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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 16–18 January 2018

Diethanolamine removed from the 'out of scope list'

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for type II variation applications for **Advocate** and **Panacur AquaSol** to add new therapeutic indications, and for **Vectormune ND** to add a new category of target species.

The Committee also adopted by consensus positive opinions for type II variation applications for **Meloxidyl** and **Suvaxyn PCV** concerning quality changes.

The Committee also adopted by consensus a positive opinion for a type II variation application (subject to a worksharing procedure) for **Procox** concerning quality changes.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewals of the marketing authorisations for **Equilis West Nile** and **Oncept IL-2**. 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 renewals of the marketing authorisations. Based on pharmacovigilance grounds (limited data) the Committee concluded that a further 5-year renewal was necessary for Equilis West Nile. An indefinite authorisation was recommended for Oncept IL-2.

Maximum residue limits

The Committee agreed to remove **diethanolamine** from the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 and adopted a revised list (EMA/CVMP/519714/2009-Rev.37). This decision was taken by the Committee in light of information on potential genotoxicity and carcinogenicity.

The document will be published on the Agency's website.

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Scientific advice

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

- Initial advice on quality, safety and efficacy issues for an immunological product for pigs; and
- Follow up advice on MRL issues for a veterinary medicinal product with a musculoskeletal disease indication for horses.

Minor use, minor species (MUMS)/limited market

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

- A product (immunologicals) for red foxes and raccoon dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as the product is intended for use in non-food-producing species.
- A product (antiparasitic products, insecticides and repellents) for goats as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as products for the same indication/species are authorised in the EU.

Pharmacovigilance

The Committee reviewed the PSURs for **Coliprotec F4/F18, Kexxtone, NEXGARD SPECTRA, Porcilis PCV ID, ProZinc, Semintra, Stronghold Plus** and **Vectra 3D** and concluded that no further action or changes to their product information were required.

Concept papers, guidelines and SOPs

Safety

The Committee adopted a concept paper for the revision of the guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/SWP/779037/2017) for a 1-month period of public consultation. The revision of the guideline (EMEA/CVMP/SWP/66781/2005-Rev.1) is proposed to take account of the rules described in Commission Regulation (EU) 2017/880.

The document will be published on the Agency's website.

Environmental Risk Assessment

The Committee adopted Questions and Answers on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH GL6 (Phase I) and GL38 (Phase II).

The Questions and Answers will be published on the Agency's website.

International harmonisation

Following sign-off by the VICH Steering Committee, the CVMP adopted the following VICH guideline for a 5-month consultation period:

- VICH GL57: 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.

The guideline 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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