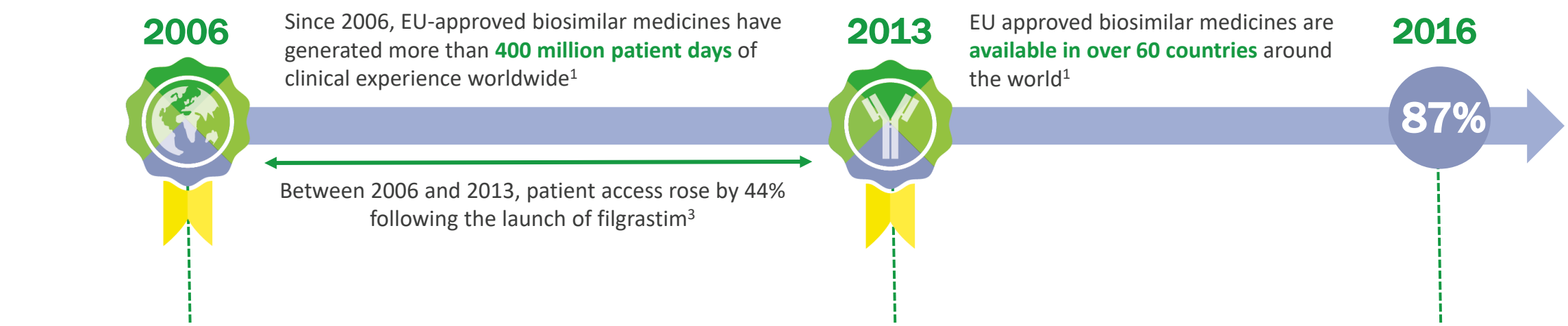
Chapter 5

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 has the largest clinical experience



The first worldwide biosimilar medicine (somatropin) was approved in the EU in 2006[2]

The first biosimilar monoclonal antibody (infliximab) was approved in the EU in 2013[2]

European uptake accounts for 87% of the global biosimilar medicines market[3]

There is nearly 15 years' worth of real-world evidence demonstrating the benefits that biosimilar medicines offer to patients and healthcare systems[1]

References: 1. Biosimilar Medicines Group. Factsheet on Biosimilar Medicines. 2016. Accessed July 2020; **2.** EMA. European public access reports; **3.** QuintilesIMS Health MIDAS 2016.

Biosimilar medicines offer benefits to patients, healthcare professionals, and payers[1]

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 payers[1]

References: 1. Biosimilar Medicines Group. Biosimilar Medicines Group handbook 2016. Accessed March 2020; **2.** Simon-Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market; **3.** Cornes P, Muenzberg M. *Pharma Horizon* 2016;1:35–38.

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 conditions[1]
- 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.. Accessed March 2020; **2.** QuintilesIMS. The impact of biosimilar competition on price, volume and market share - update 2017. Accessed March 2020.

