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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 7-9 June 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Emdocam** (meloxicam), from Emdoka bvba, for the use in acute respiratory infections and in diarrhoea in cattle and as adjunctive therapy in the treatment of mastitis. In pigs it is used to reduce the symptoms of lameness and inflammation in non-infectious locomotor disorders and as adjunctive therapy in the treatment of puerperal septicaemia and toxaemia. In horses it is used in the alleviation of inflammation and relief pain in musculo-skeletal disorders as well for the relief of pain in equine colic.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Proteq West Nile** (West Nile recombinant canarypox virus (vCP2017 virus)), from MERIAL, a vaccine for the active immunisation of horses from 5 months of age against West Nile disease.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application under exceptional circumstances for **Zulvac 1 Bovis** (inactivated Bluetongue virus, serotype 1, strain BTV-1), from Pfizer Limited, for the active immunisation of cattle from 2 ½ months of age for the prevention of viraemia caused by Bluetongue Virus, serotype 1.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application under exceptional circumstances for **Zulvac 1 Ovis** (inactivated Bluetongue Virus, serotype 1, strain BTV-1), from Pfizer Limited, for the active immunisation of sheep from 1 ½ month of age for the prevention of viraemia caused by Bluetongue Virus, serotype 1.

More information about the above mentioned veterinary medicines, including their full indications, can be found on the Agency's website.

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

Equilis Prequenza - reduction of the specification limits of the batch potency test for the equine influenza components;

Equilis Prequenza Te - reduction of the specification limits of the batch potency test for the equine influenza components.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for:

Previcox and EQUIOXX - to extend the re-test period of the active substance from 48 months to 60 months.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Porcilis Pesti** (vaccine against classical swine fever in pigs) and **Cerenia** (maropitant citrate). The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated.

Community referrals and related procedures

The Committee concluded the procedure for **Clavudale 50 mg tablet for cats and dogs** (amoxicillin and clavulanic acid) from Dechra Limited. The matter was referred to the CVMP by the United Kingdom, acting as the reference Member State in a mutual recognition procedure under Article 33(4) of Directive 2001/82/EC due to concerns raised by the Netherlands and Sweden on the basis of disputed demonstration of bioequivalence in the cat target species. The Committee concluded that the overall benefit/risk balance for the use of this product in cats was positive and therefore the Committee adopted by consensus an opinion concluding that the concerns raised by the Netherlands and Sweden should not prevent the granting of the marketing authorisations.

The Committee concluded the procedure for **Synulox Lactating Cow and associated names** (amoxicillin trihydrate, potassium clavulanate, prednisolone) from Pfizer Limited. The matter was referred to CVMP 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. The Committee concluded that the overall benefit/risk balance for this product remains positive and agreed harmonised indications, posology and withdrawal periods for the concerned products. Therefore the Committee adopted by majority an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

Maximum Residue Limits

Further to the request from the European Commission under Article 11 of Regulation (EC) 470/2009, for the Committee to revise the previous opinion on ivermectin and to consider the possibility of establishing a maximum reside limit (MRL) for muscle, the Committee adopted by consensus an opinion recommending the modification of the current entry in table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for **ivermectin** (all mammalian food producing species). The recommendation includes a proposal for a muscle MRL as well as a residue level not to be exceeded at the injection site.

Further to a request in accordance with the CVMP guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, the Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) 470/2009 (EMA/CVMP/519714/2009), in order to include macrogol cetostearyl ether under the heading of excipients.

More information about the above recommendations, can be found on the Agency's website.

Further to a request from the United Kingdom under Article 11 of Regulation (EC) 470/2009, the Committee started a procedure for the review of the maximum residue limits (MRLs) for altrenogest considering that, since the establishment of MRLs for altrenogest, new information has become available relevant for the re-consideration of the MRLs.

Scientific advice

The Committee agreed five separate scientific advice reports; on clinical development of a sedative product for dogs; on quality, safety and clinical development of an immunological for wild boar; clinical development of an immunological for goats; follow-up clinical development advice for an anti-viral for cats; safety and clinical development of an anti-viral for cats.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/limited markets policy, which concerned products with an oncology indication in dogs, a zootechnical for rabbits and a vaccine for dogs, cats and horses;

the CVMP considered that the oncology product was indicated for MUMS/Limited market and was eligible for financial incentives;

the CVMP considered that the zootechnical product and the vaccine were indicated for MUMS/Limited market but were not eligible for financial incentives as there are alternative authorised products for the same indications.

Pharmacovigilance

The Committee reviewed the PSURs for **Convenia**, **Equilis Prequenza**, **Equilis Prequenza Te**, **Gonazon**, **Gripovac 3**, **Melovem**, **Naxcel**, **Nobilis Influenza H5N2**, **RESPIPORC FLU3**, **Rheumocam**, **Slentrol, Startvac**, **Superlorin** and **Zactran** and concluded that no further action or changes to their product literature were required. The Committee also reviewed the PSUR for **Ibaflin** and recommended amendments of the product literature concerning the inclusion of a new adverse reaction.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted the following standard lists used for electronic reporting of suspected adverse reactions following the yearly review and update:

- CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009-Rev.3)
- List of species and breeds for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance (EMA/CVMP/PhVWP/377827/2011);

The Committee also adopted the revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.4).

These lists and related documents will be published on the Agency's website. The implementation of these lists in EudraVigilance Veterinary is provisionally scheduled for 10 October 2011.

The Committee endorsed the Standard operating procedure - Annual review of standard lists to be used in EudraVigilance Veterinary (SOP/V/4019) which was revised to take into account the new Agency corporate identity and restructuring, the VeDDRA sub-group composition (including VICH partners) and updates of references.

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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