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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 18-20 June 2019

The Committee elected Gerrit Johan Schefferlie from the Netherlands as the CVMP vice-chair for a 3-year mandate

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Advocate** concerning the addition of new therapeutic indications and the amendment of the product information relating to an existing indication.

The Committee adopted by consensus positive opinions for type II variation applications concerning quality changes for **Meloxidyl** and **Suprelorin**, and for **Suvaxyn Circo** and **Suvaxyn Circo+MH RTU** (subject to a worksharing procedure).

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Inflacam** and **Rheumocam** to change the product information to align adverse reactions with the reference product.

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

Community referrals and related procedures

The Committee concluded the referral procedure for **veterinary medicinal products containing tylosin presented as solutions for injection for intramuscular use in sheep**. The matter was referred to the Committee by the Netherlands, under Article 35 of Directive 2001/82/EC, due to concerns related to the withdrawal periods in sheep. The Committee agreed that the maximum injection volume per site and the withdrawal periods for sheep meat and offal and milk 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.

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Scientific advice

The Committee adopted 5 separate scientific advice reports further to requests for:

- follow-up advice on quality, safety and efficacy issues for a new diagnostic veterinary medicinal product for pigs;
- initial advice on efficacy issues for a new veterinary medicinal product for a gastrointestinal disease indication in dogs;
- initial advice on quality issues for a new immunological veterinary medicinal product for cattle;
- initial advice on efficacy issues for a new antiparasitic medicinal product for cats; and
- initial advice on safety issues for a new anti-inflammatory veterinary medicinal product for sheep and goats.

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 an immunological product for pigs as not indicated for MUMS/limited market.

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP reclassified 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.

Pharmacovigilance

The Committee reviewed the PSURs for **ERYSENG**, **ERYSENG PARVO**, **Innovax ILT**, **LEUCOGEN, Nobivac Leufel, Nobilis OR Inac**, **Trifexis**, **ZACTRAN** and **ZULVAC 8 Bovis,** and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a scientific advice on preliminary risk profiling for new antimicrobials following the close of the public consultation. This document was developed to answer a request from the European Commission on the impact on public health and animal health of the use of antibiotics in animals. The comments received during the consultation procedure have been taken into account. The advice is now foreseen to be adopted by CHMP at its meeting on 24-27 June 2019.

The scientific advice (EMA/CVMP/CHMP/682199/2017) together with the overview of comments (EMA/CVMP/CHMP/201533/2019) will be published on the Agency's website.

A complementary scientific advice revising the categorisation of antimicrobials is under finalisation and will be adopted at a later meeting.

Novel therapies

The Committee adopted revised questions and answers documents to remove reference to human guidelines on the following topics:

- Stem cell-based products for veterinary use: specific questions on extraneous agents (EMA/CVMP/ADVENT/803494/2016);
- Allogeneic stem cell-based products for veterinary use: specific questions on sterility (EMA/CVMP/ADVENT/751229/2016).

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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