European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 9-11 October 2007

Maximum Residue Limits

Further to an appeal from the applicant, the Committee reviewed its assessment and confirmed its original opinion recommending provisional Maximum Residue Limits for **gamithromycin** in bovine (non-lactating), but established a revised ADI (Acceptable Daily Intake). The initial opinion was adopted at the July 2007 meeting.

Further to an appeal from the applicant, the Committee reviewed its assessment and adopted by consensus a revised opinion recommending the modification of the ADI for **tylvalosin**. The initial opinion was adopted at the June 2007 meeting.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Metacam**. The Committee, having re-assessed the benefit-risk balance of the product, concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community Referrals

The Committee adopted by consensus an opinion recommending a harmonised SPC text for **Methoxasol-T** (and associated names) of Eurovet Animal Health BV. The product was referred to the Committee under article 34 of Directive 2001/82/EC as amended, as divergent decisions had been taken by Member States in national marketing authorisation procedures.

The Committee started a referral procedure for all authorised veterinary medicinal products containing toltrazuril intended for use in poultry species, under article 35 of Directive 2001/82/EC as amended. The procedure was referred to the Committee by Germany due to concerns on a potential serious risk to the environment. The European Commission extended the scope of the referral to all veterinary medicinal products, including generics, containing toltrazuril for use in poultry.

The EMEA will shortly be publishing summaries of CVMP conclusions on recent referrals; this information has already been published on the European Commission's website (http://ec.europa.eu/enterprise/pharmaceuticals/register/refv_others.htm).

Scientific advice

The Committee agreed scientific advice regarding a bioequivalence study for a generic veterinary medicinal product.

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Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Meloxidyl**, **Naxcel**, **Previcox**, **Promeris**, **Promeris Duo** and **Slentrol** and concluded that no further action or changes to the products literature were required.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted a "Guideline on Management and Assessment of Periodic Safety Update Reports (PSURs) of Veterinary Medicinal Products" (EMEA/CVMP/PhVWP/4550/2006-CONSULTATION) for release for a 6-month period of public consultation. This guideline gives guidance to assessors in their scientific and regulatory assessment of PSURs and aims at assessments of high quality as well as standardisation of the format of PSUR assessment reports across the EU. The guideline was developed in consideration of comments received during the public consultation on the Concept Paper on a PSUR assessment guideline for Veterinary Medicinal Products (EMEA/CVMP/PhVWP/145320/05. The consultation ended September 2005).

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

Efficacy

The Committee adopted a concept paper for the revision of the "Guideline on Efficacy of veterinary medicinal products for use in farmed aquatic species" (EMEA/CVMP/EWP/85954/2007-CONSULTATION) for release for a 3-month period of public consultation. The concept paper was considered necessary following considerable changes in recent years in fish farming and an increasing need for medicines to treat diseases which are not satisfactorily covered by vaccines, particularly diseases emerging in newly farmed species of fish.

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

Quality

The Committee adopted a revised Guideline on Stability Testing: Stability testing of existing active substances and related finished products (EMEA/CVMP/QWP/846/99-Rev.1) for release for a 6-month period of public consultation. The aim of this revision is to update provisions in line with the recently updated VICH guideline on stability (GL3).

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

Regulatory Issues

The Committee adopted a questions and answers document regarding application of the so-called 'sunset clause' to centrally authorised veterinary medicinal products (EMEA/CVMP/120559/2006) following the close of the public consultation. This document addresses questions that the Marketing Authorisation Holder may have on this topic and gives practical information on how EMEA will monitor any centrally authorised veterinary medicinal product never marketed within the EEA after granting of the marketing authorisation and any complete cessation of marketing for a three consecutive year-period.

The overview of the comments received during the public consultation of this document (EMEA/CVMP/175326/2007) is available on the EMEA web site.

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

Availability of Veterinary Medicines

The Committee considered the "HMA Action Plan for HMA-V for follow up of recommendations of the Task force on Availability of Veterinary medicines" and further discussion on the action to be undertaken by CVMP are expected to take place at the next HMA meeting in November.

Organisational Matters

The Committee endorsed the work programmes for 2008 for the CVMP Scientific Advice, Pharmacovigilance, Efficacy, Safety, Immunologicals, Quality and Environmental Risk Assessment working parties as well as for the Scientific Advisory Group on Antimicrobials.

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

The next meeting of the CVMP will be held on 6-8 November 2007

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http://www.emea.europa.eu