



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2013
EMA/CVMP/330061/2013
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 June 2013

The Committee elected Dr Anja Holm from Denmark as its Chair for a second 3-year mandate.

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Econor** (*valnemulin*) from Novartis Animal Health GmbH concerning the addition of a new target species, rabbits for reduction of mortality during an outbreak of epizootic rabbit enteropathy.

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 of existing authorisations for:

Locatim from Biokema Anstalt to introduce a composition change,

MS-H vaccine from Pharmsure Ltd to add two new suppliers of swine serum.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for the **Zulvac** range of vaccines concerning quality changes.



Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Trocoxil**. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community referrals and related procedures

The Committee concluded the referral procedure for **all injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food producing species**. The matter was notified to the Committee by the Netherlands under Article 35 of Directive 2001/82/EC, due to concerns relating to withdrawal periods and environmental risk mitigation measures. The Committee adopted by consensus an opinion recommending changes to the product information of the concerned products related to the harmonisation of the withdrawal periods, inclusion of warning sentences concerning the use in dairy animals and environmental risk mitigation measures. The Committee recommended that variations are necessary to the terms of the marketing authorisations for all injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food producing species.

The Committee considered the grounds for re-examination of the CVMP opinion for **Soludox 500 mg/g powder for use in drinking water for pigs and chickens and associated names** (*doxycycline hyclate*) adopted on 7 March 2013 in the context of a referral procedure initiated under Article 13 of Commission Regulation (EC) No 1234/2008. The Committee concluded that the recommendations included in their previous opinion should be maintained.

The matter was referred to the Committee under Article 13 of Commission Regulation (EC) No. 1234/2008 by the United Kingdom as the reference Member State in the type II variation work-sharing procedure, due to concerns raised by the Netherlands relating to the potential risk to human health resulting from the proposed withdrawal period for chickens. The Committee adopted by majority a final opinion concluding that the objections raised by the Netherlands should not prevent the granting of the variation to the terms of the marketing authorisations subject to changes in the product information recommending a withdrawal period of 9 days for chicken meat and offal at a dose rate of 20 mg/kg body weight for 4 consecutive days.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the extension of the “No MRL required” classification for butafosfan to all mammalian species, and the removal of the restriction concerning the route of administration for bovine species.

The Committee adopted by consensus a positive opinion recommending the removal of chloroform from table 2 of the Annex to Regulation (EU) No 37/2010 and establishment of a “No MRL required” classification when used as an excipient in vaccines in all mammalian food producing species.

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

Further to a request in accordance with CVMP guidance on inclusion of 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 (EMA/CVMP/519714/2009-Rev.16) in order to amend the entry for cetearyl ethylhexanoate increasing the maximum dose allowed.

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

Scientific advice

The Committee adopted four scientific advice reports concerning quality, safety and efficacy requirements for a musculoskeletal product for horses, MRL requirements for a musculoskeletal product for horses, quality, safety and efficacy requirements for a blood product for cats and efficacy requirements for a hormonal product for pigs.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl Tick Plus, Cardalis, Comfortis, Emdocam, Equilis Prequenza, Equilis Prequenza Te, Equilis Te, Melosus, Melovem, Nobilis OR inac, Rheumocam, Suprelorin, Suvaxyn PCV, ZACTRAN, ZULVAC 8 Bovis and ZULVAC 8 Ovis**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **CERTIFECT** and recommended addition of a new adverse reaction to the summary of product characteristics and the product literature.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a Question and Answer document on the following quality topic:

Setting specifications for impurities in veterinary medicinal products.

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

Pharmacovigilance

The Committee adopted the 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.5) following the yearly review.

The implementation of the VeDDRA list in EudraVigilance Veterinary is provisionally scheduled for 1 October 2013.

The Committee 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.6) and a revised **call for comments on standard lists for EudraVigilance Veterinary** (EMA/123352/2001-Rev.7).

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

Working Parties

The Committee re-elected Rory Breathnach as chair of the Scientific Advice 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

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu