18 November 2021
EMA/373229/2021
Veterinary Medicines Division

Overview of comments received on 'Guideline on veterinary good pharmacovigilance practices (VGVP)' (EMA/63454/2021)

Module: Veterinary pharmacovigilance communication

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	Federation of Veterinarians of Europe (FVE)
3	European Group for Generic Veterinary Products (EGGVP)

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1. General comments – overview

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 attached. Should you have further questions, AnimalhealthEurope is happy to provide any clarification needed.	The feedback is appreciated and the responses, following consideration of the specific comments, are detailed below.
2	FVE welcomes the EMA proposal on a communication guideline that will ensure proper communication about pharmacovigilance issues coming from the use of veterinary medicinal products. FVE is very pleased that EMA recognises that significant new or emerging information should be brought to the attention of veterinarians in priority using direct communication, in order to enable them to take action and respond adequately and promptly. Although, it is clearly noted that the update of product information to include new adverse events remains part of the routine communication and the general pharmacovigilance procedures in place for marketing authorisation and therefore it is not the subject of this module, FVE would like to highlight that unfortunately these changes in the SPC are not visible to the veterinarian, except for the date of revision of the text on the SPC. It would be appropriate if information about the implemented changes on the SPC could be added as part of the pharmacovigilance communication especially if these changes are of clinical relevance.	The feedback is appreciated and the responses, following consideration of the specific comments, are detailed below.

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	Finally, there is an inconsistency about terminology. The text notes Annex I, II, etc. but relevant information at the end are noted as Appendices.	
3	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 allows us to support in building an efficient new veterinary pharmacovigilance era in Europe. Generally, the requirements in the draft seem much inspired in practices at human side, where wide communication is performed. This is our main and very serious concern, as **it will be a very difficult task for MAHs to reach this level of communication for the veterinary sector. The establishment of a communication plan is a new task for marketing authorization holders, at risk it involves huge administrative burden for them**. Care should be taken that requirements are proportionate and adapted to veterinary practice and business scale. The two main areas where EGGVP believes burden should be alleviated are: - Extent of activities: Responsibilities for MAHs involve not only the implementation of a communication system, but also the follow-up and measurement of its effectiveness (which is not always feasible and realistic). On top, the system will have to be kept up to date and reviewed periodically, involving constant workload. This seems disproportionate administrative burden and not in the spirit of Regulation 2019/6 seeking reduction of administrative burden.	The feedback is appreciated and the responses, following consideration of the specific comments, are detailed below.

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	- Direct animal healthcare professional communication: this is a very complex issue as presented in the guideline. It will be very difficult for MAHs to reach every animal healthcare professional, while MAHs are uncomfortable with obligations whose fulfilment is not feasible and it is also not entirely dependent on them (if, for instance, cooperation with professional associations or statutory bodies is required); it is also questionable if it is possible for MAHs to have access to animal healthcare professionals contacts under current GDPR. Cooperation with such professional associations and statutory bodies is urgently needed to perform this direct animal healthcare professional communication. The above is aggravated since requirements for the inclusion of non-urgent safety concerns in the overarching communication plan are also very stringent. It should be noted that in the Implementing Act, art 20 (1)* only urgent issues are mentioned and so deletion of the requirements on the inclusion on non-urgent issues should be removed along the module. ** COMMISSION IMPLEMENTING REGULATION (EU) 2021/1281 of 2 August 2021 - Article 20 - Communication* *1. Marketing authorisation holders shall have an overarching communication plan that identifies the relevant stakeholders in the Union, including veterinarians, other healthcare professionals, customers and the general public. In cases of **urgent safety concerns**, it shall outline the approach to be taken to communicate in a timely manner concerns arising from pharmacovigilance data or in relation to other relevant pharmacovigilance information.*	

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	As the establishment of a communication plan is a new task for marketing authorization holders, many questions on details and request for examples are popping up. It is acknowledged that this guideline may not be the appropriate tool to provide a response to these detailed questions. Therefore it is suggested that additional support is provided separately and later on i.e. by developing a Q&A document (references under the "specific comments" section).	

