HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Improving understanding of biosimilars:

Toolkit for Member States

PCWP/HCPWP, 15 November 2023

Presented by Bernard Duggan, HMA Biosimilar working group

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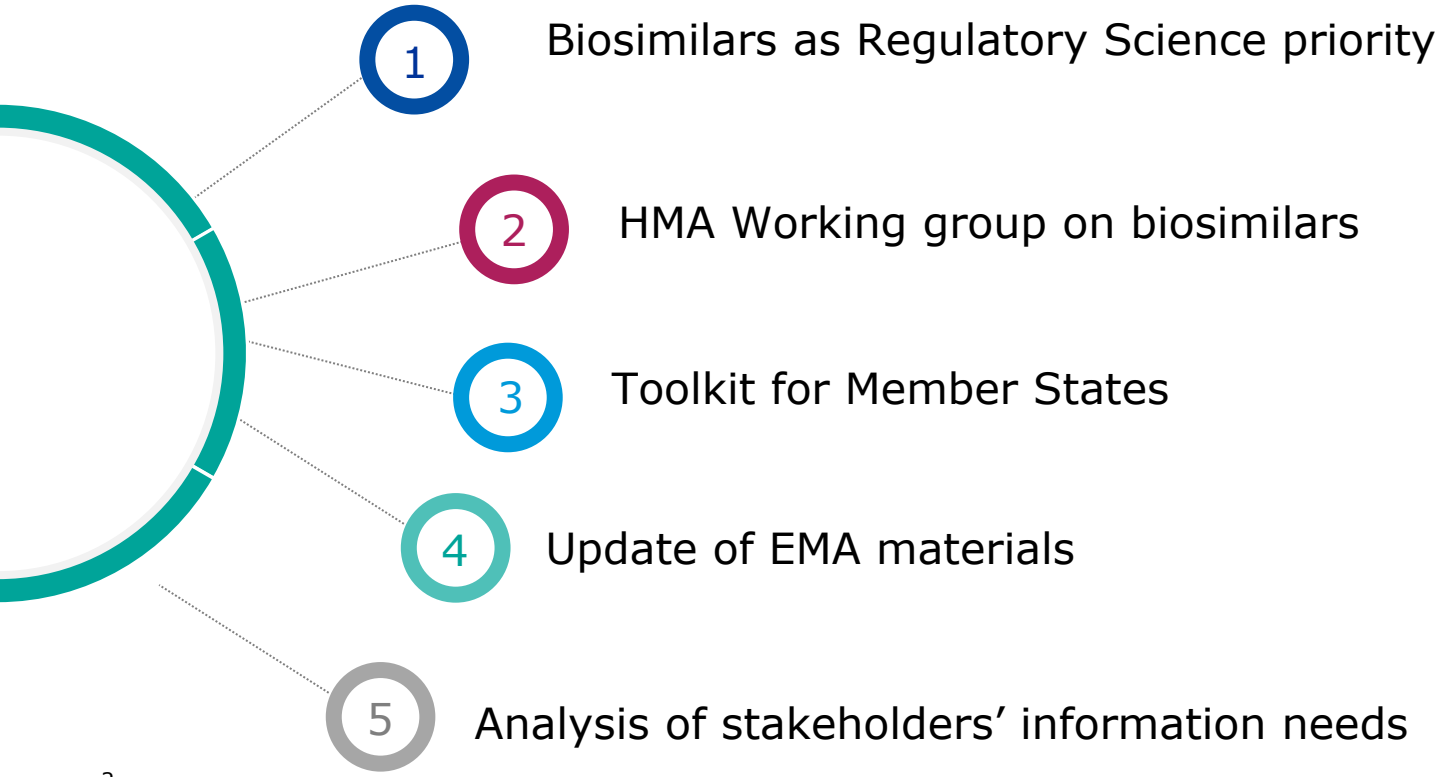
Outline



Biosimilars as a Network priority

Promote the availability and support uptake of biosimilars in healthcare systems

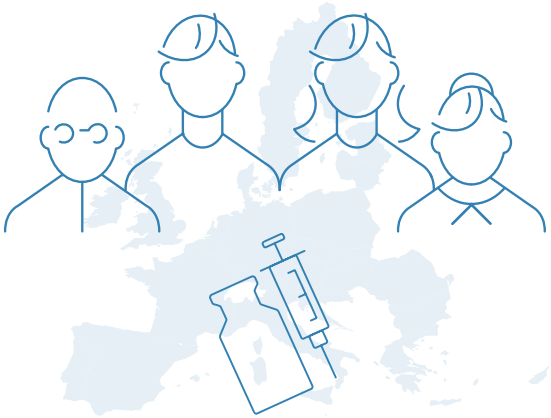
- Strategic **communication campaigns** to patient and healthcare professional to **reinforce trust**
- Enhance **training of non-EU regulators in evaluation of biosimilars**
- **Address** regulatory **challenges**

HMA Working Group on Biosimilars

Experience communicating on biosimilars

- Lack of **unbiased and reliable information is still** a barrier to sustainable uptake
- **Taking seriously** all **concerns** from patients and healthcare professionals is key
- **Public health initiative** for enhanced credibility:
  - ✓ involving scientific experts + healthcare professionals/patients
- Important to get consistent messages **across the EU**
- Need to **anticipate upcoming challenges** & information needs
  - ✓ Address understanding of interchangeability and gaps in information

Biosimilar toolkit for Member States



HMA Working Group on Biosimilars

- **New modular information pack** on biosimilars targeting healthcare professionals and patients.
- Toolkit available to Member States to support their own communication campaigns – **flexibility based on needs**
- **Including up-to-date EU materials** developed to date
- **New information elements** on:
  - ✓ Biosimilar regulatory **approval process**
  - ✓ **Efficacy and safety** of biosimilars
  - ✓ **Interchangeability**
  - ✓ **Case studies** on uptake of biosimilars resulting in savings

