Revision of the variation framework for medicines

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Introduction

- **Pharmaceutical strategy for Europe**

- regulatory framework needs the simplification and streamline of procedures and reduce costs
- management of variations of marketing authorisations is one of the examples of areas in which simplification is required.
- proposal to revise the variation framework for medicines to make the lifecycle management of medicines more efficient and adapted to digitalisation – 2021-2023

- **Revision of the variation framework for medicines**

- **Commission Work Programme 2023.**

Stepwise approach of the revision

- **Full revision** of variation framework is planned as a 2-step approach
- **1st step:**

  → amendments **independent** of the proposed revision of the EU pharmaceutical legislation

  → **Variation Regulation** (EC) No 1234/2008 and **further update** of the **Variation Guideline**

- **2nd step** amendments in the general pharmaceutical legislation.

Feedback mechanisms

- Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use
- Evaluation of the **general pharmaceutical legislation**
- **Public consultations for other initiatives** (e.g. evaluation of the EMA fee system, pharmaceutical strategy for Europe which has led to announcing the variation framework revision and the revision of the pharmaceutical legislation
- **Call for Evidence** for revision of the variation framework for medicines
- EMA/CMDh **Concept Paper on Variation.**

Amendments to the Variation Regulation

- The main aim as proposed earlier mostly remain:

- **flexibility** and **regular update** of Variation Guideline and inclusion of new classifications of variatiations

- **simplifying** requirements and procedures

- improve the efficiency of the variation system for all stakeholders reduce costs and administrative burden.

Amendments to the Variation Regulation

- update the framework for **biological medicinal products**
- medicinal products with **medical devices** and **in-vitro diagnostic medical devices**
- remove references to **veterinary medicinal products**
- update of the variations of the vaccines
- adaptation of some ICH Q12 principles into Regulation
- general and administrative amendments.

Next steps

- Member States Expert Group on Variations feedback
- Preparation of the draft amendment of the Delegated Regulation
- 4 weeks consultation period in Q1 2024
- Q1 2024 → Q2 2024, transitional period
- Variation Regulation and Variation Guideline apply together
- Full revision of variation framework follows the adoption of revision of pharmaceutical legislation.

Thank you

European Commission