European Medicines Agency
Veterinary Medicines and Inspections

London, 18 April 2008
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PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 15-17 April 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for **Reconcile** chewable tablets for dogs which are intended as an aid in the treatment of separation-related disorders in dogs (manifested by destruction and inappropriate behaviours) in combination with behavioural modification techniques.

The Committee adopted by consensus a positive opinion for **Posatex** ear-drops suspension for dogs, intended for treatment of acute otitis externa and acute exacerbations of recurrent otitis externa.

Summary of opinions are available on the EMEA web site: http://www.emea.europa.eu

The Committee adopted by consensus a positive opinion for a type II variation for **Convenia** regarding the inclusion of an additional statement in the SPC and package leaflet concerning possible gastrointestinal adverse reactions.

The Committee adopted by consensus a positive opinion for a type II variation for **Metacam** regarding a new presentation (parenteral use).

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Gonazon**. 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.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the extension of the current Annex II entry of Council Regulation (EEC) No. 2377/90 for **tiludronic acid** to include poultry, restricted to parenteral use only and for use in laying and breeder birds only.

The Committee adopted by consensus an opinion recommending the amendment of the current entries in Annex I and II of Council Regulation (EEC) No. 2377/90 for **cefacetrile** in bovine species to cover buffalo, further to a request from a company.

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The Committee adopted by consensus an opinion recommending the inclusion of **iron fumarate** in Annex II of Council Regulation (EEC) No 2377/90 further to a request from a company to consider if the substance would be covered by the previous assessments of other iron salts and fumaric acid. The Committee concluded that, given that iron fumarate dissociates completely in solution and that several iron salts are already included in Annex II and that fumaric acid is an authorised food additive under European Parliament and Council Directive No 95/2/EC and therefore included in Annex II of Regulation 2377/90, the previous assessments performed for iron salts and fumaric acid would apply to iron fumarate.

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

Referrals

The Committee initiated the assessment of new residue studies in cattle and pigs with Suramox 15% LA submitted by Virbac in order to establish withdrawal periods for the product. The submission of the new data is a follow-up to the European Commission Decision for the suspension of the marketing authorisations for Suramox 15 % LA and the associated name Stabox 15% LA, following a CVMP opinion on an Article 35 referral concluding that the data available at that time did not allow to establish withdrawal periods for the products in both cattle and pigs.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Purevax FeLV, Porcilis Pesti, Yarvitan, Draxxin, PRILACTONE, Poulvac Flufend, Incurin and Ibaflin,** and concluded that no further action or changes to the products literature were required. The Committee also reviewed PSURs for **Previcox, Promeris** and **Promeris Duo** and recommended to the marketing authorisation holders that there was a need to include information on new adverse reactions in the product literature.

Concept Papers, Guidelines and SOPs

Safety

The Committee adopted a Concept paper for the revision of the Guideline on User Safety (EMEA/CVMP/SWP/173804/2008-CONSULTATION) for release for a 1-month period of public consultation. This follows a recent Focus Group meeting with Industry, where issues requiring clarification or revision were discussed. This concept paper provides details of the main points in the guideline that will be reviewed and sets out a timetable for the revision.

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

Antimicrobial resistance

The Committee agreed that its Scientific Advisory Group on Antimicrobials (SAGAM) would assess the impact of the use of antimicrobials in livestock and companion animals on the risk of colonisation or infection with Methicillin Resistant *Staphylococcus aureus* (MRSA) and would prepare a reflection paper for public consultation. Appropriate coordination will take place with EFSA and other organisations and stakeholders known to be already considering these issues during the drafting of the reflection paper.

International harmonisation

The Committee endorsed the appointment of the chairman Dr Gerard Moulin as VICH Steering Committee member representing the CVMP.

The Committee agreed on its position on the draft VICH guideline 43 on Target Animal Safety for pharmaceuticals in preparation of the upcoming VICH Expert Working Group meeting, where the guideline will be finalised by the group. The comments will be submitted to the VICH partners.

PROCEDURAL ANNOUNCEMENT

Applicants/MAHs are advised that the EMEA has revised its procedure on out of office hours cover including EMEA holidays.

The EMEA can be contacted on the following Product Emergency Hotline number: +44 207 523 7600. This number is for use **only** to inform the EMEA about a potentially serious problem with a centrally authorised medicinal product, excluding product defects and recalls (see below).

The number is for use **only** outside of business hours including EMEA holidays. During business hours (Monday to Friday, 9:00-17:30h), please contact the main switchboard: +44 207 418 8400.

Please note there will no longer be permanence for any EMEA holiday and the above contact number is for emergencies only.

It should, however, be reminded that in case of product defects and recalls, dedicated procedures are in place. For further information, please consult the EMEA website (http://www.emea.europa.eu/Inspections/Defects.html). The following telephone number should be used for product defects and recalls outside business hours including EMEA holidays: +44 7880 550697.

1st WORKSHOP ON SCIENTIFIC ADVICE

The CVMP is pleased to announce the first workshop on scientific advice will be held at the EMEA offices at 7 Westferry Circus, Canary Wharf London E14 4HB on 19 June 2008 from 14.00-17.00. Speakers from the EMEA, CVMP Scientific advice working party and industry will address the functioning and scope of the scientific advice procedure, as well as scientific advice for SMEs, MUMS products, possible co-operation with the FDA and how to maximise the benefits of using the procedure. A detailed programme will be published on the EMEA website shortly.

The next meeting of the CVMP will be held on 13-15 May 2008

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