European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

CONCEPT PAPER ON A REVISION OF THE GUIDELINE FOR AN ASSESSOR PREPARING ASSESSMENT REPORTS

ADOPTION BY CVMP FOR RELEASE FOR CONSULTATION	October 2009
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 December 2009

The proposed guideline will replace the current "Guideline for an Assessor Preparing Assessment Reports for Veterinary Medicinal Products" (EMEA/CVMP/115769/2005)

Comments should be provided using this template to vet-guideline@emea.europa.eu
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KEYWORDS	Guideline, Assessment, Veterinary medicinal product

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1. INTRODUCTION

The revised "Guideline for an Assessor Preparing Assessment Reports for Veterinary Medicinal Products" came into effect in May 2005. Since then, changes have been made to the underlying legislation and the current guideline therefore needs to be revised to be in line with these changes.

2. DISCUSSION

In 2009, Annex I of Directive 2001/82/EC was revised and amended by Directive 2009/9/EC, which includes changes to several sections of a dossier that needs to be submitted by an applicant for a marketing authorisation. As a consequence, the relevant sections of the assessor guideline need to be revised.

In addition, recent recommendations by the CVMP in particular in regard to the benefit-risk evaluation in accordance with Directive 2001/82/EC, as amended, should be implemented into the guideline.

3. RECOMMENDATION

The CVMP recommends revising the current guideline in line with current legislation and CVMP recommendations. CVMP Working Parties and Scientific Advisory Group (QWP, SWP, EWP, IWP, ERAWP and SAGAM) as well as CMD(v) members should be involved in the review, as appropriate.

4. PROPOSED TIMETABLE

30 November 2009	Deadline for comments
Q1 2010	Discussion in CVMP and Working Parties
Q2 2010	Release of draft guideline for public consultation

5. RESOURCE REQUIREMENTS FOR PREPARATION

The revision will involve the EMEA Secretariat, the CVMP and relevant Working Parties and its Scientific Advisory Group as well as CMD(v), who would be consulted, as necessary.

6. IMPACT ASSESSMENT (ANTICIPATED)

The proposed revision will provide clearer and more practical guidance for assessors in Member States on study requirements. The revised guideline will also facilitate harmonised assessment in Member States and hence, indirectly, provide benefits for the pharmaceutical industry.

7. INTERESTED PARTIES

Experts involved in the assessment of a veterinary medicinal product in Member States.
Pharmaceutical industry and Veterinary Consultants (indirectly).

8. REFERENCES TO LITERATURE, GUIDELINES ETC

Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Directive 2004/28/EC of the European Parliament and the Council of the 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

CVMP Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products (EMEA/CVMP/248499/2007)