

# Streamlining product-specific bioequivalence guidance

MWP CP-OEG

Demy van den Haak, Kevin Blake



# Follow-up points after last R&D meeting

- EMA to further progress the development of the calls also considering the comments received, and communicate through the platform the final arrangements
- Industry associations to raise awareness of this planned consultation
- EMA to consider strengthening of proactive communication on planned product-specific bioequivalence guidelines

# Updates since last meeting

## ICH M13A

- List of expected PSBGLs in 2026 published on EMA's product specific bioequivalence guideline webpage [Product-specific bioequivalence guidance | European Medicines Agency \(EMA\)](#)

**Product-specific guidelines that can be expected for 2026:** Aripiprazole, Cladribine, Etonogestrel, Fidaxomicin, Ivacaftor, Liraglutide, Naproxen, Niraparib, Piribedil, Raltegravir, Rifaximin, Semaglutide (tablets + SC solution), Tafamidis, Tofacitinib.

- Oncology-related PSBGLs will be updated this month
  - Ongoing discussions with FDA regarding study population

# Update of Q&As in line with ICH M13A

- [Clinical pharmacology and pharmacokinetics: questions and answers | European Medicines Agency \(EMA\)](#)
- Review of all Q&As in section 4 – product-specific bioequivalence within scope of ICH M13A
- Updates include, but are not limited to:
  - Update of references and citations
  - Rephrasing standardized texts, e.g. regarding high-risk products

# Proposals for products

Concrete idea on proactive PSBGL approach:

- Annual EU Survey: stakeholder name + up to **5 proposed products**
  - Each product with a scientific rationale
  - The individual stakeholder survey results will remain confidential
  - Product specific guidelines of the five most frequent nominated products will be prepared in 2027
- Published on EMA's corporate website, notify stakeholders via MWP's workplan and stakeholder meetings
  - MWP is aiming for: consultation of work plan **mid-July until end of August 2026**
  - Announcement of nominated products Q4 2026
  - If successful, hopefully a **yearly activity**



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# Thank you

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