Work to date

- Review of material that is available in relation to biosimilar medicines
  - EMA information considered gold standard
- Documents drafted in relation to:
  - Regulatory approval process
  - Interchangeability
  - Safety and efficacy
- Suggested approach:
  - Update of current EMA material
  - Repurposing of current EMA material so as to provide in alternative formats
  - Stakeholder survey to capture information needs of our stakeholders

Improving understanding of biosimilars:

EU materials and Stakeholder gap analysis

PCWP/HCPWP, 15 November 2023

Presented by Rosa Gonzalez-Quevedo, Stakeholders and Communication Division

EU strategy for improving understanding on biosimilars

Improving understanding to increase trust

Continuous education

Guide for HCPs
2017

Patients' Q&A
2016

Enhanced transparency on benefit-risk

Medicine overviews

Collaboration with stakeholders

Building up on a successful multi-stakeholder approach set up by the EC

- **EMA working parties with healthcare professionals and patients/consumers**

Supporting consistent messages

Guide for HCPs translations

Video

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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
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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

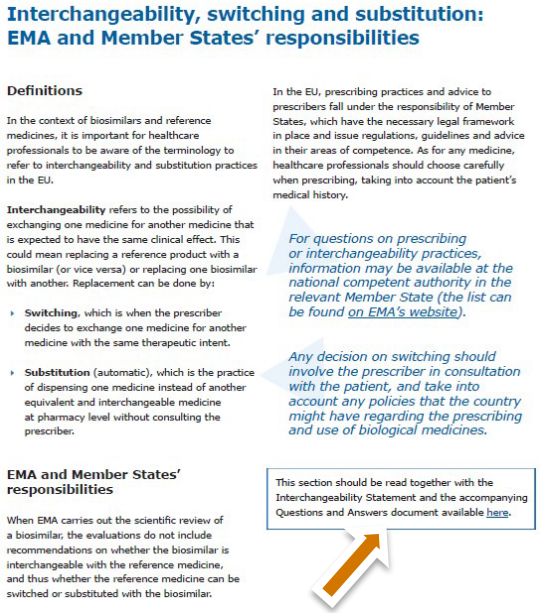
Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

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.

Updating the HCP guides with links to the interchangeability statement

Translations of the biosimilar guide into **23 official languages**

Updated guides for HCPs with disclaimer and link to interchangeability statement and Q & A



Interchangeability, switching and substitution: EMA and Member States' responsibilities

Definitions

In the context of biosimilars and reference medicines, it is important for healthcare professionals to be aware of the terminology to refer to interchangeability and substitution practices in the EU.

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference product with a biosimilar (or vice versa) or replacing one biosimilar with another. 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 and Member States' responsibilities

When EMA carries out the scientific review of a biosimilar, the evaluations do not include recommendations on whether the biosimilar is interchangeable with the reference medicine, and thus whether the reference medicine can be switched or substituted with the biosimilar.

The decision on whether to allow interchangeable use and substitution of the reference biological medicine and the biosimilar is taken at national level. Information on the scientific evaluation performed by EMA's scientific committees is available on EMA's website and could be used to support decisions.

In the EU, prescribing practices and advice to prescribers fall under the responsibility of Member States, which have the necessary legal framework in place and issue regulations, guidelines and advice in their areas of competence. As for any medicine, healthcare professionals should choose carefully when prescribing, taking into account the patient's medical history.

For questions on prescribing or interchangeability practices, information may be available at the national competent authority in the relevant Member State (the list can be found on EMA's website).

Any decision on switching should involve the prescriber in consultation with the patient, and take into account any policies that the country might have regarding the prescribing and use of biological medicines.

This section should be read together with the Interchangeability Statement and the accompanying Questions and Answers document available here.

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

Outcome of March 2023 discussion with stakeholders

- 26% of registered participants replied to the pre-meeting survey (n=26) , with 77% of respondents (20 out of 26) based in the EU
- Wide representation of stakeholders, including patients, consumers and HCPs
- **There is room for increasing information on biosimilars - over 50% of respondents (13 out of 25) are not very informed or somewhat informed**
- **84% (21 out of 25) of respondents have no reason not to trust interchangeability of biosimilars**
- **Reasons for lack of trust on interchangeability** (16%, 4 out of 25) include lack of comparative studies, resource implications when training patients to use another device after switching and potential loss of efficacy due to immunogenicity

Need identified for further analysis of stakeholder needs to feedback into Toolkits

2023-2024 work – External collaboration

Objectives

- **Review and update of current EMA communication materials** on biosimilars.
- Review and progress on translations.
- **Gap analysis of communication needs**, including on 'interchangeability', between MSs, patients and healthcare professionals (HCPs), with a view to informing further communication activities or refreshing/reusing existing materials.

Deliverables

- **Update of EMA guide on biosimilars for HCPs and proposal for update of other materials** (patient Q&A, videos) if needed.
- **Analysis of stakeholders' information needs** on biosimilars, in particular on interchangeability and recommendations for improving EMA information materials.
- **Input into national toolkit** discussions.

Points for discussion

- **Stakeholder survey to gather information needs on biosimilars**
    - Scope of the survey
    - Survey timelines - expected Q1 2024
    - Inform ongoing work on the toolkit
    - Follow up with organisations on outcome of survey
- **Review and update of EMA materials**
    - Guide for HCPs – addition of disclaimer done
- **Toolkit discussion**
    - Objective of engagement with eligible organisations representing patients, consumers and healthcare professionals
        - Plans for user-testing of toolkit materials

Thank you for your attention

With thanks to Toolkit drafting group, BSWG and Steffen Thirstrup

Further information

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