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.

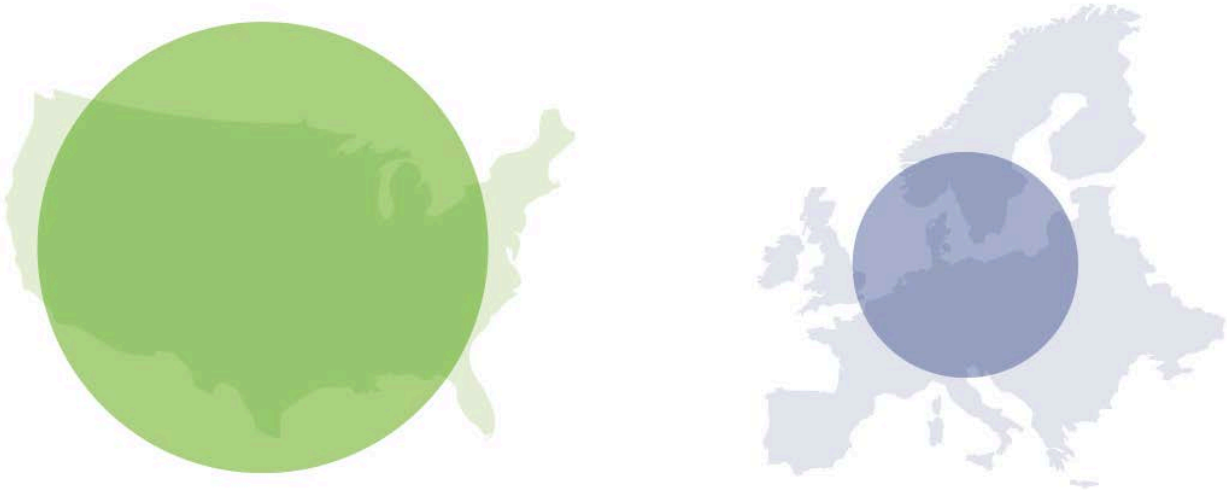
Biosimilar medicines are providing more cost-effective biological treatments, but what are biosimilar medicines, and how do they meet this challenge?

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:

Potential savings in
USA
250 billion USD***



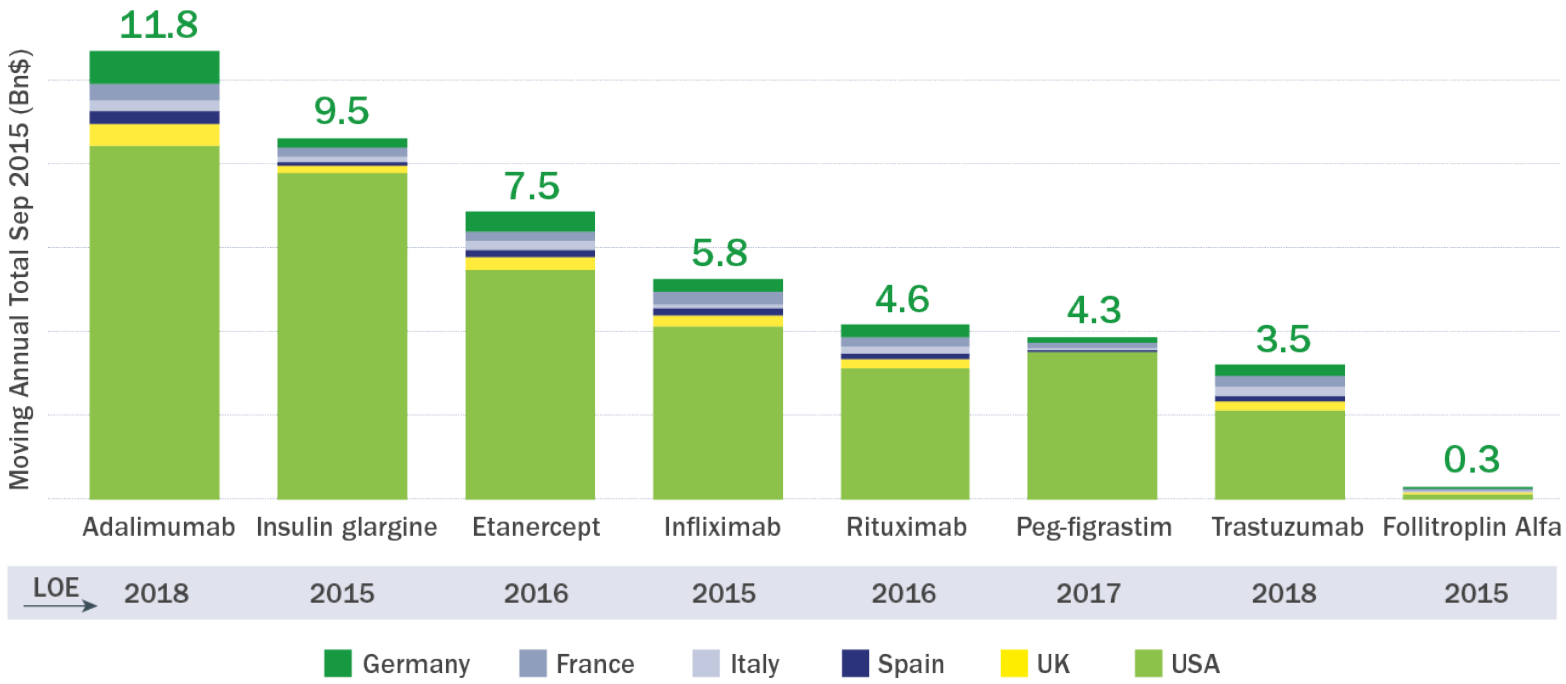
Potential combined savings of
France, Germany, Italy, Spain and the UK:
50 billion USD**

