EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 8-10 February 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a marketing authorisation under exceptional circumstances for an application for **BLUEVAC BTV8** (inactivated blue tongue virus, serotype 8) from CZ Veterinaria S.A., a vaccine for the active immunisation against bluetongue disease in sheep and cattle.

Further to a request from the European Commission, the Committee re-considered the opinion adopted in July 2010 recommending the granting of a marketing authorisation for **Veraflox** (pradofloxacin), from Bayer Animal Health GmbH. The Committee, having reviewed the issues raised, revised the opinion and adoped by consensus a positive opinion for a marketing authorisation application for Veraflox for the treatment of dogs and cats with particular infections caused by certain specified and susceptible pathogens, confirming its previous opinion.

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Procox** (emodepside and toltrazuril) from Bayer Animal Health GmbH intended for use in dogs when mixed parasitic infections, caused by certain specified roundworms and coccidia, are suspected or demonstrated.

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

The Committee adopted by consensus a positive opinion for a type II variation application for:

Zulvac 8 Bovis (inactivated blue tongue virus, serotype 8) - revision of sections 4.2 of the SPC in order to provide precise information on the duration of immunity;

Improvac (Gonadotropin releasing factor (GnRF) analogue-protein conjugate) - extension of the shelf-life of the active substance.

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Community referrals and related procedures

The Committee started a procedure under Article 33(4) of Directive 2001/82/EC for **Clavudale 50 mg tablet for cats and dogs** (amoxicillin and clavulanic acid) from Dechra Limited. The application was referred to the CVMP for arbitration by the United Kingdom acting as the reference Member State in a mutual recognition procedure due to concerns raised by the concerned Member States, the Netherlands and Sweden, on the basis of disputed demonstration of bioequivalence in the target species the cat.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **octenidine dihydrochloride** in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for all mammalian food producing species.

Further to a number of requests 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 the following substances under the heading of excipients:

- Carbomer copolymer A (CAS No: 1456857-02-1): for topical administration at doses of up to 1.6 mg/kg bw;
- Cetearyl ethylhexanoate (CAS No: 59130-70-7): for topical administration at doses of up to 4.0 mg/kg bw;
- Denatonium benzoate (CAS No: 3734-33-6): for topical administration at doses of up to 0.025 mg/kg bw;
- Dimethyl ether (CAS No: 115-10-6): for use as a propellant for topical administration
- Gamma hexalactone (CAS No: 685-06-7): for topical administration at doses of up to 14 mg/kg bw;
- Propolis.

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

Scientific advice

The Committee agreed scientific advice concerning quality, safety and efficacy requirements for an antidot product for dogs.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/limited markets policy, which concerned products with an indication for oncology in dogs, an ectoparasiticide for bees and an antibiotic for turkeys;

- the CVMP considered that the product for dogs was indicated for MUMS/Limited market but not eligible for financial incentives as alternative authorised products already exist for the same indication,

- the CVMP considered that the product for bees was indicated for MUMS/Limited market but was not eligible for financial incentives as alternative authorised products already exist for the indication,

- the CVMP considered that the product for turkeys was indicated for MUMS but was not eligible for financial incentives as the market was not limited and an alternative authorised product already exists for the indication.

Pharmacovigilance

The Committee reviewed the PSURs for **Ingelvac CircoFLEX** and **Netvax** and concluded that no further action or changes to their product literature were required. The Committee also reviewed the PSUR for **Trocoxil** and recommended amendment of the product literature concerning the inclusion of new adverse reactions and enhancing special precaution for use in animals.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted a Recommendation on the basic surveillance of EudraVigilance Veterinary (EVVet) data (EMA/CVMP/PhVWP/471721/2006) following the close of public consultation. This recommendation has been developed to provide a simple approach for surveillance of veterinary medicinal products, making optimal use of the electronic tools available via EVVet, and to facilitate harmonised surveillance across the European Union with efficient utilisation of resources.

The document and the overview of comments will be published on the Agency's web site.

The Committee adopted the Agency's public bulletin on veterinary pharmacovigilance for 2010 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/PhVWP/44873/2011). Annual public bulletins on veterinary pharmacovigilance are being produced by the Agency with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the European Union. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides also an overview of the outcome of pharmacovigilance matters that have been considered during 2010 by the Committee and its Pharmacovigilance Working Party (PhVWP-V).

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

Organisational matters

The Committee agreed the programme for the EMA/IFAH-Europe Info Day to be held on 10-11 March 2011 at the Agency, which will focus on the latest developments in scientific reviews, legislation and marketing authorisation procedures.

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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