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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 3-5 May 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **Recuvyra** (fentanyl), from Nexcyon Pharmaceuticals Ltd, for the control of post-operative pain associated with major orthopaedic and soft tissue surgery in dogs.

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

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

Metacam (meloxicam) – an addition of a new indication and additional information on posology in cats;

Naxcel (ceftiofur) – an extension of the current indication to include the treatment of acute post-partum metritis in cattle.

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

Annual reassessment of marketing authorisations

The Committee adopted opinions on the annual reassessment for **BTVPUR AlSap 8**, **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis**, further to the evaluation of the data submitted by the marketing authorisation holders. The Committee recommended the continuation of the Community marketing authorisations under exceptional circumstances for these veterinary medicinal products.

[1] Corrigendum to correct the name of the applicant for Recuvyra

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Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Poulvac Flufend H5N3 RG** (recombinant inactivated avian influenza virus) and **Nobilis Influenza H5N2** (inactivated avian influenza virus vaccine). The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated however both authorisations should remain under exceptional circumstances.

Community referrals and related procedures

The Committee started a procedure under Article 33(4) of Directive 2001/82/EC for **Prontax 10 mg/ml solution for injection for sheep, cattle and pigs** (doramectin) from Pfizer Limited. The matter was referred to the CVMP by Ireland, as the reference Member State in the decentralised procedure, due to concerns raised by France and the Netherlands in relation to the withdrawal periods for cattle and the potential risk to the environment from use of the product.

The Committee started a procedure under Article 33(4) of Directive 2001/82/EC for **Prontax 5 mg/ml pour-on solution for cattle** (doramectin) from Pfizer Limited. The matter was referred to the CVMP by Ireland, as the reference Member State in the decentralised procedure, due to concerns raised by France and the Netherlands in relation to the potential risk to the environment from use of the product.

The Committee started a procedure under Article 35 of Directive 2001/82/EC for **all pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix** and administered to rabbits. The matter was referred to the CVMP by the European Commission in order to consider the recommended use, dose and amounts to be administered in feed of these products in rabbits.

The Committee started a 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 notified to the CVMP by France due to concerns relating to animal safety.

The Committee concluded the procedure for **Doxycycline 50% WSP and associated names** (doxycycline hyclate) from Dopharma Research B.V. The matter was referred to CVMP by the United Kingdom under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in the product information. The Committee agreed harmonised indications, posology and withdrawal periods for the concerned products and therefore 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 procedure for **Doxyfar 50% and associated names** (doxycycline hyclate) from Eurovet Animal Health B.V. The matter was referred to CVMP by the United Kingdom under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in product information. The Committee agreed harmonised indications, posology and withdrawal periods for the concerned products and therefore 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.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **pegylated bovine granulocyte colony stimulating factor** in table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for bovine species.

The Committee adopted by consensus an opinion recommending the extension of the current entry in table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 for **lasalosid** to bovine species.

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

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/Limited markets policy, which concerned two separate oncology products, one indicated for cats and one indicated for dogs and an immunological for cattle and goats; the CVMP considered that the three products were indicated for MUMS/Limited market and were eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Onsior**, **Circovac**, **Equilis Te**, **EQUIOXX** and **Previcox**, **Leucogen**, **Meloxidyl**, **Porcilis PCV** and **Suvaxyn Aujeszky 783 + O/W** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish (EMA/CVMP/EWP/459868/2008) following the close of a public consultation. The guideline provides clearer details about the requirements for the study design of preclinical and clinical tests for pharmaceutical products in finfish.

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

Environmental Risk Assessment

The Committee adopted a Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products (EMA/CVMP/ERAWP/409328/2010) for a 3-month period of public consultation. This reflection paper was developed to provide a critical review of the adequacy/appropriateness of risk mitigation measures used in marketing authorisations and to provide a starting point whereby all stakeholders can work on the development of practical and effective risk mitigation measures.

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

Organisational matters

The Committee held a meeting with the interested parties on 4 May 2011 attended by representatives of Association of Veterinary Consultants (AVC), European Federation of Honey Packers and Distributors (F.E.E.D.M), European Group for Generic Veterinary Products (EGGVP), Federation of Veterinarians of Europe (FVE), International Council on Animal Protection in Pharmaceutical Programs (ICAPPP) and the International Federation of Animal Health Europe (IFAH-Europe).

The topics discussed concerned:

- Quality issues
- Revision of the veterinary legislation

- EMA/ IFAH-Europe Info Day
- Update on EMA/CVMP activities in relation to the 3Rs
- Developments in the availability of medicines for bees and MRLs for honey

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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