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. Available at: http://bit.ly/2es03mY. Accessed July 2017.
*** The $250 Billion Potential of Biosimilars, Express Scripts Int'l (April 23, 2013). Available at: http://bit.ly/2qYIu4Z . Accessed December 2017.

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

- US and European* sales of key biological medicines are scheduled to lose 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.

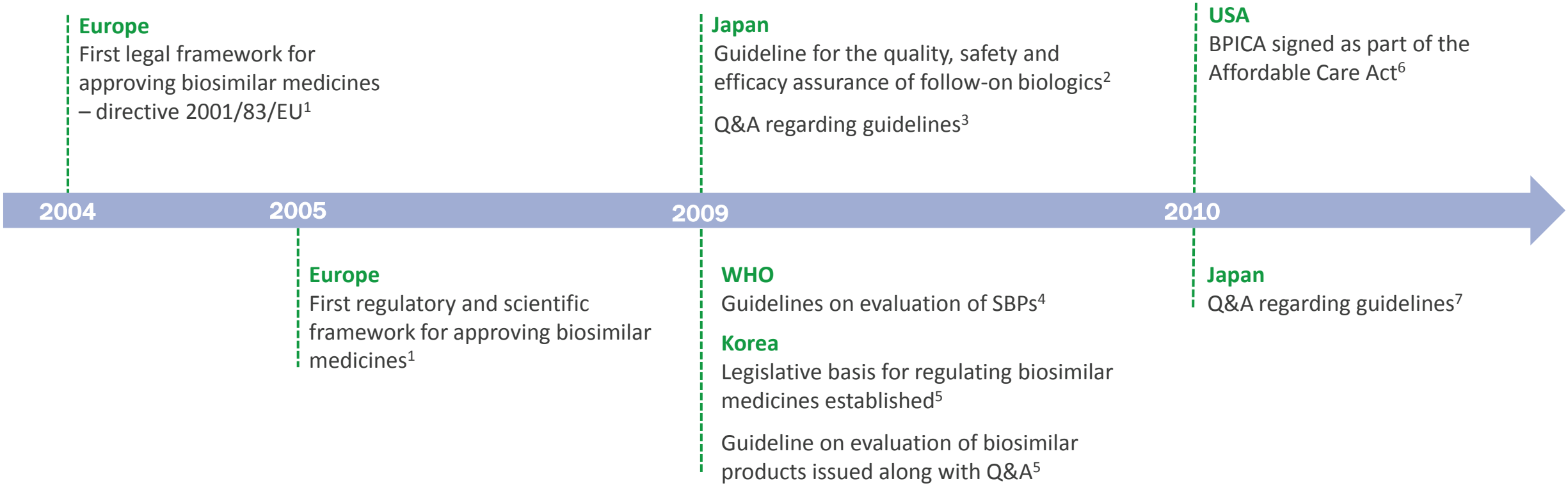
Europe was the first region in the world to develop a framework for biosimilar medicines

- 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 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 **700 million patient days of safe clinical experience**[1]

Europe has pioneeed the development, licensing, and marketing of biosimilar medicines[2]

References: 1. Medicines for Europe: Biosimilar Medicines clinical use Available at: http://bit.ly/2j0EJGt Accessed December 2017; **2.** EMA Biosimilar Guidelines. Available at: http://bit.ly/2ryTPpM. Accessed July 2017; **3.** Weise M. Evolving landscape on data requirements to demonstrate biosimilarity – The EU perspective. Presented at 14th Biosimilar Medicines Group Conference, London 2016. Available at: http://bit.ly/2qATrsQ. Accessed July 2017.

