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Press Office

Press release

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

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Activyl Tick Plus** (indoxacarb and permethrin), from Intervet International B.V., for the treatment of flea and tick infestations in dogs.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Rheumocam** (meloxicam), from Chanelle Pharmaceuticals Manufacturing Limited, to include a 5 mg/ml solution for injection for dogs and cats.

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

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

Cerenia (maropitant citrate) – modification of the product information concerning the special precautions for use of the product in animals to lower the age at which the product can safely be used for certain indications in dogs;

Hiprabovis IBR Marker Live (Live gE^- tk^- double-gene deleted Bovine Herpes Virus type 1 (BoHV-1) vaccine) - addition of a new presentation (30-dose package size).

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

ZULVAC 1 Ovis and **ZULVAC 1 Bovis** (Inactivated Bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1) – concerning a change to the 20 ml vial dimensions.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Community referrals and related procedures

The Committee concluded the referral procedure for **Fortekor and associated names** (benazepril hydrochloride) from Novartis Animal Health Inc. The matter was referred to CVMP by Sweden under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in the product information. The Committee agreed harmonised target species, indications and posology for the concerned products and therefore 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

The Committee adopted by consensus an opinion recommending the modification of the MRLs for **neomycin** in liver and kidney for all food producing species, in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010.

Further to a request of Ireland under Article 27 of Regulation (EC) 470/2009, the Committee adopted by consensus opinions recommending the extrapolation of the current MRLs for **closantel**, **nitroxinil** and **triclabendazole** to milk.

The Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, (EMA/CVMP/519714/2009-Rev.8), in order to include oleic acid under the heading of excipients.

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

Scientific advice

The Committee agreed scientific advice for a product intended to treat gastrointestinal infections in pigs, cattle and poultry and for a product intended to treat mastitis in cows.

MUMS / Limited markets

Following the Committee's review of a request for classification under the MUMS/Limited markets policy, which concerned an antiparasitic product for goats, the CVMP considered that the product was indicated for MUMS/Limited markets but was not eligible for financial incentives as authorised products already exist for the same indication.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 1**, **BTVPUR AlSap 1-8**, **EQUIOXX and Previcox oral paste for horses**, **Hiprabovis IBR Marker Live**, **Masivet**, **Meloxoral**, **Onsior**, **Porcilis Porcoli**, **Posatex** and **Prac-tic** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Promeris** and recommended amendment of the product literature concerning the section on special precaution for use.

The Committee also reviewed the PSUR for **Promeris Duo** and recommended amendments of the product literature concerning the section on adverse reactions and the section on special precaution for use.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a revised Question and Answer document (EMA/CVMP/EWP/82829/2009-Rev.1) in relation to the CVMP guideline on testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats.

The revised Question and Answer document will be published on the Agency's website.

Immunologicals

The Committee adopted a Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines (EMA/CVMP/IWP/314550/2010) following the close of the public consultation. The guideline has been updated following comments from various stakeholders during consultation. In addition to providing guidance on safety and efficacy studies, the guideline outlines aspects to be considered in the determination of the duration of immunity for vaccines intended for use in fish. This guideline replaces the specific requirements for the production and control of live and inactivated vaccines intended for fish (Document reference: 7BIm9a).

The guideline together with the overview of comments will be published on the Agency's website. The guideline will come into effect in 6 months.

The Committee adopted a draft Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs) (EMEA/CVMP/IWP/594618/2010) for a 6-month period of public consultation. The guideline has been developed to provide guidance on the data requirements to support authorisation of combined vaccines and a claim for the use of two or more IVMPs, each with its own separate marketing authorisation, in association with one another. Association was introduced as a term during the amendment of Annex I to Directive 2001/82/EC by Directive 2009/9/EC (Title II) and there is a need to define the items covered by this term and to identify the scientific data which are necessary to justify association use.

The draft guideline will be published on the Agency's website for a 6-month consultation period.

Working Parties

The Committee adopted the work plans for 2012 for the CVMP Working Parties on Scientific Advice, Pharmacovigilance, Efficacy, Safety, Immunologicals and Environmental Risk Assessment as well as for and the CVMP Scientific Advisory Group on Antimicrobials.

The work plans will be published on the Agency's website.

The Committee also adopted the work plan for 2012 for the Joint CHMP/CVMP Quality Working Party. The work plan will be published on the Agency's website further to the adoption by the CHMP.

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

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu