EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 8-10 March 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Zuprevo** (tildipirosin), from Intervet International BV, for the treatment of swine and bovine respiratory disease.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **CERTIFECT** (fipronil, (s)-methoprene, amitraz), from MERIAL SAS, for the treatment and prevention of infestations in dogs by ticks, fleas and lice.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Rheumocam** (meloxicam), from Chanelle Pharmaceuticals Manufacturing Limited, to include a 20 mg/ml solution for injection for cattle, pigs and horses.

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

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

ZACTRAN (gamithromycin) - addition of a new pack size (a type I glass bottle of 50 ml).

Community referrals and related procedures

The Committee started a procedure under Article 35 of Directive 2001/82/EC for **veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk**. The matter was referred to the CVMP by the European Commission in order to consider whether use of such products during the non-lactating period might lead to unacceptable levels of residues in milk.

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Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of MRLs for **monepantel** in caprine species. This recommendation follows resolution of the outstanding issues identified by the Committee in its opinion recommending the establishment of provisional MRLs.

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

Scientific advice

The Committee agreed three separate scientific advice requests concerning: efficacy requirements for a hormone inhibitor to be used in cattle; requirements for the establishment of maximum residue limits for an antifungal in birds; and requirements for the establishment of maximum residue limits for an analgesic for cattle and horses.

MUMS / Limited markets

Following the Committee's review of two requests for classification under the MUMS/limited markets policy, which concerned one product for use as an antibiotic in horses and a separate product with immunosuppressant properties for use in dogs, the Committee considered that both products were indicated for MUMS/Limited markets but were not eligible for financial incentives as alternative authorised products already exist for the indications claimed.

Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 8**, **Ibraxion**, **Masivet**, **Purevax FeLV**, **Rabigen SAG2**, **Trocoxil** and **ZOLVIX** and concluded that no further action or changes to their product literature were required. The Committee also reviewed the PSURs for **Reconcile, Metacam and Novem** and recommended amendments of the product literature concerning the inclusion of new adverse reactions.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a Guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010) for a 6-month period of public consultation. This guideline provides information on items to be considered for the production and control of all immunological veterinary medicinal products (IVMPs). The guideline outlines important items related to the quality, safety and efficacy parts of the marketing authorisation dossier that are not clearly defined in the requirements of the existing texts (Directive 2001/82/EC, Directive 2009/9/EC, European Pharmacopoeia). Therefore compliance with this guideline (and with previous mentioned texts) provides an assurance that the quality of the IVMP will be considered satisfactory by all the Member States.

The Committee adopted a Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines (EMA/CVMP/IWP/314550/2010) for a 6-month period of public consultation. This guideline provides information on items to be considered in the design and conduct of studies to support the safety and efficacy of immunological veterinary medicinal products in fin fish. The guideline outlines important items to take into account for both laboratory and field trials so that the studies are representative of the safety and efficacy of the vaccine when administered in accordance with the intended use (e.g. type of fish to be used, water conditions, method of administration, use of control

groups etc). The guideline also outlines aspects to be considered in the determination of the duration of immunity for vaccines intended for use in fish including recommendations for the wording of the duration of immunity claims in the SPC.

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

Environmental Risk Assessment

The Committee adopted a Reflection paper on the testing strategy and risk assessment for plants (EMA/CVMP/ERA/147844/2011) for a 3-month period of public consultation. This reflection paper has been developed to address the recommended testing strategy and risk assessment for plants in the VICH Environmental Risk Assessment Phase II.

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

The Committee adopted a Guideline on determining the fate of veterinary medicinal products in manure (EMA/CVMP/ERA/430327/2009) following the close of public consultation. The guideline is intended to provide guidance on the design and interpretation of studies on the transformation of veterinary medicinal products in manure, which could then be used in preparation of the environmental risk assessment by the applicant and in the evaluation of the studies by the competent authorities.

The document and the overview of comments will be published on the Agency's website.

Organisational matters

The Committee elected Fredrik Hultén as vice-chair of the Efficacy Working Party and re-elected Alex Tait as vice-chair of the Environmental Risk Assessment Working Party, both for a 3-year mandate.

The Committee adopted at the February meeting a policy document entitled 'Summary of procedures for consultation by CVMP of Scientific Advisory Groups (SAGs) and ad-hoc expert groups functioning as SAGs in relation to applications for authorisation for veterinary medicinal products' (EMA/347137/2010).

Attention is drawn to the procedural announcement of 3 February 2011 regarding provision by applicants of final translations of product information in PDF which is applicable for opinions adopted as of March 2011.

Further information is available on the website.

International harmonisation

The Committee adopted the following VICH guidelines in relation to metabolism and residue kinetics following their sign-off by the VICH Steering Committee for implementation:

- GL46: Metabolism study to determine the quantity and identify the nature of residues (EMEA/CVMP/VICH/463072/2009);
- GL47: Laboratory animals comparative metabolism studies (EMEA/CVMP/VICH/463104/2009);
- GL48: Marker residue depletion studies to establish product withdrawal periods (EMEA/CVMP/VICH/463199/2009);
- GL49: Validation of analytical methods used in residue depletion studies (EMEA/CVMP/VICH/463202/2009).

The Committee also adopted a draft VICH GL36: General approach to establish a microbiological ADI (EMA/CVMP/VICH/467/2003) following its sign-off by the VICH Steering Committee for public consultation.

The documents 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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