

Call to Action!

New Variations Guideline 2026

Key Information for the
transition



What to do

Before January 15

All types of variations

- **Current Guideline** applies.
- **Current version** of the electronic form (e-AF).

If the MAH uses:
the updated version of the electronic form (e-AF) or the new Guideline.

The submission will not be validated and the MAH will need to review its application.



Next Actions

From January 15

All types of variations

The MAH will use:

- The **new Guideline**.
- The **updated version** of the electronic form (e-AF).

The new e-AF is already available!

Including the variations classification according to the new guideline.



Type-IA Variations

Before January 15

- If an annual update is planned, it is recommended to: Submit the information either as an **Early Annual Update** or through **individual notifications** outside the annual update cycle.

The cover letter must clearly indicate whether it relates to:

**Annual Update / Early Annual Update /
Single (individual)**



From January 15

The implementation of the first Type IA variation will trigger a new annual update cycle, unless an exemption applies.



Ensure a seamless transition

Contact us:

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