European Medicines Agency
Veterinary Medicines and Inspections

London, 12 July 2007
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OVERVIEW OF COMMENTS RECEIVED ON REFLECTION PAPER ON PUBLICATION OF WITHDRAWALS OF MARKETING AUTHORISATION APPLICATIONS FOR VETERINARY MEDICINAL PRODUCTS

Table 1: Organisations that commented on the draft Guideline as released for consultation

	Name of Organisation or individual	Country
1	IFAH Europe	EU

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Table 2:Discussion of comments

GENERAL COMMENTS - OVERVIEW		
SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION TITLE		
Line no.[1] + paragraph no.	**Comment and Rationale**	**Outcome**
Section 3 penultimate paragraph	There is no reason for setting a time line of 2 months; it should be made clear at least that this is not binding and should not restrict the review time for the applicant.	The text now reads "usually within 2-3 months".
Section 4 "Applicant's withdrawal letter"	It should be sufficient to provide the letter either as paper or as electronic copy but not both.	The EMEA would prefer to receive an original paper copy of the withdrawal letter.
Section 4 "Q/A document" 1st paragraph	See comment on 2 months time line above.	The document has been revised and the proposal to produce a Question and Answer document has been deleted. The EMEA will review the revised procedure over a period of 18 months and may introduce a proposal for a Question and Answer document if the need for this becomes evident.
Section 4 "Q/A document" 3rd paragraph	In view of the items to be presented, this is a duplicate of the WPAR. This is unnecessary work and should therefore be avoided. It is recommended to only publish one document!	The document has been revised and the proposal to produce a Question and Answer document has been deleted. The EMEA will review the revised procedure over a period of 18 months and may introduce a proposal for a Question and Answer document if the need for this becomes evident.

[1] Where applicable

Section 4 "Q/A document" 4th paragraph.	It is stated that "*The CVMP view on an application cannot be considered as "commercially confidential information" and therefore should not raise any comments from the applicant.*" This statement is considered not appropriate as even if a CVMP view does not contain confidential information, it could unintentionally contain misinterpreted or misrepresented information, which could damage the MA or MAH. Furthermore, the intended contents of the document as mentioned in the previous paragraph cannot be claimed to be "views of the CVMP". Thus, this sentence should be deleted or revised.	The document has been revised and the proposal to produce a Question and Answer document has been deleted. The EMEA will review the revised procedure over a period of 18 months and may introduce a proposal for a Question and Answer document if the need for this becomes evident.
Section 4 "WPAR" 4th paragraph.	The 10 working days for checking the draft report by the applicant should not be a strict time line. Again, see comment with regard to the 2 months time line.	Text has been amended to read: "The draft WEPAR will be sent to the applicant who will usually be asked to verify the deletion of commercially confidential information within 10 working days (See Principles to be applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA Documents - EMEA/45422/2006)".
Section 5	Again the issuance of two documents (Q/A and WPAR) is questioned. This is double and therefore unnecessary work.	The document has been revised and the proposal to produce a Question and Answer document has been deleted. The EMEA will review the revised procedure over a period of 18 months and may introduce a proposal for a Question and Answer document if the need for this becomes evident
Section 5 - Last paragraph	Why is a revision of the Q/A document necessary?	The document has been revised and the proposal to produce a Question and Answer document has been deleted. The EMEA will review the revised procedure over a period of 18 months and may introduce a proposal for a Question and Answer document if the need for this becomes evident
Annex 1	It is at the discretion of the applicant how to formulate and what information to provide in a withdrawal letter. Thus, providing reasons should be optional.	Not accepted; see Article 36 of Regulation (EC) No. 726/2004 which requires that "if an Applicant withdraws….the Applicant shall communicate its reasons for doing so to the Agency. The Agency shall make this information publicly available."

[1] Where available