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European Medicines Agency

Outcome of the Public Consultation – Reflection Paper on a Tailored Clinical Approach in Biosimilar Development

Summary report of comments received during the public consultation

1. Introduction

The European Medicines Agency (EMA) launched a public consultation on the *Reflection Paper on a Tailored Clinical Approach in Biosimilar Development*, which was adopted by the Committee for Medicinal Products for Human Use (CHMP) for release on **17 March 2025**. The consultation ran from **1 April to 30 September 2025** and sought stakeholder views on the proposed shift towards a proportionate, science-based, and streamlined framework for clinical data requirements in biosimilar development.

The consultation was also supported by a workshop held in a hybrid format, at the EMA offices in Amsterdam and online, on 22 September 2025. A report from the workshop can be found at the following link: meeting-report-workshop-tailored-clinical-approach-biosimilar-development_en.pdf

This report summarises the discussion held during the session and the feedback received from the public consultation, outlining how these insights will inform the finalisation of the reflection paper.

2. Contributors

A total of **400 comments** were received from a broad and diverse range of stakeholders. Contributors included:

- National Competent Authorities and EU regulatory bodies.
- Industry associations representing originator and biosimilar manufacturers.
- Individual pharmaceutical companies.
- Academic and research institutions.
- Healthcare professional organisations.
- Patient organisations.

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- International regulators and scientific societies.
- Individual comments.

The breadth of engagement reflects the significant scientific, regulatory and public health interest in modernising the biosimilar development paradigm.

3. Overall Expression of Comments

Stakeholders were **broadly supportive** of the proposed tailored approach. Many recognised the need to update clinical requirements in line with:

- extensive EU regulatory experience with biosimilars;
- advances in analytical technologies;
- growing international convergence towards more efficient biosimilar development pathways.

Supportive feedback emphasised that:

- the tailored approach is scientifically well justified, noting that analytical technology is highly sensitive to detect differences during biosimilarity assessment, while comparative clinical data is much less sensitive;
- reduced reliance on comparative efficacy studies (CES) can shorten development timelines and improve patient access by facilitating earlier access to biosimilar medicines for EU citizens;
- the proposed framework aligns with global regulatory evolution.

However, several areas were identified where clarification or further elaboration would be beneficial. These included:

- expectations for the robustness of the analytical similarity assessment;
- circumstances under which PK and immunogenicity studies are sufficient;
- alignment with ICH and other international initiatives.

4. Summary of Key Themes and Stakeholder Feedback

4.1. Quality-related Considerations

Stakeholders requested clearer, operational descriptions of:

- prerequisites for demonstrating similarity and data analysis;
- management of uncertainties in the comparability exercise;
- criteria for the selection of batches included in analytical comparisons;
- analytical methodologies, including those required for characterisation of critical quality attributes.

Revisions incorporated:

The final version has refined definitions, enhanced clarity on quality expectations, including batch selection and statistical approaches, and emphasises the general scientific principles underpinning comparability/similarity assessments.

4.2. Clinical Development Pathway

Stakeholders supported the reduced reliance on CES but asked for further clarity on:

- explicit criteria or decision trees indicating when CES would not be required;
- the evidentiary role of pharmacodynamic markers, particularly where data may be limited;
- circumstances in which extended PK studies are recommended;
- approaches to immunogenicity assessment when CES are not performed.

Revisions incorporated:

The final version provides additional structure, examples, and clearer decision-making parameters, including strengthened guidance on immunogenicity assessment.

5. Conclusions and Next Steps

Overall, stakeholders endorsed the tailored clinical approach proposed in the reflection paper, viewing it as a scientifically robust and timely evolution of the EU biosimilar regulatory framework.

Following the public consultation, the BMWP revised and agreed on the final reflection paper, which has been adopted by CHMP.

Further engagement with regulators and stakeholders across the EU network is envisaged.

The final reflection paper is available at the EMA website: https://www.ema.europa.eu/en/reflection-paper-tailored-clinical-approach-biosimilar-development