EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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The VGVP draft modules are released for consultation and may change further, pending the finalisation and publication of the Commission Implementing Regulation 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.

Guideline on veterinary good pharmacovigilance practices (VGVP)

Annex: Glossary

Draft

Endorsed by Coordination group for Mutual recognition and Decentralised procedures (veterinary) for release for consultation	14 May 2021
Draft agreed by Committee for Medicinal Products for Veterinary Use (CVMP) Pharmacovigilance Working Party (PhVWP-V)	26 May 2021
Adopted by CVMP for release for consultation	17 June 2021
Start of public consultation	5 July 2021
End of consultation (deadline for comments)	5 September 2021

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

Keywords	***veterinary pharmacovigilance; adverse event; signal management; pharmacovigilance system master file; veterinary pharmacovigilance inspections; Regulation (EU) 2019/6***

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Term	Abbreviation (if applicable)	Definition	Reference (if applicable)
Animal healthcare professional	Not applicable	Terminology to use to within the context of good veterinary pharmacovigilance practice (VGVP) guidance when referring to healthcare professionals working with animals including, for example, veterinarians, para-veterinarians (i.e. veterinary nurse, veterinary technician and veterinary assistants) etc.	VGVP Pharmacovigilance communication
Emerging safety issue	ESI	A safety issue considered to require urgent attention because of the potential major impact on the benefit-risk balance of the concerned veterinary medicinal product, on animal or public health, or protection of the environment, to the point that urgent regulatory action and communication may be needed.	VGVP Signal management
Environmental incident	Not applicable	A situation where an ecosystem is adversely affected through exposure to a veterinary medicinal product or its metabolites present in different environmental compartments (e.g. soil, water) or animal remains. Such incidents may consist of, for example, presence of the active substances in soil or water or wildlife poisoning by a substance to levels considered harmful for the ecosystem affected. Events related to user safety are not considered environmental incidents.	VGVP Collection and recording of suspected adverse events for veterinary medicinal products
Medically important VeDDRA term	MI VeDDRA term	A list of selected relevant VeDDRA terms per species used for prioritisation of signal management.	Appendix X VGVP Signal management
Pharmacovigilance alert	Not applicable	Potential concerns, including emerging safety issues arising from pharmacovigilance data or other information impacting animal or public health or the environment that may require urgent	VGVP Pharmacovigilance communication

Term	Abbreviation (if applicable)	Definition	Reference (if applicable)
		consideration by the competent authority responsible for the veterinary medicinal product(s).	
Pharmacovigilance system master file	Not applicable	A detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products.	VGVP Pharmacovigilance systems and their pharmacovigilance system master files and quality management systems, VGVP Controls and Pharmacovigilance Inspections
Post-marketing surveillance study	Not applicable	Any study with an authorised veterinary medicinal product under normal condition of marketing, which is conducted to identify, describe or quantify a safety risk, including a lack of efficacy, to confirm the safety profile (including environmental safety) and efficacy of a medicinal product or to measure the effectiveness of risk management measures.	VGVP Collection and recording of suspected adverse events for veterinary medicinal products, VGVP Signal management
Same pharmaceutical veterinary medicinal product	Not applicable	A veterinary medicinal product originating from the same marketing authorisation holder being responsible for pharmacovigilance of this/these veterinary medicinal product(s) with same formulations.	VICH GL24 on pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs)
Similar pharmaceutical veterinary medicinal product	Not applicable	A veterinary medicinal product: • originating from the same marketing authorisation holder being responsible for pharmacovigilance of this/these veterinary medicinal product(s) • the same active ingredients • major excipients with the same or similar pharmaceutical function • at least one common	VICH GL24 on pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs)

Term	Abbreviation (if applicable)	Definition	Reference (if applicable)
		registered species. The concept of a similar biological veterinary medicinal product does not exist.	
Supervisory authority	Not applicable	The competent authority of the Member State in which the pharmacovigilance system master file (PSMF) is located that is responsible for carrying out the inspections of that PSMF (in accordance with Article 126(4) of Regulation (EU) 2019/6).	VGVP Controls and Pharmacovigilance Inspections

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