EUROPEAN MEDICINES AGENCY
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News announcement

Biosimilar medicines can be interchanged

EMA and the Heads of Medicines Agencies (HMA) have issued a joint statement confirming that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or with an equivalent biosimilar.

While interchangeable use of biosimilars is already practiced in many Member States, this joint position harmonises the EU approach. It brings more clarity for healthcare professionals and thus helps more patients to have access to biological medicines across the EU.

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Interchangeability in this context means that the reference medicine can be substituted by a biosimilar without a patient experiencing any changes in the clinical effect.

"*EMA has approved 86 biosimilar medicines since 2006. These medicines have been thoroughly reviewed and monitored over the past 15 years and the experience from clinical practice has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference products and are therefore interchangeable",* says Emer Cooke, EMA's Executive Director. *"This is good news for patients and healthcare professionals, who have wider access to important therapeutic options to treat serious diseases such as cancer, diabetes and rheumatoid arthritis*."

The statement, drafted by EU experts from the Biosimilar Working Party and the Heads of Medicines Agencies Biosimilar Working Group, was endorsed by EMA's human medicines committee, the CHMP, on 22 July 2022.

EMA's position is based on the experience gained in clinical practice, where it has become common that doctors switch patients between different biological medicinal products. Approved biosimilars have demonstrated similar efficacy, safety and immunogenicity compared with their reference medicines, and analysis of more than one million patient-treatment years of safety data did not raise any safety concerns. Thus, EU experts considered that when a biosimilar is granted approval in the EU, it can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.

Decisions regarding substitution at pharmacy-level (the practice of dispensing one medicine instead of another without consulting the prescriber) are managed by individual Member States.

EMA will update its communication materials on biosimilars for patients and healthcare professionals to highlight the common position.

1. This press release, together with all related documents, is available on the Agency's website at: <LINK>
2. <Note>.
3. <Note>.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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