EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 10-12 April 2017

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Prevomax** (*maropitant*), from Le Vet Beheer B.V., a generic anti-emetic product for the treatment and/or prevention of nausea and emesis in dogs and cats.

The Committee adopted a positive opinion for a type II variation application to add a new therapeutic indication for **Activyl Tick Plus**. The Committee also adopted by consensus a positive opinion for a grouped type II variation application for **Suvaxyn Circo+MH RTU** regarding a change to the duration of immunity, as well as a quality change.

The Committee also adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure), regarding quality changes, for **ZULVAC 1+8 Bovis**, **ZULVAC 8 Ovis, ZULVAC 8 Bovis**, **ZULVAC 1+8 Ovis**, **ZULVAC 1 Ovis**, **ZULVAC SBV** and **ZULVAC 1 Bovis**.

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 a positive opinion for the renewal of the marketing authorisation for **Cardalis**. The Committee, having re-assessed the benefit-risk balance of the product, 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 concluded the referral procedure for **Denagard 45% and its associated names** (*tiamulin hydrogen fumarate*) from Elanco Animal Health (Novartis Animal Health Inc.). The matter was referred to the Committee by Germany, under Article 34 of Directive 2001/82/EC, due to divergent decisions taken by Member States resulting in discrepancies in the product information. The Committee agreed to harmonised product information for the concerned products, and adopted by

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consensus 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 inclusion of **alarelin** in table 1 of Annex to Regulation (EU) No 37/2010 with a "No MRL required" classification for rabbits. Furthermore, and with reference to Article 5 of Regulation (EC) No 479/2009, the Committee agreed to extrapolate the recommendation for rabbits to all food producing species.

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

Scientific advice

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

- Initial advice on efficacy issues for an antimicrobial product for pigs; and
- Follow up advice on quality, safety and efficacy issues for a diagnostic product for pigs.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of the request for classification under the MUMS/limited market policy, the CVMP classified an immunological product in sheep as indicated for MUMS/limited market and eligible for reduced data requirements. No financial incentives will apply as authorised products already exist in the EU for the indications.

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin, Broadline**, **BTVPUR AlSap 2-4**, **Contacera**, **Draxxin**, **Equip WNV**, **Improvac**, **NexGard, Oncept IL-2**, **Panacur AquaSol**, **Parvoduk**, **Porcilis ColiClos**, **Porcilis PCV M Hyo**, **Purevax FeLV**, **Suvaxyn Circo+Mh RTU**, **Vectra Felis**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R** and **Zycortal**, and concluded that no further action or changes to their product information were required. In addition, with regard to **NexGard** the Committee requested a targeted PSUR on all neurological adverse events.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a reflection paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013) following the close of a second public consultation. The reflection paper addresses the current views on issues in relation to anthelmintic resistance. The comments received during the consultation procedure and at a focus group meeting have been taken into account for the revision of the reflection paper.

The reflection paper, together with the overview of comments (EMA/CVMP/EWP/526298/2016), will be published on the Agency's website.

The Committee adopted a draft revised guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.3) for a 6-month period of public consultation. The current guideline has been revised to align CVMP requirements with the new VICH GL52 on Bioequivalence: blood level bioequivalence study, and specifies requirements for the design, conduct,

and evaluation of bioequivalence studies for pharmaceutical forms with systemic action. In addition, guidance is given on how *in vitro* data in specific cases may be used to allow bridging of safety and efficacy data.

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

Immunologicals

The Committee adopted a revised guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/IWP/123243/2006-Rev.3) following the close of the public consultation. The revised guideline describes the data requirements regarding immunological veterinary medicinal products classified as MUMS/limited market.

The guideline, together with the overview of comments (EMA/CVMP/IWP/506137/2016), will be published on the Agency's website.

Pharmacovigilance

The Committee adopted updated questions and answers on the following pharmacovigilance topic:

- Serious non-fatal adverse events and reporting rules

The Question and Answer document 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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