18 November 2021
EMA/367598/2021
Veterinary Medicines Division

Overview of comments received on 'Guideline on veterinary good pharmacovigilance practices (VGVP)' (EMA/118227/2021)

Annex: Glossary

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	AnimalhealthEurope
2	German Environment Agency (UBA)

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1. General comments – overview

[Add tables with general overview as received from interested party.]

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
1	AnimalhealthEurope would like to thank the Agency for this important document and is grateful for the opportunity to comment. Please find some comments. Should you have further questions, AnimalhealthEurope is happy to provide any clarification needed. Compared with GVP Annex I Definitions, VGVP Annex I Glossary might also include some more terms used in the VGVP modules, e.g. adverse event, adverse reaction, signal, off-label.	Noted

2. Specific comments on text

[Add tables with specific comments as received from interested party.]

Line no.	Stakeholder no. *(To be completed by the Agency)*	Comment and rationale; proposed changes	Outcome *(To be completed by the Agency)*
Pharmacovigilance system master file	1	Comment: No Abbreviation is proposed for the Pharmacovigilance system master file. Term Pharmacovigilance system master file is abbreviated in VGVP module 'Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files'. Proposed change: Please include abbreviation PSMF	Accepted. The guideline will be amended accordingly.
Same pharmaceutical veterinary medicinal product	1	Comment: No definition is provided for the same biological veterinary medicinal product whereas this definition exists in VICH GL24 Proposed change: Please include the following definition for "**Same biological veterinary medicinal product":** "A veterinary medicinal product originating from the same marketing authorisation holder being responsible for pharmacovigilance of this/these veterinary medicinal product(s) with same manufacturing specifications."	Accepted

Line no.	Stakeholder no. *(To be completed by the Agency)*	Comment and rationale; proposed changes	Outcome *(To be completed by the Agency)*
Environmental incident	2	Comment: The definition of "environmental incident" is not fully in line with the intention outlined in recital 56 of 2019/6. There it is said, that, "*Such incidents may consist, for example, in a significant increase of soil contamination by a substance to levels considered harmful for the environment or in high concentrations of veterinary medicinal products in drinking water produced from surface water."* In this respect, besides direct observed adverse effects of a VMP on an ecosystem, also the occurrence of the active substance in the environment, which could potentially result in an environmental impact, is considered as 'environmental incident'. An approach to assess whether a concentration of an active substance detected in an environmental compartment may have an environmental impact is to compare MEC data (measured environmental concentrations) with PNEC data (predicted no effect concentration), which are available in the marketing authorization dossier. Proposed change (if any): Please add "its active substances of" as follows: A situation where an ecosystem is adversely affected through exposure to a veterinary medicinal product***, its active substances or*** its metabolites present in different environmental compartments (e.g. soil,	Accepted. The guideline will be amended accordingly.

Line no.	Stakeholder no. *(To be completed by the Agency)*	Comment and rationale; proposed changes	Outcome *(To be completed by the Agency)*
		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.	