Biosimilar Breakout Session :

HMA-EMA Multi-stakeholder workshop on shortages

1-2 March 2023

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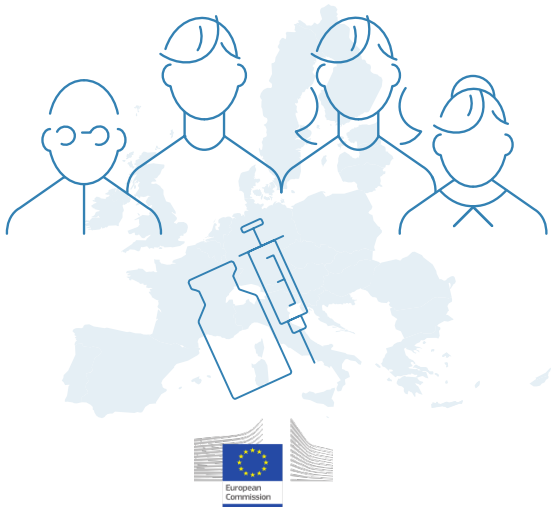
Objectives of session on biosimilars

HMA-EMA multi-stakeholder workshop on shortages



- **Understand stakeholders' experience on shortages** of biological medicines, including biosimilars and gather views on **whether availability of biosimilars could** be a good way to **prevent shortages** of biologicals
- Provide an **overview** of the work **of HMA working group on biosimilars** and explain the **EU scientific position on interchangeability**
- Understand how the work undertaken by the **European Medicines Agencies Network** could **prevent potential shortages of biologicals** and **increase the uptake of biosimilars**

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 ← → Biosimilar

Biosimilar ← → Biosimilar (w/same ref prod)

EMA

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.

Member state

EMA information guide to healthcare professionals

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

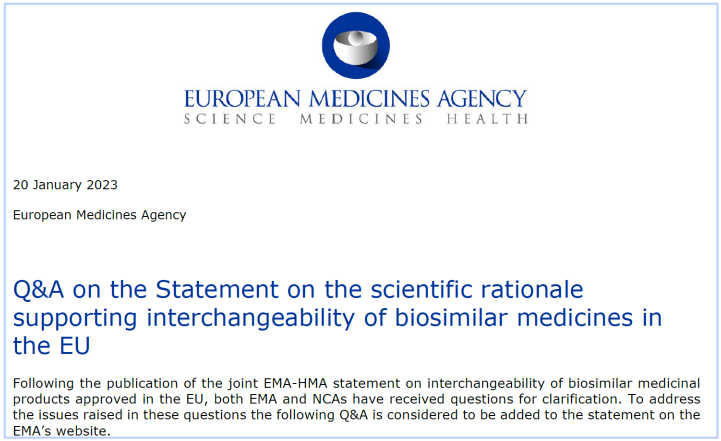
HMA
Heads of Medicines Agencies

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)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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**

Outcome of pre-meeting survey

- Survey run pre-meeting to understand stakeholders' experiences
- Responses from all stakeholder groups low response rate (26%, n=26)
- Some relevant **observations:**
  - **Need for increasing information on biosimilars** over 50% (13 out of 25)
  - **Experience of shortage of a biological or a biosimilar medicine** 50% (13 out of 26)
  - **Most respondents trust interchangeability** 84% (21 out of 25)
  - **Various reasons for lack of trust on interchangeability** (16%, 4 out of 25) including lack of comparative studies, resource implications when training patients to use another device after switching and potential loss of efficacy due to immunogenicity
  - Perception of **biosimilars as useful alternatives to prevent shortages** of biological medicines (62%, 16 out of 26)

Breakout session on Biosimilars

- **Extensive scientific and clinical experience** with biosimilars, including on safety and prescriber-led switching
- Need for **more timely communication** on the regulatory science underpinning biosimilars to **foster trust**
- **Consistent messaging needed** across all the different players of the healthcare system, while adapting to the needs of different therapeutic areas
- **Need to address concerns on interchangeability**, such as off label use and the importance of patient consent
- **Varied reasons for lack of availability** (e.g., procurement, market forces, patent issues, etc.)
- **Different speed of access to biosimilars across EU** – need for MSs to prepare and engage early with tenderers
- Need to address **sustainability of biosimilar development** as pipeline forecast predicts lack of biosimilars for some products
- **HTA and payers support biosimilarity** but identified hurdles on implementation of interchangeability

  (e.g., switching studies for devices to prove compatibility)
- Biosimilars are different from generic medicines, but **implementation has to follow a similar approach**
- **Biosimilars can prevent shortages** of biological medicines

Thank you for listening

Further information

https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview

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