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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 18-20 February 2020

CVMP recommends authorisation of a new vaccine and two generic medicines

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Vectormune FP ILT + AE**, from Ceva-Phylaxia Co. Ltd, a new vaccine for the active immunisation of chickens to reduce skin lesions due to fowlpox, clinical signs and tracheal lesions resulting from avian infectious laryngotracheitis, and to prevent egg production losses due to avian encephalomyelitis.

The Committee adopted by consensus positive opinions for initial marketing authorisation applications for **Tulissin** (tulathromycin) from Virbac and for **Tulaven** (tulathromycin) from Ceva Santé Animale, both new generic products for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep.

The Committee adopted by consensus a positive opinion for a type II variation application for **Clynav** to extend the duration of immunity from 3 to 12 months. The Committee adopted by consensus a positive opinion for a type II variation application (subject to a worksharing procedure) for **Porcilis PCV M Hyo** to modify the product information to include associated use combinations for Porcilis PCV M Hyo, Porcilis Lawsonia and Porcilis PRRS.

The Committee adopted by consensus positive opinions for type II variation applications for **Evicto**, for **Imrestor** and for **Panacur AquaSol**, all concerning quality-related changes.

The Committee also adopted by consensus positive opinions for type IB variation applications (subject to worksharing procedures) concerning quality-related changes for **Bravecto**, **Bravecto Plus** and **Exzolt**, and for **Vaxxitek HVT+IBD** and other related nationally authorised products.

Renewals of marketing authorisations

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Canigen L4, Innovax ILT** and **Sileo**. 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 (ongoing monitoring and limited data), the Committee concluded that a further 5-year renewal was necessary for Canigen L4. Indefinite authorisations were recommended for Innovax ILT and Sileo.

Community referrals and related procedures

The Committee started a procedure for **Valbazen 100 mg/ml total spectrum wormer oral suspension, its associated names, and generic products (including hybrid generic products) thereof**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC. This referral concerns the appropriateness of the current withdrawal periods (milk, meat and offal) in cattle for the aforementioned veterinary medicinal products containing 100 mg albendazole per ml.

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for bupivacaine in pigs.

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

Scientific advice

The Committee adopted one scientific advice report further to a request for initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for horses.

Minor use, minor species (MUMS)/limited market

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

- An immunological product for sea bass and turbot as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as authorised alternative products already exist for the indication.
- A specific indication for three products (classified as antiparasitic, insecticide and repellent, respectively) for cats as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The products are not eligible for financial incentives as they are intended for use in non-food producing species.

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

Pharmacovigilance

The Committee reviewed the PSURs for **Arti-cell Forte**, **Forceris**, **Fortekor Plus**, **Imrestor**, **Incurin**, **Previcox** and **Suvaxyn PRRS MLV**, and concluded that no further action or changes to their product information were required.

Working parties

The Committee re-elected Elisabeth Begon as vice-chair of the Pharmacovigilance Working Party for a 3-year mandate.

Upcoming events

The Committee noted the preparation of the 3rd EMA International Awareness Session on science and regulation for animal health and welfare, public health and the environment to be held on 2-3 April 2020.

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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