

# Variations Regulation and guideline implementation

Presented by Thomas Girard (Regulatory Affairs  
Office) on 23 June 2025

# Comments/questions - Annual update of Type IA

- *Submission in 2025 of remaining type IA variations implemented in 2024*

Type IA variations implemented before 1 January 2025 can be submitted as stand-alone (or as a voluntary annual reporting with Type IA variations implemented in 2025 provided that the timelines for the mandatory annual update are met)

-> Please clearly identify them to avoid any issue at validation

- *Timing for submission of annual updates (9-month window)*

Flexibility offered to MAHs as fixed date was considered too rigid -> optional 3-month submission window was introduced

- *Submission requirements for Type IA annual updates*

One cover letter and eAF, including combined justification, rationale, detailed present and proposed table and supporting documents. Important to clearly list all changes with the proposed classification per change to avoid problems at validation

# Comments/questions - Annual update of Type IA

- *Third countries that require a CPP*

This remains an exception to the annual update – further experience needed before revising the list  
EMA agrees to raise awareness of regulators relying on EMA CPP

- *Grouping of unrelated type IA/IAINs outside the annual update*

As a rule, Type IA variations to be submitted in the annual update, unless it falls under one of the exception foreseen.  
For CAPs, the Agency accepts groups of related Type IA/IAINs variations outside the annual update - as for any grouping, unrelated variations can not be grouped

- *Grouping of Type IA with Type IAIN variations affecting the same Module 3 sections*

As a rule, Type IA variations are expected to be submitted as part of the annual update

Type IA variations affecting Module 3 can be grouped with related Type IAIN variations and/or an acceptable groups that include a variation of a higher level

- *Status of annual update*

No annual update received so far – first submissions expected from September – report-back at the platform in December.

# Comments/questions - resubmissions of Type IA variations

- *Concern remains that recategorization of a Type IA to Type IB (where classification is grey area) at the time of an annual update could impact supply.*
  - Applicant's responsibility to classify the change according to guideline on variation
  - No difference with the current system
  - If remains as a Type IA variation, it can be resubmitted forthwith as stand-alone
  - The Agency has a variation' query service to provide specific guidance for Type IA variations. However, this service should not be used routinely and does not pre-empt responsibility of the MAHs or the outcome of the procedure

# Comments/questions – Worksharing

*Clear understanding of what is within the scope of '**same change**'.*

- Same change = absence or limited need for product specific assessment.
- Timing of implementation is not a criterion to determine the change is the same or not but this is a point that may be considered in the justification for not submit worksharing, notably for quality variations
- MAH are invited to inform the Agency at least 2 months in advance of the submission of worksharing procedure by means of a [letter of intent template](#). Upon receipt of the letter of intent, the Agency will review and decide whether the proposed worksharing procedure is acceptable.
- Use pre-submission query service in preparation of your worksharing in case of doubts/questions.

*Clarification on the optional use of a worksharing procedure for a PAM resulting from a worksharing*

- Post-authorisation measures (PAMs) as an outcome of a worksharing procedure are expected to be rare
- Provided that no or limited product specific assessment is needed such a proposal can be considered for CAPs affected – this should be discussed upfront with the Agency.
- More complex for WS including CAPs and NAPs as the handling of PAM is different

# Comments/questions – implementation of the new Variations Guidelines (2025)

- No possibility to make use of new classifications in advance of the date of entry into force
- Information on implementation intended to be published shortly as an update to the [EMA dedicated webpage](#) and [EMA' Pharmaceutical industry webpage](#)
- Specific guidance for Type IA variations will also be available. MAH will be asked to submit before the cut-off date all Type IA variations that are implemented before 15 January 2026
- EMA is updating/preparing Q&A and technical guidelines to support the entry into force of the guideline (e.g. guidance on the additional regulatory tools; complex manufacturing, changes for drug-devices combinations). Publication will be stepwise.
- Information session to stakeholders considered
  
- Amended Regulation introduced a provision to annually update the EC Variations guidelines, if needed. A period before implementation of a new changes will be considered vis-à-vis the impact of the change



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Thank you

thomas.girard@ema.europa.eu

Follow us

