



European Medicines Agency
Veterinary Medicines and Inspections

EMA/CVMP/177266/2005
London, 16 June 2005-corrigendum¹

PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
Meeting of 14 to 15 June 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension application for **Novem 5 mg/ml** from Boehringer Ingelheim Vetmedica GmbH. The extension concerns a revised indication in cattle and the addition of pigs as a new target species.

The Summary Opinion is available on the EMA web site: <http://www.emea.eu.int>

The Committee adopted by consensus a positive opinion for a type II variation for **Suvaxyn Aujeszky 783+O/W** regarding an addition of a site where the target animal safety test takes place. In addition, the batch release safety test is brought into line with new Ph. Eur. requirements.

Maximum Residue Limits

The Committee adopted a revised opinion concerning the extrapolation of the current maximum residue limits (MRL) for **morantel** to all food producing species with an amended MRL value for milk. The opinion was initially adopted by the Committee in February 2005 with an MRL for milk of 100 µg/kg. The MRL value has now been corrected to 50 µg/kg, in line with the milk MRL previously established for bovine and ovine species, following the request from the Commission for reconsideration of the opinion.

*The Summary opinion will be available on Monday 20 June 2005 on the EMA web site:
<http://www.emea.eu.int>*

Scientific Advice

The Committee adopted advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning quality, safety and efficacy requirements for an antimicrobial for swine.

¹ Correction of document reference number under Concept Papers, Guidelines and SOPs/ General

Pharmacovigilance

The Committee adopted an European harmonised reporting form for veterinarians and veterinary health professional following consideration of the comments received during the public consultation (EMEA/CVMP/893/04) which will be made available in all EU languages, plus in the relevant languages on the websites of the national agencies.

The Committee adopted a revised Standard Operating Procedure (SOP) on adverse reaction reporting for centrally authorised veterinary medicinal products (EMEA/CVMP/SOP/693/99-Rev.1). The SOP was revised in order to facilitate a more transparent process of assessing adverse reactions reported for centrally authorised veterinary products, and to ensure that all suspected adverse reactions (SARs) are assessed by the respective Rapporteurs and is addressed to Marketing Authorisation Holders, CVMP members and alternates, CVMP Pharmacovigilance Working Party members, Rapporteurs, European Commission and EMEA.

Quality

The Committee adopted a revised Joint CHMP/CVMP Guideline on Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products (EMEA/CVMP/815/00-Rev.1) for release for 3-month consultation. The guideline was revised in order to take into account the provisions of the new Human legislation for traditional herbal medicinal products.

Efficacy and Safety

The Committee adopted a Concept Paper on dossier requirements for oncology products (EMEA/CVMP/EWP/79590/2005-CONSULTATION), for release for a 3-month period of public consultation. The proposed guidance document is to provide recommendations for the efficacy and safety requirements of anticancer products for use in non-food producing animals.

General

The Committee adopted a Concept Paper on a revision of the current guideline on the SPC for antimicrobial products, for release for a 3-month period of public consultation (EMEA/CVMP/67951/2005-CONSULTATION). Since the finalisation of the guideline in 2002, development in the field of antimicrobial therapy and antimicrobial resistance has been fast and initiatives have been started by different bodies and authorities, as a result, the CVMP has considered that more guidance is needed in the SPC with the aim to improve the use of antimicrobials and reduce antimicrobial resistance. This should also allow improved harmonisation of SPCs in the EU.

*The documents will be available on Monday 20 June 2005 on the EMEA web site:
<http://www.emea.eu.int>*

International Harmonisation

The Committee adopted the revised VICH Quality guidelines GL10(R): Impurities in new veterinary drug substances and GL11(R): Impurities in new veterinary medicinal products for release for 3-months public consultation.

*The documents will be available on Monday 20 June 2005 on the EMEA web site:
<http://www.emea.eu.int>*

Regulatory issues

The Committee reviewed certain aspects of the implementation of the new legislation for the authorisation of veterinary medicinal products and agreed draft guidelines to be referred to the Commission regarding:

- Pharmacovigilance for veterinary medicinal products on procedure for marketing authorisation holders (revision of existing guideline, Volume 9B of the Notice to Applicants);
- Monitoring compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections.

These guidelines will be reviewed by the European Commission before release for consultation.

The next meeting of the CVMP will be held on 12-14 July 2005

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This press release and other documents are available on the Internet at the following address:

<http://www.emea.eu.int>