EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 08-10 October 2013

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **Vectra 3D** (*dinotefuran/pyriproxyfen/permethrin*), from Ceva Santé Animale, an ectoparasiticide product for spot-on use for dogs.

The Committee also adopted by consensus a positive opinion for an initial marketing authorisation application for **Broadline** (*fipronil/eprinomectin/praziquantel/S-methoprene*), from Mérial, an antiparasitic product for spot-on use for cats.

The Committee adopted by majority a positive opinion for an extension of the existing authorisation for **Aivlosin** (*tylvalosin*), from Eco Animal Health Ltd, concerning the addition of a new target species, turkeys, to Aivlosin 625 mg/g granules for use in drinking water.

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

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

Prilactone, **Coxevac**, **Cardalis** and **Meloxidyl** (subject to a worksharing procedure) regarding pharmacovigilance system changes;

and a grouped variation for:

Suvaxyn PCV regarding manufacturing changes and amendments introduced to the product literature.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisation for **Acticam** and **Porcilis PCV**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

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Community referrals and related procedures

The Committee concluded the referral procedure for **Suvaxyn PCV** (*inactivated vaccine*) from Zoetis. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns relating to quality and target animal safety. The Committee adopted by consensus an opinion concluding that no action was required at this time as satisfactory changes had been made via a type II variation. The opinion will be transmitted to the European Commission.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the modification of the ADI and maximum residue limits for tulathromycin in bovine and porcine species.

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

Scientific advice

The Committee adopted three separate scientific advice reports concerning: safety and efficacy requirements for a cardiovascular veterinary medicinal product for dogs; safety and efficacy requirements for a pharmaceutical veterinary medicinal product with neurological effects for cats and follow-up advice on safety requirements for an antiviral veterinary medicinal product for cats.

MUMS / Limited markets

Following the Committee's review of one request for classification under the MUMS/ Limited markets policy which concerned a biological product intended for non-food producing horses, the CVMP considered that the product was indicated for MUMS but was not eligible for financial incentives as according to the revised MUMS policy only products for use in food-producing species are eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Certifect**, **Easotic**, **Leucofeligen FeLV/RCP**, **MS-H Vaccine**, **Naxcel**, **Panacur AquaSol**, **Porcilis PCV**, **TruScient** and **Zolvix** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted a recommendation on harmonising the approach to causality assessment for adverse events to veterinary medicinal products (EMA/CVMP/PhVWP/552/2003-Rev.1) following the close of the public consultation. The former causality assessment guideline was renamed as a recommendation and the content revised for consistency with Volume 9B of The Rules Governing Medicinal Products in the European Union and to improve a harmonised approach for causality assessment.

Efficacy

The Committee adopted a revised guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMEA/CVMP/EWP/141272/2011) for a 6-month period of public consultation. The guideline provides guidance on the conduct of efficacy studies and their evaluation for veterinary medicinal products that are administered via the teat canal to cattle. In particular, it addresses the treatment of clinical and subclinical mastitis during the lactation period, the treatment of subclinical mastitis at drying off, and the prevention of new intramammary infections during the dry period. The scope of the guideline has been extended in order to include recommendations on pre-clinical data, in addition to those on clinical field studies for the demonstration of efficacy. Also, a new section has been added providing information for generic intramammary product applications.

Safety

The Committee adopted a draft revised reflection paper on injection site residues (EMA/CVMP/520190/2007-Rev.1) for a 6-month period of public consultation. The reflection paper has been developed to describe an approach that would be used consistently in the derivation of muscle MRLs for injectable substances.

The Committee adopted a concept paper proposing the review of the Note for Guidance on withdrawal time determination (EMA/CVMP/SWP/285070/2013) for a 3-month period of public consultation. The concept paper proposes a review of the way residue values below the limit of quantification are treated in the evaluation of withdrawal period studies.

Antimicrobials

The Committee adopted a draft reflection paper on the risk of antimicrobial resistance transfer from companion animals (EMA/CVMP/AWP/401740/2013) for a 3-month period of public consultation. The reflection paper considers the selection in companion animals of multidrug-resistant bacteria that could carry risks for public health and its possible transmission from companion animals to humans.

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

Organisational matters

The Committee re-appointed the following four co-opted members for a further 3-year mandate to complement its expertise:

- Boris Kolar as an expert with specific expertise in environmental risk assessment for pharmaceuticals.
- Rory Breathnach as a veterinarian with specific expertise in large and small animal clinical practice with regard to specific therapeutic areas, such as dermatology.
- Christian Friis as an expert with specific expertise in residue metabolism, pharmacokinetics and MRL assessment.
- Wilhelm Schlumbohm as an expert with specific expertise in the quality of veterinary medicinal products.

The Committee re-elected Stane Srčič as vice-chair of the Scientific Advice Working Party for a further 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

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