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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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The EU regulatory network has been assessing, authorising and monitoring biosimilars for over 15 years and has gained very profound understanding of biosimilars after reviewing more than one hundred biosimilar candidate submissions, and monitoring their safety once they are placed onto the market.

Switching between biological medicinal products manufactured and commercialised by different companies has become common in clinical practice, and interchangeability of EU-licensed biosimilars has been confirmed (1, 2, 3, 4).

Approved biosimilars have demonstrated comparable efficacy, safety and immunogenicity compared with their reference products (5). Thus, EU experts consider that when approval for a biosimilar is granted in the EU, additional systematic switch studies are not required to support the interchangeability at prescriber level.

Considering all the available scientific evidence and the successful experience with biosimilars in clinical practice over the years, the CHMP and all working parties with expertise in biological medicines and biosimilars support that medicines approved as biosimilars in the EU may be prescribed interchangeably. This will allow more patients to have access to biological medicines necessary for treating diseases such as cancer, diabetes and rheumatic diseases.

Member States will continue to decide which biological medicines are available for prescribing in each territory and whether automatic substitution is allowed at pharmacy level.

Information sources on biosimilars

Patients and healthcare professionals with specific questions on interchangeability practices are recommended to contact the medicines regulatory agency in their member state: National competent authorities (human) | European Medicines Agency (europa.eu).

For questions on how biosimilars are approved and monitored in the EU, patients and healthcare professionals can contact EMA: Send a question to the European Medicines Agency | European Medicines Agency (europa.eu).

References:

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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, Munzenberg M, Schellekens H. Expert Opinion Biol Ther. 2012;12:1473-85
5. Biosimilars in the EU - Information guide for healthcare professionals (europa.eu)