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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 3–5 October 2017

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for initial marketing authorisation applications for:

MiPet Easecto (*sarolaner*), an informed consent application from Zoetis Belgium SA, a new antiparasitic product for the treatment of tick infestations, flea infestations, sarcoptic mange, ear mite infestations, and demodicosis 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; and

Rabitec, from IDT Biologika GmbH, a new live attenuated vaccine for the active immunisation of foxes and raccoon dogs against rabies.

The Committee adopted by consensus a positive opinion for a type II variation application for **SevoFlo** to add a new target species (cats). The Committee also adopted by consensus positive opinions for type II variation applications for **Hiprabovis IBR Marker Live**, **Imrestor** and **Porcilis PCV M Hyo** concerning quality changes.

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 renewals of the marketing authorisations for **Kexxtone** and **Pexion**. 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.

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Community referrals and related procedures

The Committee concluded the referral procedure for **Girolan and its associated name Apralan** (*apramycin sulfate*) from Elanco Animal Health. The matter was referred to the Committee by Spain, under Article 34 of Directive 2001/82/EC due to divergent decisions taken by Member States resulting in differences in the product information. The Committee agreed a harmonised product information for the concerned products and adopted by majority an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 for **solvent naphtha, light aromatic** in all food producing species.

The Committee adopted by consensus a positive opinion recommending the extension of maximum residue limits in accordance with Regulation (EC) No 470/2009 for **fluazuron** in fin fish. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the established MRLs for fluazuron in bovine species to tissues of all ruminants except ovine species and to milk of bovine species.

More information about the above recommendations will be published on the Agency's website.

Scientific advice

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

- Initial advice on MRL issues for an antiparasitic veterinary medicinal product for farmed Atlantic salmon;
- Initial advice on quality issues for a veterinary medicinal product with a musculoskeletal disease indication in dogs.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP reclassified a veterinary medicinal product (antiparasitic products, insecticides and repellents) for honeybees as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives due to the existence of a currently authorised alternative product in the EU.

Pharmacovigilance

The Committee reviewed the PSURs for **Apoquel, DRAXXIN, Fungitraxx, Imrestor, Porcilis PCV M Hyo, ProMeris (WD), ProMeris Duo (WD), Simparica, Suvaxyn Circo MH RTU, Versican Plus DHPPi L4, Versican Plus DHPPi L4R** and **Zycortal**, and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSUR for **Bravecto** and recommended amendments to the product information of Bravecto spot-on solution.

Concept papers, guidelines and SOPs

Quality

The Committee adopted draft guidance on a phased implementation of requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017) for a one-month period of public consultation. This guidance aims to provide a pragmatic approach for the implementation of Ph. Eur. requirements in relation to the control of elemental impurities in veterinary medicinal products.

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

Working parties

The Committee elected Els Dewaele as chair of the Pharmacovigilance Working Party (PhVWP-V) for a 3-year mandate.

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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