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Human Medicines Division

Concept paper on revision of: Guideline on similar biological medicinal products, CHMP/437/04 Rev.1

Agreed by BMWP	June 2026
Adopted by CHMP for release for consultation	13 July 2026
Start of public consultation	22 July 2026
End of consultation (deadline for comments)	31 October 2026

The proposed guideline will replace: *Guideline on similar biological medicinal products* (CHMP/437/04 Rev.1)

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Keywords	Biosimilars

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1. Introduction

Legal, regulatory and especially scientific developments require a revision of biosimilar guidelines, including the overarching *Guideline on similar biological medicinal products* (CHMP/437/04 Rev.1).

2. Problem statement

The *Guideline on similar biological medicinal products* (CHMP/437/04 Rev.1) was last revised in 2015. Since then, major progress has been made in the analytical sciences and regulatory field of biosimilars. This is especially evident from the following two developments:

- The Reflection paper on a tailored clinical approach in biosimilar development | European Medicines Agency (EMA) and initiation of ICH M18 *Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs*.
- The New Pharmaceutical Legislation (NPL)[1] which will amend the legal-regulatory definition of a biosimilar.

Therefore, the Guideline should be updated to reflect the changing legal, regulatory and scientific landscape.

3. Discussion (on the problem statement)

The Biosimilar Working Party (BMWP) recommends revising the *Guideline on similar biological medicinal products*, taking into account the new developments identified above.

The main intention is to provide updated high-level guidance regarding the necessity and utility of Comparative Efficacy Studies (CES) taking into account the scientific considerations reflected in the Reflection paper on a tailored clinical approach in biosimilar development | European Medicines Agency (EMA), the current development of the ICH M18 guideline, and recent regulatory experience obtained with Scientific Advices on biosimilar developments and CHMP decisions on biosimilar marketing authorisation applications (MAAs).

The guideline also needs to be updated to reflect the new legal definitions and associated high level data requirements for biosimilars in the NPL. In addition, some other parts of the Guideline may need to be reviewed/updated/clarified in light of recent experience.

4. Recommendation

The Working Party/Committee recommends revising the *Guideline on similar biological medicinal products*, taking into account the issues identified above.

In addition, the guideline needs to be updated to reflect the new legal definitions and associated high level data requirements for biosimilars.

Finally, other points may also be amended or clarified based on current experience.

5. Proposed timetable

A three-month consultation period is proposed.

[1] The NPL is not yet formally published but the agreed draft subject to final review is available here:

The BMWP aims to publish a draft revision of the guideline for consultation in Q2 2027 and to adopt of final document 2028. The main risk for delay arises from the necessity to have thorough discussion/evaluation of the impact of updated definitions in the NPL.

6. Resource requirements for preparation

BMWP will not create a separate drafting group but may set up dedicated subgroups to address specific issues/sections. Regular BMWP meetings will form the basis for the drafting process.

7. Impact assessment (anticipated)

Since the Reflection paper on a tailored clinical approach in biosimilar development | European Medicines Agency (EMA) has already been published with several regulatory procedures following immediately, the additional scientific impact of the foreseen guideline revision on biosimilar developments is not considered major. However, the guideline needs to be aligned with the reflection paper and is supposed to strengthen the regulatory basis for tailored biosimilar developments. It will also take into account global harmonisation efforts and valuable experience with MAAs for biosimilars without CES.

8. Interested parties

An interested parties meeting is foreseen after publication of the concept paper in order to receive external expert input regarding the guideline revision. Whether further interested parties' meetings will be necessary/helpful will be decided during the revision process.

9. References to literature, guidelines, etc.

See Revised Overarching guideline on biosimilar for *Guideline on similar biological medicinal products*

See Reflection paper on a tailored clinical approach in biosimilar development | European Medicines Agency (EMA)