EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 16-18 July 2013

The Committee elected Dr David Murphy from Ireland as its vice-chair for a 3-year mandate.

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Apoquel** (*oclacitinib maleate*), from Zoetis Belgium S.A., for the treatment of pruritus associated with allergic dermatitis in dogs, and for the treatment of clinical manifestations of atopic dermatitis in dogs.

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **Trifexis** (*spinosad/milbemycin oxime*), from Eli Lilly and Company Limited, for the treatment and prevention of flea infestations in dogs when the concurrent prevention of heartworm disease and/or treatment of specified gastrointestinal nematode infections is indicated.

The Committee adopted by consensus positive opinions for two extensions of the existing authorisation for **Melovem** (*meloxicam*), from Dopharma Research B.V. concerning the addition of new strengths meloxicam 20 mg/ml solution for injection in cattle, pigs and horses and meloxicam 30 mg/ml solution for injection in cattle and pigs.

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

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

Advocate from Bayer Animal Health GmbH regarding the addition of new therapeutic indications for cats and dogs,

Cerenia from Zoetis Belgium S.A. regarding the addition of a new therapeutic indication for the solution for injection for dogs, and

Nobivac L4 from Intervet International B.V. to introduce quality changes.

The Committee adopted by consensus a negative opinion for a type II variation application for **Suvaxyn PCV** from Zoetis Belgium S.A. regarding modifications of the therapeutic indication.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Equip WNV** and **Masivet**. 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.

Community referrals and related procedures

The Committee concluded the referral procedure for **Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle** (*deltamethrin*) from Virbac. The matter was referred to the Committee by the United Kingdom as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by the Netherlands and Germany relating to a potential risk to the environment from use of the product. The Committee adopted by majority an opinion concluding that the objections raised by the Netherlands and Germany during the decentralised procedure should not prevent the granting of the marketing authorisations for Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle.

The Committee concluded the referral procedure for **Suifertil 4 mg/ml oral solution for pigs** (*altrenogest*) from aniMedica GmbH. The matter was referred to the Committee by France as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Germany relating to a potential risk to the environment from use of the product. The Committee adopted by consensus an opinion concluding that the objections raised by Germany during the decentralised procedure should not prevent the granting of the marketing authorisation for Suifertil 4 mg/ml oral solution for pigs.

The Committee concluded the referral procedure for **Micotil 300 Injectie and its associated names** (*tilmicosin*) from Eli Lilly Nederland, Elanco Animal Health. The matter was referred to the Committee by the Netherlands under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in discrepancies in the product information. The Committee agreed harmonised product information for the concerned products and adopted by consensus an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

The Committee concluded the referral procedure for **Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications** (*dexamethasone*). The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns related to withdrawal periods in cattle and horses. The Committee adopted by consensus an opinion recommending changes to the product information of the concerned products related to the

harmonisation of withdrawal periods in cattle and horses. The Committee recommended that variations were necessary to the terms of the marketing authorisations for the concerned products.

The Committee considered the grounds for re-examination of the CVMP opinion for **all long acting formulations for injection containing barium selenate for all food producing species** adopted on 10 April 2013 in the context of a referral procedure under Article 35 of Directive 2001/82/EC. The Committee concluded that the recommendations included in their previous opinion should be maintained. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns relating to the safety of residues. The Committee concluded that benefit-risk balance for the products concerned is negative as following treatment at the recommended doses barium selenate remains at the injection sites for long time periods after treatment and consequently consumption of injection site residues could pose a significant risk to human health. The Committee adopted by majority a final opinion recommending suspension of the marketing authorisations for long acting formulations for injection containing barium selenate for all food producing species.

The Committee concluded the referral procedure for **Cydectin TriclaMox pour-on solution for cattle** (*moxidectin and triclabendazole*) from Zoetis. The matter was referred to the Committee under Article 13(2) of Commission Regulation (EC) No. 1234/2008 by France as the reference Member State in the type II variation procedure, due to concerns raised by Belgium relating to the efficacy of the product against lice species. The Committee adopted by consensus an opinion concluding that the objections raised by Belgium during the variation procedure should not prevent the granting of the variation to the terms of the marketing authorisation for Cydectin TriclaMox pour-on solution for cattle.

Maximum Residue Limits (MRLs)

The Committee adopted by consensus a positive opinion recommending a 'No MRL required' classification for **triptorelin acetate** with regard to porcine species. The Committee further agreed that this recommendation could be extrapolated to all food producing species.

Further to the adoption of an opinion recommending the establishment of maximum residue limits for **tildipirosin** in bovine, caprine and porcine species, the European Commission requested the CVMP to review its opinion and in particular to consider alternatives to the recommended inclusion of an injection site residue limit in Regulation (EU) No. 37/2010. The Committee, having reviewed the previous opinion and having considered the available options to allow the advancement of the MRL procedure, agreed to revise its recommendation and adopted, by consensus, a revised positive opinion recommending the establishment of MRLs for **tildipirosin** in bovine, caprine and porcine species without reference to injection site residues in Regulation (EU) No. 37/2010. Information on residue levels at the injection site, to be taken into account for the establishment of withdrawal periods, is now provided in the European public MRL assessment report (EPMAR), which will be published following adoption of the MRLs by the European Commission and their publication in the Official Journal of the European Union.

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

Scientific advice

The Committee adopted five separate scientific advice reports (three of which were for follow-up requests) concerning quality, safety and efficacy requirements for an antiparasitic veterinary medicinal product for bees; efficacy requirements for a diuretic veterinary medicinal product for dogs; efficacy requirements for a cardiovascular veterinary medicinal product product for dogs; efficacy, safety and MRL requirements for an analgesic product for horses and quality requirements for an ectoparasiticide for dogs.

MUMS/Limited markets

Following the Committee's review of four requests for classification under the MUMS/Limited markets policy, which concerned an anti-parasitic for rabbits, guinea pigs, ferrets and rats, an anti-parasitic product for rabbits, an anti-fungal product for rabbits and guinea pigs and a dermatology product for dogs;

- The CVMP considered that the product for rabbits, guinea pigs, ferrets and rats was indicated for MUMS/Limited market but was not eligible for financial incentives as the market was not considered to be limited.
- The CVMP considered that the product for rabbits was indicated for MUMS/Limited markets and would be eligible for financial incentives.
- The CVMP considered that the product for rabbits and guinea pigs was indicated for MUMS/Limited market and would be eligible for financial incentives.
- The CVMP considered that the product for dogs was not indicated for MUMS/Limited market.

Pharmacovigilance

The Committee reviewed the Periodic Safety Updated Reports (PSURs) for **Cerenia**, **Cimalgex**, **Coxevac**, **Dexdomitor**, **Nobilis Influenza H5N2**, **Proteq West Nile**, **Purevax Rabies**, **Reconcile**, **RevitaCAM**, **RHINISENG**, **ZULVAC 1 Bovis** and **ZULVAC 1 Ovis**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Nobivac Myxo RHD** and recommended the addition of new adverse reactions to the product literature.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a guideline on the requirements for combined vaccines and association of immunological veterinary medicinal products (IVMPs) (EMA/CVMP/IWP/594618/2010) taking into account the comments received during the second 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.

During the public consultation phase stakeholders expressed their concern that the guideline would still require a major re-development package if a marketing authorisation holder were to seek a compatibility claim for an existing product. In recognition of this, the effect of this guideline will be assessed by the Agency two years after coming into effect. This report on the effects of the guideline will involve a consultation of the interested parties which provided comments on this guideline.

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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