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
38, 40, 41, 460, 512, 515	2	Comment: Proposed change (if any): Replace word 'Annex' by 'Appendix'.	Accepted. Module amended accordingly.
49	1	Comment: Is it PV information, or should this be safety information? The information that will be shared is not the PV information itself, but the relevant (safety) message that is based on the PV information.	Partly accepted. Text amended in module as pharmacovigilance information is a broader term which includes messages on the safety of medicinal products In the case of pharmacovigilance information addressed to the public this would usually be information on the safety of medicinal products used in animals. However, marketing authorisation holders and competent authorities and the Agency may share pharmacovigilance information prior to agreeing on a final safety information to be published.
77-79 167-168 193	3	Comment: Examples would be welcome in paragraph lines 167-168 and 193, as it is not clear what kind of (important) product information change is concerned. These can be developed via Q&A separately (see general comments). This would help avoiding confusion as in lines 167-168 it is mentioned that *"Routine communication, for example, update of product information to include new adverse events, is addressed as part of general pharmacovigilance procedures in place for marketing authorization holders and competent authorities and the Agency, alike, and is not the subject of this module".*	Agreed. Section 2.1.3 of module amended to include examples.

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115	1	Comment: "at least simultaneously to the public". Communications about products should be communicated IN ADVANCE to the MAH (and by reciprocity, MAH has to communicate in advance to agencies) Proposed change (if any): Please keep only "**in advance**"	The reference cited relates to Article 79(3) of Regulation (EU) 2019/6 which cannot be changed. However as emphasised in the guidance, prior communication to marketing authorisation holders is the preferred recommendation, whilst acknowledging that the legislation also includes reference to 'simultaneous notification'.
167-168	2	Comment: It is important that veterinarians are informed as soon as possible about changes on the SPC of the different products through direct communication. Please see also general comment above. Proposed change (if any):	Comment agreed in principle however this will be addressed as part of the legislative requirements (Article 79(3) of Regulation (EU) 2019/6) for making all important information on adverse events relating to the use of a veterinary medicinal product publicly available and as also highlighted in the spirit of the legislation (Recital 57) to facilitate that veterinarians receive appropriate feedback on reporting made.
218-238	3	Comment: It will be extremely difficult for the MAH to ensure they reach every animal healthcare professionals (such as veterinarians, pharmacists, pet-shop owners,….); on the other hand organisations cited in lines 227-231 can guarantee reaching the required audiences. The role of these organisations should be therefore reinforced and be mentioned as responsible for sending this information, not as examples only. Proposed change: *"Other organisational bodies **are urgently needed to** ~~can~~ act as information multipliers, by disseminating important information to the target audiences".*	As stated in the module and highlighted at a number of stakeholder meetings the 'main target audience comprises veterinarians and other animal healthcare professionals, including people who handle, dispense or administer the veterinary medicinal product (or medicinal products for human use administered to animals)' which is not synonymous with *every* animal healthcare professional. Marketing authorisation holders are responsible for their products including communication concerning them. Although it is acknowledged that other organisations are instrumental in facilitating dissemination of communication,

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			this should be done in collaboration with marketing authorisation holders.
229	2	Comment: Proposed change (if any): …veterinary colleges **and veterinary education establishments**;…	Agreed and module amended accordingly.
251-256	3	Comment: This form of communication (direct information from MAHs to veterinarians and other animal healthcare professionals) is not possible on the veterinary sector, as contact information is not always available to MAHs (i.e. many MAHs place their products on the market through distributors and do not have access to the information on the veterinarians and other healthcare professionals using/purchasing their products). MAHs may end up with a responsibility they cannot entirely met / assure. MAHs have pharmacovigilance agreements with all direct partners where they agree to act accordingly in case of a product recall. MAHs assure that all direct partners are properly informed (by email, phone or in person, through our sales team) and requested to urgently pass the message to their clients (from whom they have the contact / information data).	Not accepted. As highlighted previously that a number of stakeholder meetings, direct animal healthcare professional communication is established practice even under the current legislation, albeit fortunately not regularly used. It is not intended or expected that marketing authorisation holders have access to all veterinarians and other animal healthcare professionals. However it is reasonable to assume that marketing authorisation holders have procedures and structures in place which could make use of their existing agreements with direct partners (e.g. distributors, to disseminate communication to veterinarians and other animal healthcare professionals to whom they have sold their VMPs) for communication, in an analogous way, for example, to those required for managing and conducting a product recall.
263-265	3	Comment: Clear indication that, for VMPs registered in many MSs via DCP/MRP, agreement with the Reference Member State would only is necessary would be welcome.	Not accepted. The text in the module includes a general reference to competent authorities which is sufficient and appropriate. Details on the roles and responsibilities for agreeing communication will be addressed in the procedure under development.

