EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Concept paper on a Guideline on stability testing for applications for variations to a marketing authorisation for veterinary medicinal products

Agreed by Quality Working Party	September 2023
Adopted by CVMP for release for consultation	5 October 2023
Start of public consultation	13 October 2023
End of consultation (deadline for comments)	5 January 2024

The proposed guideline will replace the 'Guideline on stability testing for applications for variations to a marketing authorisation' (EMA/CHMP/CVMP/QWP/441071/2011- Rev.2) for veterinary medicinal products only. The Guideline is still applicable for human medicinal products.

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	Stability, veterinary medicinal products, variations, Regulation (EU) 2019/6

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1. Introduction

The Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) became applicable on 28 January 2022 and updated the rules on the authorisation and use of veterinary medicinal products in the European Union (EU).

With Regulation (EU) 2019/6, the classification system of variations to the terms of marketing authorisations for veterinary medicinal products has been revised. Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment, and the Guidance on the details of the classification of variations requiring assessment (EMA/CMDv/7381/2021) further develop the provisions on variations in Regulation (EU) 2019/6 for veterinary medicinal products.

2. Problem statement

Former legislation, Commission Regulation (EC) No 1234/2008, applied to variations to the terms of marketing authorisations for medicinal products for human and veterinary use. The classification system for variations under this Regulation, which is still applicable for human medicinal products, is different to the current rules for veterinary medicinal products established by Regulation (EU) 2019/6, Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment, and the Guidance on the details of the classification of variations requiring assessment (EMA/CMDv/7381/2021).

The different legislative frameworks for variations for human and veterinary medicinal products result in the need to have separate guidelines for human and veterinary medicinal products.

A new guideline on stability testing for applications for variations to a marketing authorisation for veterinary medicinal products is necessary in which the new classification system for variations will be used.

3. Discussion (on the problem statement)

The current guideline on stability testing for variation applications (EMA/CHMP/CVMP/QWP/441071/2011- Rev.2) is applicable to chemical active substances and related finished products, herbal substances, herbal preparations and related herbal medicinal products. Radiopharmaceuticals, biologicals/immunologicals and products derived from biotechnology are not within the scope of the guideline. It is applicable to both human and veterinary medicinal products and is structured in accordance with the former classification system of variation to the terms of a marketing authorisation, *i.e.* type IA, IB and II variations, still applicable for human medicinal products.

With Regulation (EU) 2019/6 a new classification system for variations is now in force for veterinary medicinal products. Variations for veterinary medicinal products are now classified as variations requiring assessment (VRA) and variations not requiring assessment (VNRA) while variations for human medicinal products remain classified under the Type IA, IB and II system. In addition, the former procedures called "extensions" to marketing authorisations can be submitted as VRAs for veterinary medicinal products and thus the new guideline should cover also these cases.

Since the currently applicable guideline on stability testing for variation applications is structured in accordance with the former classification system, it is considered necessary to split the guidance provided for human and veterinary medicinal products and develop a new one for veterinary medicinal products only.

The current guideline will be used as the basis for developing the new one for veterinary medicinal products but it is also necessary to consider Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment, and the Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products (EMA/CMDv/7381/2021), and decide whether any further information should be provided in the new guideline.

4. Recommendation

The Joint CHMP/CVMP Quality Working Party (QWP) recommend the development of a new guideline on stability testing for variations for veterinary medicinal products taking into account the variations classification system for veterinary medicinal products since Regulation (EU) 2019/6 became applicable.

5. Proposed timetable

September 2023 – discussion and adoption of the concept paper by QWP.

October 2023 – discussion and adoption of the concept paper by CVMP and release for a 2-month public consultation.

It is anticipated that the draft guideline will be available within 6 months after adoption of the concept paper by the CVMP. The draft guideline will then be released for external consultation for 3 months. The guideline will be finalised within 6 months of the end of public consultation.

It is expected that the guideline will come into operation 3 months after adoption by the CVMP since it is not expected that the new guideline will result in increased data requirements for marketing authorisation holders.

6. Resource requirements for preparation

The revision will involve the QWP, the CVMP and EMA-QWP secretariat.

The QWP should appoint a rapporteur from within the members of the QWP.

7. Impact assessment (anticipated)

Developing a new guideline for veterinary medicines aligned with the current variations classification system is expected to provide clearer and up-to-date guidance to the veterinary pharmaceutical industry and regulators in terms of stability data requirements for variation applications.

The new guideline is not expected to impact industry in terms of increased data requirements.

8. Interested parties

Veterinary pharmaceutical industry and consultants, EU Regulatory authorities for veterinary medicinal products.

9. References to literature, guidelines, etc.

- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
  EUR-Lex - 02019R0006-20220128 - EN - EUR-Lex (europa.eu)
- Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
  EUR-Lex - 02021R0017-20230613 - EN - EUR-Lex (europa.eu)
- Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations
  Variations requiring assessment (veterinary medicines) | European Medicines Agency (europa.eu)
- Guideline on Stability testing for applications for variations to marketing authorisation
  Stability testing for applications for variations to marketing authorisation - Scientific guideline | European Medicines Agency (europa.eu)