



HMA/EMA statement on interchangeability of biosimilars

HMA/EMA multi-stakeholder workshop on shortages
1-2 March 2023

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Let's get terms and responsibilities right!

Interchangeability is exchanging one medicine for another medicine that is expected to have the same clinical effect.

Reference product $\leftarrow \rightarrow$ *Biosimilar*

Biosimilar $\leftarrow \rightarrow$ *Biosimilar (w/same ref prod)*

Replacement can be done by:

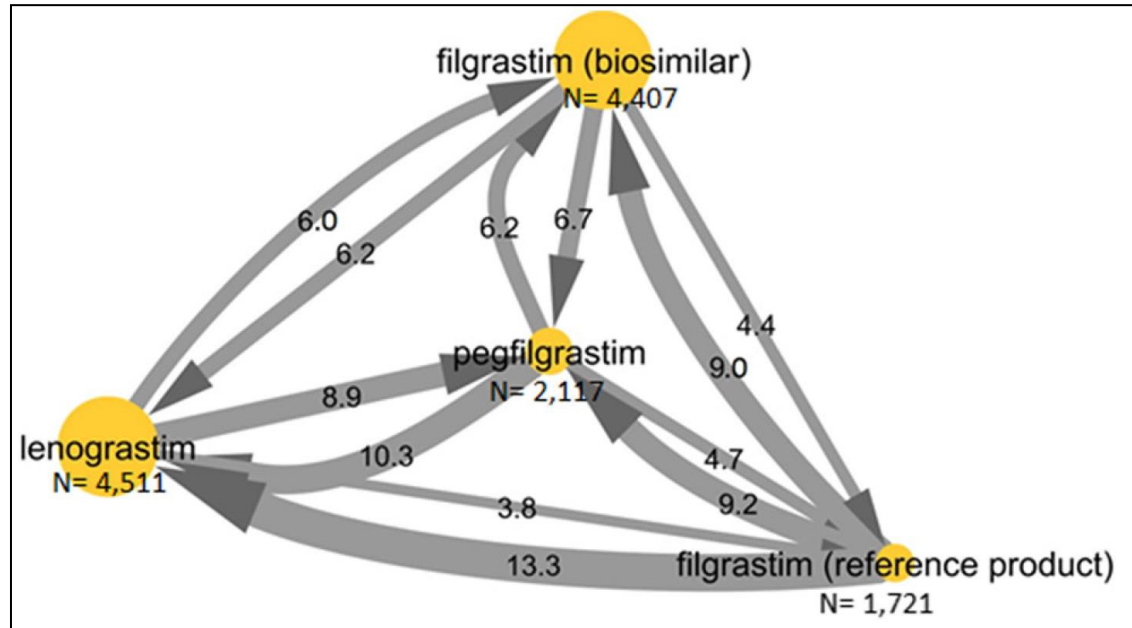
- **Switching**, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent.
- **Substitution (automatic)**, which is the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the prescriber.

