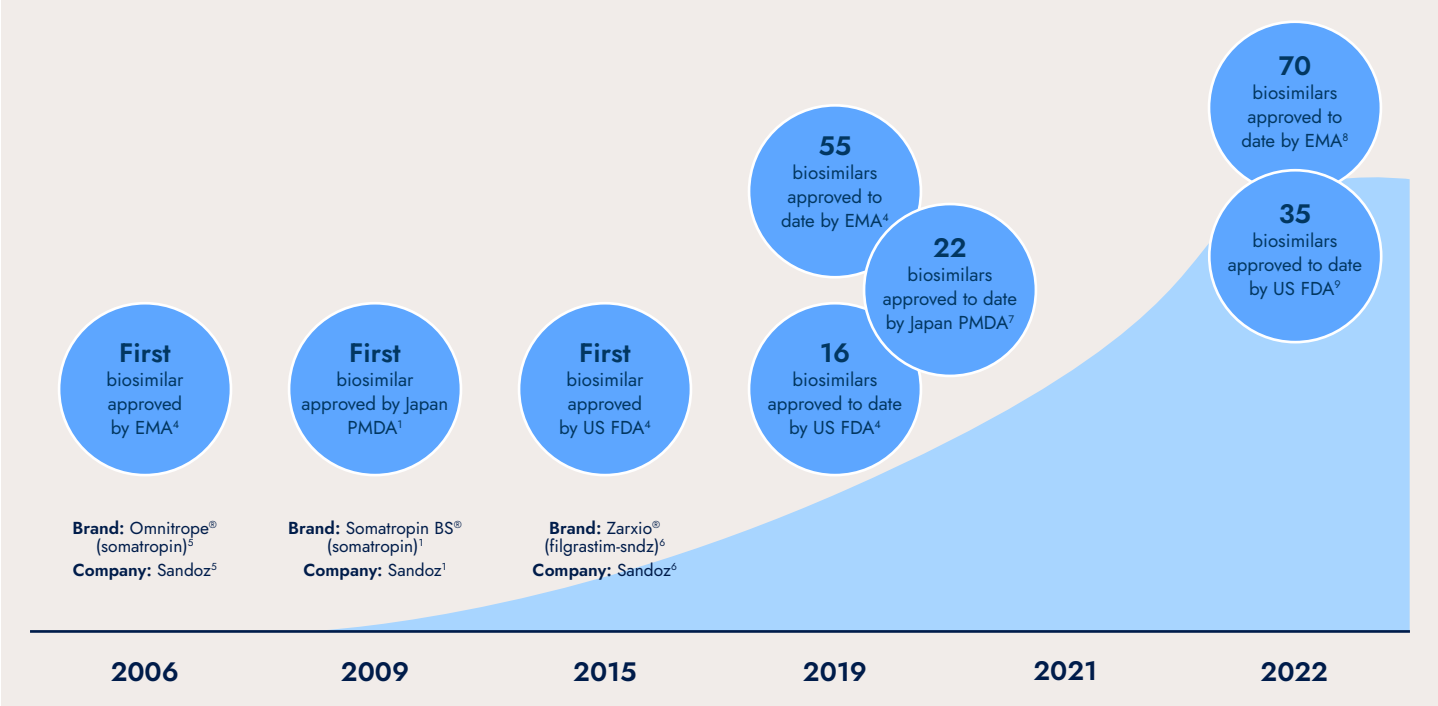
The 15-year rise of biosimilar medicines

What is a biosimilar?

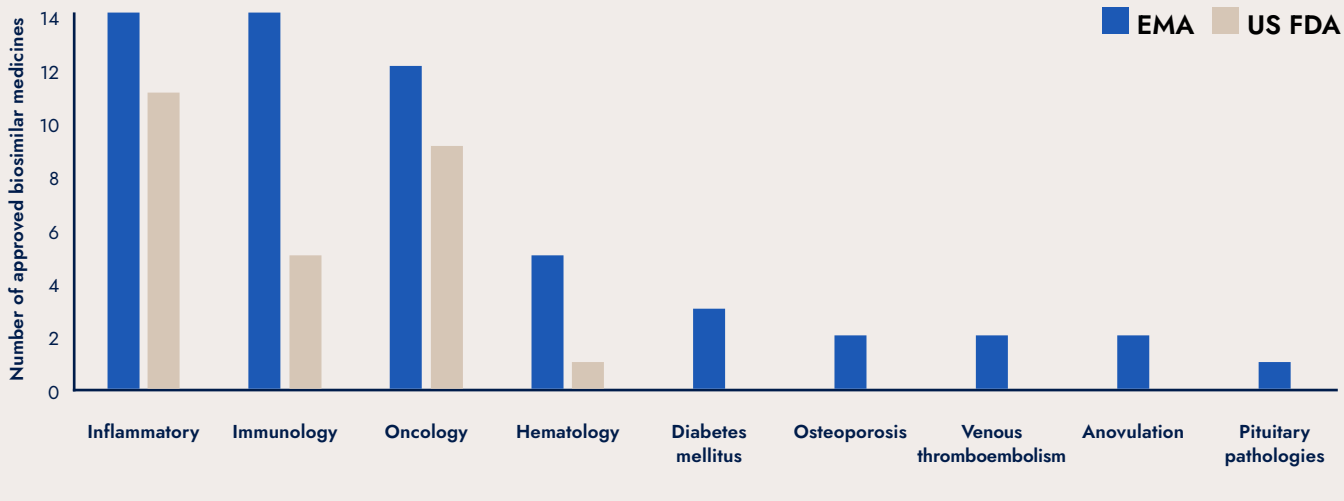
A biosimilar is a successor to a reference biologic – a medicine made from living organisms or cells – for which the patent has expired[1]

