EUROPEAN MEDICINES AGENCY
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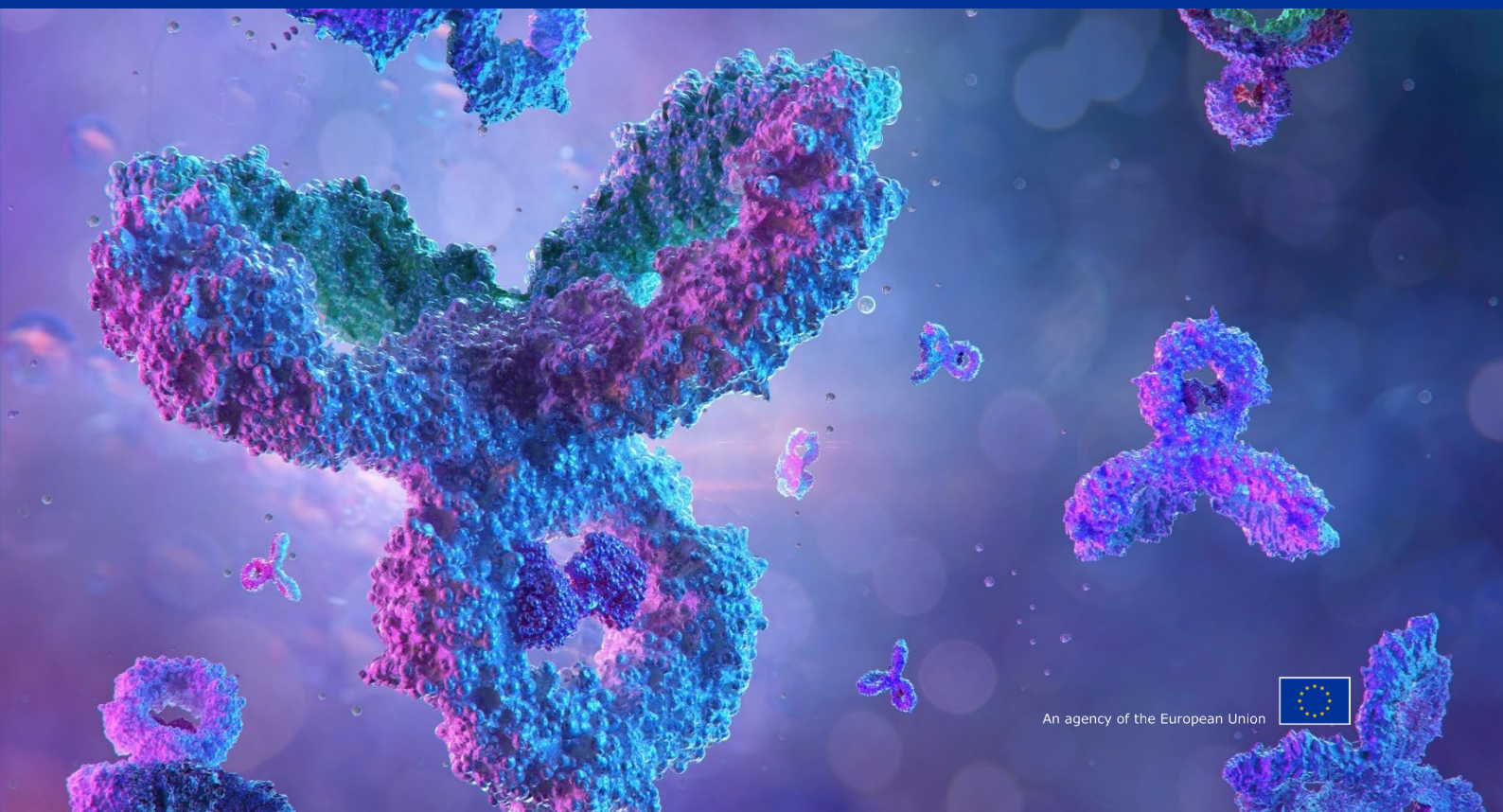
Biosimilar Medicinal Products Working Party (BMWP)

Workshop on a tailored clinical approach in biosimilar development – Meeting Report

22 September 2025



Introduction

The Biosimilar Medicinal Products Working Party (BMWP) is a multi-disciplinary expert group that brings together expertise in both quality and clinical assessment of biosimilar medicinal product applications.

The BMWP provides recommendations to the Committee for Medicinal Products for Human Use (CHMP) on quality and clinical matters relating to biosimilar medicines. The BMWP works closely with the Biologics Working Party (BWP), the Scientific Advice Working Party (SAWP) and other groups such as the Methodology Working Party (MWP).

Details on the composition, objectives and work plan of the BMWP can be found on the Agency website:

CHMP: Working parties and other groups | European Medicines Agency (EMA)

The Agency has 20 years of experience and is a global leader in the area of biosimilars regulation and development, with over 200 Marketing Authorisation Applications received and experience of authorised biosimilars in the EU, which have an excellent safety record.

On 22 September 2025, the BMWP hosted a multi-stakeholder workshop with the objective to discuss with its stakeholders the tailored clinical approach in biosimilar development. This workshop was part of the consultation process of the Draft Reflection paper on a tailored clinical approach in biosimilar development, with the public consultation ending on 30 September 2025. The information gathered during the workshop will inform the revision and finalisation of the Reflection Paper.

The Reflection Paper has a primary goal of utilising the advances in analytical technology and extensive experience from assessing and approving biosimilars to propose tailored regulatory requirements for their development, with a view to increasing patient access to biosimilars and biological medicines. The tailoring proposal is the next step in the evolution of the biosimilars regulatory framework and considers that, in cases where the biological substance can be well characterised, analytical data and comparative PK studies will be sufficient, eliminating the need for redundant comparative efficacy studies (CES). This approach will thereby accelerate development and patient access to biosimilars without compromising quality, safety or efficacy.

The workshop brought together EU and non-EU regulators, international partners, patient and healthcare professional organisations, academia, and industry stakeholders to discuss the proposed approach of the draft guidance. The workshop was attended by the EU drafting group of the draft Reflection Paper as well as chairs and members of the BMWP, BWP, SAWP, MWP and the CHMP. The meeting was open to interested parties via the hybrid meeting, for which over 800 participants were registered.

In summary, the Workshop Objectives were:

- Support the finalisation of the Reflection Paper through stakeholder feedback and insight.
- Promote awareness and understanding of the proposed tailored approach.
- Continue EU leadership in biosimilars and facilitate future international convergence.

Workshop summary

This report includes a summary of the case studies and discussions held at the workshop including views from stakeholders and regulators.

The meeting comprised the following sessions:

Opening remarks and summary of the draft Reflection Paper by the chair of the BMWP

Session 1: Tailored Approach – Framework and Utility of Comparative Efficacy Studies (CES)
Talk 1 | Framework for determining the utility of CES – when is a CES needed? (Medicines for Europe)
Talk 2 | Recommendations and ICH harmonisation (EFPIA)
Talk 3 | Tailored approach: framework and utility of CES (Europabio)

General Discussion

Session 2: Quality comparability – Analytical similarity approach and statistical issues
Talk 4 | Quality comparability: analytical, similarity approach and statistical issues (Europabio/EFPIA)
Talk 5 | Analytical similarity in a tailored biosimilar development (Medicines for Europe)
Talk 6 | Statistical recommendations (Medicines for Europe)
– Case Study *on the Application of statistical concepts of EMA Reflection Paper on biosimilar medicines*

General Discussion

Session 3: Clinical studies: PK, PD, and immunogenicity aspects
Talk 7 | Limitations of PK studies to address immunogenicity and safety (Europabio/EFPIA)
Talk 8 | Safety and Immunogenicity Information from PK Similarity Studies are Generally Sufficient for Biosimilar Development (Medicines for Europe)
– Case Study *on how Analytical Data and SingleDose PK are Sufficient to Conclude Comparable Immunogenicity for Biosimilars*
- Case Study *on the knowledge gain of larger and longer safety study*

General Discussion

Session 4: Closing remarks
Overall conclusion

Discussion

The background to the Reflection Paper was presented in the opening workshop session, which highlighted the agreed principle that the tailoring process is appropriate when the biological active substance can be well characterised and the analytical data generated at the quality level provides a high level of assurance of biosimilarity, obviating the need for a CES. Notably, this was also endorsed by professional associations, that shared their comments and support for the draft reflection paper during the meeting.