EMA

Member
state

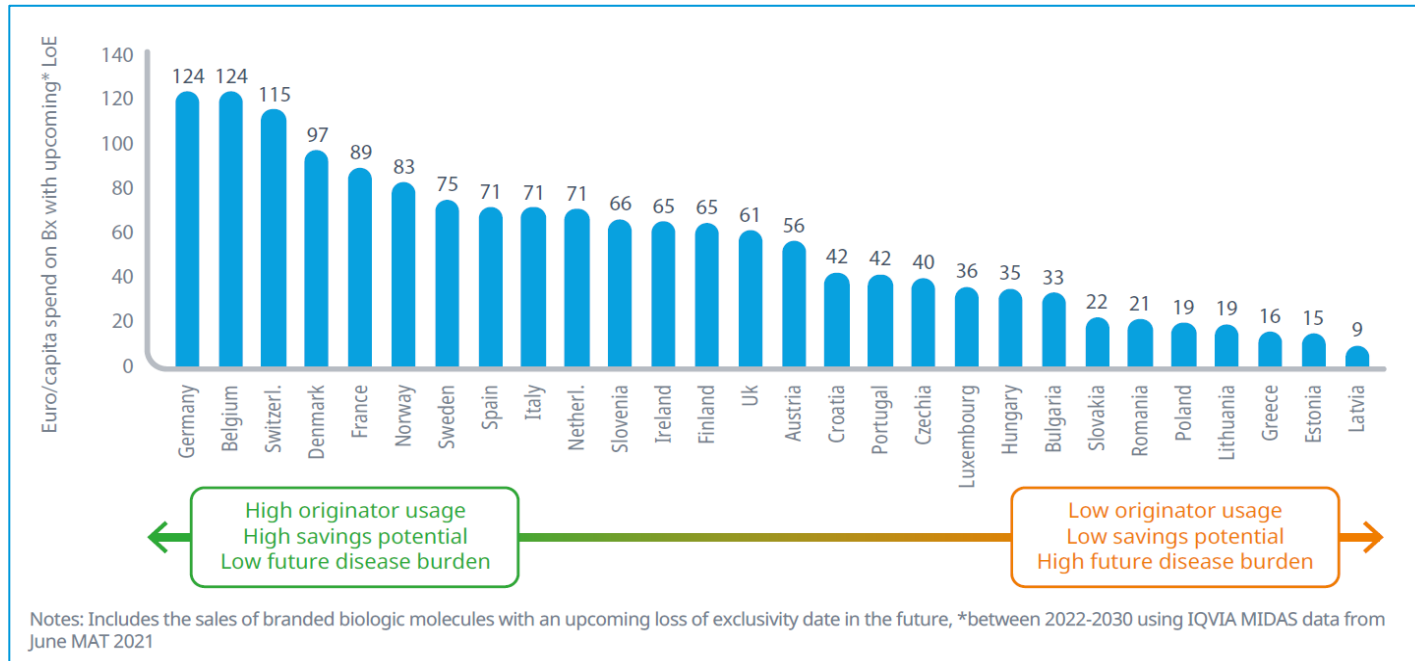
[EMA information guide to healthcare professionals](#)

Switching is a common clinical practice!



BioDrugs (2016) 30:295–306

Uneven use of biologics has consequences for biosimilar uptake



IQVIA: The Impact of Biosimilar Competition in Europe, December 2021

Evidence in support of interchangeability

Switching between non-biosimilar biologicals are seldomly associated with adverse reaction, incl. in patients with pre-existing anti-bodies

EU approved biosimilars are highly similar to their reference product

No signs of change in efficacy nor safety in head-to-head clinical trials

- This is also supported by dedicated 'multiple switch studies'

Extensive clinical exposure (>1.3 mio Patient-Years) with no sign of difference in adverse reaction pattern biosimilar><reference product



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2022
EMA/627319/2022



Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

References:

1. Interchangeability of Biosimilars: A European Perspective. Pekka Kurki, Leon van Aerts, Elena Wolff-Holz, Thijs Giezen, Venke Skibeli, Martina Weise. *BioDrugs* 2017 Apr;31(2):83-91
2. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice messaging. Liese Barbier, Allary Mbuaki, Steven Simoens, Paul Declerck, Arnold G. Vulto, and Isabelle Huys. *Frontiers in Medicine* 2022, Vol 9, 820755
3. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. Pekka Kurki, Sean Barry, Ingrid Bourges, Panagiota Tsantili, Elena Wolff-Holz. *Drugs* 2021 Nov;81(16):1881-1896
4. The safety of switching between therapeutic proteins. Ebbers H, Muenzberg M, Schellekens H. *Expert Opinion Biol Ther.* 2012;12:1473-85
5. [Biosimilars in the EU - Information guide for healthcare professionals \(europa.eu\)](#)



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20 January 2023

European Medicines Agency

Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

Following the publication of the joint EMA-HMA statement on interchangeability of biosimilar medicinal products approved in the EU, both EMA and NCAs have received questions for clarification. To address the issues raised in these questions the following Q&A is considered to be added to the statement on the EMA's website.

