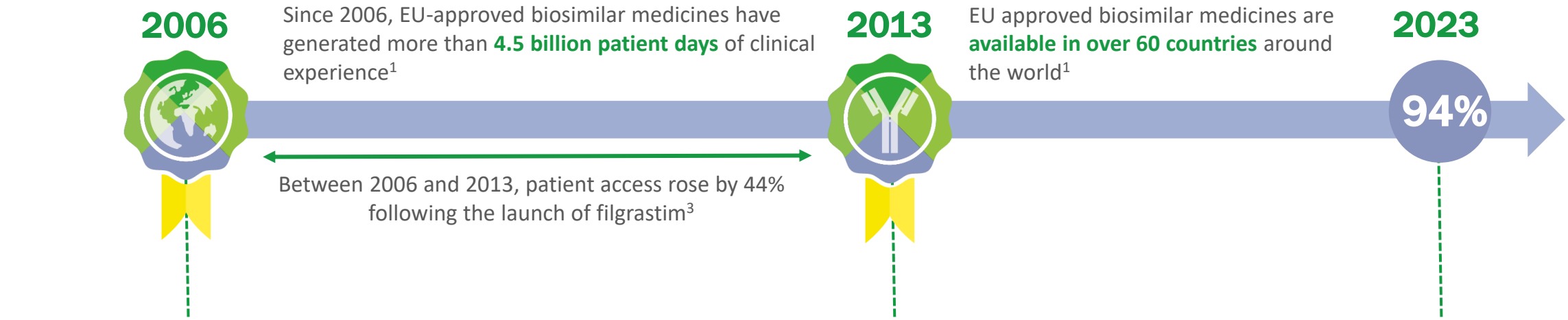
Chapter 5

# 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 was the 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]**

**Europe and U.S. uptake accounts for over 90% of the global biosimilar medicines market[3]**

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

**References: 1.** IQVIA report Biosimilar competition in Europe (Dec 2022) Accessed Sept 2023. **2.** EMA. European public access reports; **3.** IQVIA, MIDAS MAT Q2 2023.

# 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 and opportunities for treatment pathways evolution
- 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
- Creation of opportunities for re-investment into workforce, other medicines or healthcare services

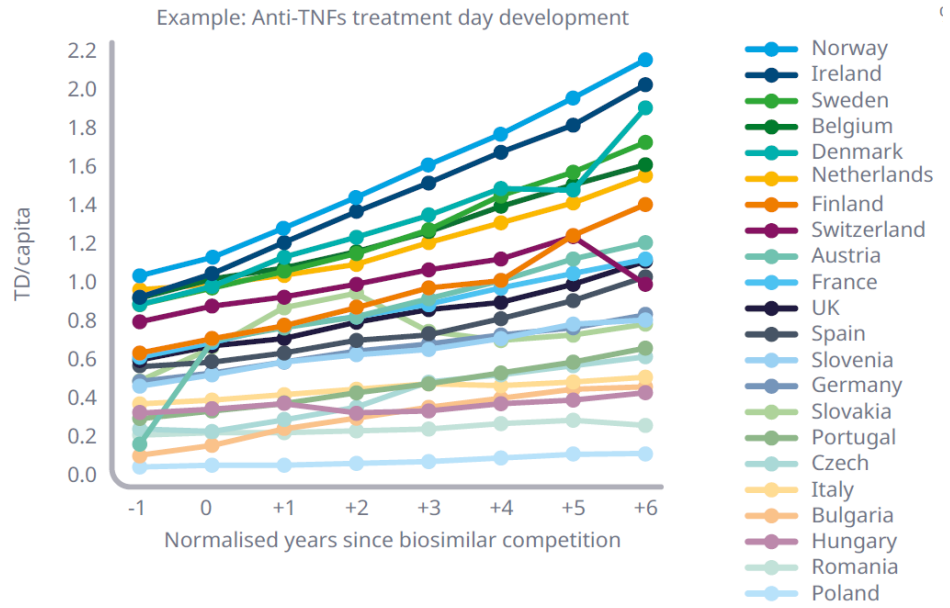
**Biosimilar medicines increase the available treatment options available to patients, healthcare professionals, and payers[1]**

**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 Europe, **access to biologic therapies** is **increasing** in all countries following biosimilar medicines entry, signalling progress[2]
- Using **anti-TNF class** as an example, prescribing of anti-TNF molecules has increased an average of **11% across Europe** (~0.5 treatment days per capita) since the entry of biosimilars.

