Interchangeability of biosimilars: Joint EMA-HMA statement

PCWP/HCPWP

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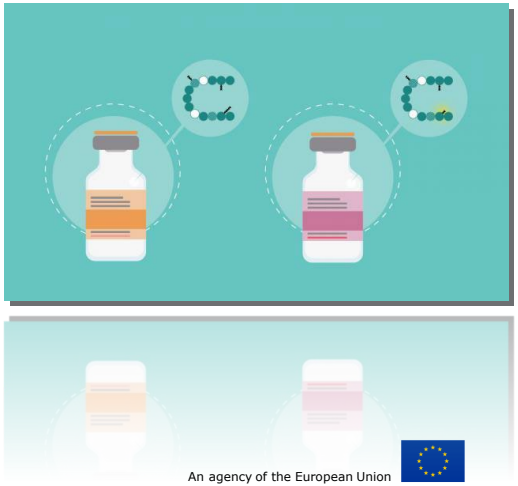

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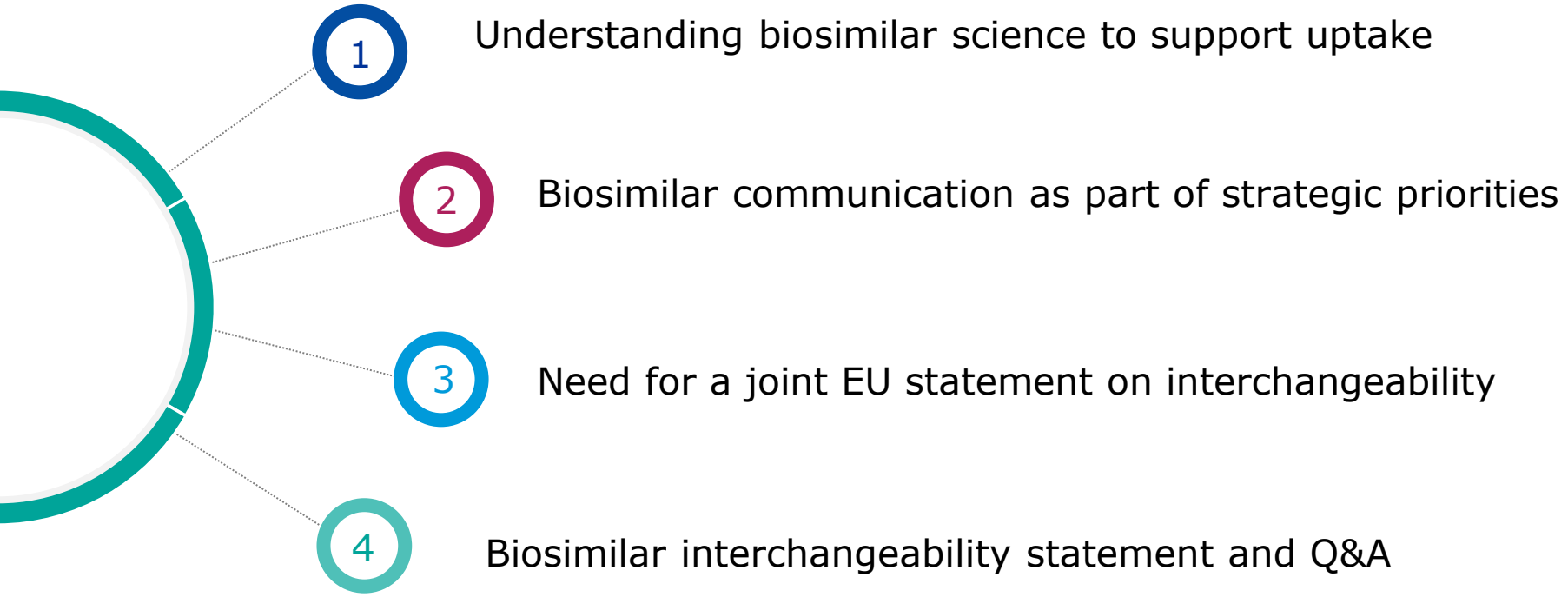
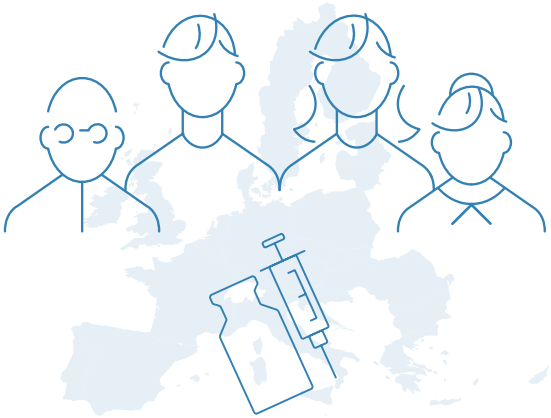
Outline



