



European Medicines Agency  
*Veterinary Medicines and Inspections*

London, 12 July 2007  
Doc. Ref. EMEA/CVMP/247827/2007

**OVERVIEW OF COMMENTS RECEIVED ON  
REFLECTION PAPER ON PUBLICATION OF THE CVMP'S NEGATIVE OPINION AND  
REFUSAL TO RECOMMEND THE GRANTING OF A MARKETING AUTHORISATION 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

Table 2: Discussion of comments

GENERAL COMMENTS - OVERVIEW		
SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION TITLE		
Line no. <sup>1</sup> + paragraph no.	Comment and Rationale	Outcome
Section 4 “Q/A document” 4 <sup>th</sup> paragraph.	It is stated that “ <i>The CVMP view on an application cannot be considered as “commercially confidential information” and therefore should not raise any comments from the applicant.</i> ” 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.
4. Refusal EPAR 1 <sup>st</sup> paragraph, 2 <sup>nd</sup> sentence	The 10 working days for checking the draft report by the applicant is recognised as important to enable the revised document to be adopted at the next CVMP meeting. However an escape clause is necessary when some flexibility is necessary to accommodate busy schedules in under a veterinary regulatory departments. Amend to read: “ <i>The CVMP assessment report will be sent to the applicant for deletion of commercially confidential information (See Principles to be applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA Documents - EMEA/45422/2006) , within 10 working days. Applicants unable to meet this deadline should contact the EMEA Project Manager immediately to discuss a solution.</i> ”	Text has been amended to read  “The draft Refusal EPAR 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)”. .

<sup>1</sup> Where available

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