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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 13-15 April 2010

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Metacam** (*meloxicam*) from Boehringer Ingelheim Vetmedica GmbH concerning the addition of a new strength 2 mg/ml solution for injection for cats and an additional indication for the post-operative use of Metacam in cats.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Metacam** (*meloxicam*) from Boehringer Ingelheim Vetmedica GmbH concerning the addition of a new strength 15 mg/ml oral suspension for pigs.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Suprelorin** (*deslorelin acetate*) from Virbac S.A. concerning the addition of a new strength 9.4 mg implant for dogs with extended duration of effect to 12 months for this strength.

The Committee adopted by consensus positive opinion for a type II variation application for **Metacam –** addition of a new post-operative indication for Metacam 0.5 mg/ml oral suspension for cats.

The Committee adopted by consensus a negative opinion for an application for a type II variation to widen the indication for the use of **Masivet** to allow treatment of non-recurrent mast cell tumours independent from receptor status.

The summary opinions are available on the Agency web site:
http://www.ema.europa.eu/htms/vet/opinion/opinion.htm

The Committee also adopted by consensus a positive opinion for a type II variation application for **Naxcel** concerning a new supplier of an intermediate.

[1] The document is revised to correct the information related to Type II variations.

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Annual reassessment of marketing authorisations

The Committee adopted an opinion on the annual reassessment for **BTVPUR Alsap 8**, further to the evaluation of the data submitted by the marketing authorisation holder. The Committee recommended the continuation of the community marketing authorisation under exceptional circumstances for the veterinary medicinal product.

Renewals of marketing authorisation

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

Community referrals

The Committee started a referral procedure for **Synulox Lactating Cow and associated names** (*amoxicillin, clavulanic acid, prednisolone; intramammary suspension*). The matter was referred to the Committee by Belgium and Denmark under Article 34 of Directive 2001/82/EC, due to divergent national decisions having been taken across the European Union with regard to the marketing authorisations of this product.

Scientific advice

The Committee agreed scientific advice concerning the safety studies for an antimicrobial product for cats and dogs.

Pharmacovigilance

The Committee reviewed the PSURs for **Draxxin**, **Easotic**, **Masivet**, **Onsior**, **Palladia**, **SevoFlo** and **Virbagen Omega** and concluded that no further action or changes to their product literature were required.

The Committee considered a recent scientific publication on the presence of the feline endogenous retrovirus RD114 in some vaccines for dogs and cats produced on feline cell lines. The Committee noted that marketing authorisation holders in the EU were already conducting studies to provide specific information on the potential presence of RD 114 in their vaccines to enable a risk assessment of these findings to be conducted with respect to the quality of vaccines produced on feline cell lines. The Committee observed that the detection of previously unsuspected viral agents, or viral components, in live attenuated vaccines due to recent advances in detection technology was currently a topic of active consideration for both human and veterinary vaccines and noted that the Agency was currently considering the most appropriate regulatory tools to initiate and follow up any necessary action.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted **Volume 9B of the Rules Governing Medicinal Products in the European Union - Pharmacovigilance for veterinary medicinal products** (EMA/CVMP/PhVWP/430286/2007). This document was revised further to comments received during the public consultation by the European Commission in 2009. The document includes guidance for marketing authorisation holders and the competent authorities on roles, responsibilities and procedures in relation to pharmacovigilance systems and reporting of adverse events.

The document will be submitted to the European Commission for finalisation and publication.

Immunologicals

The Committee adopted a revised **Guideline on data requirements for immunological veterinary medicinal products intended for Minor Use or Minor Species/Limited markets (EMEA/CVMP/IWP/123243/2006-Rev.2)** following the close of public consultation. The guideline has been revised to take into account data that supported the inclusion of *Mycoplasma synoviae* in chickens in Table 2 listing the diseases and animal species currently considered as limited markets. The revision will come into effect on 1 May 2010.

The guideline will be published on the Agency web site:
http://www.ema.europa.eu/htms/vet/vetguidelines/immunologicals.htm

Notes

1. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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