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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 08-10 January 2013

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Loxicom** (*meloxicam*) from Norbrook Laboratories Limited to add meloxicam 50 mg/g oral paste for horses.

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

The Committee adopted by consensus a positive opinion for a work-sharing type II quality variation application for **Rheumocam** and **Inflacam**.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **ProteqFlu** and **ProteqFlu-Te**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that their quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Community referrals and related procedures

The Committee started a procedure to prepare a scientific opinion, under Article 30(3) of Regulation (EC) No 726/2004, regarding the substance lidocaine. The matter was submitted to the European Medicines Agency by the Netherlands, on the basis of new scientific data on metabolism, in order to address potential risks to the consumer resulting from the use of lidocaine in food producing species.

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Maximum Residue Limits

Further to requests and 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 concluded that the excipients PPG-2 myristyl ether propionate and polybutene do not fall within the scope of Regulation (EC) 470/2009.

MUMS / Limited markets

Following the Committee's review of one request for classification under the MUMS / Limited markets policy, which concerned a product with musculoskeletal indication for horses the CVMP considered that the product was indicated for MUMS/Limited market and was eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Cimalgex**, **Emdocam**, **Gripovac 3**, **Ingelvac CircoFLEX**, **Loxicom**, **Proteq West Nile**, **Reconcile**, **RevitaCAM**, **STARTVAC**, **ZULVAC 1 Bovis** and **Zuprevo** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Safety

The Committee adopted a concept paper on genotoxic impurities (EMA/CVMP/SWP/398880/2012) for a 3-month period of public consultation. The concept paper proposes the development of guidance outlining the data requirements and assessment approach needed for the determination of acceptable levels for impurities with genotoxic potential in veterinary medicinal products, taking account of both target animal safety and consumer safety.

Antimicrobials

The Committee adopted a concept paper on the development of a guideline on antimicrobial risk assessment (EMA/CVMP/680258/2012) for a 3-month period of public consultation. The concept paper proposes the development of a guideline on antimicrobial resistance risk assessment to be applied for all classes of antimicrobial agents. The guideline will provide a basis for transparent and consistent assessment of public health risk related to antimicrobial resistance to be applied both by companies and regulatory bodies.

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

Working Parties

The Committee elected Helen Jukes as chair of the newly established Antimicrobials Working Party for a 3-year mandate.

International Harmonisation

The Committee adopted a draft revised VICH safety guideline for release in the EU following the sign-off by the VICH Steering Committee:

- GL 23(R) on Safety: Studies to evaluate the safety of residues of veterinary drugs in human food: Genotoxicity testing – 3-month public consultation.

The guideline 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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