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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 23–25 May 2018

New vaccine to reduce the incidence of intramammary infections in cows/heifers recommended for approval

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **UBAC**, from Laboratorios Hipra, S.A., an emulsion for injection, intended for active immunisation of healthy cows and heifers to reduce the incidence of clinical intramammary infections caused by *Streptococcus uberis,* to reduce the somatic cell count in *Streptococcus uberis* positive quarter milk samples and to reduce milk production losses caused by *Steptocoocus uberis* intramammary infections.

The Committee adopted by consensus a positive opinion for a type II variation application for **Porcilis PCV M Hyo** to modify the approved therapeutic indication.

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Pexion** to add a new therapeutic indication and to implement amendments to the product information.

The Committee also adopted by consensus positive opinions for grouped type II variation applications for **CLYNAV** and **Exzolt** 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 positive opinions for the renewal of the marketing authorisations for **APOQUEL** and **Reconcile**. 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 indefinite renewal of the marketing authorisations.

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Scientific advice

The Committee adopted a scientific advice report further to a request for follow-up advice on efficacy issues for a new antiparasitic veterinary medicinal product for cats.

Minor use, minor species (MUMS) / limited market

Following the Committee's review of a request for classification under the MUMS/limited market policy, the CVMP classified a veterinary medicinal product (antiparasitic products, insecticides and repellents) for honey bees as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as authorised products already exist in the EU for the proposed indication.

Pharmacovigilance

The Committee reviewed the PSURs for **BROADLINE**, **Cerenia**, **Circovac**, **Contacera, Innovax IL-T, Panacur AquaSol**, **Posatex**, **Poulvac E. Coli**, **Spironolactone Ceva**, **Vectra Felis**, **Velactis** and **Zycortal**, and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSUR for **Suvaxyn Circo MH-RTU** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted a revised recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data for centrally authorised products (CAPs) (EMA/CVMP/PhVWP/171122/2016-Rev.1) following the close of the public consultation. The main aim of the revision was to improve the overall pharmacovigilance surveillance process by integrating periodic safety update report (PSUR) evaluation and signal detection processes based on EVVet data and using risk-based principles. The recommendation is applicable to veterinary medicinal products (VMPs) authorised via the centralised procedure only on a voluntary basis for marketing authorisations holders (MAHs) who choose to implement it.

The recommendation together with the overview of comments (EMA/CVMP/PhVWP/519126/2017) will be published on the Agency's website.

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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