EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 11-13 September 2018

CVMP invites comments on a reflection paper dealing with resistance development of certain antimicrobials and its impact on human and animal health

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for the extensions of the existing marketing authorisations for **Inflacam** and **Rheumocan** (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Ltd, concerning the addition of a new pharmaceutical form (oral suspension) and strength (0.5 mg/ml) for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures, and alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

The Committee also adopted by consensus positive opinions for type II variation applications for **ORSURNIA**, **Porcilis PCV M Hyo** and **RESPIPORC FLUpan H1N1** regarding quality changes.

The Committee adopted by consensus a positive opinion for a type II grouped variation application for **ZACTRAN** regarding quality changes.

The Committee adopted by consensus a positive opinion for a type II variation application for **Econor**, concerning updates of the SPC due to new preclinical data.

The Committee adopted by consensus a positive opinion for a type II grouped variation application (subject to a worksharing procedure) for **NexGard** and **NEXGARD SPECTRA** concerning the addition of new therapeutic indications for the treatment of demodicosis and sarcoptic mange.

The Committee adopted by consensus a positive opinion for a type II variation application (subject to a worksharing procedure) for **Versican Plus DHPPI**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R**, **Versican Plus L4**, **Versican Plus Pi**, **Versican Plus Pi/L4** and **Versican Plus Pi/L4R** concerning the introduction of changes in the product information regarding use during pregnancy.

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

The Committee adopted by consensus positive opinions for type II variation applications (subject to a worksharing procedure), concerning quality changes, for:

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

- Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4R and **Versican Plus Pi/L4**;

- Versican Plus DHPPi, Versican Plus Pi, Versican Plus Pi/L4, Versican Plus DHPPi/L4, Versican Plus DHPPi/L4R and **Versican Plus Pi/L4R**; and

- Versican Plus DHPPi, Versican Plus Pi, Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus Pi/L4R and **Versican Plus Pi/L4**.

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

Scientific advice

The Committee adopted 2 separate scientific advice reports further to requests for:

- Initial advice on safety and efficacy issues for a pharmaceutical veterinary medicinal product for cats;
- Initial advice on efficacy issues for a pharmaceutical veterinary medicinal product for dogs.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of 5 requests for classification under the MUMS/limited market policy, the CVMP:

- Did not classify a product (musculo-skeletal system) for dogs as indicated for MUMS/limited market.
- Did not classify a product (immunologicals) for chickens as indicated for MUMS/limited market.
- Reclassified a product (musculo-skeletal system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as, according to the MUMS policy, products for horses are generally not eligible for fee incentives.
- Reclassified a product (musculo-skeletal system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as, according to the MUMS policy, products for horses are generally not eligible for fee incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **LETIFEND, Meloxidolor, Nobilis IB Primo QX** and **Zeleris,** and concluded that no further action or changes to their product information were required.

The Committee reviewed the PSURs for **CYTOPOINT, Nobilis IB4-91, OSURNIA, RHINISENG** and the targeted PSUR for **Easotic**, and recommended amendments to the product literature.

Concept papers, guidelines and SOPs

Safety

The Committee adopted a guideline on determination of withdrawal periods for edible tissues (EMA/CVMP/SWP/735325/2012) following the close of the public consultation. The guideline replaces and updates the previous Note for Guidance: Approach towards harmonisation of withdrawal periods (EMEA/CVMP/036/95 FINAL). In addition to providing guidance on determination of withdrawal periods the new document reports on considerations relating to alternative approaches for dealing with residue data below the limit of quantification and incorporates a number of updates to references and clarifications, as described in Annex E of the document.

The guideline together with the overview of comments (EMA/CVMP/SWP/81095/2017) will be published on the Agency's website.

Efficacy

The Committee adopted a draft reflection paper on ectoparasitic resistance (EMA/CVMP/EWP/310225/2014) for an 11-month period of public consultation. The reflection paper aims to give an overview of the known resistance of ectoparasites to active substances used in veterinary medicinal products with a special focus on Europe, and to provide a review of the current knowledge on resistance mechanisms.

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

Antimicrobials

The Committee adopted a draft reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union (EMA/CVMP/AWP/842786/2015) for a 3-month period of public consultation. The objective of this document is to review available information on the use of aminopenicillins and their beta-lactamase inhibitor combinations in veterinary medicines in the EU, their effect on the emergence of antimicrobial resistance (AMR) and the potential impact of resistance on human and animal health. The document provides information for the risk profiling, as recommended by the Antimicrobial Advice ad hoc Expert Group (AMEG) of the EMA.

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

The Committee agreed to extend the consultation period of the guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1) until the end of August 2019 when the CVMP working party activities are expected to resume.

Working parties

The Committee reviewed and adopted the revised mandate (EMA/CVMP/ERA/705470/2009-Rev.5) for the CVMP Environmental Risk Assessment Working Party (ERAWP) for a further period of 3 years.

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 officers

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu

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