Biosimilar medicines match their reference biologic in terms of safety, efficacy and quality, and demonstrate no clinically meaningful differences[1–3]

A brief history of biosimilar medicine approvals



Biosimilar medicines approvals by therapeutic area by 2019[4]



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Impact of biosimilar medicines uptake to date

Experience in other therapy areas, such as rheumatoid arthritis (TNF inhibitors) and oncology (G-CSF), illustrates that biosimilar medicines positively impact patient treatment access and sustainability of care[10,11]

19%

Introduction of biosimilar TNF inhibitors for rheumatoid arthritis led to **19% increase** in TNF inhibitor **volume use per treatment day** in Europe, compared with 1 year before market release[10]

Introduction of G-CSF biosimilar medicines led to:

- **5-fold increase** in **reimbursed usage** of a **G-CSF biologic medicine** in Sweden[11]
- A **decline** in volume of **hospitalizations** for chemotherapy-induced febrile neutropenia in patients with breast cancer from **33% to <7%** in New Zealand[12]

13%

Introduction of biosimilar TNF inhibitors for rheumatoid arthritis led to **13% decrease** in **treatment price per treatment day** in Europe, compared with 1 year before market release[10]

An estimated **over $1.6 million USD* in annual saved purchase costs** were recorded in the UK following uptake of a G-CSF biosimilar medicine for prevention of chemotherapy-induced neutropenia[11]

Using a G-CSF biosimilar instead of the reference biologic yielded **cost savings** from **$65** for **1-day regimen** to **$916** for a **14-day regimen** in the US[13†]

Future impact of biosimilar medicines

Rapid uptake of biosimilar medicines in the US is set to reduce drug costs by $100 billion between 2020–2024[14]

Biosimilar medicines are estimated to deliver $285 billion savings worldwide between 2021–2026[15]

EU countries have been shown to save as much as 66% on the total market price following the introduction of biosimilar medicines[16]

Biosimilar medicines can expand access to life-changing medicines by providing more treatment options and introducing competition, thus increasing affordability[7]

*Approximate value in USD calculated from GBP using 2011 values.[17]
†2016 cost efficiency analysis of prophylaxis during one chemotherapy cycle under 1–14 days' time horizon.
EMA, European Medicines Agency; G-CSF, granulocyte colony stimulating factor; PMDA, Pharmaceuticals and Medical Devices Agency; TNF, tumor necrosis factor; US FDA, US Food and Drug Administration; USD, United States dollar.

1. Farhat F, et al. Oncologist 2018;23(3):346–352; **2.** Biosimilar medicines. Biosimilar medicines handbook 2016. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/04/BIOSIMILAR-MEDICINES-HANDBOOK_INT_web_links2.pdf. Accessed September 2022; **3.** McCamish M, et al. Clin Pharmacol Therap 2015;97(3):215–217; **4.** Gherghescu I, Delgado-Charro MB. Pharmaceutics 2021;13(1):48; **5.** Omnitrope®. Summary of product characteristics, 2021. Available at: https://www.ema.europa.eu/en/documents/product-information/omnitrope-epar-product-information_en.pdf. Accessed April 2022; **6.** Zarxio®. Prescribing Information, 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125553s023lbl.pdf. Accessed June 2022; **7.** Kang HN, et al. Biologicals 2020;65:1–9; **8.** Generics and Biosimilar Initiative. Available at: https://gabionline.net/biosimilars/general/biosimilars-approved-in-europe. Accessed February 2022; **9.** FDA. Biosimilar Product Information. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed April 2022; **10.** Smolen JS, et al. RMD Open 2019;5:e000900; **11.** Gascon P, et al. Support Care Cancer 2013;21:2925–2931; **12.** Cornes P, et al. BioDrugs 2020;34:255–263; **13.** McBride A, et al. J Med Econ 2017;20:1083–1093; **14.** IQVIA. Biosimilars in the US 2020–2024. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024. Accessed February 2022; **15.** IQVIA Institute for Human Data Science Study. Available at: https://www.iqvia.com/newsroom/2021/04/global-medicine-spending-to-reach-16-trillion-in-2025-excluding-spending-on-covid-19-vaccines-accord.Accessed February 2022; **16.** QuintilesIMS. The impact of biosimilar competition in Europe, 2017. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf. Accessed February 2022; **17.** XE. Historical Rates Tables. Available at: https://www.xe.com/currencytables/?from=GBP&date=2011-06-08#table-section. Accessed June 2022.

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