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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 22-24 January 2019

CVMP initiates review of withdrawal periods of certain tylosin injectable products used in pigs

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a type II variation application (subject to a worksharing procedure) for **Purevax RC**, **Purevax RCP**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV** and **Purevax RCPCh** concerning quality changes.

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Fungitraxx**, **Versican Plus DHPPi** and **Versican Plus Pi**. 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, the Committee concluded that a further 5-year renewal is required for Versican Plus DHPPi and Versican Plus Pi. An indefinite authorisation was recommended for Fungitraxx.

Community referrals and related procedures

The Committee started a procedure for **veterinary medicinal products containing tylosin base presented as solutions for injection for intramuscular use in pigs.** The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC. This referral procedure concerns the appropriateness of the current withdrawal period in pigs for the aforementioned veterinary medicinal products containing tylosin base as a single active substance.

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Maximum residue limits

The Committee agreed to include **polyacrylamide hydrogel** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of substances that act by purely physical mechanisms, and adopted a revised list (EMA/CVMP/519714/2009-Rev.39).

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

Minor use, minor species (MUMS)/limited market

Following the Committee's review of 5 requests for classification under the MUMS/limited market policy, the CVMP classified:

- 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 alternative products for the same indication are currently authorised in the EU.
- A veterinary medicinal product (nervous system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as according to the MUMS policy, products for horses are generally not eligible for fee incentives.
- 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 alternative products for the same indication are currently authorised in the EU.
- 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 alternative products for the same indication are currently authorised in the EU.
- A veterinary medicinal product (antiparasitic products, insecticides and repellents) for rainbow trout as indicated for MUMS/market not limited and therefore eligible for partially reduced data requirements, where applicable. The product is not eligible for financial incentives as alternative products for the same indication are currently authorised in the EU.

Pharmacovigilance

The Committee reviewed the PSURs for **Bovela, CERTIFECT**, **Innovax ND IBD**, **Prac-Tic**, **Sedadex**, **Stronghold Plus**, **Suvaxyn Circo**, **Suvaxyn PRRS MLV**, and **ZULVAC SBV** and concluded that no further action and no amendments to their product information were required.

The Committee also reviewed the PSUR for **NEXGARD SPECTRA** and recommended amendments to the product information.

Antimicrobial resistance

In the context of the European Commission request for an update of the previous scientific advice on the impact on public health and animal health of the use of antibiotics in animals (EMA/381884/2014), the Committee adopted a revised draft scientific advice on the categorisation of antimicrobials (EMA/CVMP/CHMP/682198/2017). The advice is also foreseen to be adopted by CHMP at their January 2019 meeting and then released for public consultation until 30 April 2019. The purpose of the revision

is to take into account the experience gained since the initial publication of the categorisation of antimicrobials in 2014.

Working parties

The Committee adopted the revised mandate, objectives and rules of procedure for the joint CHMP/CVMP Quality Working Party (EMA/CHMP/CVMP/QWP/65702/2016–Rev.1) following its adoption by CHMP in December 2018.

The Committee also adopted the revised mandate, objectives and rules of procedure for the Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009-Rev.6).

The revised documents 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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