European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 16 – 18 January 2007

During the December 2006 meeting the Committee endorsed the recommendation from the Scientific Advisory Group (SAGAM) to appoint Karolina Törneke as Chairperson of SAGAM. Dr Törneke is the Committee member from Sweden and joined the SAGAM group in November 2006 following the resignation of Liisa Kaartinen, the previous chairperson of SAGAM. Dr Törneke was also a member of the CVMP Efficacy Working Party from March 2004 until December 2006.

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension to **Previcox** (*firocoxib*), from Mérial S.A.S., for a new pharmaceutical form (oral paste), new indication and new target species (horses).

The summary opinion is available on the EMEA web site: http://www.emea.europa.eu

The Committee adopted by consensus positive opinions for two type II variations for **Draxxin** (*tulathromycin*), from Pfizer Ltd, regarding:

- an addition of an indication for the prevention of swine respiratory disease (SRD).
- an addition of an indication for the treatment of infectious bovine keratoconjunctivitis (IBK).

The Committee was informed of the formal notification from Pfizer Ltd of their decision to withdraw the variation application for **Draxxin** to extend the current indications of the product to treatment of foot rot in cattle. Draxxin was first authorised in the European Union on 11 November 2003 and it is curently indicated for the treatment and prevention of bovine respiratory disease (BRD) and treatment of swine respiratory disease (SRD). In their official withdrawal letter, the company acknowledged the need for additional field data to enable a true assessment of the risk/benefit balance to be made on the proposed indication and therefore decided to withdraw the current application[1]. More information about Draxxin and the current state of the scientific assessment at the time of the withdrawal will be made available in a question and answer document. The document, together with the withdrawal letter from the company will be published on the EMEA website, after the next meeting of the Committee.

The Committee adopted by consensus a positive opinion for a type II variation for **Nobivac Piro** (soluble *Babesia canis* and *Babesia rossi* antigen) from Intervet International B.V. regarding amendments to the Summary of Product Characteristics (SPC) and product literature to include new adverse reactions following consideration of pharmacovigilance data.

The Committee adopted by consensus a positive opinion for a type II variation for **Metacam** (*meloxicam*), from Boehringer Ingelheim Vetmedica GmbH regarding a reduction of the currently approved daily maintenance dose.

[1] Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage

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Community Referrals

The Committee concluded the referral procedure for **Equimectin 12mg** (ivermectin) oral gel for horses from Le Vet B.V. The procedure was referred to the Committee by the Reference Member State in the Mutual Recognition Procedure, the Netherlands under Article 33(4) of Directive 2001/82/EC due to concerns raised by the Concerned Member States, Belgium, Denmark, France, Germany, Ireland, Italy, Portugal and Spain regarding the demonstration of efficacy of the product. The Committee adopted by consensus an opinion concluding that on the basis of the data available for Equimectin, bioequivalence with the originating product, Eqvalan, had not been shown. The Committee recommended the suspension of the existing marketing authorisation and the refusal of the marketing authorisation applications.

The Committee concluded the referral procedures for **Suvaxyn Parvo/E** and **Suvaxyn Ery** from Fort Dodge. The procedures were referred to the Committee by France under Article 40 of Directive 2001/82/EC following the completion of mutual recognition variation procedures. The products were referred to the CVMP by France due to concerns that the equivalence could not be confirmed between the reference batch validated in the original dossier and the two new reference batches introduced for each product concerned by the referral. The Committee concluded that, while there was no concern regarding safety or efficacy for the product, the large variability in the test results of the reference batches in the serological potency test was not acceptable. The Committee therefore adopted by consensus an opinion recommending a variation of the marketing authorisations. The marketing authorisations should be varied to reduce the variability of the serological potency test by appropriate measures such as the replacement of the use of a reference vaccine in the serological potency test with the use of reference serum.

Pharmacovigilance

The Committee reviewed a Periodic Safety Update Report (PSUR) for **Nobivac Piro** and concluded that no further action or changes to the product literature of the products were required. Furthermore, the Committee reviewed a PSUR for **Metacam/ Novem**, and concluded that there was a need to include information on new adverse reactions in the product literature of all formulations, and to add new special precautions for use in animals in the product literature of the oral formulations intended for use in dogs.

Guidelines, SOPs and Position Papers

The Committee adopted a revised Guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005-CONSULTATION) for release for a 6-month period of public consultation. This revision of the guideline has been made in view of the need to improve the SPC for antimicrobials on the pharmacodynamic properties, recommendations to decrease the risk of development of resistance and posology and method of administration. The guideline should also improve harmonisation of the SPCs of products containing antimicrobials across the Member States.

The document will be available on Monday 22 January 2007 on the EMEA web site:
http://www.emea.europa.eu

Organisational issues

On Monday 15th January 2007 a workshop on risk benefit analysis was held at the EMEA with members of the CVMP and the Pharmacovigilance Working Party. Presentations were given by an external consultant, by an invited industry expert and by members of the Committee and the Secretariat on all aspects of risk benefit analysis through the active lifecycle of a product from discovery to post-authorisation. This was the first of a series of workshops to develop the views of the Committee on this important subject.

International harmonisation

In preparation of the 19th VICH Steering Committee meeting to be held on 24-25 January 2007 in Washington, the Committee considered the meeting documents in preparation of the EU position on technical matters.

The next meeting of the CVMP will be held on 13-15 February 2007.

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http://www.emea.europa.eu