20 March 2020
EMA/CVMP/120715/2020
Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 17-18 March 2020

CVMP holds its first entirely virtual meeting as part of the measures taken due to the COVID-19 pandemic

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Lydaxx** (*tulathromycin*), from Vetoquinol, a new generic product for treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis.

The Committee adopted by consensus a positive opinion for a grouped type II variation application (subject to a worksharing procedure) for **Vectra Felis** (*dinotefuran/pyriproxyfen)* and **Vectra 3D** (*dinotefuran/pyriproxyfen/permethrin*) concerning quality-related changes. The Committee also adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Equisolon** (*prednisolone*) and **Meloxoral** (*meloxicam*) concerning a new pharmacovigilance system.

Renewals of marketing authorisations

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

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending that the current maximum residue limits for **ketoprofen** in bovine, porcine and *Equidae* remain unchanged. Ketoprofen is

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

currently included in Table 1 (allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with a 'no MRL required' classification for bovine, porcine and *Equidae*.

Scientific advice

The Committee adopted one scientific advice report further to a request for initial advice on efficacy issues for an antiparasitic veterinary medicinal product for dogs and cats.

Minor use, minor species (MUMS)/limited market

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

- A product (antiparasitic products, insecticides and repellents) for Atlantic salmon as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is eligible for financial incentives as it is intended for use in food producing species.
- A product (various) for pigs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is eligible for financial incentives as it is intended for use in food producing species.
- A product (immunologicals) for cattle as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is eligible for financial incentives as it is intended for use in food producing species.

Pharmacovigilance

The Committee reviewed the PSUR for **Galliprant** and recommended amendments to the product information.

The Committee also reviewed the PSURs for **Cytopoint**, **Evalon**, **Exzolt** and **Vaxxitek HVT+IBD,** and concluded that no further action or changes to their product information were required.

The Committee adopted the public bulletin on veterinary pharmacovigilance for 2019 summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/CVMP/PhVWP/33617/2020). 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 reaction reports and safety updates and provides an overview of the activities and issues addressed during 2019.

The public bulletin will be published on the Agency's website.

Procedural Announcement

Applicants and marketing authorisation holders for veterinary medicinal products intended for assessment or authorised under the centralised procedure are encouraged to avoid submitting general regulatory queries to the European Medicines Agency vet applications email address (vet.applications@ema.europa.eu).

That email address should **only** be used to submit pre-submission queries about intended pre- or post-authorisation procedures for a specific veterinary medicinal product, e.g. to request a procedure number, advice on the variation classification.

Queries related to any ongoing procedure should be directed to the respective, designated procedure coordinator, according to the information given in the validation letter.

Questions that are more general in their nature should be sent via AskEMA. Such queries are typically related to regulatory strategy for intended projects.

From 1 April 2020 the vet applications team will no longer respond to any general regulatory queries and the applicant/marketing authorisation holder will be requested to re-submit the query via the AskEMA channel.

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. +31 (0)88 781 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News