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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 12-14 January 2010

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Meloxidyl** (meloxicam) from Ceva Santé Animale concerning the addition of a new strength 20 mg/ml for the existing pharmaceutical form solution for injection for new target species cattle, pigs and horses.

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

The Committee adopted by consensus positive opinions for type II variation applications for:

Improvac – removal of the Target Animal Batch Safety Test (TABST);
Previcox – change in excipient specification.

Renewals of Marketing Authorisations

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

Maximum Residue Limits

Further to the adoption of an opinion recommending that the existing entry in Annex II for **sodium salicylate** for oral use is extended to turkeys, the European Commission expressed concerns with that recommendation and requested the Agency and the CVMP to review it with the aim to recommend the

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establishment of MRL values for the substance. The Committee, having reviewed the previous opinion and considered all available options to allow the advancement of the MRL procedure, agreed to revise its recommendation and adopted by consensus a revised positive opinion recommending the establishment of provisional MRLs for **sodium salicylate** in turkeys.

The revised summary opinion is available on the Agency web site:
http://www.ema.europa.eu/htms/vet/mrls/mrlop.htm

Scientific Advice

The Committee agreed scientific advice for the clinical development programme for an ectoparasiticide for dogs.

MUMS/Limited markets

The Committee reviewed a request for classification under the new MUMS/limited markets policy which commenced on 1 September 2009. The request which is in relation to an anti-viral product for cats, was not considered as qualifying for the criteria for MUMS/limited markets.

Pharmacovigilance

The Committee reviewed the PSURs for **Nobilis Influenza H5N2**, **Nobilis Influenza H7N1** and **Prac-Tic** and concluded that no further action or changes to the product literatures were required. The Committee also reviewed the PSUR for **Cerenia**, **Ingelvac CircoFLEX**, and **Profender**, and recommended the inclusion of new adverse reactions in the product literature.

Concept Papers, Guidelines and SOPs

Quality

The Committee adopted a '*Concept paper on the revision of the guideline on process validation*' (EMA/CHMP/CVMP/QWP/809114/2009). The concept paper will be available on the Agency web site: http://www.ema.europa.eu/htms/vet/vetguidelines/quality.htm

Procedural Announcements by the Agency

The Agency will shortly be publishing a separate procedural announcement regarding the separation of pre- and post-authorisation procedures and the creation of a central point of entry for all applications and queries concerning the intended applications for veterinary medicinal products including scientific advice, MRL and centralised marketing authorisation applications.

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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