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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 9-11 October 2018

CVMP initiates two referral procedures to harmonise consumer safety aspects of veterinary medicines containing paromomycin and tylosin, respectively

CVMP opinions on veterinary medicinal products

The Committee adopted a negative opinion for an initial marketing authorisation application for **HorStem**, from EquiCord-Ymas S.L., which was proposed for the treatment of lameness and other clinical symptoms associated with mild to moderate degenerative joint disease (osteoarthritis) in horses.

The Committee adopted a negative final opinion for an initial marketing authorisation application for **LONGRANGE** *(eprinomectin)*, from MERIAL, which was proposed for the treatment and the prevention of reinfections with certain specified parasites in cattle, further to the re-examination of the negative opinion adopted during the Committee meeting held on 19-21 June 2018.

More information about the above mentioned medicines 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 **Bravecto** and **NexGard**. 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 the Committee concluded that a further 5-year renewal was necessary for Bravecto. An indefinite authorisation was recommended for NexGard.

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Community referrals and related procedures

The Committee started a procedure for **veterinary medicinal products containing paromomycin to be administered parenterally to pigs.** The matter was referred to the Committee by Belgium under Article 35 of Directive 2001/82/EC. This referral procedure concerns the appropriateness of the current indications, posology and withdrawal periods.

The Committee started a procedure for **veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep.** The matter was referred to the Committee by the Netherlands under Article 35 of Directive 2001/82/EC. This referral procedure concerns the appropriateness of the current withdrawal periods (milk, meat and offal) in sheep for the aforementioned veterinary medicinal products.

Scientific advice

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

- Initial advice on safety and efficacy issues for a new antiparasitic veterinary medicinal product for dogs;
- Initial advice on quality, safety and efficacy issues for a new anti-inflammatory veterinary medicinal product for dogs;
- Initial advice on efficacy issues for a new ophthalmic veterinary medicinal product for dogs;
- Follow-up advice on efficacy issues for a new veterinary medicinal product acting on the nervous system in dogs;
- Follow-up advice on quality and efficacy issues for a new immunological veterinary medicinal product for pigs.

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 rabbits as indicated for MUMS/limited market and eligible for reduced data requirements, when applicable. The product is not eligible for financial incentives as alternative products for the same indication/species are authorised in the EU.

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP reclassified an immunological product for chickens as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as an alternative authorised product already exists for the same indication/species.

Pharmacovigilance

The Committee reviewed the PSURs for **BLUEVAC BTV8, BTVPUR Alsap1, BTVPUR Alsap8**, **DRAXXIN**, **EQUIP WNVM**, **Meloxivet, Meloxoral**, **Porcilis AR-T-DF**, **Porcilis PCV M Hyo**, **RESPIPORC FluPan H1N1**, **SevoFlo** and **Suvaxyn Circo MH RTU,** 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 literature.

Concept papers, guidelines and SOPs Quality

The Committee agreed to extend the consultation period of the draft guideline on the manufacture of veterinary finished dosage form (EMA/CVMP/QWP/798401/2015-Rev.1) until the end of August 2019.

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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