Supporting understanding of biosimilars: the science matters



Building on the stakeholder dialogue set up by the EC

- **Biosimilars** as a **paradigm** of **regulatory science:**
  - at the time, **novel approach** to medicines' development
  - conveying the **scientific principles** matter
- Lack of **unbiased and reliable information** can be a barrier to sustainable uptake
- **Continuous dialogue/outreach** with **stakeholders** is key
  - **Responding** to patients/ health professionals needs for information
  - Continuous **education & professional development**

Biosimilar communication as part of key strategic priorities

Advancing patient-centred access to medicines in partnership with healthcare systems

HTA's preparedness and downstream decision making for innovative medicines

Collaboration with Payers

Relevance of patients in evidence generation

Big data

electronic Product Information

High-quality real world data

Understanding the EU regulatory system

Promote the availability and support uptake of biosimilars in healthcare systems

- **Strategic communication campaigns to patient and healthcare professional to reinforce trust**
- Enhance **training of non-EU regulators in evaluation of biosimilars**
- **Address** regulatory **challenges**

Need for a joint EU statement on interchangeability

- Until now, biosimilars approved via EMA could be **used interchangeably if the national regulatory agency allowed it**
- Switching is successfully taking place in **clinical practice**
- From a scientific viewpoint, interchangeability of approved biosimilars has **always been considered acceptable and did not raise any concern**
- However, **EMA has to date not issued any recommendation on interchangeability**
- The EU medicines regulatory network has identified the **need to issue an explicit statement**
- The absence of a clear EU-wide position on interchangeability has been identified as a **factor causing uncertainty among stakeholders on the use of biosimilars in clinical practice**
- A harmonised and clear EU wide position on interchangeability is needed **to reduce any uncertainty** that prescribers may have when deciding to prescribe biological medicines

EU statement on interchangeability

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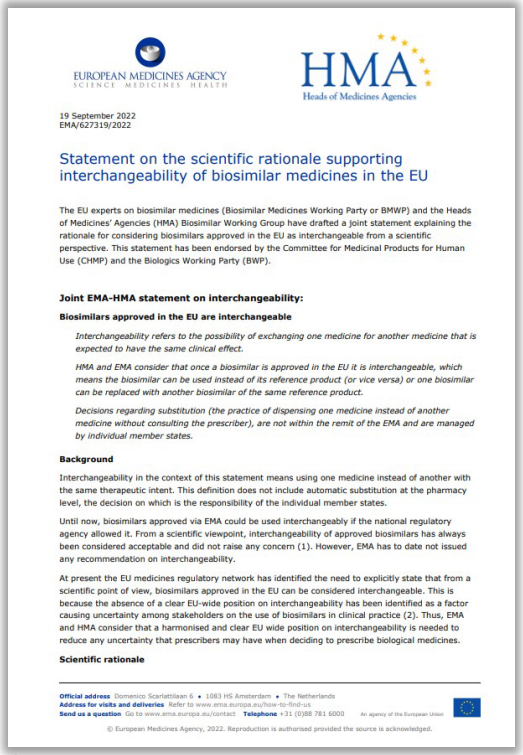

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HMA
Heads of Medicines Agencies

19 September 2022
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Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

The EU experts on biosimilar medicines (Biosimilar Medicines Working Party or BMWP) and the Heads of Medicines' Agencies (HMA) Biosimilar Working Group have drafted a joint statement explaining the rationale for considering biosimilars approved in the EU as interchangeable from a scientific perspective. This statement has been endorsed by the Committee for Medicinal Products for Human Use (CHMP) and the Biologics Working Party (BWP).

Joint EMA-HMA statement on interchangeability:

Biosimilars approved in the EU are interchangeable

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

HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product.

