European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

CONCEPT PAPER ON THE NEED FOR REVISION OF THE POSITION PAPER ON COMPLIANCE OF VETERINARY VACCINES WITH VETERINARY VACCINE MONOGRAPHS OF THE EUROPEAN PHARMACOPOEIA

AGREED BY IMMUNOLOGICAL WORKING PARTY	9 October 2006
ADOPTION BY CVMP FOR RELEASE FOR CONSULTATION	8 November 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 January 2007

The proposed guideline will replace the position paper on compliance of veterinary vaccines with veterinary vaccine monographs of the European Pharmacopoeia (EMEA/CVMP/140/97)

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1. INTRODUCTION

The European Union is a signatory of the convention on the Elaboration of a European Pharmacopoeia and compliance with monographs of the Pharmacopoeia is mandatory within the Member States. Monographs, including those on veterinary vaccines, are used during marketing authorisation procedures.

The position paper was prepared to provide a statement on several aspects of compliance and its implications for manufactures, Marketing Authorisation Holders and Applicants.

2. PROBLEM STATEMENT

While the position paper has been very useful in providing an authoritative interpretation of different aspects of the need for compliance with monographs, experience over the last seven years shows that there remain some areas where differences of interpretation exist and hamper smooth operation of regulatory procedures, for example:

- The mandatory or non-mandatory status of different sections of monographs;
- The impact of new and revised monographs on existing marketing authorisations;
- The implications for veterinary vaccines of the relatively short period for implementation of new and revised monographs (one year after adoption by the European Pharmacopoeia Commission, about six months after publication);
- The need for agencies to alert the European Pharmacopoeia where a requirement of a monograph appears to need revision.

3. RECOMMENDATION

The Immunologicals Working Party should prepare a revised and enlarged guideline in order to deal with the above and any other necessary issues.

4. PROPOSED TIMETABLE

Following the end of the consultation period for this concept paper on 31 January 2007 it is expected that a draft guideline will be released for consultation by Q4 2007.

5. RESOURCE REQUIREMENTS

1 Rapporteur, drafting group of 3 persons, working solely by correspondence

6. IMPACT ASSESSMENT

A guideline should facilitate authorisation and other regulatory procedures, reducing costs for industry and providing resource savings for agencies.