The workshop discussed the analytical approaches and interpretation / analysis of quality data in a dedicated session which reflected on the extensive experience gained with regard to the characterisation and comparability assessment of biologicals and biosimilars according to international standards, e.g. ICH Q5E guideline.

In a session reflecting on clinical requirements, it was considered that in most cases, PK studies are sufficient to detect differences between a biosimilar and its reference (originator's) product at the clinical level. However, there may be situations where additional dedicated studies will be needed. In general, PD studies were not considered to be additionally informative (i.e. as stated for clinical efficacy studies). Immunogenicity has long been a potential issue for biologicals, however, workshop participants noted

the large safety database for biosimilars, which has not brought forward specific safety concerns for authorised biosimilars. The workshop participants agreed that relevant safety aspect should be addressed using an appropriate assessment of risk, and that additional studies could be included in the biosimilar development if deemed necessary.

Key discussion points:

- The science-driven tailored approach is supported as the next step in the evolution of the biosimilar regulatory pathway. This is due to the regulatory experience gained in assessing biosimilars and advances in analytical methods, that reduce the need for comparative efficacy studies, which have been shown to be less sensitive in detecting differences between Biosimilars and Reference products.
- Maintaining high scientific standards while considering a tailored approach is key. Comparative efficacy studies (CES) shall be reserved for specific cases (e.g., poorly characterized molecules, clinical PK not meaningful, etc.), when the necessary information cannot be generated by other means. In such a case, it should be clearly identified in advance which specific scientific question a CES should answer.
- Statistical approaches need to be further discussed considering their impact on biosimilar assessments (Case studies were presented).
- The type and amount of data potentially required from the PK studies, supportive PD and immunogenicity data, when implementing a tailored approach was discussed (Case studies were presented).
- Harmonisation of the requirements for international convergence and global acceptance is important.
- Although pharmacovigilance and post-marketing safety monitoring could be referenced, the evidence for biosimilarity must be established pre-approval.
- The RP should provide flexibility to accommodate scientific advances and evolving product classes.
- Emphasis on transparency is important, by providing the rationale for a tailored development approach in public information, for stakeholders' trust and knowledge.

Conclusions and next steps

The workshop provided a valuable opportunity for the BMWP experts and drafting group to hear stakeholders' feedback and comments on the draft reflection paper, and to illustrate, by means of case studies, how the tailored approach could be practically applied to actual Biosimilar product development, and which challenges remain.

Overall, it was agreed that analytical data and comparative PK studies can determine minor differences versus the reference product and can act as a suitable surrogate for the clinical pharmacology (PD / efficacy) studies.

Biosimilars are a priority for the EMA as they provide treatment options to much-needed medicines and have the potential to facilitate patient access to many medicines of biological origin. The tailored development described in the draft Reflection Paper supports a more efficient regulatory pathway, consequently enabling development and delivery of biosimilar / biological medicines to patients.

During the workshop, valuable feedback was received for the drafting group to continue their work in finalising the RP. The revision of the RP is planned to be completed by mid-2026. BMWP also observes that some feedback relates to broader aspects of biosimilar development, beyond the initial scope of the Reflection Paper, which will be considered during subsequent guideline revisions.

The workshop also served to further mature a common European regulators' position, which will help to support the upcoming ICH guideline on Biosimilars (ICH M18).

EMA encourages industry to continue to come for scientific advice to apply the tailored approach and keep sharing their feedback through IP/interactions as this helps inform and build confidence with the tailored approach. It is a shared mission of all stakeholders to make Biosimilars a success in Europe for the benefit of patients.

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