12 October 2012
EMA/CVMP/639731/2012
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 9-11 October 2012

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Contacera** (*meloxicam*), from Pfizer Limited, an anti-inflammatory and anti-rheumatic product intended for use in cattle, pigs and horses.

More information about the above mentioned medicine, including its full indication, can be found on the Agency's website.

The Committee adopted by consensus positive opinions for type II variation applications for **CORTAVANCE** and **Improvac** regarding quality and manufacturing changes.

Annual reassessment of marketing authorisations

The Committee adopted opinions on the annual reassessments for **Coxevac** and **Nobilis Influenza H5N2** 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 Coxevac. Since all specific obligations for Nobilis Influenza H5N2 have been fulfilled the Committee recommended the conversion of the Community marketing authorisation from under exceptional circumstances to a normal status for Nobilis Influenza H5N2.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Rheumocam**. The Committee, having re-assessed the benefit-risk balance of this product,

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concluded that the quality, safety and efficacy continues to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community referrals and related procedures

The Committee started a procedure for **Linco-Spectin 100 and its associated names** (lincomycin and spectinomycin) from Pfizer Animal Health. The matter was referred to the Committee by Belgium, under Article 34 of Directive 2001/82/EC due to divergent decisions taken by Member States resulting in discrepancies in the product information.

Maximum Residue Limits

Further to a request to amend an entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, the Committee adopted a revised list (EMA/CVMP/519714/2009-Rev.12), in which the dose restriction for the excipient triethanolamine has been removed.

The document will be available on the Agency's website.

Scientific advice

The Committee agreed scientific advice (in parallel with the US FDA) concerning the data requirements for an antiparasitic for a dermal indication in dogs.

MUMS / Limited markets

Following the Committee's review of one request for classification under the MUMS/Limited markets policy which concerned a product for analgesia in horses the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives. The CVMP reviewed a classification given earlier in 2012 for a product with an indication of analgesia in horses and amended the previous decision, now awarding the financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam**, **BTVPUR AlSap 2-4**, **Easotic**, **Fevaxyn Pentofel**, **LEUCOFELIGEN FeLV RCP**, **LEUCOGEN**, **Meloxivet**, **MS-H Vaccine**, **Naxcel**, **Palladia**, **Porcilis AR-T DF** and **Purevax RCP** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Coxevac** and recommended amendments to the special precautions for use in animals and use during lactation.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a Concept paper on the revision of the 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 (EMA/CVMP/EWP/290691/2012) for a 3-month period of public consultation. The concept paper was developed to cover new aspects of guidance for generic or hybrid applications (according to Art. 13 (3) of Directive 2001/82/EC) and to clarify the type of mean value to be used in

Abbott's formula for efficacy calculations in laboratory studies. Additionally, consideration will be given to the potential inclusion of guidance concerning systemic acaricides based on their likely introduction to the market.

The document above will be available on the Agency's website.

Working Parties

The Committee reviewed and adopted updated mandates for the CVMP Efficacy Working Party (EMA/CVMP/EWP/208686/2004-Rev.1), Immunologicals Working Party (EMA/CVMP/IWP/336720/2012), Quality Working Party (EMA/CVMP/QWP/80473/2004-Rev.1) for a period of 3 years. No substantial changes were introduced to the documents.

The mandates will be available on the Agency's website.

Organisational matters

The Committee elected Boris Kolar as chair of the Environmental Risk Assessment Working Party for a 3-year mandate.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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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