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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 September 2012

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for extension of the existing authorisations for:

Inflacam (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Limited to include 5 mg/ml solution for injection for cattle and pigs, and

Rheumocam (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Limited to include 5 mg/ml solution for injection for cattle and pigs.

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

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

Prilactone regarding the addition of a new flavoured tablet formulation, in a new container type, and

Oxyglobin regarding changes in the manufacturing process, the manufacturer and the control laboratory of the intermediates and active substance, addition of new suppliers of raw materials, changes in the manufacturing process and manufacturers of the active substance and finished product, addition of a new supplier of the packaging material and changes in packaging of the finished product.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Meloxivet**. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continues to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

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Community referrals and related procedures

The Committee started a procedure for **Suanovil 20 and associated names, Captalin and associated names, and generic products thereof, including pending applications** (spiramycin). The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns related to efficacy, antimicrobial resistance and withdrawal periods.

The Committee started a 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.

Maximum Residue Limits

Further to a request to amend an entry 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.11), in order to amend the maximum dose allowed for cetearyl ethylhexanoate under the heading excipients.

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

Scientific advice

The Committee agreed six separate scientific advice requests concerning;

Follow-up advice on the clinical development of a hormone inhibitor for cows; quality, safety and clinical development of a pharmaceutical product for a parasitic indication for bees; safety and clinical development of a cardiovascular pharmaceutical product for dogs; clinical development of a cardiovascular pharmaceutical product for dogs; clinical development of an anti-inflammatory product for horses; quality, safety and clinical development of an immunological product for sheep and goats.

MUMS / Limited markets

Following the Committee's review of three requests for classification under the MUMS/ Limited markets policy, which concerned an immunological product for cattle, an anti-parasitic product for dogs, an anti-anemic product for cats;

The CVMP considered that the anti-parasitic product for dogs was not indicated for MUMS/Limited market and was not eligible for financial incentives; and considered that the immunological product for cattle and the anti-anemic product for cats were indicated for MUMS/Limited market and were eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl, BLUEVAC BTV8, Bovilis BTV8, BTVPUR AlSap 8, Comfortis, Emdocam, Inflacam, Meloxoral, Netvax, Nobivac Myxo-RHD, Purevax Rabies, Purevax RC, Purevax RCP FeLV, Purevax RCPCh, Purevax RCPCh FeLV, Trocoxil, Veraflox, ZOLVIX** and **ZULVAC 1+8 Ovis**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **Procox** and recommended amendments to the special precautions for use in animals.

The Committee also reviewed the PSUR for **Suvaxyn PCV** and recommended changes to the nature of adverse events already included in the current product literature.

Concept papers, guidelines and SOPs

Environmental Risk Assessment

The Committee adopted an updated Questions and Answers document on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II). The Questions and Answers document was revised to further clarify the 2nd question regarding Phase II concerning the Koc values to use in assessing leaching to groundwater and run off to surface water

The Questions and Answers will be published on the Agency's website.

Incident management for medicines for veterinary use

The Committee endorsed the standard operating procedure to be followed when the incident management plan for medicines for veterinary use is triggered (SOP/V/4003). The procedure was developed to ensure effective support and coordination for management of incidents and potential crises in a harmonised and transparent manner.

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

Procedural announcements

Post-authorisation measures

In the context of the exercise on the quality of opinions started in 2011 together with the European Commission, the Agency has started to review the post-authorisation measures (frequently called "follow-up measures" or "FUMs") for centrally authorised veterinary medicinal products. In collaboration with CVMP the current follow-up measures will be reclassified either as recommendations for further development or as conditions under Annex II of the opinions of the CVMP.
Marketing authorisation holders affected by these changes will be informed, together with information on any actions which need to be taken.

Update of summary of product characteristics of generics following changes to the reference product

The Committee agreed that, when the text under sections 4.4 (Special warnings), 4.5 (Special precautions for use) and 4.6 (Adverse reactions) of the summary of product characteristics is amended for a reference product, the marketing authorisation holder for the generic product will be requested to submit a variation (Type IB, C.I.2.a) to amend their product information to come into line with that of the reference product.

This is consistent with the approach taken for centrally authorised medicinal products for human use and will help to ensure equality and consistency of information between products with regard to the information made available to the practitioner and the general public in the veterinary community.

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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