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		Proposal: Addition in text: *"For VMPs registered in many MSs via DCP/MRP, agreement with the Reference Member State would only is necessary"*	
278-288	3	Comment: As stated in previous comment, direct information from MAHs to veterinarians and other animal healthcare professionals presents significant hurdles. Publishing on MAHs websites should fulfil the requirements as a dissemination tool / obligation to inform by MAHs. Proposed change: When published on the MAHs website, direct animal healthcare professional communications from MAHs, as agreed by the competent authorities or the Agency, can be considered as fulfilment of the requirements as a dissemination tool / obligation to inform by MAHs.	Comment not accepted. Please also see response to comment on lines 251-256 regarding the concept of direct animal healthcare professional communication. Although publication on marketing authorisation holder's websites is welcomed, communication with veterinarians and other animal healthcare professionals should not be limited to this, particularly since many marketing authorisation holder websites require veterinarians to register for access to their websites, which may be a hinderance to veterinarians accessing information via such websites. Website publication is not an appropriate substitute for direct communication, which may be necessary, in particular, for urgent or important safety concerns, which is established practice.
289 - 295	2	Comment: In the case of an urgent need for communication, tools for direct digital communication like email or messenger apps should be part of the process as these are often checked by vets multiple times a day. This should be used in particular if other communication like the ordering of VMPs by the vet is also done via these communication channels Proposed change (if any): Online platforms, including social media, and other digital	Comment agreed in principle. Module amended with some rephrasing of the text suggested.

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		tools**, such as email or messenger apps which are often used by veterinarians for ordering of medicines,** may also be useful…	
297-299	3	Comment: Clarification would be welcome: Are such press releases prepared and published by marketing authorisation holders subject to previous agreement by the competent authorities or the Agency?	Press releases prepared and published by marketing authorisation holders would be subject to agreement by the regulatory authorities only if they concern veterinary pharmacovigilance information.
325	1	Comment: In the text above (lines 265/266, 287/288), there is no mention of approval by competent authorities, only of agreement. Why does this line include the text 'approval by competent authorities'? Proposed change: Please modify the text to read: "..internal review, quality control and approval process; **~~approval by~~ agreement with** competent authorities and the..'	Agreed. Module amended accordingly.
331-362	3	Comment: The full section will be very resource intensive for MAHs, it is not always possible to be met, and will increase administrative burden both significantly. Furthermore, MAH do not always have the local contact details as they sometimes place their products in the market through distributors. The same situation will occur for the follow-up information, in certain countries/ regions MAHs will have to rely on their distributors as they are not able to perform the communications themselves: how to evaluate their measurements? Who and what actions must be taken?	Comment acknowledged however not agreed. Article 20 of Commission Implementing Regulation (EU) 2021/1281 specifies to 'measure the effectiveness of the communication'. However the challenges of this are recognised and indicated in the module 'However, it should be acknowledged that in practice such assessment is difficult to make, and to interpret, and to ascribe to the communication initiative. Therefore, methods for measuring effectiveness should be practicable and proportionate in relation to the urgency and importance of the subject communicated'.

