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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 6-8 October 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Velactis** (*cabergoline*), from CEVA Santé Animale, a veterinary medicinal product for use in the herd management programme of dairy cows as an aid in the abrupt drying-off by reducing milk production to reduce milk leakage at drying off, the risk of new intramammary infections during the dry period and discomfort; and

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for **Imrestor** (*pegbovigrastim*), from Eli Lilly and Company Limited, a veterinary medicinal product for use in the herd management programme as an aid to reduce the risk of clinical mastitis in periparturient dairy cows and heifers during the 30 days following calving.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Inflacam** (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Limited, to add a new pharmaceutical form (granules in sachet) and a new strength (330 mg) for the existing target species horses.

The Committee adopted by consensus positive opinions for type II variation applications for **Hiprabovis IBR Marker Live** and **Vaxxitek HVT+IBD** regarding quality changes.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Ibraxion, Purevax RCPCh** and **Purevax RCPCh FeLV** regarding quality changes.

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

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Purevax Rabies**. The Committee, having re-assessed the benefit-risk balance of the product,

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concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community referrals and related procedures

The Committee started a procedure for **CattleMarker IBR Inactivated emulsion for injection for cattle** (*Infectious bovine rhinotracheitis (IBR) vaccine*). The matter was referred to the Committee by Belgium as the reference Member State in the mutual recognition procedure, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Germany relating to a potential serious risk to animal health.

The Committee concluded the procedure under Article 78 of Directive 2001/82/EC for **Closamectin Pour-On Solution and associated names** (*closantel and ivermectin*). The matter was referred to the Committee following the suspension of the marketing authorisation for CLOSAMECTIN POUR-ON SOLUTION POUR BOVINS in France further to the evaluation of pharmacovigilance data related to animal health concerns. The Committee adopted by consensus an opinion concluding that overall the benefit-risk balance for the products concerned by this procedure is positive subject to changes to the product information and conditions concerning risk mitigation and surveillance measures. Accordingly, the CVMP recommended variations of the marketing authorisations for the products concerned and also that the suspension of the marketing authorisation for CLOSAMECTIN POUR-ON SOLUTION POUR BOVINS in France be lifted.

Maximum Residue Limits

Further to a request from the European Commission under Article 27(2) of Regulation (EC) 470/2009, the Committee adopted by consensus an opinion recommending the extrapolation of the current MRLs for **gentamicin** to all mammalian food producing species and to fin fish.

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

MUMS/limited market

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

- An immunological veterinary medicinal product for mink as indicated for MUMS/limited market and eligible for reduced data requirements. As the product is indicated for a non-food producing species, it is not eligible for financial incentives.
- An immunological veterinary medicinal product for wild boar as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives.
- An analgesic veterinary medicinal product for dogs and horses as indicated for MUMS/limited market and eligible for reduced data requirements. As the product is indicated for non-food producing species, it is not eligible for financial incentives.
- An immunological veterinary medicinal product for cattle, sheep and goats as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives.
- An immunological veterinary medicinal product for chickens as indicated for MUMS/limited market and eligible for reduced data requirements. As an alternative product is already authorised for the same target species for the same indication, it is not eligible for financial incentives.

- An anti-parasitic veterinary medicinal product for bees as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Apoquel**, **Bovela**, **BTVPUR AlSap 2-4**, **Contacera**, **Equip WNV**, **Fevaxyn Pentofel**, **Meloxivet**, **MS-H vaccine**, **Oncept IL-2**, **Panacur AquaSol** and **Vectra Felis**, and concluded that no further action or changes to their product literature were required.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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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