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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 14-16 June 2016

The Committee elected **Dr David Murphy** from Ireland as Chair for a three-year mandate.

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Sedadex** (*dexmedetomidine hydrochloride*), from Le Vet Beheer B.V., a new generic product for sedation and analgesia in dogs and cats.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Metacam** (*meloxicam*), from Boehringer Ingelheim Vetmedica GmbH, concerning the addition of a new route of administration (subcutaneous use) for the 40 mg/ml solution for injection in the target species cattle.

More information about the above mentioned medicines, including their full indication, will be published on the Agency's website.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Panacur AquaSol**. 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 started a procedure for Velactis (cabergoline) from Ceva Santé Animale. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns for animal health arising from pharmacovigilance data.

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Scientific advice

The Committee adopted four separate scientific advice reports further to a request for:

- Initial advice on MRL issues for an antiparasitic veterinary medicinal product for chickens;
- Initial advice on safety and efficacy issues for an anti-inflammatory veterinary medicinal product for dogs;
- Initial advice on safety issues for an antiparasitic veterinary medicinal product for cattle and sheep; and
- Follow up advice on efficacy issues for a veterinary medicinal product for a respiratory condition in cattle.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of one request for classification under the MUMS/limited market policy, the CVMP classified:

- Certain indications for an antiparasitic product for use in cats as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species.

Pharmacovigilance

The Committee reviewed the post-authorisation safety study for **Trifexis** and concluded that no further action or changes to product literature were required as a result of the outcome of the study.

The Committee reviewed the PSURs for **Emdocam**, **Equisolon**, **ERYSENG**, **ERYSENG PARVO**, **Innovax ILT**, **Locatim**, **Melosus**, **NexGard Spectra**, **Nobilis Influenza H5N2**, **Nobivac L4 & Canigen L4**, **Nobivac Myxo RHD**, **RevitaCam**, **Versican Plus DHPPi**, **Versican Plus L4**, **Versican Plus Pi/L4**, **ZACTRAN**, **ZULVAC 1 Bovis** and **ZULVAC SBV**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Broadline** and **Cardalis** and recommended amendments to their product literature.

Concept papers, guidelines and SOPs

Quality

The Committee adopted Questions and Answers on the following quality topic:

- Product specific active substance information.

The Question and Answer document will be published on the Agency's website after its adoption by the CHMP which is foreseen for their June meeting next week.

Safety

The Committee adopted a draft guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014) for a 6-month period of public consultation. The guideline was developed to provide specific guidance and advice on how user risk assessments should be

conducted for such products. This guideline should be used in conjunction with the guideline on user safety for pharmaceutical veterinary medicinal products.

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/90241/2009-Rev.8) used for electronic reporting following the yearly review and update. Implementation of the VeDDRA list in EudraVigilance Veterinary is scheduled for 1 October 2016. The guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.9) were also adopted, and the call for comments on the VeDDRA standard list for EVVet (EMA/123352/2004 - Rev9) including the template for submission of proposals (EMA/380688/2010) were also updated.

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

Novel therapies

The Committee agreed for the release of a problem statement prepared by the CVMP Ad hoc Expert Group on Novel Therapies (ADVENT) on stem cells for veterinary use for a 2-month period of public consultation. The problem statement provides the basis for development of guidance on the following topic:

- Stem cell based products for veterinary use; specific questions on extraneous agents.

The consultation is used as a means to further facilitate identification of additional pertinent questions relevant to each particular topic. The aim is to take comments received into account for developing guidance in the form of Questions and Answers (Q&A).

The problem statement will be published on the Agency's website.

Working Parties

The Committee re-elected Dr Rory Breathnach as chair of the Scientific Advice Working Party (SAWP-V) for a three-year mandate.

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: www.ema.europa.eu

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