European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 6 to 8 September 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a type II variation for **Aivlosin** regarding the replacement of the manufacturer of the active substance.

The Committee adopted by consensus a positive opinion for a type II variation for **Porcilis Porcoli** regarding minor changes in production of the antigens.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **toltrazuril** in Annex I of Council Regulation (EEC) No. 2377/90 for all mammalian food producing species and poultry further to the establishment of provisional MRLs for cattle. Toltrazuril had already maximum residue limits established for pigs, chicken and turkeys. The new recommendation for all mammalian food producing species and poultry was made in application of the CVMP guidance on extrapolation of MRLs.

The Committee adopted by consensus a positive opinion recommending the extension of the current entry for **diethylene glycol monoethyl ether** in Annex II of Council Regulation (EEC) No. 2377/90 to all ruminants further to a request from a company.

The Committee adopted by consensus an opinion recommending the inclusion of **polyoxyethylene sorbitan monooleate** in Annex II of Council Regulation (EEC) No 2377/90 for all food producing species further to a request for clarification from a company. This new entry will cover the substances commonly known as Polysorbate 80 (currently included in Annex II for all food producing species) and Polysorbate 81 with both substances falling under the same chemical name.

The Summary opinions will be available on Monday 12 September 2005 on the on the EMEA web site: http://www.emea.eu.int

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Pruban**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

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Community Referrals

The Committee considered the notification for a referral under article 35 of Council Directive 2001/82/EC, as amended, for Suramox 15% (amoxicilin). The referral was submitted by Belgium following a mutual recognition procedure and subsequent to the withdrawal of the application in Belgium. The referral was initiated due to concerns with regard to the withdrawal period for the product in cattle and pigs. A rapporteur and co-rapporteur were appointed and a list of questions agreed to be sent to the Marketing Authorisation Holder.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Advocate**, **Equilis StrepE** and **Zubrin** and concluded that no further action or changes to the product literature of the products were required. The Committee also reviewed the PSUR for **Eurifel RCP FeLV**, however no final conclusions were taken and the MAH was invited to comment on questions that had arisen during the assessment of the PSUR.

The Committee adopted the revised and updated VEDDRA list of clinical terms for reporting adverse reactions in animals to veterinary medicines (EMEA/CVMP/413/99 Rev. 2) as well as the VEDDRA list of clinical terms for reporting adverse reactions in human beings (EMEA/CVMP/891/04 Rev. 1) to include new terms that have been reported in spontaneous reactions since the first publication of the terminology. For the first time the codes used in the VEDDRA database will be published alongside the terms, since transmission of the codes is required for EudraVigilance Veterinary.

The revised lists will be published on the EudraVigilance veterinary website

Concept Papers, Guidelines and SOPs

Efficacy

The Committee adopted a concept paper on a revision of the existing Guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats for release for 3-month period of public consultation (EMEA/CVMP/EWP/202810/2005-CONSULTATION).

General

The Committee adopted two revised Guidelines on the Summary of Product Characteristics:

- for pharmaceutical veterinary medicinal products (EMEA/CVMP/064/05-CONSULTATION)
- immunological veterinary medicinal products (EMEA/CVMP/065/05-CONSULTATION)

for release for a 3-month period of public consultation. The guidelines have been updated to reflect current practice and the new order of the sections of the SPC as specified in Directive 2004/28/EC.

The documents will be available on Monday 12 September 2005 on the EMEA web site: http://www.emea.eu.int

Antimicrobial Resistance

The CVMP took note of the FDA withdrawal of approval of the new animal drug application for enrofloxacin in poultry, as published at the FDA web page. The FDA made the original proposal for this withdrawal in October 2000. In February 2001 the CVMP issued the document "Reflection by the CVMP within a European context on the intention of the FDA to withdraw the use of fluoroquinolone enrofloxacin in poultry (EMEA/CVMP/014/01)" addressing the intended FDA withdrawal. The CVMP is currently reviewing the use of fluoroquinolones in food-producing animals including the development of resistance and impact on human and animal health in general. Within this work the FDA withdrawal of the animal drug application for enrofloxacin in poultry will also be considered. The Committee will publish its conclusions once the work has been finalised.

Organisational matters

The Committee discussed the preparation of the Informal CVMP meeting to be held in Windsor, United Kingdom on 20-21 September 2005 at the initiative of the United Kingdom under the activities of the Presidency of the European Union. The Committee agreed that the meeting would consider the following items:

- Experience of new procedure for provision of scientific advice
- Assessment procedure for ADRs
- Transparency and availability of pharmacovigilance information
- Readable EPARs
- Procedural and organisational issues regarding CVMP meetings and procedures
- Appointment of rapporteurs
- Legal and regulatory training for CVMP members and alternates
- Co-operation with the future co-ordination group.

In a Joint session with the Veterinary Mutual Recognition Facilitation Group the Committee would discuss Medicines for Minor Species focusing on bees, goats and turkeys.

The next meeting of the CVMP will be held on 4-6 October 2005

CVMP Secretariat
Veterinary Medicines and Inspections Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int