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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 21-22 May 2019

The Committee re-elected David Murphy from Ireland as its Chair for another 3-year mandate

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **EVICTO** (*selamectin*), from VIRBAC, 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 **NASYM**, from LABORATORIOS HIPRA, S.A, a new vaccine for the active immunisation of cattle to reduce virus shedding and respiratory clinical signs caused by bovine respiratory syncytial virus infection.

The Committee adopted by consensus positive opinions for the following type II variation applications for:

- **Bravecto Plus**, concerning the addition of a new therapeutic indication;

- **CLYNAV**, **Clomicalm** and **CYTOPOINT**, concerning quality changes.

The Committee adopted by consensus positive opinions for type II grouped variation applications for **Ingelvac CircoFLEX,** for **Melovem** and for **Porcilis PCV M Hyo**, all concerning quality changes.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **MiPet Easecto**, **Stronghold Plus** and **Simparica** concerning quality changes. The Committee also adopted by consensus a positive opinion for a type IB grouped variation application (subject to a worksharing procedure) for **Fevaxyn Pentofel** and nationally-authorised products concerning quality changes.

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

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Scientific advice

The Committee adopted one scientific advice report further to a request for initial advice on safety issues for a new pharmaceutical veterinary medicinal product for musculoskeletal disorder indications in dogs.

Minor use, minor species (MUMS) / limited market

Following the Committee's review of one request for classification under the MUMS/limited market policy, the CVMP classified the indication of an immunological product for turkeys as MUMS/market not limited, and therefore eligible for partially reduced data requirements, where applicable. The proposed indication is not eligible for financial incentives as alternative products for the same indication are currently authorised in the EU.

Pharmacovigilance

The Committee reviewed the PSURs for **Canigen L4 & Nobivac L4**, **CLYNAV**, **HALAGON**, **Locatim**, **Poulvac E. coli**, **Sileo**, **Vectra Felis** and **ZUPREVO** and concluded that no further action or changes to their product information were required.

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

Working parties

The Committee elected Frida Hasslung Wikström as chair of the CVMP Scientific Advice Working Party for a 3-year mandate, renewable once.

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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