Decisions regarding substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber), are not within the remit of the EMA and are managed by individual member states.

Background

Interchangeability in the context of this statement means using one medicine instead of another with the same therapeutic intent. This definition does not include automatic substitution at the pharmacy level, the decision on which is the responsibility of the individual member states.

Until now, biosimilars approved via EMA could be used interchangeably if the national regulatory agency allowed it. From a scientific viewpoint, interchangeability of approved biosimilars has always been considered acceptable and did not raise any concern (1). However, EMA has to date not issued any recommendation on interchangeability.

At present the EU medicines regulatory network has identified the need to explicitly state that from a scientific point of view, biosimilars approved in the EU can be considered interchangeable. This is because the absence of a clear EU-wide position on interchangeability has been identified as a factor causing uncertainty among stakeholders on the use of biosimilars in clinical practice (2). Thus, EMA and HMA consider that a harmonised and clear EU wide position on interchangeability is needed to reduce any uncertainty that prescribers may have when deciding to prescribe biological medicines.

Scientific rationale

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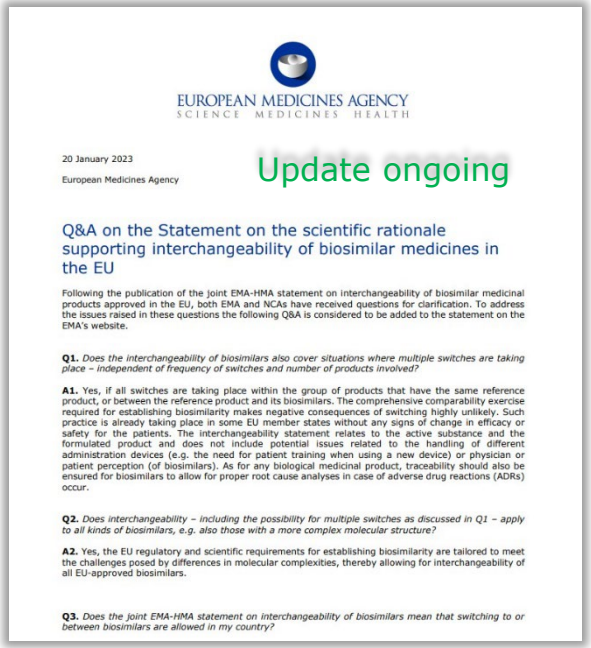
Biosimilars approved in the EU are interchangeable

- Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the **same clinical effect**
- HMA and EMA consider that **once a biosimilar is approved in the EU it is interchangeable**, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product
- Interchange should only take place after careful consideration of the **approved conditions of use** (i.e., consulting the **most recent product information**)
- **Decisions regarding substitution** (the practice of dispensing one medicine instead of another medicine without consulting the prescriber), are not within the remit of the EMA and are managed by **individual member states**

Scientific rationale and references included

Q & A to complement statement on interchangeability

Available for healthcare professionals, patients and other stakeholders to further address issues related to the interchangeability of biosimilars in EU countries



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European Medicines Agency

Update ongoing

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?*

A1. Yes, if all switches are taking place within the group of products that have the same reference product, or between the reference product and its biosimilars. The comprehensive comparability exercise required for establishing biosimilarity makes negative consequences of switching highly unlikely. Such practice is already taking place in some EU member states without any signs of change in efficacy or safety for the patients. The interchangeability statement relates to the active substance and the formulated product and does not include potential issues related to the handling of different administration devices (e.g. the need for patient training when using a new device) or physician or patient perception (of biosimilars). As for any biological medicinal product, traceability should also be ensured for biosimilars to allow for proper root cause analyses in case of adverse drug reactions (ADRs) occur.

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?*

A2. Yes, the EU regulatory and scientific requirements for establishing biosimilarity are tailored to meet the challenges posed by differences in molecular complexities, thereby allowing for interchangeability of all EU-approved biosimilars.

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

- **Multiple switches**
- More **complex molecular structure**
- Switching **allowed in my country**
- Switching when biosimilar and reference have **different indications**
- Switching when the Product Information contains **different conditions of use** (e.g. different excipient that may trigger a contraindication)
- **Interchangeability after manufacturing changes** to biosimilar or reference medicine

Thank you for listening

Further information

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

See websites for contact details

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