EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 February 2026
EMA/CVMP/PhVWP/31941/2026
Committee for Veterinary Medicinal Products (CVMP)

Concept paper for the revision of the Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management (EMA/522332/2021)

Agreed by PhVWP-V	January 2026
Adopted by CVMP for release for consultation	12 February 2026[1]
Start of public consultation	13 February 2026[2]
End of consultation (deadline for comments)	15 March 2026

The proposed guideline will replace the current "Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management" (EMA/522332/2021).

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

Keywords	VGVP, signal management, signal submission, annual statement

1. Introduction

Article 17(5) of Commission Implementing Regulation (EU) 2021/1281 requires the European Medicines Agency (EMA) to publish guidance on best practice for signal management.

The Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management (EMA/522332/2021) was initially adopted in November 2021 and came into effect in January 2022. The current 2021 version of the document makes reference to future revisions, should these be warranted by the experience gained by all stakeholders involved in the signal management process.

[1] Last day of relevant Committee meeting
[2] Date of publication on the EMA public website

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

This concept paper addresses the need for a thorough revision of the guideline, applying the experience gained with the implementation of Regulation (EU) 2019/6 on the signal management process.

2. Problem statement

This module of the guidelines on VGVP brings together general guidance for marketing authorisation holders (MAHs), national competent authorities and EMA on signal management for veterinary medicinal products authorised in the European Union (EU).

In general, most of the recommendations included in the existing guideline are still relevant. However, based on the experience gained by all stakeholders with the signal management process and current scientific knowledge, it is considered that some sections of the guideline would benefit from establishing clearer definitions and from the inclusion of more detailed guidance in several sections. This would aid all MAHs in managing signals more efficiently and in the preparation of signal management submissions in IRIS: the Agency's secure online platform for handling product-related scientific and regulatory procedures.

Such amendments would include, for example: clarifications on signal validation and signal prioritisation, submission and documentation requirements and follow-up actions for signals with different proposed actions. Additionally, the list of Medically Important (MI) VeDDRA terms will be reviewed.

3. Discussion (on the problem statement)

The need for a major revision of this guideline was identified based on the experience gained since the Regulation (EU) 2019/6 became applicable on 28 January 2022. The current guideline was drafted at an early stage of implementation of the Regulation and therefore before processes could be fully tested and before supportive IT functionalities could fully be developed. Since then, a large variety of signal management practices have been observed, possibly stemming from disharmonised interpretation of the current version of the VGVP module, thereby highlighting the current need for clarifications within the guidance.

This revision aims at achieving the following:

- An improved structure of the module;
- Improved clarity of definitions relevant to signal management, e.g. data sources, signal detection, prioritisation, validation, evaluation, outcomes of signal management at different steps, risk mitigation measures etc.;
- A more detailed description of the concept of risk-based signal management which has since been developed, including the main steps of risk management;
- Improved understanding of the requirements for documentation and submission of signals;
- Highlighting the importance of applying clinical knowledge and judgement throughout the signal management process and the role of mechanism of action of the active substance in the signal evaluation;
- Highlighting the importance of the concepts of signal detection and establishing causality in signal evaluation in a systematic and consistent way;

- Providing guidance on the methodology used for the evaluation of causality during signal evaluation;
- Providing guidance on the process of notifying authorities in different scenarios; e.g. Emerging Safety Issues (ESIs) and other outcomes of the signal management process;
- Update of definition and list of Medical Important Terms (MITs).

4. Recommendation

The CVMP recommends the revision of the existing Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management in order to provide clearer guidance and to align the guideline with current scientific and regulatory requirements, taking into account the challenges identified above.

5. Proposed timetable

Mid-February 2026	Concept paper released for public consultation
15 March 2026	Deadline for comments from interested parties
Q2 2026	Expected date for adoption of the draft revised guideline by CVMP for release for 2 months public consultation
Q3 2026	Expected end of consultation on the draft revised guideline
Q4 2026	Expected date for adoption by CVMP and publication of the revised guideline

6. Resource requirements for preparation

The revision of the guideline will be performed by a drafting group consisting of several members of the CVMP Pharmacovigilance Working Party (PhVWP-V), supported by EMA staff. Other relevant working parties or working groups may also be consulted if required.

The preparation of the draft revised guideline will require discussions within the PhVWP-V, as needed.

Drafting group meetings will be organised (virtually), as needed.

7. Impact assessment (anticipated)

The revision of this VGVP module is expected to improve the guidance for MAHs, as well as for competent authorities. It is not intended to increase the requirements for pharmacovigilance activities for either party.

8. Interested parties

- Veterinary pharmaceutical industry and regulatory consultants;
- EU regulatory authorities involved in pharmacovigilance for veterinary medicinal products;
- Veterinary organisations and professional bodies;

- Scientific veterinary associations.

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 [link]

Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products [link]

Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Collection and recording of suspected adverse events for veterinary medicinal products [link]

Guideline on Veterinary Good Pharmacovigilance Practices (VGVP) Module: Controls and pharmacovigilance Inspections [link]

Guideline on veterinary good pharmacovigilance practices (VGVP) Annex: Glossary [link]

Veterinary Union Pharmacovigilance Database – Best Practice Guide [link]