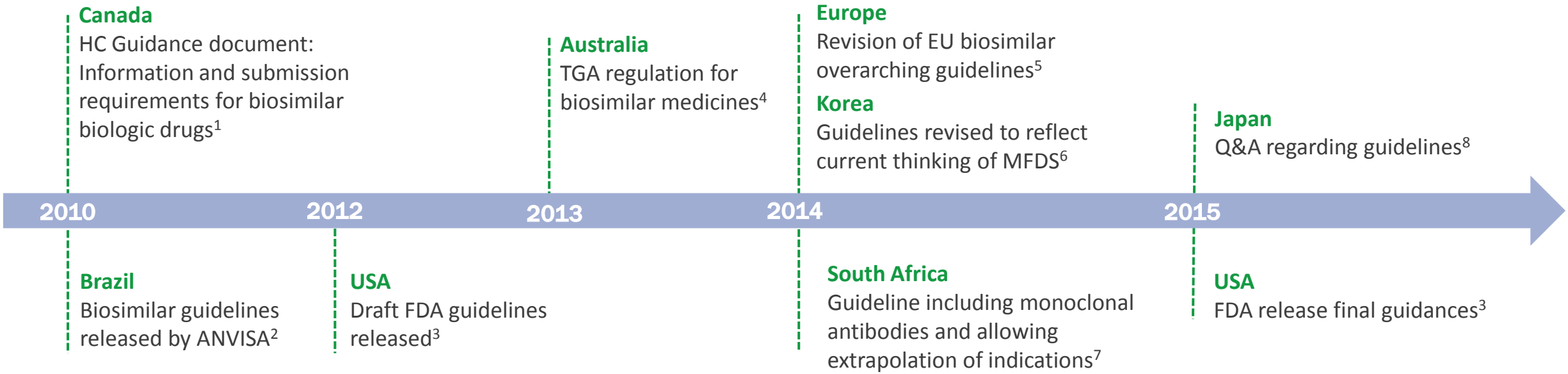
Scientific, regulatory, and legal frameworks have been established in key markets around the world



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

References: 1. EMA. Biosimilar. Available at: http://bit.ly/2qfmPF0. Accessed July 2017; **2.** MHLW. Guideline for the Quality, Safety, and Efficacy Assurance of Follow-on Biologics. Available at: http://bit.ly/2pq8AKX. Accessed July 2017; **3**.JGA. Available at: http://bit.ly/2rnaVqm. Accessed July 2017; **4.** WHO. Guidelines on evaluation of similar biotherapeutic products (SBPs). Available at: http://bit.ly/2oU099B. Accessed July 2017; **5.** Park Y, et al. Presented at Biosimilars Medicines Group conference, London 2016; **6.** US government. Available at: http://bit.ly/2qo3Dl6. Accessed July 2017; **7.** JGA. Available at: http://bit.ly/2qooDee. Accessed July 2017.

Scientific, regulatory, and legal frameworks have been established in key markets around the world



