18 November 2021
EMA/368440/2021
Veterinary Medicines Division

Overview of comments received on 'Guideline on Veterinary Good Pharmacovigilance Practices (VGVP)' (EMA/328998/2021)

Module: Controls and pharmacovigilance Inspections

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	EGGVP– European Group for Generic Veterinary Products

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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. Should you have further questions, AnimalhealthEurope is happy to provide any clarification needed.	
2	EGGVP is grateful for this draft guideline and also for the opportunity to comment. We also thank the EMA for the previous discussions on this topic, as it allow us to support in building an efficient new veterinary pharmacovigilance era in Europe. In general, the guideline is clear and well written and so there are few questions and comments on it. However, two main issues of concern have been raised and those are also addressed under the "specific comments" section: - The guideline does not specify how confidentiality of sensitive information of the MAH will be preserved. Guarantees should be provided that such information is not being released to the public via inspection reports. - Timelines for announcements of inspections should be agreed and harmonised within MS to allow an equal level playing field and preparedness time for all MAHs in the EU.	We accept the comment, but in accordance with art 75 of Regulation 219/06 the general public will not have access to the results of inspections recorded in the Database. These will be accessible to the Competent Authorities. The MAH concerned with the phv system inspected will receive the report as part of the inspection. We accept the comment and the need of harmonised processes, the details on inspection process will be included in the inspection procedure and not in VGVP.

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)

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)*
68-69	2	Comment: The guideline should provide an indication on the level of access of information of such results in the union product database (i.e. who can see these results?). As mentioned under "general comments", guarantees should be provided that such information is not being released to the public via inspection reports.	Accepted. Please see general response to the general comment above. We can reference also to the art 75 that clarify the access to the database as below: The results of pharmacovigilance inspections shall be recorded by the competent authority performing the inspection in the Union pharmacovigilance database [Regulation (EU) 2019/6, Articles 74(1), 75 and 126(6)].
75-77	2	Comment: this paragraph is redundant with text in lines 60 to 62. Proposal: delete paragraph.	Accepted to delete text in 60-62.
156 161	2	Comment: it would be helpful if parameters such as "Large sales volumes" or "many products on the market" could be defined or a threshold indicated. These can be developed via Q&A separately.	Accepted to be discussed with phV IWG and provide practical guidance/Q&A outside this VGVP Module.
156	2	Comment: Typo - Suppress the repeat Proposal: *"Product(s) with large sales volume, i.e. products associated with large animal exposure ~~in~~ in the EU."*	Accepted.

Line no.	Stakeholder no. *(To be completed by the Agency)*	Comment and rationale; proposed changes	Outcome *(To be completed by the Agency)*
162-163	2	Comment: It is uncertain how do competent authorities know which resources are available to the MAH.	The competent authorities will have this information either after request of information (e.g. questionnaires, surveys) or from PSMF review and/or previous inspection. The PhV IWG will discuss the more efficient way to receive this kind of information.
373-374	2	Comment: Specific requirements of computerised systems should be proportionate to company size and characteristics. Proposal: Addition – ***"The size and characteristics of the marketing authorisation holder will be taking into account when evaluating that such specific requirements are fitness for purpose"***	We agree with the comment, but this is already included in the Implementing Regulation. The text should not change as it reflects the Implementing Regulation. The reference to Implementing Regulation art 10 (2e) means that the MAH need to assess and justify the fitness for purposes of the record management systems. The specific requirements of computerised systems are affected by several factors that are not limited to the company size and characteristics, for example the marketed products and their safety profiles is also important.
401	1	Comment: It is the AnimalhealthEurope's understanding that the suspension of a marketing authorisation is a national competent authority activity. If the NCA is responsible for making the decision on a suspension of a MA, how could a MAH implement a suspension with no advance notice to the competent authorities? Proposed change: As this item does not seem to be relevant, it is suggested to delete this bullet point from the list.	Accepted to delete.

Line no.	Stakeholder no. *(To be completed by the Agency)*	Comment and rationale; proposed changes	Outcome *(To be completed by the Agency)*
435-437	2	Comment: Timelines for announcements of inspections should be agreed and harmonised within MS to allow an equal level playing field and preparedness time for all MAHs in the EU.	Accepted. See general comments above.
507-508	2	Comment: This is very sensitive information for marketing authorisation holders, it would be welcome if further details (to whom and by which means) will this information be made available.	This is presented as a possible action for competent authorities and not EMA. This could potentially apply for MAHs following serious and persistent non-compliance. We expect the publication will happen in the competent authorities website.