17 September 2010
EMA/CVMP/559704/2010
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 14-16 September 2010

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Meloxoral** (meloxicam 0.5 mg/ml Oral Suspension for cats and 1.5 mg/ml oral suspension for dogs), from LeVet B.V. for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs and the alleviation of inflammation and pain in chronic musculo-skeletal disorders in cats.

The summary of opinion is available on the Agency's website.

The Committee also adopted by consensus a positive opinion for a type II variation application for **Novem** (meloxicam 5 mg/ml Solution for injection for cattle and pigs) - new indication for the relief of post operative pain associated with minor soft tissue surgery in pigs, and four new presentations.

Community referrals and related procedures

The Committee concluded the procedure considering the potential presence of **retrovirus RD114** in some live attenuated vaccines for use in dogs and cats. The procedure responds to the request from the Executive Director of the European Medicines Agency for the Committee to give a scientific opinion under Article 30 of Regulation 726/2004 due to a recent scientific publication reporting the presence of the feline endogenous retrovirus RD114 in some vaccines produced on feline cell lines. The Committee adopted by consensus an opinion concluding that the benefit risk balance for these products remains strongly positive but that consideration needs to be given to amending the requirements for authorisation with respect to testing for, and if possible, eliminating such viruses from live attenuated vaccines.

The full opinion and assessment report will be published on the Agency's website.

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The Committee concluded the referral procedure for **Acticam 1.5 mg/ml Oral Suspension for Dogs** (meloxicam) from Ecuphar NV. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No 726/2004 due to concerns regarding the quality of the product. The Committee adopted by consensus an opinion concluding that the marketing authorisation of the product should be suspended until appropriate resolution of the issues by the marketing authorisation holder.

Following a notification from Sweden under Article 34 of Directive 2001/82/EC, the Committee agreed on the extension of the scope of the ongoing referral procedure for **Fortekor vet and associated names** (benazepril hydrochloride) to all tablet formulations.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **isoeugenol** in fin fish and a one year extension of the provisional maximum residue limits for **monepantel** in goats which expire on 1 January 2011.

The Committee also adopted a positive opinion recommending the establishment of provisional maximum residue limits for **closantel** in cow and sheep milk. The opinion follows the assessment of a request from the Irish Medicines Board to the European Medicines Agency under Article 9.1b of Regulation (EC) No. 470/2009 concerning the establishment of maximum residues limits for substances intended for use under Article 11 of Directive 2001/82/EC (the "cascade"). The Irish Medicines Board had expressed serious concerns with potential animal welfare problems due to the lack of available treatment of immature fluke in dairy cattle and sheep due to the lack of an MRL for milk and requested an urgent opinion of the Committee on the matter.

Summary of opinions are available on the Agency's website.

Scientific advice

The Committee agreed two separate scientific advice requests concerning quality and efficacy questions for the development of an immunological for dogs, and quality, safety, efficacy and MRL questions for the development of a novel immunostimulant.

MUMS / Limited markets

The Committee reviewed five requests for classification under the MUMS/limited markets policy, which concerned:

- a product for a respiratory indication in horses, where the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives;
- an oncology product for cats where the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives;
- a product to treat hypersensitivity reactions in horses and donkeys where the CVMP considered that the product was indicated for MUMS/Limited markets but was not eligible for financial incentives as an alternative authorised products already exists for the same indication;
- an immunological product for dogs where the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives;
- an immunological for fish where the CVMP considered that the product was indicated for MUMS but was not eligible for financial incentives as the market was not limited.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **Dicural**, **Duvaxyn WNV**, **Easotic**, **Masivet**, **Meloxivet**, **Nobivac Bb for Cats**, **Nobivac Piro**, **Quadrisol**, **Yarvitan** and **ZOLVIX** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a draft revised **Guideline on statistical principles for veterinary clinical trials** (EMA/CVMP/EWP/81976/2010) for a 6-month period of public consultation. This guideline has been amended in view of experience by regulators in recent years. The changes introduce mainly clearer guidance on issues relating to hypothesis testing (superiority, non-inferiority), confidence intervals for response variables, power calculations and other statistical methods.

The Committee adopted a **Concept paper for the revision of the guideline on the conduct of efficacy studies for intramammary for use in cattle** (EMA/CVMP/EWP/87114/2010) for a 3-month period of public consultation. This concept paper has been developed in order to clarify issues on the treatment period (dry vs. lactation), type of infection (clinical vs. subclinical) and type of treatment (curative vs. preventive). Furthermore, new diagnostic methods and treatments have been developed, and should be taken into consideration.

During the public consultation of the **Concept paper for the revision to the Guideline for the conduct of efficacy studies for NSAIDs** (EMA/CVMP/EWP/62867/2009) no comments were received. The Committee, therefore agreed to extend the deadline for public consultation for another 3-month period of public consultation.

The documents will be published on the Agency's web site.

Antimicrobial Resistance

The Committee adopted a Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius* (MRSP) (EMA/CVMP/SAGAM/736964/2009) for a 2-month period of public consultation. This reflection paper has been developed to address a sudden emergence of meticillin-resistant *Staphylococcus pseudintermedius* (MRSP) in dogs and cats mainly due to clonal spread. The document considers the risks to animal and human health derived from MRSP and makes recommendations for action.

The document will be published on the Agency's web site.

Working Parties

The Committee elected Dr Stane Srčič as the vice-chair of the Scientific Advice Working Party for another 3-year mandate.

International harmonisation

The Committee adopted three VICH guidelines for release in the EU following their sign-off by the VICH Steering Committee. These guidelines are interlinked and are the core to guarantee standardised electronic exchange of adverse event information between all partners in the VICH regions.

- GL30 – Controlled lists of terms (EMA/CVMP/VICH/647/2001) – step 7 in the VICH process. This guideline consolidates all controlled lists that are applicable for the exchange of adverse event information.

- GL35 – Electronic standards for transfer data (EMA/CVMP/VICH/123940/2006) – step 4 in the VICH process, the guideline is being released for 6 months consultation. This guideline initiates the discussion and the further development of implementing rules and technical details for the exchange for adverse event information in line with the relevant ISO guidelines.
- GL42 – Data Elements for submission of adverse event reports (EMA/CVMP/VICH/355996/2005) – step 7 in the VICH process. This guideline describes all the data elements that are relevant to the exchange of adverse event information.

The documents will be published on the Agency's web site once released on the VICH Website.

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.

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