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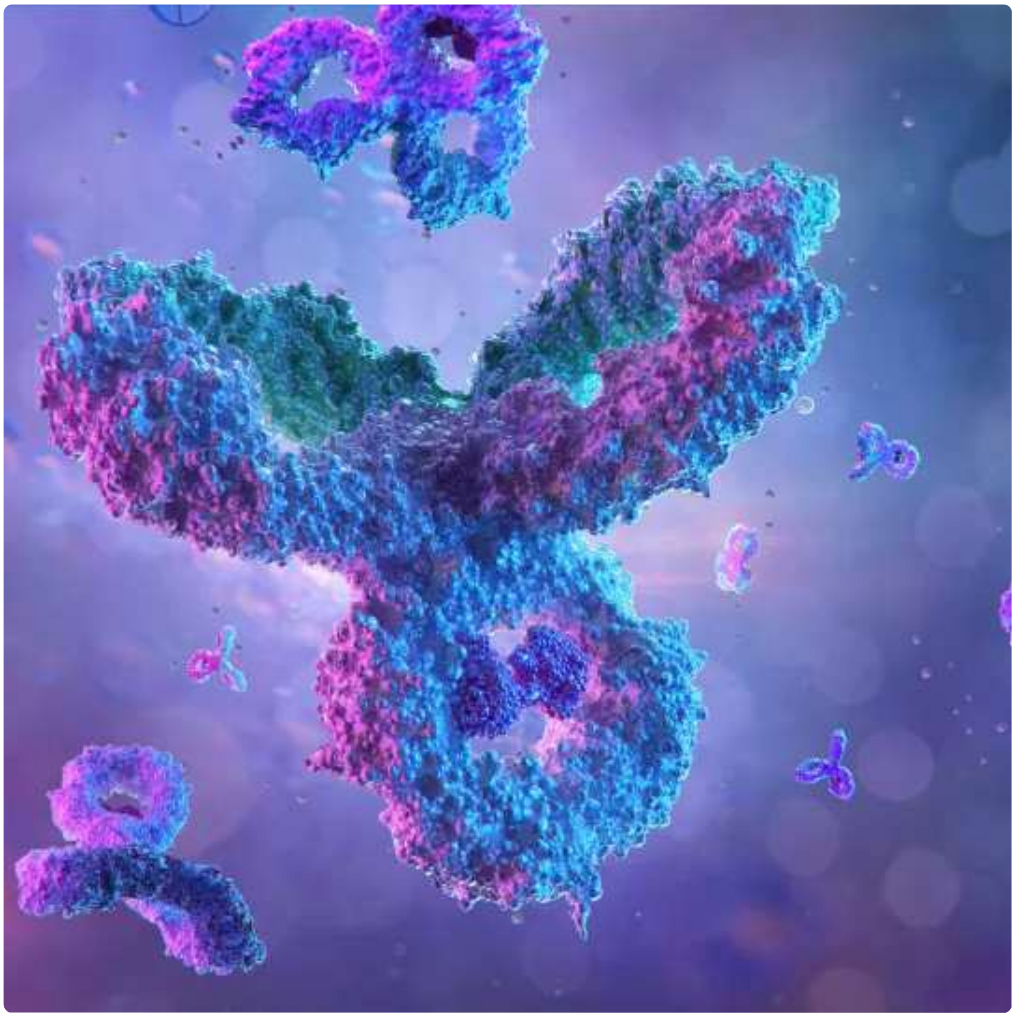

Streamlining development and assessment of biosimilar medicines

1 April 2025

Proposal aims to encourage development and improve patient access

News Human Biosimilars

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EMA is exploring improvements to the development and evaluation of biosimilar medicines, while upholding strict European Union (EU) safety standards. With over two decades of experience in evaluating biosimilar medicines, EMA anticipates that this approach will improve access to biosimilars for patients in the EU and ensure that Europe is an attractive market to develop these treatments.

The approach, which is outlined in a new draft reflection paper, would potentially reduce the amount of clinical data required for the development and approval of biosimilar medicines.

Stakeholders are invited to send their comments on the reflection paper via an online EUSurvey until 30 September 2025.

A biosimilar is a biological medicine that is highly similar to another already approved biological medicine (the 'reference medicine'). Biosimilar medicines have become important therapeutic options improving patient access to essential treatments. They are used to treat a variety of diseases such as cancer, rheumatoid arthritis and inflammatory bowel disease. They offer the same clinical effectiveness and safety as their reference product. By providing competition in the market, they can expand patient access to critical medicines.

Biosimilars are authorised based on studies comparing them to their reference medicine. This includes a comparability exercise on quality aspects of the active substances of the biosimilar and the reference medicine, and the demonstration of clinical efficacy and safety of the biosimilar in confirmatory clinical trials.

Building on extensive experience with biosimilar medicines and advances in analytical methods, the draft reflection paper suggests that demonstrated structural and functional comparability, together with comparative data on how the

body interacts with the medicines (pharmacokinetic data), may be sufficient to demonstrate similarity with the reference medicine. This could potentially reduce the need for extensive clinical efficacy studies. Waiving certain clinical data requirements would simplify the development and evaluation process while maintaining the highest standards of safety and efficacy.

This more streamlined approach would ultimately ensure wider availability of biosimilar medicines to patients in the EU.

The draft reflection paper builds on the 2024 concept paper on a tailored clinical approach in biosimilar development.

Related documents

Reflection paper on a tailored clinical approach in biosimilar development

Draft: consultation open

Consultation dates: 01/04/2025 to 30/09/2025

Reference Number: EMA/CHMP/BMWP/60916/2025

English (EN) (344.69 KB - PDF)

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