EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 08-10 November 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Coliprotec F4/F18**, from Prevtec Microbia GmbH, a vaccine for the active immunisation of pigs against enterotoxigenic F4-positive and F18-positive *E. coli*.

The Committee adopted by consensus positive opinions for type II variation applications for **COXEVAC** and **Metacam** regarding quality changes. The Committee also adopted a positive opinion for a type II variation application to add a new therapeutic indication for **Trifexis**.

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

Cortavance and **Easotic**;

Purevax RCPCh FeLV, **Purevax RCP**, **Purevax RC**, **Purevax RCP FeLV** and **Purevax RCPCh**; and

Versican Plus DHPPi, Versican Plus DHPPi/L4 and **Versican Plus DHPPi/L4R**.

More information about the above mentioned medicines, including their full indication, will be published on the Agency's website.

Community referrals and related procedures

The Committee concluded the referral procedure for **veterinary medicinal products containing gentamicin presented as solutions for injection for cattle and pigs**. The matter was referred to the Committee by Belgium under Article 35 of Directive 2001/82/EC due to concerns related to the withdrawal periods set for the aforementioned products. The Committee agreed that the withdrawal periods for cattle (meat and milk) and pigs should be amended to provide assurance for consumer safety and also agreed that the subcutaneous route should no longer be recommended for cattle and pigs since the depletion kinetics from the injection site remain unknown. The Committee adopted by majority an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the product information accordingly.

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Minor use, minor species (MUMS)/limited market

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

- An immunological veterinary product 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;
- An antiparasitic veterinary medicinal product for use in honey bees as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as an alternative product for the same indication is available in the EU; and
- Reclassified a veterinary medicinal product with a cardiovascular indication 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.

Pharmacovigilance

The Committee reviewed the PSURs for **Bovela**, **Inflacam**, **Poulvac E. coli**, **Prac-tic**, **Sileo**, **Vectra 3D**, **Vectra Felis** and **Versican Plus DHPPi/L4R**, and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Metacam, Novem** and **Porcilis PCV** and recommended amendments to their product literature.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a draft guideline on the chemistry of active substances (EMA/CVMP/QWP/637000/2016) for a 6-month period of public consultation. The guideline aims to replace the 'Note for guidance on chemistry of new active substances' (EMEA/CVMP/541/03/Final) and 'Chemistry of active substances' (3AQ5a), to cover new and existing active substances in one document.

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

The Committee adopted the revised guideline on process validation for finished products - information and data to be provided in regulatory submissions (EMA/CHMP/CVMP/QWP/70278/2012-Rev.1.1). The revision updates the definition for on-line measurement included in the glossary, which is considered a minor change and consequently no consultation phase is foreseen.

The revised guideline will be published on the Agency's website after adoption by the CHMP which is foreseen for their meeting to be held on 7-10 November 2016.

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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