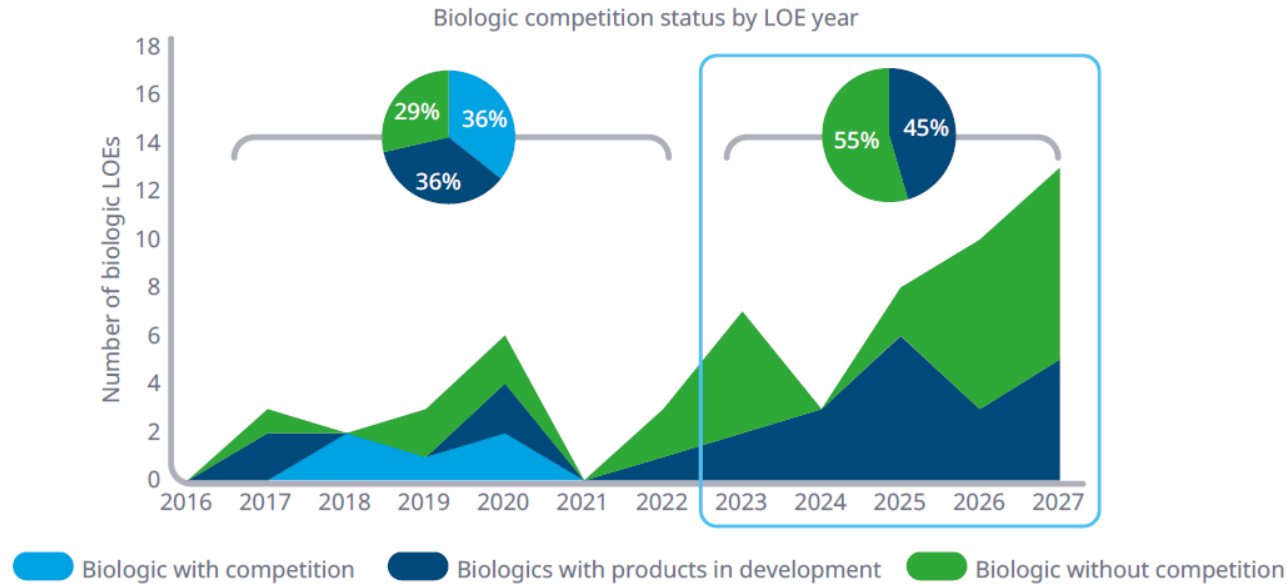
Q1 *Does the interchangeability of biosimilars also cover situations where multiple switches are taking place – independent of frequency of switches and number of products involved?*

Q2 *Does interchangeability – including the possibility for multiple switches as discussed in Q1 – apply to all kinds of biosimilars, e.g. also those with a more complex molecular structure?*

Q3 *Does the joint EMA-HMA statement on interchangeability of biosimilars mean that switching to or between biosimilars are allowed in my country?*

.....Ongoing updates to capture new questions

Exhibit 13: Forecast number molecules losing exclusivity in Europe and respective pipeline



Source: IQVIA Patent Intelligence, Pipeline Intelligence, and IQVIA Forecast Link analysis (November 2022); Historic analysis sourced from IQVIA Institute report, Protection expiry and Journey into the Market (2022)

Note: The intellectual property for biologics can involve multiple patents, patent timelines, data exclusivity, and litigation for each individual product and therefore it is difficult to give an exact date for protection expiry for biologics. It should be noted that these results are estimates as determined from IQVIA MIDAS® and ARK Patent Intelligence where available, and historical products are cross-referenced to public sources

IQVIA: The Impact of Biosimilar Competition in Europe, December 2022

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union