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

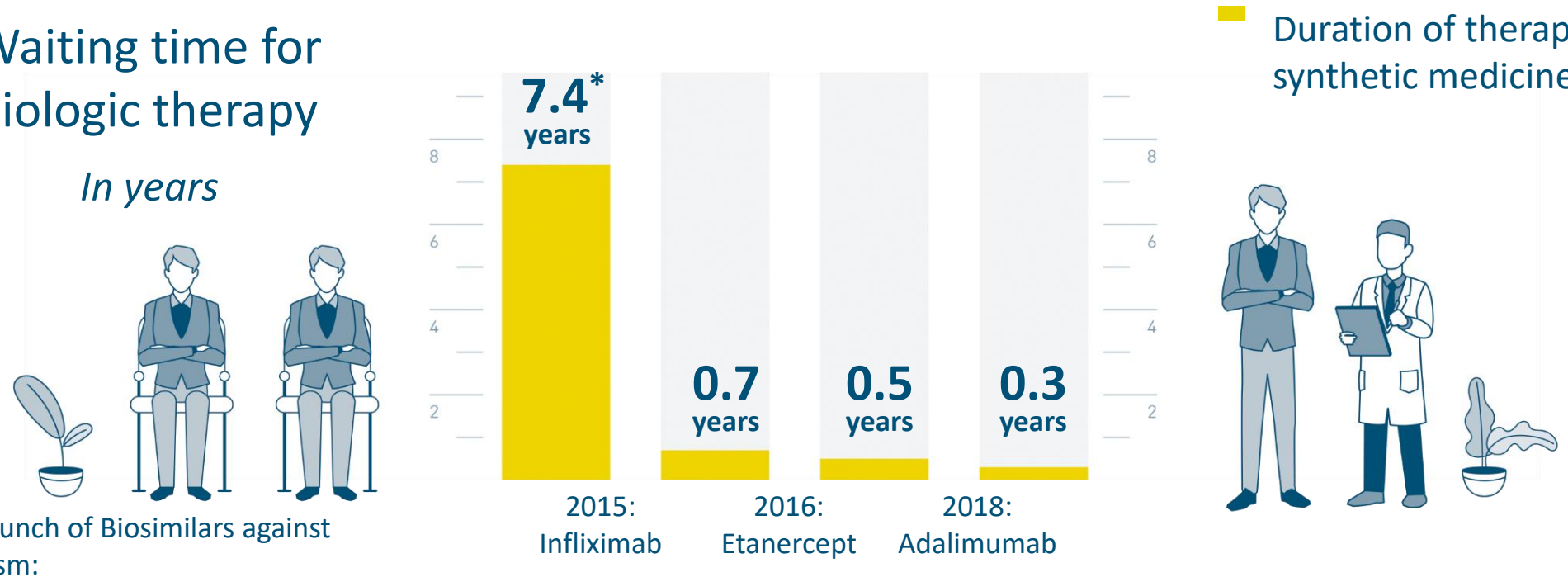
Driven by the use of biosimilar filgrastim, clinical use of G-CSF increased five fold in the Southern Healthcare region

x5

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

Reference: 1. Simon-Kucher & Partners; Accessed March 2020.

In Bavaria[1], biosimilar competition led to rheumatic patients receive faster access to biological therapy[2]



*until 2015, exclusively synthetic standardised therapy or original biological agents were available[3]

Biosimilar infliximab, etanercept and adalimumab translated in a significant reduction of the duration of synthetic medicines therapy for rheumatic patients from 7,4 years to 4 months[2]

References: 1. Bavaria, Germany. **2.** ProBiosimilars preliminary results of the PHARAO study - https://probiosimilars.de/presse/versorgung/studie-biologika-und-rheuma-patienten/ **3.** AG Pro Biosimilars, patient survey at the DocCheck rheumatologist

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 not[1]
- In the UK, biosimilar medicines have introduced new treatment options for ankylosing spondylitis, and for treatment-induced anaemia in patients with cancer[1,2]

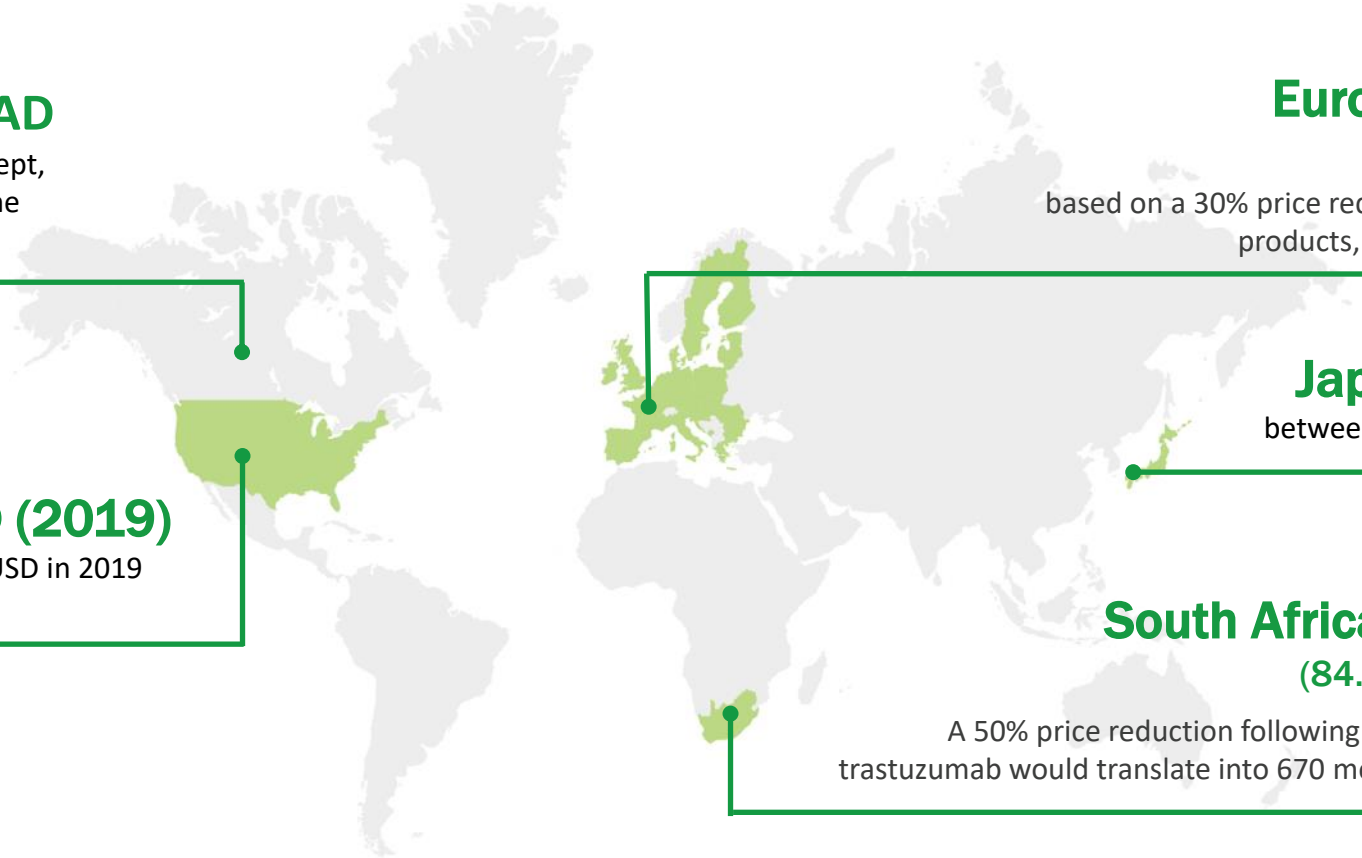
Ankylosing spondylitis	 According to 2008 UK National Institute for Health and Clinical Excellence (NICE) guidelines, **infliximab (originator) should not be used at all**	2015 NICE guidance **recommends use of infliximab biosimilar medicines** in adults with non-radiographic axial spondyloarthritis
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 options[1]

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. Accessed March 2020; **2.** NICE. Accessed March 2020.

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]

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]

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 years[4]

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 2020 Report; **5.** Biologics in Canada. Part 2: Biosimilar Savings, 2018. Accessed October 2020.

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

Reference: Simon-Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market. Accessed March 2020.

Summary: The benefits of biosimilar medicines

The use of biosimilar medicines has been **successfully implemented** within **Europe for over a decade**[1]

Benefit sharing models involve all stakeholders and help to **demonstrate the cost benefits** associated with biosimilar medicine adoption[3]

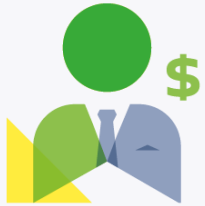
Biosimilar medicines improve the treatment options available to:[2–4]

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

References: 1. Biosimilar Medicines Group. Factsheet on Biosimilar Medicines 2016. Accessed March 2020; **2.** Medicines for Europe. Biosimilar Medicines Handbook 2016. Accessed March 2020; **3.** Simon-Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market. Accessed March 2020; **4.** Cornes P, Muenzberg M. *Pharma Horizon* 2016;1:35–38.