European Medicines Agency
Veterinary Medicines and Inspections

London, 18 September 2007
Doc. Ref. EMEA/CVMP/248860/2007

OVERVIEW OF COMMENTS RECEIVED ON DRAFT GUIDELINE ON PROCEDURES FOR RE-EXAMINATION OF CVMP OPINIONS

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

	Name of Organisation or individual	Country
1	Intervet International BV	Netherlands
2	Bayer HealthCare AG	Germany

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20)
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Table 2:Discussion of comments

GENERAL COMMENTS - OVERVIEW	
Generally the timeframe of 60 calendar days for the re-examination of the CVMP opinion (after receipt of the grounds for the request) by the CVMP is a very tough time frame, particularly if the re-examination procedure includes the consultation of a SAG or constitution of an AHEG and an oral explanation at CVMP. To guarantee a careful re-examination of the CVMP opinion even under exceptional circumstances (e.g. summer holiday period or Christmas time), the opportunity to prolong the procedure by EMEA for 30 days (1 month) seems to be reasonable. However, as the timeframe for re-examination of the CVMP opinion is based on the new legislation an amendment seems to be difficult. Thus, in any case a very close co-operation between EMEA (Project manager) and applicant/MAH is mandatory.	As the legislation defines the timelines it is not possible to make any amendments, but the comment is noted.

SPECIFIC COMMENTS ON TEXT		
2. LEGAL BASIS FOR RE-EXAMINATION		
Line no. + paragraph no.	**Comment and Rationale**	**Outcome**
2. Between sections 'Centralised Procedures' and 'Variations'	In contrast to the human "Guideline on Procedures for Re-Examination of CHMP Opinions" (EMEA/CHMP/50745/2005) a separate section considering "Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, as amended (Referrals)" has been excluded. **Is there any reason for that?** If not it seems reasonable to adapt the veterinary guideline as far as possible to the human guideline, i.e. including Article 36 (4) of Directive 2001/82/EC, as amended, between the section for CP and Variations	As the working procedures for Veterinary Referrals are not yet finalised (following recent changes and clarifications with the Commission) they have been excluded from the scope of this Guideline, which is needed for re-examinations now. Once all the outstanding issues have been clarified for Referrals then appropriate guidance will be produced.

3. SCOPE		
Line no. + paragraph no.	**Comment and Rationale**	**Outcome**
1st main bullet point	A 4th bullet point should be added to include Art. 33/34/35 and 39/40/41 of Directive 2001/82 (community referrals). As described in the NtA, Vol. 6A chapter 3 a re-examination of the CVMP opinion is possible for this type of procedure.	Referrals are now clearly excluded from the scope.

4. TIMING OF RE-EXAMINATION PROCEDURE		
Line no. + para no.	**Comment and Rationale**	**Outcome**
4.1 1st paragraph, 4th line	We suggest to add already here the Ad Hoc Expert Group (AHEG) as throughout the document always reference is made to both 'possibilities'.	Accepted and amended.
4.1 1st paragraph, last sentence	Although we understand that EMEA and CVMP would like to be informed ASAP whether the applicant/MAH would like to go for an oral hearing, in our experience it is often difficult to decide at this stage. Therefore we recommend to move the announcement to the stage when the detailed grounds for re-examination have to be submitted, i.e. to the end of the second para.	Accepted, but 1st paragraph last sentence amended as follows: "If the applicant/MAH wishes to have an oral explanation before the CVMP, this should ~~also~~ be requested ~~at this time~~ as early as possible."
4.2 2nd paragraph, 3rd sentence	To our opinion it should be specified that the discussions of the CVMP on the need for consultation of SAG/AHEG is related to its OWN need and has nothing to do with the wish of the applicant/MAH, being announced with the request for re-examination of the opinion.	Not accepted. It does state that "…the Committee may have preliminary discussions on the need……."

5. DOCUMENTATION TO BE SUPPLIED		
Line no. + para no.	**Comment and Rationale**	**Outcome**
5.2	To our opinion this para. should be deleted or moved to 6.1: The contents has nothing to do with the documentation to be supplied. The involvement of a SAG/AHEG can be required both by applicant and by CVMP and the timetable for the applicant is already mentioned under 4.1.	Not accepted as such. It clarifies exactly what the Applicant/MAH needs to provide, however the title of this section is now revised to "Information to be supplied".

6. CVMP ASSESSMENT AND FINAL OPINION		
Line no. + para no.	**Comment and Rationale**	**Outcome**
6 2nd line	Add SAG/AHEG after EMEA?	Accepted and amended.
6.1. Consultation	Experience has shown that oral explanations provided by the applicant/MAH to both, the new rapporteur/co-rapporteur and the	Not accepted. An oral explanation before the CVMP will always be offered, however, any request for an oral explanation before the

of a SAG/ AHEG paragraph before the last sentence	SAG/AHEG, are of fundamental importance for the understanding of applicant's/MAHs request for re-examination. Accordingly, an applicant/MAH requesting the CVMP to consult a SAG/AHEG should automatically be invited for an oral presentation to the SAG/AHEG (including the new rapporteur/co-rapporteur) before an oral explanation at CVMP.	SAG/AHEG will be considered on a case-by-case basis by the CVMP.
6.2 Favourable opinion	Re-examinations may not only have granting/maintaining of a licence as subject, but also other issues, which have no influence on all or any of the annexes. Example: in case of a variation the product lit. may not be concerned. All documents are to be provided in English only. To prevent any unnecessary annexes, we strongly advise to reword this section into: ".....the following documents shall be annexed (in English) to the opinion, <u>if relevant</u>". It is assumed that also a scientific conclusion is provided as for an unfavourable opinion (additional bullet point).	Although product literature will usually be available in all languages for all procedures covered by it, for the re-examination of a procedure which does <u>not</u> affect the annexes (for example, a Quality Type II variation which results in no changes to the annexes), no annexes need be attached. Accepted, but worded as "if applicable". Not accepted. In case of a favourable opinion the CVMP assessment report (containing the scientific conclusion) is appended to the CVMP opinion.
6.2 not favourable opinion:	2nd indent: Two points are of importance here: (a) In case the scientific conclusion + grounds for refusal are to be translated this is not the duty of the applicant, but has to be done by the official institutions. (b) If the EC wishes to publish the decision on their website, i.e. it will become public, the applicant/MAH must be given the chance (including the time) to review it and request deletion of confidential information.	(a) Not accepted. It only states that these "needs to be translated" (without specifying exactly who is responsible for the translations). Acceptable as it stands. (b) Not accepted. The current policy is to have a short Scientific conclusions and grounds for refusal so these would only include the main conclusions and not include detailed confidential information.