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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 06-08 September 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a final positive opinion for an extension of the existing authorisation for **Draxxin** (*tulathromycin*), from Zoetis Belgium SA, to include a new target species (sheep).

The Committee adopted by consensus positive opinions for a type II variation application for **Draxxin** relating to pharmacodynamic properties and for a type II variation application for **Bovela** regarding quality changes.

The Committee adopted by consensus positive opinions for type IB variation applications (subject to worksharing procedures) for:

Inflacam and **Rheumocam;**

Versican Plus DHPPi and **Versican Plus Pi**; and

Versican Plus Pi/L4, **Versican Plus DHPPi/L4** and **Versican Plus L4** concerning quality changes.

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

Renewals of marketing authorisation

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

Community referrals and related procedures

The Committee started a procedure for **Zanil and associated names, and generic products thereof** (oxyclozanide). The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC due to concerns related to the withdrawal periods in cattle, sheep and goats.

Scientific advice

The Committee adopted one scientific advice report further to a request for:

- Initial advice on quality, safety and efficacy issues for a new combination product for pigs.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of four requests for classification under the MUMS/limited market policy, the CVMP classified:

- A veterinary medicinal product for a urinary system indication for use in dogs as not indicated for MUMS/limited market and therefore not eligible for reduced data requirements;
- Two antiparasitic indications in cats and one in dogs as indicated for MUMS/limited market and eligible for reduced data requirements, and classified one antiparasitic indication in cats as not indicated for MUMS/limited market and therefore not eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in non-food producing species (cats and dogs);
- An antiparasitic veterinary medicinal product for use in honey bees as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as alternative products for the same indication are available in the EU; and
- A veterinary medicinal product for a musculoskeletal system indication for use in horses as indicated for MUMS/limited market further to a request for re-classification. The product is not eligible for financial incentives as it is intended for use in horses.

Pharmacovigilance

The Committee reviewed the PSURs for **Bravecto, HALOCUR, Meloxidolor, Parvoduk, Recuvyra** and **Velactis** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a reflection paper on the risks that should be considered prior to the use of unauthorised vaccines in emergency situations (EMA/CVMP/IWP/49593/2013). This reflection paper has been developed to explain the risks associated with the use of such products by describing the basis by which a standard marketing authorisation is granted and outlining the risks posed for use of unauthorised vaccines where the complete data for a standard marketing authorisation (as required by Directive 2001/82/EC) are not available. The primary target group of this reflection paper are decision and policy makers with responsibility for disease control measures.

The Committee adopted a concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD) (EMA/CVMP/IWP/867388/2015) for a 3-month period of public consultation.

The Committee adopted a concept paper for the revision of the note for guidance on the use of adjuvanted immunological veterinary medicinal products (EMA/CVMP/IWP/867395/2015) for a 3-month period of public consultation.

Notes

1. 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

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu