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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 October 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **TruScient** (dibotermin-alfa), from Pfizer Limited, for the treatment of diaphyseal fractures as an adjunct to standard surgical care using open fracture reduction in dogs. The product has been classified as MUMS/ Limited markets.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Panacur AquaSol** (fenbendazole), from Intervet International B.V., for the treatment and control of gastro-intestinal nematodes in pigs infected with *Ascaris suum* and *Oesophagostomum* spp.

The Committee adopted by consensus a positive opinion for the granting of a marketing authorisation application for the generic **Inflacam** (meloxicam), from Chanelle Pharmaceuticals Manufacturing Limited, for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs, horses, cattle and pigs.

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

Econor (valnemulin) – relating to the update of the specific test requirement for batch release.

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

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Meloxidyl** (meloxicam) and **Ypozane** (osaterone acetate). The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated.

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Community referrals and related procedures

The Committee started a procedure for **Nuflor 300 mg/ml solution for injection for cattle and sheep** (florfenicol) from Intervet/Schering-Plough Ltd. The matter was referred to the Committee for arbitration by Ireland under Article 33(4) of Directive 2001/82/EC, due to concerns relating to the efficacy of the product in sheep.

The Committee started a procedure for **Hipralona Enro-S and its generics** (enrofloxacin), administered to rabbits,, from Laboratorios Hipra, S.A. The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC, due to concerns relating to the benefit/risk balance of the products.

The Committee concluded a procedure under Article 35 of Directive 2001/82/EC for all veterinary medicinal products containing systematically administered (parenteral and oral) 3rd and 4th generation cephalosporins intended for use in food producing species. The matter was referred to the CVMP by the European Commission in order to consider the inclusion of prudent use advice for these antimicrobials and to address the risk associated with potential misuse in poultry and the need for specific measures, in particular the need for warning sentences in the product literature. The Committee concluded that the most important risk identified relates to extended-spectrum beta-lactamases (ESBL) producing organisms and that to limit their selection pressure it is important to avoid unnecessary use by restricting use of 3rd to 4th generation cephalosporins to situations where other antimicrobials with more narrow spectrum of activity (such as e.g. betalactams) would not be effective.
In addition, preventive use and use for group and flock medication should be avoided. To achieve this, warning sentences should be included in the product information and some indications need to be updated accordingly. Poultry is of special concern and the magnitude of risk for this species is high in case of treatment of parent and grandparent flocks due to dissemination of ESBL in the poultry production pyramid and therefore use in poultry should be strictly contraindicated. The Committee adopted by consensus an opinion concluding that the overall benefit-risk balance for these products remains positive subject to the recommended changes of the product information and that variations to implement the recommendations above are necessary to the terms of the marketing authorisation for all veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins intended for use in food producing species.

Maximum Residue Limits

Further to a request of the United Kingdom under Article 11 of Regulation (EC) 470/2009, the Committee adopted by consensus an opinion recommending the modification of the current entry in table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for altrenogest in porcine species and *Equidae*.

Further to a request in accordance with CVMP guidance, to include 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.7), in order to include simethicone 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 quality, safety and efficacy development of an immunological for cats.

MUMS / Limited markets

Following the Committee's review of two requests for classification under the MUMS/limited markets policy, which concerned an immunological for turkeys and a gastrointestinal product for cats, the CVMP considered that both products were indicated for MUMS/ Limited markets and were eligible for reduced data requirements and financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Flexicam**, **Improvac**, **Leucofeligen FeLV/RCP**, **Leucogen**, **Meloxivet**, **Palladia** and **Porcilis PCV** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Naxcel** and recommended amendment of the product literature concerning the section on administration route.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a Question and Answer document in relation to the following CVMP guideline:

- Guideline on pharmaceutical fixed combination products (EMEA/CVMP/83804/05).

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

Immunologicals

The Committee adopted a Concept paper on the need of revision of the position paper on indications for veterinary vaccines (EMA/CVMP/IWP/785621/2011) for a 2-month period of public consultation. This concept paper has been developed in preparation of the revision of the position paper on indications for veterinary vaccines (EMEA/CVMP/042/97-Rev.1-FINAL) which was last amended in 2003. The relevance of the current approach of this existing guidance will be reviewed and depending on the outcome words such as "prevention" and "reduction" will be better defined.

The concept paper will be published on the Agency's website.

Antimicrobials

The Committee adopted a Concept paper on Use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/SAGAM/435644/2011) for a 3-month period of public consultation. This concept paper has been developed in preparation of a reflection paper to critically review recent information on the use of pleuromutilins in food producing animals in the EU, its effect on development of resistance and its potential impact on human and animal health.

The concept paper will be published on the Agency's website.

The Committee adopted a Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/SAGAM/741087/2009) following the close of a public consultation. The reflection paper provides information on the use of macrolides, lincosamides and streptogramins in food producing animals in the EU, its effect on development of resistance to these classes of antimicrobial agents in bacterial species that are of importance for human and animal health, and the potential impact on human and animal health.

The reflection paper together with the overview of comments will be published on the Agency's website.

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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