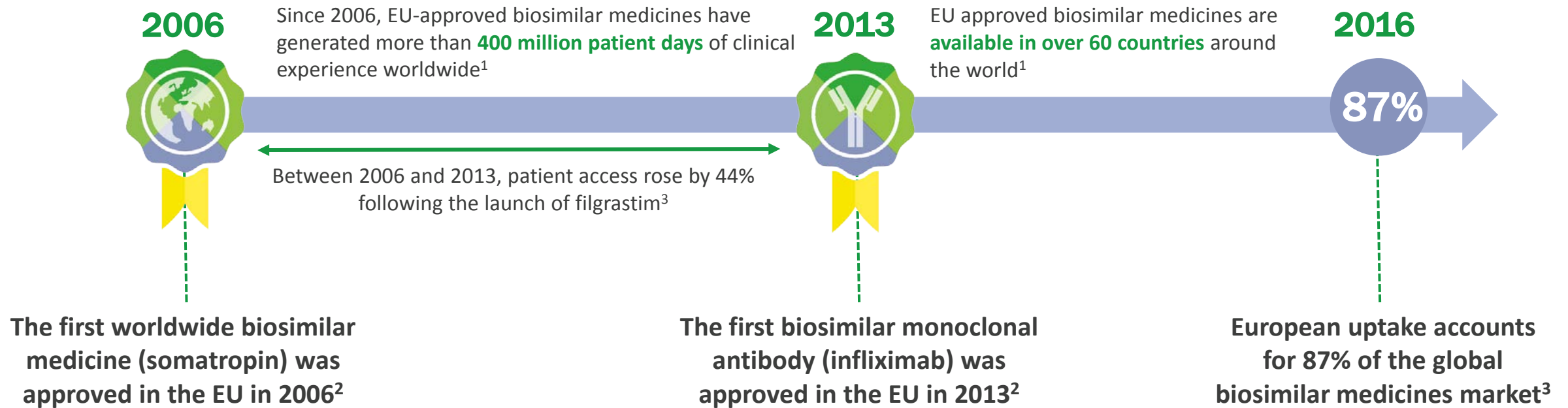


Chapter 5

The benefits of biosimilar medicines

Biosimilar medicines have demonstrated similarity with reference biologicals in terms of structure, function, safety and efficacy, but what are their benefits?

Europe is a pioneer of biosimilar medicines and continues to inspire the world



There is more than 10 years' worth of real-world evidence demonstrating the benefits that biosimilar medicines offer to patients and healthcare systems¹

Biosimilar medicines offer benefits to patients, healthcare professionals, and payers¹



Patients^{1,2}

- More patients gain access to biologic treatments, and at earlier stages of the therapy cycle
- Improved access drives better outcomes for patients



Healthcare professionals^{1,2}

- Access to a wider spectrum of treatment options
- Development of value-added services for patients via benefit-sharing models
- Reduced pressure on the prescribers' budget



Payers^{1,3}

- Creation of a more competitive market with a broader range of cost-effective treatment options
- Generation of savings across healthcare systems, supporting their sustainability

Biosimilar medicines increase the treatment options available to patients, healthcare professionals, and payers¹



Availability of biosimilar medicines increases patient access to biologic therapies



- According to WHO, biosimilar medicines provide a good opportunity to **expand access** and to become a **game-changer** for access to medicines for certain complex conditions¹
- In countries with low initial usage or availability of biological products, the launch of biosimilar medicines appears to **lead to increased access**^{2*}

Product/Country	Treatment days per capita (Year before biosimilar entrance)	Volume change of treatment days following introduction of biosimilar
HGH		
Romania	0.02	152%
Czech Rep	0.08	68%
Poland	0.04	82%
G-CSF		
Romania	0.02	2542%
Bulgaria	0.02	581%
Slovakia	0.05	509%
Anti-TNF		
Bulgaria	0.10	190%
Czech Rep	0.24	59%
Slovakia	0.49	93%

Biosimilar medicines allow access to highly innovative treatments

Abbreviations: G-CSF, granulocyte-colony stimulating factor; HGH, human growth hormone; TNF, tissue necrosis factor; WHO, World Health Organisation.

Reference: 1. WHO. WHO to begin pilot prequalification of biosimilars for cancer treatment. Available at: <http://bit.ly/2q1WOtp>. Accessed July 2017; 2. QuintilesIMS. The impact of biosimilar competition on price, volume and market share - update 2017. Available at: <http://bit.ly/2rpB1rW> Accessed July 2017.



Swedish launch of biosimilar filgrastim led to improved patient access

Initiation of treatment with filgrastim reference medicine required the formal approval of **three physicians**



Launch of filgrastim biosimilar

Following the launch of biosimilar filgrastim:

- Treatment costs for granulocyte colony-stimulating factor (G-CSF) treatment of febrile neutropenia were reduced
- Regional authorities relaxed restrictions on the prescribing of G-CSF treatments
- Prescriptions do not need additional authorization

Driven by the use of biosimilar filgrastim, clinical use of G-CSF increased five fold in the Southern Healthcare region



Biosimilar medicines allow access for more patients, and at earlier stages in the treatment cycle



Biosimilar medicines make biotherapeutics a cost-effective option, broadening treatment choice

- Biosimilar medicines are often able to reach an acceptable incremental cost-effectiveness ratio (ICER) in situations where reference products are not¹
- In the UK, biosimilar medicines have introduced new treatment options for ankylosing spondylitis, and for treatment-induced anaemia in patients with cancer^{1,2}

Ankylosing spondylitis



According to 2008 UK National Institute for Health and Clinical Excellence (NICE) guidelines, **infliximab (originator) should not be used at all**

2015 NICE guidance **recommends use of infliximab biosimilar medicines** in adults with non-radiographic axial spondyloarthritis

Cancer-treatment-induced anemia



According to 2008 NICE guidelines, **epoetin** is clinically effective for cancer treatment-induced anaemia, but **is not cost-effective**

According to 2014 NICE guidelines, **epoetin is both clinically effective and cost-effective**

Biosimilar medicines empower physicians, providing cost-effective treatment options¹

Abbreviations: NICE, The National Institute for Health and Care Excellence.

References: 1. Simon-Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market. Available at: <http://bit.ly/2q3qx0w>. Accessed July 2017; 2. NICE. Available at: www.NICE.org.uk. Accessed July 2017.



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

USA – 44–250 billion USD
over a ten-year period

Value dependent upon the policies adopted in the coming months and years^{5,6}

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)⁴

Europe – 16 billion USD
(15 billion Euros) between 2016 and 2020 in Europe

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

Japan – 1.3 billion USD
(141.7 billion Yen) from biosimilars between 2015 and 2020²

Australia – 676 million USD
(880 million AUD) from biosimilars between 2015 and 2020³

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

References: **1.** QuintilesIMS. Delivering on the potential of biosimilar medicines. Available at: <http://bit.ly/2es03mY>. Accessed July 2017; **2.** Japanese generic medicines association. Data on file; **3.** Australian Government. Pharmaceutical Benefits Scheme to be reformed. Available at: <http://bit.ly/2q3xQp0>. Accessed July 2017; **4.** NAPM. National Association of Pharmaceutical Manufacturers. Available at: napm.co.za. Accessed July 2017; **5.** Mulcahy AW, *et al.* *RAND* 2014; **6.** Express Scripts. The \$250 Billion Potential of Biosimilars. Available at: <http://bit.ly/1FQmNAM>. Accessed July 2017.

Sharing the benefits of clinical use of biosimilar medicines

- In Germany, the medical association KV Westfalen-Lippe, and the statutory health insurance provider Barmer GEK, agreed a contract geared towards **improving care of patients** with inflammatory bowel disease
- Under the contract, patients with ulcerative colitis or Crohn's disease will be primarily treated with **infliximab biosimilars**
- **Absolute savings** generated from prescribing infliximab biosimilar will be equally split between the treating physician and Barmer GEK

Benefit sharing models help physicians to see the tangible benefits from generated savings due to more cost-effective prescribing, leading to increased biosimilar medicine uptake and patient care

Summary: The benefits of biosimilar medicines



The use of biosimilar medicines has been **successfully implemented** within Europe for over a decade¹



Benefit sharing models involve all stakeholders and help to **demonstrate the cost benefits** associated with biosimilar medicine adoption³

Biosimilar medicines improve the treatment options available to:²⁻⁴



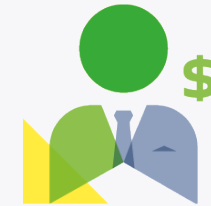
Patients

Biosimilar medicines allow access for more patients, and at earlier stages in the treatment cycle



Healthcare professionals

Biosimilar medicines empower physicians, providing cost-effective treatment options



Payers

Globally, biosimilar medicines introduce competition by representing a cost-effective alternative to reference biologicals, and generate savings

Biosimilar medicine policies are necessary to drive uptake and provide the benefits of biosimilar use



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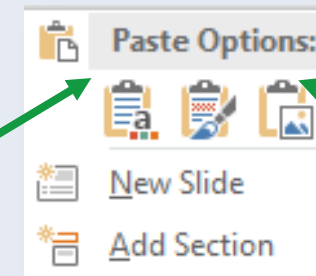
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