

Implementation of the Classification Guideline on variations

Presented by Thomas Girard (Regulatory Affairs
Office) on 28 November 2025

Comments/questions - Guidance on the application of the revised variations guideline for type IA

- **Cut-off date:**

- All Type-IA variations implemented before 15 January 2026 should be submitted before 15 January 2026.
- If no annual update is due before 15 January 2026, the MAH should submit an earlier annual update/individual notification(s) outside the annual update.
- Date of implementation drives the version of the guideline to apply
- Non-compliance / rejection : discuss with EMA in such occurrence on a case-by-case basis.

- **‘End of the year’ recommendation** - 21 November 2025 to January 2026

- Predictability for companies on the TT for outcome - This is not a mandatory deadline
 - Companies can still implement Type IA variations and submit during this period
 - *Confirm Type IBs or groupings of type IBs and type IAs can still be submitted after 30 Nov if start of procedure is not needed in 2025 – Yes, groups of variations submitted before 15 January 2026 will follow the EC Variations Guidelines (2013) until their conclusion.*

Comments/questions

- Revised PAG published this week takes some of the comments into consideration:
 - Supergrouping is an exception to annual update and therefore can be submitted at any time within the 12-month period of the oldest Type IA in the supergroup.
 - Annual update can include IAIN if timelines fit.
- ‘9-month window’: as a general principle, Type IA variations should be submitted no earlier than 9 months and no later than 12 months after the first implementation date of the Type IA variation included in the ‘Type IA annual update’. The 3-month flexibility period is **optional**.
- General ‘z’ categories: are not visible yet in the draft published eAF but it will be added in the final version of eAF.
- Further clarifications/inconsistencies will be provided/corrected in guidance when needed or considered in a future update of the Guidelines on classification.

Comments/questions - Plasma Master File PMF-holders

- *PMF Annual Updates/PMF certifications*
 - The PMF Annual Update for PMF holder (step 1) is a specific procedure. Currently no plans to change the submission dates.
 - To avoid submitting variations under different frameworks, PMF holders should consider submitting all type IA variations implemented before 15 January 2026 to the Agency also before this date.
 - Where appropriate, PMF holders may wish to discuss any specific situations with the EMA in advance of their submission.
 - Link with a specific medicinal product (step 2) follows the standard rules.

Implementation activities

Implementation of the new Variations Guidelines 1/3

Published guidance:

- [Q&A on skip or periodic testing](#) (Oct/25)
- [Q&A on novel or complex manufacturing process](#) (Nov/25)
- [EMA's post-authorisation guidance](#) e.g.:
 - [Type IA/IB/II/Extension applications/grouping of variations](#) (Nov/25)
 - [Classification of changes: Q&A](#) (Nov/25)
- [Q&A regarding medicines used in combination with medical devices and consultation procedures by notified bodies](#) (Nov/25)

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➤ Additional **guidance upcoming**:

- Guidance on Post-Approval Change Management Protocol (**PACMP**) ([expected in Dec 2025](#))
- Guidance on Product Lifecycle Management document (**PLCM**) ([expected in Jan 2026](#))

➤ Info session upcoming:

- **Online information session** on the EC Variations Guidelines (2025) to take place on **13 January 2026**, from 13:00 to 15:00 (to be advertised on the [EMA's events webpage](#)).

Implementation of the new Variations Guidelines 3/3

➤ eAF/PLM Portal:

- **eAF v1.28.0.0** available for **external testing** purposes since 12 November
- This user acceptance testing version (UAT) contains the **new human variation classification** which will apply from **15 January 2026**. Please DO NOT USE this UAT form for submissions.
- Once the final version is available (expected in November 2025) a communication will be published on the [eSubmission website](#).



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