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		Proposed change: Line 334: "**Where appropriate and possible,** the effectiveness of the communication should be measured."	It is the prerogative of the initiator of the communication (e.g. marketing authorisation holder or competent authority) to define and determine the methods they deem as appropriate for the follow-up of communication and for measuring its effectiveness, which should be described in the topic-specific communication plan which will be reviewed by the competent authorities and Agency.
332	1	Comment: Whether 'appropriate action is taken by the target audience' may not be an appropriate measure of effective communication, as this also depends on the willingness of the target audience to follow any provided guidance.	Comment noted however no change proposed to module. Although it may be difficult to measure whether appropriate action was taken by e.g. veterinarians (in case that any action had been proposed, such as new precautions for users), the estimation of effectiveness should be based on the assumption that the guidance provided (precautions) will be followed.
339-340	3	Comment: If media / website are used by the MAH, it is not possible to know which proportion of target audience is reached. Confirmation that the list of recipients is accurate and up to date is a very difficult requirement to be met by MAHs in case of direct animal healthcare professional communication. Proposed change: Line 337-338: "**Where appropriate and possible,** consideration should be given to investigating:"	Comment noted and text amended with alternative wording to that proposed. The module states that consideration (i.e. definition: to think about something carefully) should be given to the factors described, however, this is not prescriptive. Notwithstanding the above, it is reasonable to assume that marketing authorisation holders would maintain records of their intended recipients and be aware of any deficiencies. The module provides suggestions for consideration when following up communication however it is up to the marketing authorisation holder to propose the measures they consider appropriate for the individual situation, which should be described in the topic-specific communication plan.

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343-344	3	Comment: Feedback from target audience is necessary to ascertain that the key message was understood and, where necessary, acted on or attitudes or behaviour changed in line with the message. This requirement involves a lot of burden, and action taken by MAHs and also by target audiences is considered unrealistic. Proposed change: delete the full paragraph	Comment noted but proposed change not agreed. Although feedback may be appropriate in some cases for the scenario described by the stakeholder, there may also be alternative methods of evaluating the effectiveness of communication which could be monitored via alternative means e.g. change in prescribing behaviour; decrease in off-label use etc.
351	2	Comment: Proposed change (if any): … the risks of **pyrethroid insecticide** permethrin.	Comment agreed.
359	3	Comment: This evaluation will not be possible in situations where distributors are involved. Proposed change: As above for line 337-338: **"Where appropriate and possible,** consideration should be given to investigating:"	Comment not agreed. Please also see response to similar comment concerning lines 339-340. The evaluation of the effectiveness of communication should also ensure that lessons learned are considered and acted on, which could involve, for example, distributors involved in dissemination of communication.
371	3	Comment: Clarification welcome: in case that the marketing authorisation holder has an overarching communication plan as part of a SOP, can it be separated from the PSMF/annex?	All standard operating procedures (SOP) including any making reference to the overarching communication plan, should be listed in the Annex IV of the pharmacovigilance system master file (PSMF).
387-392 Appendix III, point I, subcategor	3	Comment: The complexity of an overarching communication plan should concern only in very rare situations (urgent safety concerns). Including non-urgent veterinary pharmacovigilance information significantly broadens the	Comment not agreed. Whilst it is acknowledged that the overarching communication plan outlines the approach for timely communication arising from pharmacovigilance information

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y "Other veterinary pharmacovigilance issue including non-urgent issues"		scope and involves a very significant increase workload for industry. Furthermore, as referred under "general comments", in the Implementing Act, art 20 (1)* only urgent issues are mentioned and so deletion of the requirements on the inclusion on non-urgent issues should be removed along the module. Proposed change: deletion of lines	or concerns, in case of urgent safety concerns, the principles are equally applicable to other scenarios, including public communication concerning non-urgent issues which are recommended as part of good pharmacovigilance practice. The wording "*overarching communication plan <u>may also</u> be useful for addressing communication of non-urgent veterinary pharmacovigilance information*" indicates that marketing authorisation holders may determine whether the overarching communication plan would also address non-urgent issues and there is no obligation to do so, whilst it is recommended.
407	1	Comment: What does 'VSBs' stand for? Please clarify.	Veterinary statutory bodies (VSBs) as described earlier in the module (section 2.1.4).
407, 515 (table – 2nd line/3rd column)	2	Comment: Proposed change (if any): …Association of different veterinarian specialists (e.g. on equine, bovine, etc.) **and veterinary education establishments**. Other (non-veterinarian) animal healthcare professional associations **or federations.**	Agreed. Module amended accordingly.