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 15-16 April 2019

CVMP recommends amendments to the product information for CYTOPOINT

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Suvaxyn PRRS MLV** to reduce the onset of immunity and implement changes to the product information.

The Committee adopted by consensus a positive opinion for a type II variation application for **Broadline** concerning quality changes.

The Committee adopted by consensus positive opinions for the following type II variation applications (subject to worksharing procedures):

- Porcilis PCV M Hyo and nationally authorised products, to change the product information to allow concurrent administration with Porcilis PRRS.

- LEUCOGEN, **LEUCOFELIGEN FeLV-RCP** and **Nobivac LeuFeL**, to amend the product information to reflect that a beneficial effect of the feline leukaemia virus (FeLV) vaccination is observed 3 weeks after the first injection of the primary vaccination.

Renewals of marketing authorisations

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

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **bambermycin** in rabbits.
More information about the above recommendation will be published on the Agency's website.

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

Scientific advice

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

- Initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for a musculoskeletal disorder indication in horses; and
- Initial advice on safety and efficacy issues for a new antiparasitic veterinary medicinal product for dogs.

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:

- An immunological product 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.
- A product (cardiovascular system) for cats 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.
- An immunological product for cattle as indicated for MUMS/limited market and eligible for both reduced data requirements, where applicable, and financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **RESPIPORC FLUPan H1N1**, **SevoFlo**, **Suvaxyn Circo MH+RTU**, **Virbagen Omega** and **Zeleris**, and concluded that no further action or changes to their product information were required.

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

Organisational matters

The Committee finalised the preparation of the CVMP and CVMP/CMDv Presidency meetings to be held under the Romanian Presidency of the EU, on 6-8 May 2019. The discussions will focus on:

- New Veterinary Regulation: Impact on the CVMP;
- Functioning of CVMP Working Parties;
- SPC harmonisation: approach to prioritising of products
- Veterinary medicinal products for honey bees.

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