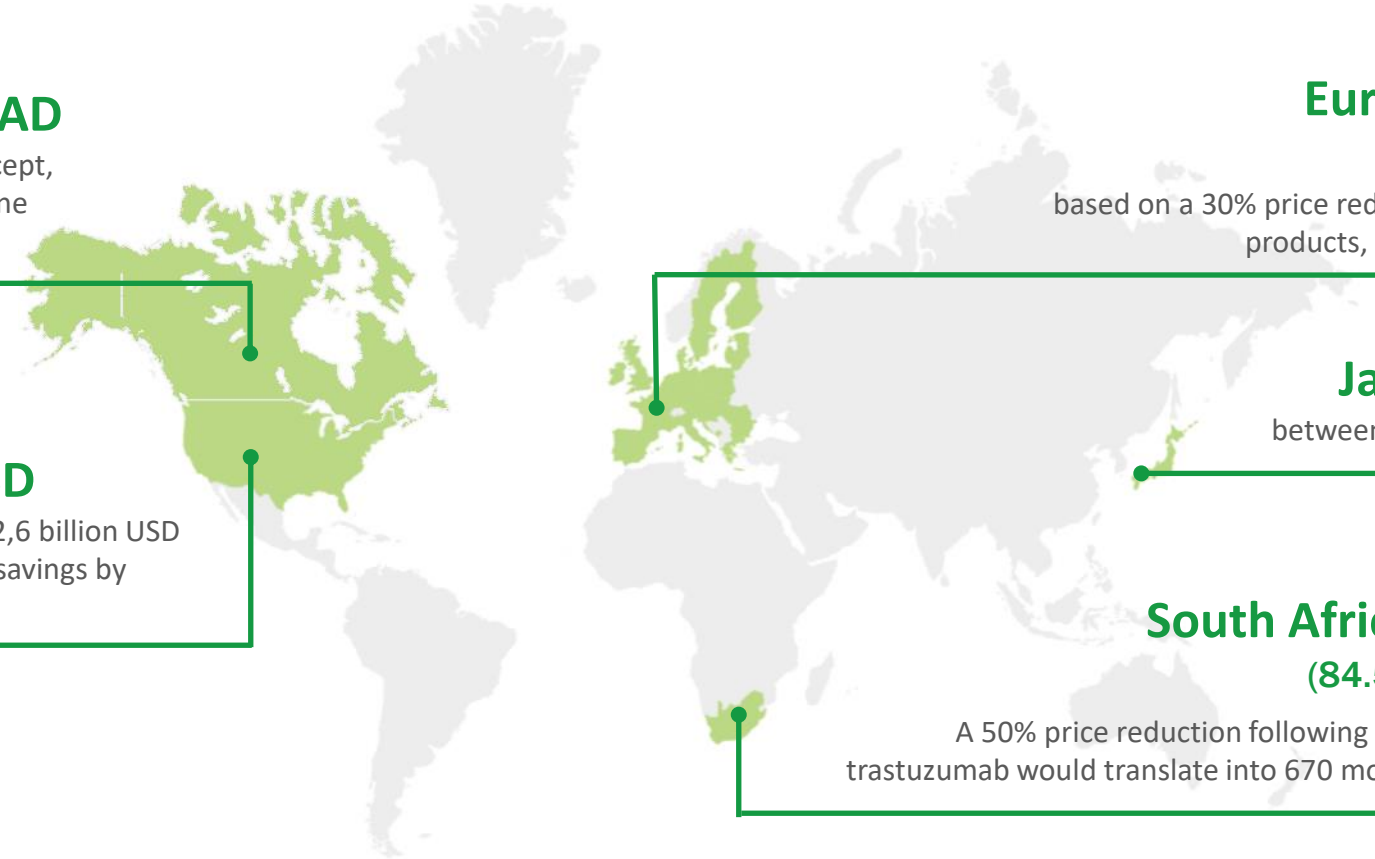


Biosimilar medicines have already delivered savings of around 1.6 billion USD in the five largest European markets alone[2]

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 2018[5]

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[4]

Europe –15 billion EUR

between 2016 and 2020

based on a 30% price reduction across eight key reference products, driven by biosimilar competition[1]

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

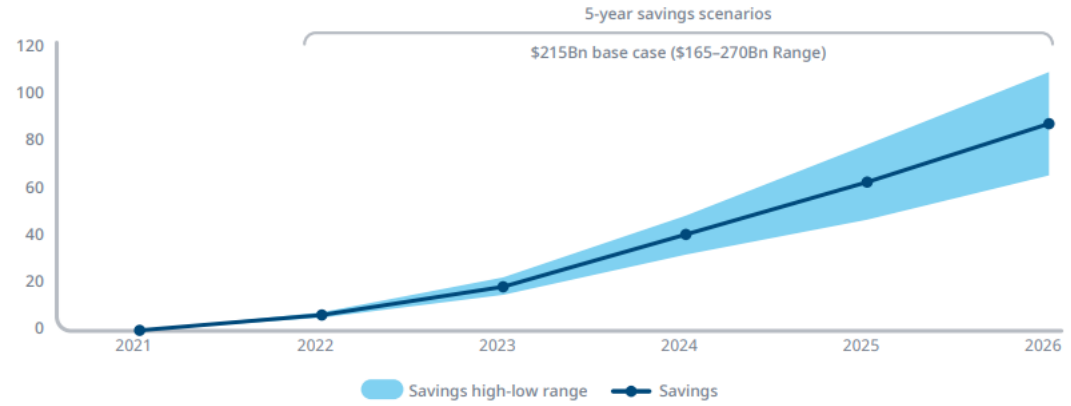
References: 1. QuintilesIMS. Delivering on the potential of biosimilar medicines; **2.** Ministry of Health, Labour and Welfare Japan; **3.** Generic & Biosimilar Medicines Southern Africa Available at: https://gbmsa.org/. Accessed October 2020; **4.** IQVIA, 2021; **5.** Biologics in Canada. Part 2: Biosimilar Savings, 2018. Accessed October 2020.

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]

Exhibit 39: Global savings from biosimilars 2021–2026



Source: IQVIA Market Prognosis, Sep 2020; IQVIA Institute Mar 2021

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]

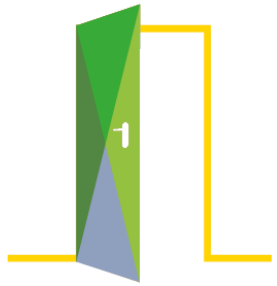
Access to relevant biologic medicines will open up to more people globally, as costs of treating patients for cancer or autoimmune disorders are reduced to affordable levels for both patients and governments across all countries[1]

Reference: 1. IQVIA Global Medicines Spending and Usage Trends 2022. Outlook 2026. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2022 . Accessed July 2022.

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]

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

The **potential savings** offered by biosimilar medicines **by 2025** could help support the **long-term sustainability** of healthcare systems[1]

References: 1. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016; **2.** Lynch C. *Pharma Horizon* 2016;1:2–3; 3. IQVIA Global Medicines Spending and Usage Trends 2021. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends-outlook-to-2025. Accessed August 2021.