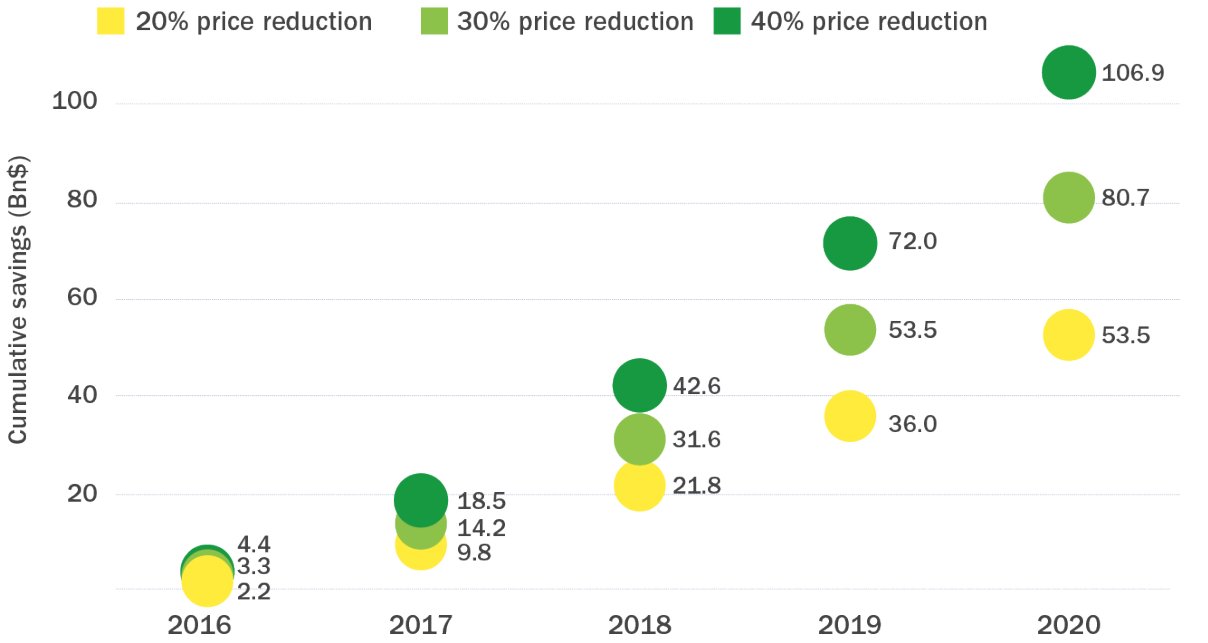
Biosimilar medicines offer more cost-effective alternative options and thereby enhance competition in the marketplace

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 July 2017; **2.** ANVISA. Resolution - RDC Nº 55. Available at: http://bit.ly/2uPanhJ. Accessed July 2017; **3.** FDA. Biosimilars. Available at: http://bit.ly/2oTOoA5. Accessed July 2017; 4**.** TGA. Regulation of biosimilar medicines. Available at: http://bit.ly/2pquwpe. Accessed July 2017; **5.** EMA. Biosimilar. Available at: http://bit.ly/1trteeH. Accessed July 2017; **6.** Park Y, *et al.* Presented at Biosimilars Medicines Group conference, London 2016; **7.** MCCZA. Biosimilar medicines quality, non-clinical and clinical requirements. Available at: http://bit.ly/2uPivil. Accessed July 2017; 8. JGA. Available at: http://bit.ly/2rcqRyt. Accessed July 2017.

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 US[1]

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

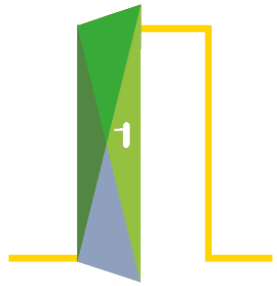
Footnotes: *Savings potential in five largest European markets plus US biosimilar accessible market dependent on change in price per treatment day. The accessible market analysis is based on adalimumab, insulin glargine, etanercept, infliximab, rituximab, peg-filgrastim, trastuzumab, and follitropin 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. Available at: http://bit.ly/2es03mY. Accessed July 2017; **2.** Lynch C. *Pharma Horizon* 2016;1:2–3.

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 opportunity** for the introduction of biosimilar medicines[1]

Around the globe, biosimilar medicines are being introduced, **enhancing competition** in the marketplace[1]

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 systems[1]

References: 1. QuintilesIMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines. 2016. Available at: http://bit.ly/2es03mY. Accessed July 2017;
2. Lynch C. *Pharma Horizon* 2016;1:2–3.

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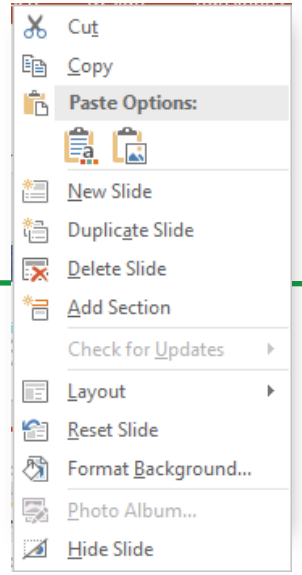

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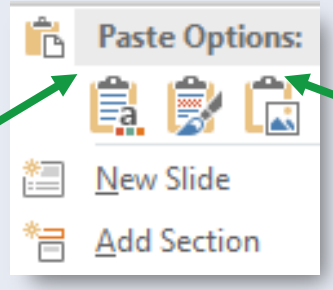

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