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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 12-14 July 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Nobivac Myxo-RHD** (live myxoma vectored RHD virus strain 009), from Intervet International BV, a vaccine for the active immunisation of rabbits to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease.

The Committee adopted by consensus positive opinion recommending the granting of a marketing authorisation for the generic **Recocam** (meloxicam), from CF Pharma, for the use in acute respiratory infections and in diarrhoea in cattle and as adjunctive therapy in the treatment of mastitis. In pigs it is used to reduce the symptoms of lameness and inflammation in non-infectious locomotor disorders and as adjunctive therapy in the treatment of puerperal septicaemia and toxaemia. In horses it is used in the alleviation of inflammation and relief pain in musculo-skeletal disorders as well for the relief of pain in equine colic. Recocam is a generic of Metacam.

The Committee adopted by consensus a positive opinion for an extension of the marketing authorisation for the generic **Loxicom** (meloxicam), from Norbrook Laboratories Limited, to include 1 mg and 2.5 mg chewable tablets for dogs. In dogs it is used for the alleviation of inflammation and pain in musculo-sceletal disorders. Loxicom is a generic of Metacam.

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 positive opinions for type II variation applications for:

Fevaxyn Pentofel – to replace current supplier of starting materials;

Improvac – addition of claim to allow a third dose of vaccination;

Ingelvac CircoFLEX – to replace the reference antigen lot in the in-process potency test;

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Purevax RCPCh – modification of the manufacturing process;

Purevax RCPCh FeLV - modification of the manufacturing process;

Zolvix – extension of the indication to *H. cortortus* strains resistant to salicylanides.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Cortavance** (hydrocortisone aceponate). The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated.

Community referrals and related procedures

The Committee concluded the procedure under Article 78 of Directive 2001/82/EC for **HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names** (inactivated *Mannheimia haemolytica* and *Histophilus somni*) from LABORATORIOS HIPRA S.A. The matter was referred to the CVMP following the suspension of the marketing authorisation of the product in France due to pharmacovigilance concerns relating to an increased frequency of anaphylactic-type events in animals. The Committee concluded that the data available indicated an association between the anaphylactic-type adverse events and the product and that the underlying cause for the adverse events could not yet be determined. Therefore the CVMP recommended by majority the suspension of the marketing authorisations for HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names until a favourable benefit-risk balance for the product can be demonstrated.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of a maximum residue limit for **phenoxymethylpenicillin** in eggs. Phenoxymethylpenicillin is currently included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with MRLs established for porcine species and poultry.

Further to a request in accordance with the CVMP guideline on data to be provided in support of a request 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.5), in order to include **sodium starch glycolate** under the heading of excipients.

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

Scientific advice

The Committee agreed three responses to requests for scientific advice, one concerning the safety and clinical development of an ophthalmic product for dogs, which was a parallel scientific advice with the FDA; one in regard to efficacy issues in the clinical development of a cardiology product for dogs and one in regard to the development of MRLs for a substance for the treatment of airway inflammatory disease in horses.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/limited markets policy, which concerned products for an oncology indication in dogs, for treatment of a parasitic disease in turkeys and an ectoparasiticide for bees:

The CVMP considered that the oncology product for dogs and the anti-parasitic product for turkeys were indicated for MUMS/Limited market and were eligible for financial incentives;

The CVMP considered that the ectoparasiticide for bees was indicated for MUMS but was not eligible for financial incentives as authorised products already exist for the same indication in bees.

Pharmacovigilance

The Committee reviewed the PSURs for **Loxicom**, **Poulvac FluFend H5N3 RG**, **RHINISENG**, **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis** and concluded that no further action or changes to their product literature were required. The Committee also reviewed the PSUR for **Onsior** and recommended amendment of the product literature concerning the inclusion of a new adverse reaction.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a revised CVMP Strategy on antimicrobials 2011-2015 (EMA/CVMP/287420/2010) following the close of the public consultation. The document has been updated following the consultation period. The CVMP strategy seeks to promote the continued availability of effective antimicrobials for use in animals whilst at the same time acting to minimise risks to animals or man arising from their use and sets out intentions for direct action by the Committee during the next 5 years.

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

The Committee adopted a Question and answers document (EMA/CVMP/414812/2005) on the CVMP guideline on the SPC for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005) providing clearer guidance on the indication "Treatment and prevention".

The document will be published on the Agency's website (QRD references and guideline).

Environmental Risk Assessment

The Committee adopted a revised Questions and answers document on implementation of ERA Guideline in support of VICH guidelines (GL 6 and GL 38) (EMEA/CVMP/ERA/172074/2008-Rev.3). This document has been updated to include a question and answer in relation to environmental risk assessment of marine water organisms and the fresh water compartment.

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

Quality

The Committee adopted a revised Guideline on stability testing for applications for variations to a marketing authorisation (EMA/CHMP/CVMP/QWP/441071/2011) for a 6-month period of public consultation. The existing guideline was revised to take into account the changes introduced in the amending Directive 2009/53/EC, the new Variations Regulation (Commission Regulation (EC) No 1234/2008) and Variations Classification guideline (Commission Communication 2010/C17/01).

The Committee adopted three Question and Answer documents on:

- Active substance definition: this document is intended to clarify that the mixing of active substances is subject to compliance to part I of the EU GMP guide (finished products), and also that it is not possible to present just one Active Substance Master File for a mixture of two or more active substances.

- Reduced testing of starting materials: this document is intended to clarify what information should be included in Marketing Authorisation application dossiers regarding the actual testing that is carried out on any starting materials by a finished product manufacturer.
- The appearance of tablets of different strengths: this short document is to clarify that different strengths of a tablet product should not be identical in appearance.

The information above will be available on the Agency's website.

Working Parties

The Committee endorsed the re-election, by the CHMP at their June 2011 meeting, of Jean-Louis Robert as the chairperson of the Joint CHMP/CVMP Quality Working Party for a further 3 year term.

The Committee adopted a mandate (EMA/256557/2011) and the work plan (EMA/263674/2011) for the joint ad-hoc CVMP/CHMP expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (JEG 3Rs). The Committee also adopted a Statement on the EMA position on the application of the 3Rs in the regulatory testing of human and veterinary medicinal products (EMA/470807/2011).

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

Procedural Announcement

Information for all applicants and marketing authorisation holders on a revised procedure for classifying and handling post-authorisation measures.

In the context of an ongoing exercise initiated in collaboration with the European Commission to improve the quality and consistency of scientific opinions, the Agency through its Scientific Committees will in future classify post-authorisation requirements placed on marketing authorisation holders into an appropriate legal framework as either 'Conditions' in Annex II (Obligations or Specific Obligations to fulfil post-authorisation measures), or as 'Recommendations' for further development.

As a consequence, the practice of requiring applicants to provide a signed Letter of Undertaking (sometimes known as a Letter of Commitment), in which all such measures (formerly follow-up measures, FUMs) were summarised, will be phased out. Instead, 'Conditions' will be reflected in Annex II of the relevant CVMP Opinions and corresponding Commission Decisions and all other remaining 'Recommendations' identified during the assessment will be included in the CVMP Assessment Report and reflected in a cumulative letter to be signed by the applicant. Procedural templates and guidance are being updated to reflect these changes.

This new system of classification and way of handling of post authorisation requirements will be phased in step-by-step. The first procedures affected are initial marketing authorisation application opinions as of July 2011. Post-authorisation procedures will follow at a later date.

Applicants and marketing authorisation holders should contact their Project Manager in case of further questions relating to ongoing procedures. General enquiries should be sent to 'vet.applications@ema.europa.eu'.

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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