Variations Guidelines

Pharmaceutical Committee

April 1, 2025

Delegated Regulation (EU) 2024/1701

- The Commission **Delegated Regulation (EU) 2024/1701** of 11 March 2024, amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and its annexes (Variations Regulation) was adopted.
- Simplification of procedures, more efficient post-marketing lifecycle management of medicines, reduction of the administrative burden, and better use of regulatory authorities' resources.

Delegated Regulation (EU) 2024/1701

- The Commission **Delegated Regulation (EU) 2024/1701** is published in the Official Journal on 17.6.2024 and is applicable from January 2025
- The amending Delegated Regulation Delegated Regulation (EU) 2024/1701 involves administrative amendments, more flexibility in the guidelines and for unforeseen variations, providing additional regulatory tools and revising the update of vaccines, and streamlining some of the procedures
- More simplification will be followed in the **Variations Guidelines** as the next step of the revision of the variation framework.

Update of the Variations Guidelines

- The revision of the Variations Guidelines aims to reflect the current experience and scientific progress and implement the changes introduced in the amended Variations Regulation.
- In cooperation with EMA, CMDh, and experts from the network, the draft proposal for the update of the Variations Guideline was also thoroughly consulted with the stakeholders via public consultation
- End of 2024 the draft prepared by the network was forwarded to the Commission
- The Commission is currently in the process of transferring this draft into a Commission document for publication later this year.

Draft Variations Guidelines

- The draft Variation Guideline follows mostly the proposal by EMA and the previous structure: Introduction and Procedural section and Annex
- **Introduction and Procedural section** provides some simplification, improved readability of the document, and new operational details; procedural amendments based on the Variation Regulation and adaptation to the framework for vaccines
- Changes in the current code numbering system.

Draft Variations Guidelines (Annex)

- **Annex** has been revised taking into consideration the experience acquired and the scientific and technical progress, e.g.:

- categories, conditions and document requirements
- unforeseen and targeted variations and changes affecting herbals have been integrated
- biological active substances and finished products have been reviewed following a risk proportionate categorization
- the majority of the detailed changes in the quality variations
- medical devices and changes in the safety, efficacy and pharmacovigilance.

Next step

- The Commission is currently in the process of transferring this draft into a Commission document
- with the aim to adopt the updated Variation Guideline and publish it in the Official Journal in the middle of 2025.