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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 17-19 January 2017

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **RESPIPORC FLU3** regarding quality changes.

The Committee adopted by consensus positive opinions for type IB variation applications (subject to a worksharing procedure), regarding quality changes, for:

ZULVAC 8 Bovis, **ZULVAC 1+8 Ovis**, **ZULVAC 1 Ovis**, **ZULVAC 1+8 Bovis**, **ZULVAC 8 Ovis** and **ZULVAC 1 Bovis**; and

Clomicalm, **OSURNIA**, **ZOLVIX**, **Econor**, **FORTEKOR PLUS**, **Onsior** and **Prac-Tic**.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Nobivac L4** and **Porcilis ColiClos**. 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.

Community referrals and related procedures

The Committee noted four requests from marketing authorisation holders for re-examination of the CVMP opinion adopted on 8 December 2016 in the context of a referral procedure under Article 35 of Directive 2001/82/EC for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species**. The procedure will be initiated once the marketing authorisation holders' detailed grounds for the re-examination are submitted.

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Minor use, minor species (MUMS)/limited market

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

- Classified a veterinary medicinal product (cardiovascular system) for cats as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species;
- Classified a veterinary medicinal product (immunological) for sea bass as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives;
- Classified a veterinary medicinal product (immunological) for sea bass as indicated for MUMS/limited market and eligible for reduced data requirements and financial incentives;
- Classified a veterinary medicinal product (immunological) for horses as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in horses;
- Reclassified a veterinary medicinal product (cardiovascular system) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species;
- Reclassified a veterinary medicinal product (cardiovascular system) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in a non-food producing species.

Pharmacovigilance

The Committee reviewed the PSURs for **Activyl**, **Bovilis BTV8**, **Clomicalm**, **Neocolipor**, **Nobilis IB 4-91**, **Nobilis IB Primo QX**, **Novaquin**, **Pexion**, **Semintra**, **STARTVAC, Vectormune ND**, **Versican Plus DHPPi, Versican Plus DHPPi L4** and **Versican Plus Pi L4**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Bravecto**, **Broadline** and **Osurnia** and recommended amendments to their product literature. In addition, with regard to **Bravecto** the Committee requested a targeted PSUR on all serious adverse event reports.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a concept paper on the need for revision of the note for guidance on quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/BWP/428135/2016) for a 3-month period of public consultation. The concept paper was developed to address the need to update and revise the note for guidance to reflect imminent changes in the European Pharmacopoeia monograph (0169) for water for injections which will allow the use of non-distillation technologies for its production.

The Committee adopted a correction to the reflection paper on the requirements for selection and justification of starting materials for the manufacture of chemical active substances (EMA/CHMP/CVMP/QWP/826771/2016). The correction aims to harmonise the wording of one paragraph with the wording of the relevant paragraph of the CHMP and CVMP guidelines on the chemistry of active substances.

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

Efficacy

The Committee adopted a revised guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMA/CVMP/344/1999-Rev.2), following comments received during a second public consultation. The guideline provides guidance on the conduct of efficacy studies and their evaluation for veterinary medicinal products that are administered via the teat canal to cattle. The scope of the guideline was extended in order to include recommendations on pre-clinical data, and a new section has been added providing information for generic intramammary product applications. In addition, a new annex on biowaivers has been included.

The revised guideline together with the overview of comments (EMA/CVMP/EWP/444475/2016) will be published on the Agency's website.

Working Parties

The Committee elected Cristina Muñoz Madero as chair of the CVMP Efficacy Working Party for a three-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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