Medicines & Healthcare products Regulatory Agency

Public Consultation on the ICH M13B Draft Guideline for Bioequivalence for Immediate-Release Solid Oral Dosage Forms

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings regulatory authorities and the pharmaceutical industry together with a mission to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner. Harmonisation is achieved through the development of ICH Guidelines.

The ICH Expert Working Group (EWG) for M13B intends to publish the second guideline in the series, which describes the scientific and technical aspects of study design and data analysis to support bioequivalence (BE) assessment for orally administered immediate-release solid oral dosage forms.

The guideline will focus on providing recommendations on obtaining waivers of BE studies for one or more additional strengths of a drug product in an application where *in vivo* BE has been demonstrated for at least one of the strengths (*'in vivo'* refers to a medical test, experiment, or procedure that is done on (or in) a living organism, such as a laboratory animal or human). See the draft M13B guideline.

We invite UK stakeholders and other ICH members to complete the consultation. Following the consultation, the feedback will be reviewed and discussed by the ICH M13B EWG.

We do not intend to publish a full response to this consultation, as comments and suggestions will be reviewed by ICH directly.

The consultation closes at 11:59pm on Thursday, 31 July, 2025.

About you

1. Are you responding as an individual or on behalf of an organisation?

- ○ Individual
- ○ Organisation

About you

2. If you are responding on behalf of an organisation, please state the name of that organisation

Draft ICH M13B guideline - Specific and general comments

3. Please provide any comments you may have on the draft guideline. Clearly indicate if the comments relate to the guideline generally, or which specific lines they refer to. (optional)

Draft ICH M13B guideline - Proposed changes or recommendations suggestions

4. Please share any proposed changes or recommendations related to the draft guideline. Clearly indicate if the proposed changes or recommendations relate to the guideline generally, or which specific lines they refer to. (optional)

5. Do you have any further comments or suggestions that you would like to share?

- ○ Yes
- ○ No

Draft ICH M13B guideline - Specific and general comments

6. Please provide any additional comments you may have on the draft guideline. (optional)

Satisfaction survey - give feedback on participating

If you do not wish to leave your feedback, please select the 'Submit' button.

7. It was easy to participate in this opportunity (optional)

- ○ Strongly Agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly Disagree

8. The supporting information was understandable (optional)

- ○ Strongly Agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly Disagree

9. What could we do better? (optional)

Thank you for responding to this consultation. Responses will be compiled and shared with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) for consideration and thus we do not intend to publish a full response to this consultation.

Complete this survey again

This survey is now closed.

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