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SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Concept paper on the revision of the Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances (EMA/CVMP/IWP/251947/2021)

Agreed by Immunologicals Working Party (IWP)	22 April 2026
Adopted by Committee for Veterinary Medicinal Products (CVMP) for release for consultation	18 June 2026
Start of public consultation	26 June 2026
End of consultation (deadline for comments)	30 September 2026

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

Keywords	Immunological veterinary medicinal products, veterinary vaccines, exceptional circumstances

1. Introduction

The "Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances" was adopted on 19 January 2022 and came into effect on 28 January 2022. This document was intended to provide advice to manufacturers seeking marketing authorisation in exceptional circumstances related to animal or public health included in Articles 25, 26 and 27 of Regulation (EU) 2019/6, based on a reduced data set regarding quality, safety and efficacy and the benefit of the immediate availability on the market to the animal or public health outweighs the risks arising from the fact that some data are not available. Based on experience with the first marketing authorisation applications submitted under Art. 25, it has become evident that several sections of the guideline require further detail and clarification to ensure consistent interpretation.

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2. Problem statement

The 'Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances' was developed to provide guidance on data requirements for applications according to Art. 25 of Regulation (EU) 2019/6. The guideline came into force before the first application in exceptional circumstances was submitted.

The initial experience with such marketing authorisation procedures and submission of the first re-examination procedures has demonstrated that certain provisions allow for a broader degree of interpretation than intended and therefore have resulted in uncertainties for both applicants and regulatory authorities. This concerns especially the quality and efficacy section of the guideline and the re-examination procedure. Accordingly, further clarification to ensure consistent understanding and application of the requirements is necessary. Additionally, some relevant references to legal texts and guidance documents should be included.

3. Discussion (on the problem statement)

Marketing authorisation applications according to Art. 25 have demonstrated their role as an essential regulatory instrument to ensure the continuous and timely availability of IVMPs in the context of emerging or re-emerging diseases. However, a common understanding of, and a consistent approach to, the applicable requirements by both applicants and competent authorities are essential to ensure the efficient and compliant conduct of the relevant marketing authorisation procedures.

It is therefore appropriate to review the guideline and to take account of the relevant chapters which require further clarification based on the experience gained to date. This is expected to pertain primarily to the following areas:

- Section 3 (Legal basis and relevant guidelines), where additional references should be included
- Section 4.2 Quality requirements:
    - Clarification of requirements and acceptable approaches for antigen quantification when data at the finished product stage are not available at submission.
    - Clarification of requirements for batch potency testing at the time of submission, including possible interim approaches to ensure adequate control of product quality where the method is not yet fully established.
    - Clarification of considerations regarding the acceptability of in-use shelf-life data derived from similar products.
- Section 4.4 Efficacy requirements
    - Clarification of expectations regarding the provision of duration of immunity data post-authorisation. 4.5. Product information: alignment of wording with Commission Notice 'Guidance to Applicants - Veterinary medicinal products' (C/2024/1443).

Furthermore, it is necessary to provide clear guidance on the data requirements to support the annual re-examination procedure.

4. Recommendation

The Committee for Veterinary Medicinal Products (CVMP) recommends that the Immunologicals Working Party (IWP) initiates a revision of the guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances taking into account the issues identified above.

5. Proposed timetable

Q2 2026	Concept paper released for consultation
Q3 2026	Deadline for comments from stakeholders
Q1 2027	Adoption of the draft guideline by CVMP and release for consultation
Q2 2027	Deadline for comments from stakeholders
Q3 2027	Expected date for adoption by CVMP and publication of the revised guideline

6. Resource requirements for preparation

The revision of the guideline will involve the IWP (including a drafting group composed of rapporteur, co-rapporteur and 3 IWP members). The IWP drafting group will meet virtually as required (e.g. 2-3 virtual meetings). Discussion is foreseen in at least 1 IWP plenary meeting.

7. Impact assessment (anticipated)

The revision of the guideline is expected to clarify essential data requirements to support new applications in exceptional circumstances submitted under Article 25. It is envisaged that the revised guideline provides clearer guidance including further details on data requirements to ensure consistent interpretation for both assessors and applicants.

Clearer guidance should enable applicants to prepare a tailored data set and facilitate both vaccine development and the submission of applications for marketing authorisation and, consequently, pave the way to quicker availability of vaccines in an emergency situation.

Overall, the revision of the guideline is expected to positively influence the assessment of marketing authorisation procedures submitted under Article 25 of Regulation (EU) 2019/6, and ultimately, to contribute to the availability of veterinary vaccines, thereby benefiting both public and animal health.

8. Interested parties

Veterinary pharmaceutical industry, veterinary consultants.

EU regulatory authorities involved in assessment of marketing authorisation applications for immunological veterinary medicinal products.

EU competent authorities responsible for animal disease control.