European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12 – 14 June 2007

The Committee re-elected Gérard Moulin from France as its Chairman for a further 3-year mandate.

The Committee also elected Rory Breathnach as Chairman of the Scientific Advice Working Party for a 3-year mandate. Rory Breathnach is a co-opted member of the Committee and has been the vice-chair of the Scientific Advice Working Party since December 2004.

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a Type II variation for **ProteqFlu** regarding the extension of the product shelf life from 18 to 27 months with a consequential change of the target formulation titre for the two active ingredients as well as the deletion of the freeze-dried formulation.

The Committee adopted by consensus a positive opinion for a Type II variation for **ProMeris Duo** regarding the removal of the contraindication for pregnant and lactating animals.

The Committee adopted by consensus a positive opinion for a Type II variation for **Halocur** regarding a change in the manufacturer of the active substance.

Maximum Residue Limits

The Committee adopted by consensus an opinion concerning the modification of the acceptable daily intake (ADI) for **tylvalosin** (previously known as acetylisovaleryltylosin) recommending that the ADI is modified to 1.04 µg/kg bw (i.e. 62.4 µg/person).

The Committee adopted by consensus an opinion recommending the inclusion of dinoprostone in Annex II of Council Regulation 2377/90 further to a request from a company to consider if the substance would be covered by the previous assessments of dinoprost and dinoprost tromethamine. The Committee concluded that given the structural similarity between the substances and the rapid metabolism of dinoprostone, the previous assessment performed for dinoprost tromethamine and dinoprost would apply to dinoprostone.

The summary opinions will be available on the EMEA web site: http://www.emea.europa.eu

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The Committee adopted a template for the European Public MRL Assessment Report (EPMAR), which will replace in the future the MRL Summary Report. The new template aims to summarise the CVMP evaluation of MRL applications in a more structured way and to be more reader friendly. The name of the document has been changed to be more explicit regarding its content and purpose of the document. The template will be implemented from the July 2007 CVMP meeting.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Dexdomitor**. The Committee concluded that the benefit-risk assessment of the product continued to be favourable and, therefore, recommended the renewal of the marketing authorisation.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Convenia, Poulvac Flufend, Nobilis Influenza H5N2** and **Vaxxitek HVT+IBD** and concluded that no further action or changes to the product literature were required.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted the following standard lists used for electronic reporting of suspected adverse reactions following the yearly review and update*:*

- VEDDRA list of clinical terms for adverse reactions in animals (EMEA/CVMP/413/99-Rev.4)
- VEDDRA list of clinical terms for adverse reactions in humans (EMEA/CVMP/891/04-Rev.2)
- List of species and breeds (EMEA/CVMP/553/03-Rev.2)

The Committee adopted a Revised Call for Comments on Standard Lists for EudraVigilance Veterinary (EMEA/123353/2004-Rev.1).

These lists and the call for comments will be published on the EMEA website in due course and the implementation of these lists in EudraVigilance Veterinary is scheduled for 30 September 2007.

The documents will be available on the EMEA web site: http://www.emea.europa.eu

Cooperation with other International Bodies

The Committee reviewed the draft agenda of the 17th session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) to be held on 3-7 September 2007 in Breckenridge, USA, and considered the proposed draft MRLs recommended by the 66th JECFA meeting, the new approach for the establishment of MRLs agreed at the same meeting and the Report of the CCRVDF working group on residues of veterinary drugs without ADI/MRLs. The Committee drafted comments in preparation of the EU position on these issues.

Regulatory Issues

The Committee adopted a revised guideline "*The acceptability of names for veterinary medicinal products processed through the centralised procedure*" (EMEA/328/98-Rev.3-CONSULTATION) for release for a 3-month period of public consultation. This revision has been made in order to bring the guideline in line with the latest version of the equivalent human guideline. The guideline now makes specific reference to vaccines and generics as well as including decision trees in relations to International Nonproprietary Names (INNs).

The document will be available on the EMEA web site: http://www.emea.europa.eu

The Committee adopted a revised guideline on "*Phamacovigilance for Veterinary Medicinal Products – Procedures for Marketing Authorisation Holders*" (update of current guideline in Volume 9 to take into account the revised legislation). This guideline describes obligations of the marketing authorisation holder of veterinary medicinal products in terms of pharmacovigilance reporting. Furthermore, this guideline implements the VICH topic GL 29 "Pharmacovigilance of veterinary medicinal products – management of periodic summary update reports". The document will be submitted to the European Commission for review and publication.

The next meeting of the CVMP will be held on 10-12 July 2007

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This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu