EUROPEAN MEDICINES AGENCY
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Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 19-21 March 2019

At its first meeting in Amsterdam CVMP adopts recommendations for two new initial marketing authorisations and one extension

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Afoxolaner MERIAL** (*afoxolaner*), an informed consent application from MERIAL, a new product for the treatment of flea and tick infestations, demodicosis and sarcoptic mange in dogs. In an informed consent application, reference is made to an authorised medicine and the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Baycox Iron** (*toltrazuril/iron (as gleptoferron)*), from Bayer Animal Health GmbH, a new product for piglets for the concurrent prevention of clinical signs of coccidiosis (such as diarrhoea) in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis,* and prevention of iron deficiency anaemia.

The Committee adopted by consensus a positive opinion for an extension of the existing marketing authorisation for **Innovax ND-IBD**, from Intervet International B.V., to add a new route of administration (*in ovo*) for chicken embryonated eggs.

The Committee adopted by majority a positive opinion for a type II variation application for **Vectra 3D** to change the legal status from prescription-only to non-prescription veterinary medicine.

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

- **ProZinc** concerning the addition of dogs as a new target species;

- **MS-H Vaccine** and for **ProZinc**, both concerning quality changes;

- **CLYNAV** and **CYTOPOINT** (grouped), also concerning quality changes.

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The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Simparica** and **MiPet Easecto** to update the product information to implement the outcome of a PSUR assessment.

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 **Nobilis IB Primo QX, Suvaxyn PCV** and **Versican Plus Pi/L4R**. 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 renewal of the marketing authorisations. Based on pharmacovigilance grounds, the Committee concluded that a further 5-year renewal is required for Versican Plus Pi/L4R. An indefinite authorisation was recommended for Nobilis IB Primo QX and Suvaxyn PCV.

Scientific advice

The Committee adopted 3 separate scientific advice reports further to requests for:

- Initial advice on quality, safety and efficacy issues for an immunological veterinary medicinal product for chickens;
- Initial advice on efficacy issues for an antiparasitic veterinary medicinal product for cats;
- Initial advice on efficacy issues for a veterinary medicinal product for a cardiovascular disease indication in dogs.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of 4 requests for classification under the MUMS/limited market policy, the CVMP classified:

- A dermatological product for dogs 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 non-food producing species.
- A product (genito-urinary system and sex hormones) for sheep as indicated for MUMS/limited market and eligible for both reduced data requirements, where applicable, and financial incentives.
- A product (musculo-skeletal system) for dogs as not indicated for MUMS/limited market.
- A product (musculo-skeletal system) 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.

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP also reclassified a product (immunologicals) for rainbow trout 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 **CaniLeish**, **Cimalgex**, **EVALON**, **Imestor**, **LETIFEND**, **Procox** and **Veraflox,** and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Quality

The Committee adopted questions and answers on the use of peptone in the manufacture of active substances via fermentation process, which were adopted by the CHMP at their February meeting and will be published on the Agency's website.

International harmonisation

The Committee adopted two VICH guidelines for publication and implementation in the EU following the sign-off by the VICH Steering Committee:

- GL57 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species (EMA/CVMP/VICH/517152/2013);
- GL36(R2) on microbiological ADI: VICH GL36 (R2) on general approach to establish a microbiological ADI (EMA/CVMP/VICH/467/2003-Rev.2). The change introduced in this revised document is limited to the figure given for the size of the human colon.

The guidelines 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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