25 March 2022
EMA/CVMP/ERA/56761/2022
Committee for Veterinary Medicinal Products (CVMP)

Overview of comments received on the "Reflection paper on the interpretation of Article 72 of Regulation (EU) 2019/6" (EMA/CVMP/ERA/245311/2021)

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

Stakeholder no.	Name of organisation or individual
1	Access VetMed (formerly EGGVP)
2	AnimalhealthEurope

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1. General comments – overview

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
1	Access VetMed is grateful for the opportunity to comment on this refection paper. The efforts to set-up clear parameters are welcomed. However, **the paper seems more oriented to define technical solutions rather than scientific, measurable and assessable parameters**. Therefore, we suggest that these are further elaborated i.e. in subsequent guidance following this reflection paper, together with provision of definitions of terms such as "potentially harmful to the environment"; those are needed to prevent divergent interpretations and disharmonised implementation, and also to enhance transparency, proof evaluation and predictability for regulators and industry to the most extent possible. Another important point of attention is the possible negative consequences for availability resulting from the implementation of Article 72 of Reg 2019/6. The possibility that MAHs of reference VMPs authorised before October 2005 which will be required to submit a Phase II ERA might decline to submit the ERA and therefore the RVMP marketing authorisations may be withdrawn. In such cases, no new generics/hybrids for such reference products would be possible.	The CVMP appreciates the reviewer's comments. If needed, the development of follow-up guidance could be considered once the process of SPC harmonisation has started. No changes to the reflection paper are considered necessary.
2	AnimalhealthEurope welcomes the opportunity to comment on this draft reflection paper. We would like to commend the cooperation of	The CVMP appreciates the reviewer's comments.

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
	CVMP with CMDv to establish a harmonised, consistent and transparent approach.	

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
74–76	1	**Comment:** As stated under "general comments", Access VetMed is of the opinion that a definition on "potentially harmful to the environment" should be established as soon as possible in order to provide certainty to MAHs i.e. in which cases will actions be triggered, and to prevent unequal and disharmonised interpretation and implementation by different competent authorities.	Not accepted. The reflection paper is only intended to provide a practical and pragmatic interpretation of Article 72 of Regulation (EU) 2019/6. As such, the present text defines "potentially harmful to the environment" as "phase II ERA required/not available". Therefore, no changes to the reflection paper are considered necessary.
112–115	1	**Comment:** Criteria for defining term "potentially harmful to the environment" is requested. This is most needed for any further actions to avoid different interpretations. The reflection paper should avoid acknowledging that "broad interpretations" are possible. Please refer to previous comments.	Not accepted. The reflection paper clearly describes criteria on what is and what is not "potentially harmful to the environment" within the specific context of Article 72 of Regulation (EU) 2019/6, i.e. "potentially harmful to the environment" is defined as "phase II ERA required/not available". Therefore, no changes to the reflection paper are considered necessary.

138–150	1	**Comment:** Access VetMed agrees with the content of these lines (and generally with the reflection paper) but reference to the time frame proposed for the submission of ERA for these RVMPs is missing.	Not accepted. As a timeframe for the submission of an ERA is not mentioned in the legislation, the definition of such a period of time is not within the remit of the CVMP and thus beyond the scope of the present reflection paper. Therefore, no changes to the reflection paper are considered necessary.
138–150	2	**Comment:** This would apply to VMPs from a single MAH, being put on the list for harmonisation by the CMDv for the purpose of harmonising SPCs of that same product across MS. It is highly unlikely that any MAH would initiate such a procedure and in case of forced harmonisation, it is likely that the product would be withdrawn. The absence of generics for a product approved prior to 1 October 2005 indicates limited commercial value and typically, those products don't support the costs required to develop a Phase II ERA.	The CVMP acknowledges the reviewer's comment. Situations such as that described by the reviewer are discussed in the CMDv "Best practice guide for the selection of products for SPC harmonisation" (EMA/CMDv/386218/2021). In this context, it has to be mentioned that marketing authorisation holders can provide input during the selection phase and point to the potential risk of removal of a VMP from the market. No changes to the reflection paper were made.

167	2	**Comment:** We are conducting environmental risk assessments where we look at more than ecotoxicity. **Proposed change:** please modify to "Phase II **environmental risk assessment**".	Accepted. The reflection paper has been revised accordingly.
183–187	2	**Comment:** This paragraph states "if the active substance is classified as persistent or toxic according to (the PBT GL)". This is incorrect. Statements are required if the substance is classified as persistent AND bioaccumulative AND toxic, not when persistent or toxic as stated. **Proposed change:** modify to state "**if the active substance is classified as persistent, bioaccumulative and toxic"**.	Partially accepted. The CVMP acknowledges the comment. It is common practice to communicate relevant environmental properties such as toxicity, persistence or bioaccumulation in the SPC. The reflection paper was amended accordingly and reference to the CVMP "Guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products" has been removed.

Figure 1	1	Comment: According to the figure, a RVMP - authorised before 1 October 2005, and - which does not need a Phase II ERA and - whose SPC does not contain environmental warnings or mitigation measures is not required to take any further actions with respect to ERA and Article 72. However, in case that the SPC of RVMP does not contain environmental warnings or mitigation measures and thus no action is needed -, but its generics, which do not need a phase II ERA according to VICH GL38 and the "Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38" do already contain environmental warnings due to preceding requirements of competent authorities, in such cases comparison and harmonisation of generics shall be processed according to Article 71(3) of the regulation 2019/6.This should be clearly stated in this RP or included in the Figure 1. Proposed change: additional steps/questions to be added in Figure 1: Does the SPC contain environmental warnings or mitigation measures? *(if the answer is no)* – no actions needed **for the RVMP** with respect to ERA and Article 72 **(new arrow)**	Partially accepted. Although reference to Article 71(3) of Regulation (EU) 2019/6 is ultimately not made, Figure 1 as well as the corresponding text were amended by adding reference to warnings/risk mitigation measures included in the SPC of generics/hybrids of the RVMP.

		(new rectangle) – Do(es) the SPC(s) of the generic(s) of the RVMP contain environmental warnings or mitigation measures?) *(if the answer is yes)* – **(new) Alignment of SPCs between RVMP and its generic(s) according to Article 71(3)**	