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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 19-21 February 2019

Last meeting in London before the move to Amsterdam - CVMP adopts opinions on five new veterinary medicines, including one vaccine and one stem-cell product

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive final opinion for an initial marketing authorisation application for **HorStem** (equine umbilical cord mesenchymal stem cells), from Equicord-Ymas S.L., a new product for the treatment of lameness and other clinical symptoms associated with mild to moderate degenerative join disease (osteoarthritis) in horses, further to the re-examination of the opinion adopted during the Committee meeting held on October 2018.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Chanhold** (*selamectin*), from Chanelle Pharmaceuticals Manufacturing Ltd, a new (generic) product for the treatment and prevention of infestation and/or diseases caused by different species of fleas, worms, lice and mites in cats and dogs.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Felisecto Plus** (*selamectin/sarolaner*), an informed consent application from Zoetis Belgium SA, a new product for the treatment and/or prevention of mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm in cats. In an informed consent application, reference is made to an authorised medicine and the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Forceris** *(toltrazuril/iron (as gleptoferron))*, from Ceva Santé Animale, a new product for piglets for the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in farms with a confirmed history of coccidiosis caused by *Cystoisospora suis*.

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The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **ReproCyc ParvoFLEX**, from Boehringer Ingelheim Vetmedica GmbH, a new vaccine for the active immunisation of gilts and sows from the age of 5 months to protect progeny against transplacental infection caused by porcine parvovirus.

The Committee adopted by consensus a positive opinion for a type II variation application for **LETIFEND** concerning quality changes. The Committee also adopted by consensus positive opinions for type II variation applications for **MS-H Vaccine** and for **Zycortal** concerning the addition of a new pharmacovigilance system.

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 positive opinions for the renewal of the marketing authorisations for **ERYSENG, ERYSENG PARVO, Versican Plus L4**, **Versican Plus Pi/L4**, **Versican Plus DHPPi/L4** and **Versican Plus DHPPi/L4R**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations. Based on pharmacovigilance grounds, the Committee concluded that a further 5-year renewal is required for Versican Plus L4, Versican Plus Pi/L4, Versican Plus DHPPi/L4 and Versican Plus DHPPi/L4R. An indefinite authorisation was recommended for ERYSENG and ERYSENG PARVO.

Community referrals and related procedures

The Committee started a procedure for **Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC. This referral procedure concerns the appropriateness of the current withdrawal periods in cattle, sheep and pigs for the aforementioned veterinary medicinal products containing 150 mg amoxicillin per ml.

The Committee concluded the referral procedure for **veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep**. The matter was referred to the Committee by the United Kingdom, under Article 35 of Directive 2001/82/EC, due to concerns related to the withdrawal periods in sheep. The Committee agreed that the withdrawal period (meat and offal) for sheep should be amended to provide assurance for consumer safety. The Committee adopted by consensus an opinion concluding that the marketing authorisations for 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 establishment of maximum residue limits for ciclesonide in horses.

More information about the above recommendation will be published on the Agency's website.

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 (musculo-skeletal system) as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as it is intended for use in non-food producing species (cats).
- A veterinary medicinal product for turkeys (immunologicals) as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as alternative products for the same indication are currently authorised in the EU.
- A veterinary medicinal product for ducks (immunologicals) as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as alternative products for the same indication are currently authorised in the EU.

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP reclassified a veterinary medicinal product (antineoplastic and immunomodulating agents) as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as it is intended for use in a non-food producing species (dogs).

Pharmacovigilance

The Committee reviewed the PSURs for **Exzolt**, **FORTEKOR PLUS**, **Galliprant**, **NexGard**, **ProteqFlu**, **ProteqFlu-Te**, **Semintra** and **VarroMed,** and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSUR for **ERAVAC**, and recommended amendments to the product information.

The Committee adopted the public bulletin on veterinary pharmacovigilance for 2018 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/809750/2018). Annual public bulletins on veterinary pharmacovigilance are published by the Agency with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2018.

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

Working parties

The Committee re-elected Mary O'Grady as the veterinary vice-chair of the joint CHMP/CVMP Quality Working Party (QWP) for a 3-year mandate.

The Committee elected Ricardo Carapeto García as chair of the CVMP Environmental Risk Assessment Working Party (ERAWP) for a 3-year mandate.

The Committee elected Christine Schwarz as chair of the Antimicrobials Working Party (AWP) for a 3-year mandate.

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

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