**Exhibit 8: Development of Anti-TNF class usage across European markets**




Notes: Calculation is based on the normalized year before biosimilar entry for each molecule in the anti-TNF class, and the treatment days before and since the LOE date in Europe
Source: IQVIA MIDAS June 2022 MAT

**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.** IQVIA report Biosimilar competition in Europe (Dec 2022) Accessed Sept 2023

# 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.

# 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.

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

- In the UK, the National Institute of Health and Clinical Excellence (NICE) has partially revised their guidelines and expanded the use of biologic therapies to a broader range of patients further to biosimilar competition and its positive impact on treatment cost efficiency
- Beyond the current pool of patients treated with a biologic medicines, **around 25,000 people with moderate rheumatoid arthritis** – who have not responded to conventional therapies – will now benefit from the recommendations[1]

**Rheumatoid arthritis**

**According to 2016 UK National Institute for Health and Clinical Excellence (NICE) guidelines, anti-TNF medicines should be used only for severe rheumatoid arthritis**

2021 NICE partially **revised guidance now recommends use of adalimumab*,** etanercept*, infliximab*, certolizumab pegol, golimumab, tocilizumab and abatacept **for moderate rheumatoid arthritis** after conventional DMARDs only have failed

**Biosimilar medicines empower physicians and healthcare systems to treat more patients, often earlier in the disease course[1]**

.*Available biosimilar medicines

**References: 1. UK NICE https://www.nice.org.uk/news/article/nice-recommends-several-treatment-options-to-help-thousands-with-moderate-rheumatoid-arthritis 2. UK NICE Guideline 2016 https://www.nice.org.uk/guidance/ta375**

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

- The availability of **biosimilar trastuzumab options** on the UK market trigger competition and positively impacted the overall cost-effectiveness of a combination therapy involving 2 biologic medicines.

| | | | |
|---|---|---|---|
| **Breast Cancer** |  | According to 2019 NICE guidance, **Pertuzumab**, with intravenous trastuzumab and chemotherapy, is **recommended** for the adjuvant treatment of human epidermal growth factor receptor 2 (HER2)-positive early stage breast cancer in adults. | Prior to that recommendation, the combination (pertuzumab + trastuzumab + chemotherapy) was **not considered cost-effective** |

**Biosimilar medicines empower physicians and healthcare systems to treat more patients with innovative therapies when used in combination with a biosimilar medicine[1]**

.References: 1. UK NICE Guidance 2019 https://www.nice.org.uk/guidance/TA569/chapter/1-Recommendations

# Biosimilar medicines allow freeing up re-investment in better care thanks to benefit-sharing

- In Cardiff, rituximab intravenous formulation biosimilar medicines were predicted to save one hospital **£300,000 -335,000 a year** over the subcutaneous reference biologic
- An additional consideration related to getting the treatment i.e. lymphoma chemotherapy and sub-cutaneous biologic therapy

**Lymphoma**

REINVEST TO IMPROVE CANCER CARE: Creating Off-site nurse clinics

In concertation with patients, feedback underlined:

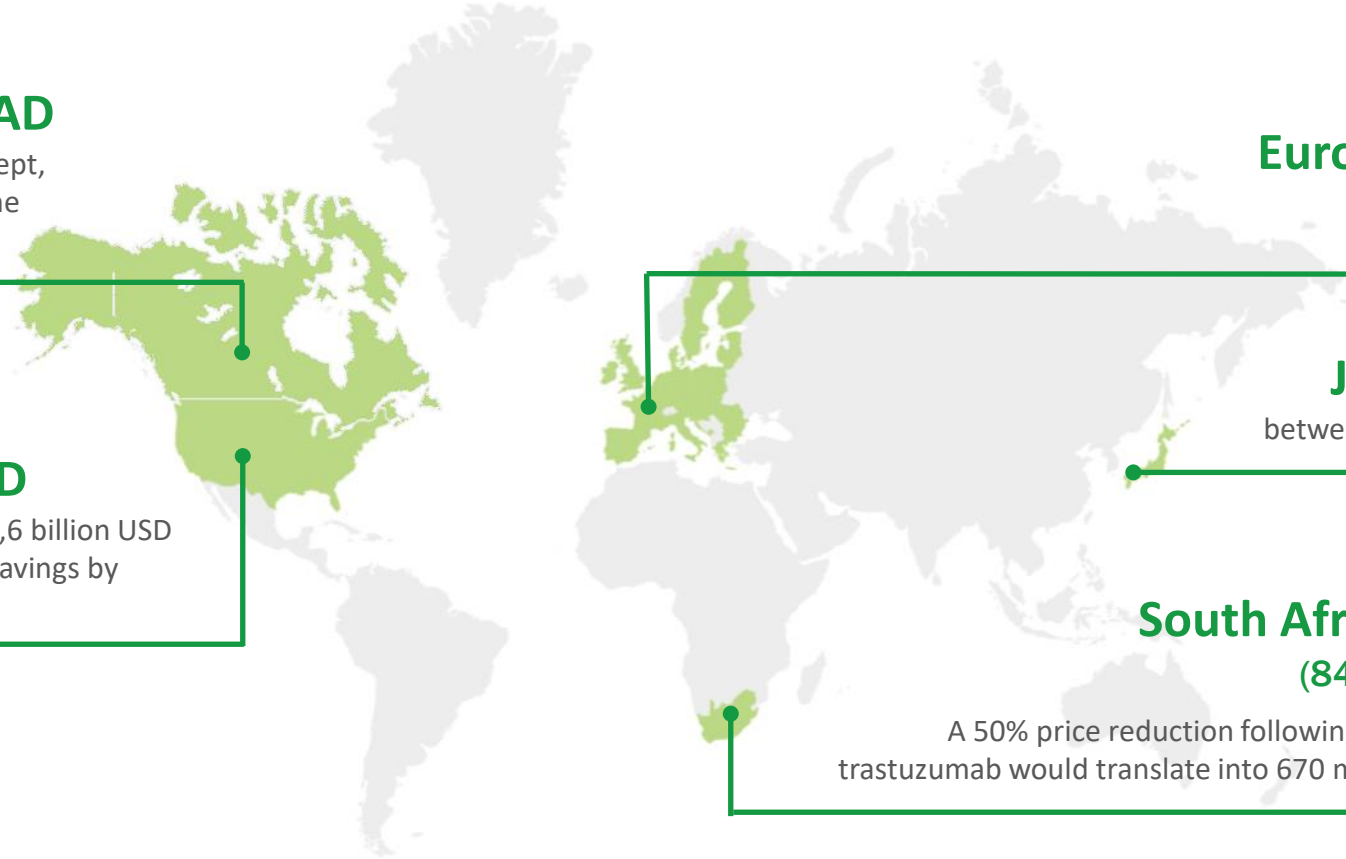
- The shorter administration time of the sub cutaneous administration would be a benefit
- However, the overall travel times across town through large urban areas to reach the infusion centres would outset the time gains from administration

To ensure **shared benefits** for both patients and the healthcare budget, decision was made to **re-invest the financial savings from intravenous rituximab biosimilar utilisation** to **develop** jointly with patients and advocates, and **staff new** infusion clinics closer to patients' homes in the city outskirts.

**Biosimilar medicines empower healthcare communities to deliver more care: more patient accessing medicines and beyond, answering specific patient needs along their treatment pathway**

**Reference:** Bloodworth C, Myson V, Harries R, Lloyd C, Rowntree C. Creating off-site nurse led treatment units for administering chemotherapy to people with lymphoma nearer to their homes. Presented at the 58th Annual Scientific Meeting of the British Society for Haematology, April 16-18, 2018; Liverpool, United Kingdom. Abstract BSH18-OR-022. https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.15226

# Globally, biosimilar medicines have the potential to offer healthcare systems huge savings for the same or better 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 – >30 billion EUR

between 2006 and 2022[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** IQVIA report Biosimilar competition in Europe (Dec 2022) Accessed Sept 2023; **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.

# 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 were 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**

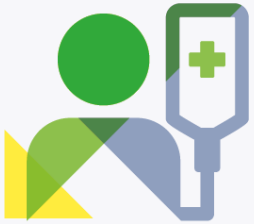
**Reference:** Simon-Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market. Accessed March 2020.

# Summary: The benefits of biosimilar medicines

The use of biosimilar medicines has been **successfully implemented** within **Europe since 2006**[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]

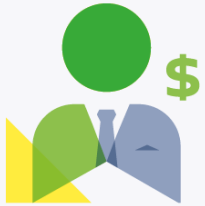


### Patients

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

### 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.