REGULATORY REQUIREMENTS

Revision of the variation framework for medicines

What?

The European Commission has introduced the Regulation (EU) 2024/1701, concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use, and amendments to the Variations Classification Guideline.

The Variations Guideline will be published in the Official Journal of the Union in all languages, expected end of August/beginning of September 2025.

From when?

Variations Regulation: From 1st January 2025.
Variations Classification Guideline: From 15th January 2026.

Applicable for

Human use medicinal products

Changes

- Annual updates for minor variations of type IA
- Procedures for grouping and super-grouping of Type IA variations
- Mandatory (same MAH) and voluntary (different MAHs) use of the worksharing procedure
- Variations to human vaccines for public health emergencies

Action required

Variations implemented from January 2025 must follow the revised Variation Regulation. Variations submitted on and after the 15th January 2026 should also follow the new guidelines/classification system.