20 May 2016
EMA/CVMP/317201/2016
Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 17-19 May 2016

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a negative opinion for an extension of the existing authorisation for **DRAXXIN** (*tulathromycin*), from Zoetis Belgium SA, concerning the addition of a new food producing target species (sheep).

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

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 **Recocam**. 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 started a procedure for **all veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC due to concerns related to the withdrawal periods in cattle (meat and offal) set for the aforementioned products.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

The Committee concluded the referral procedure for **veterinary medicinal products containing altrenogest to be administered orally to pigs and horses**. The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC due to concerns related to a potential serious risk to the environment from the use of the products. The Committee adopted by consensus an opinion concluding that the use of veterinary medicinal products containing altrenogest in mares is not considered to pose a risk to the environment given the minimal environmental exposure associated with the use in individual animals and when used as specified in the product information. With regard to the use of veterinary medicinal products containing altrenogest in gilts, the Committee concluded that a risk for fish and other aquatic organisms cannot be excluded for certain geographical areas. The Committee further concluded that these products are essential in modern pig production and there is no alternative available at present in the EU for oestrus synchronisation of gilts; therefore in order to address the risk to the environment, risk mitigation measures should be included in the product information to lower the risk and to make the user aware that altrenogest may be hazardous for fish and other aquatic organisms. The Committee concluded that the overall benefit-risk balance for the concerned products for pigs is positive and recommended variations to the terms of the marketing authorisations in order to amend the product information accordingly.

The Committee concluded a procedure for **veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry**. The matter was referred to the Committee by Belgium under Article 35 of Directive 2001/82/EC, to review indications and dosing regimen due to concerns related to antimicrobial resistance, and the withdrawal periods of the aforementioned products. The Committee adopted by majority an opinion concluding that the overall benefit-risk balance for premixes for medicated feeding stuff and powders to be administered with the feed containing a combination of lincomycin and spectinomycin is negative, as the use of these products at the recommended dosing regimens entails a higher risk of resistance selection and development due to exposure to low antimicrobial levels for prolonged periods. The Committee further concluded that the overall benefit-risk balance for powders for use in drinking water containing a combination of lincomycin and spectinomycin is positive and agreed harmonised indications, dosing regimens and warning sentences on prudent use. No amendments to the currently approved withdrawal periods for pigs and chicken for the aforementioned powders for use in drinking water were considered necessary. The CVMP recommended the withdrawal of the marketing authorisations for premixes for medicated feeding stuff and powders to be administered with the feed containing a combination of lincomycin and spectinomycin, and that the marketing authorisations for powders for use in drinking water containing a combination of lincomycin and spectinomycin should be varied in order to amend the product information accordingly.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the extension of MRLs for **monepantel** to bovine species.

More information about the above recommendations 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 safety and efficacy issues for a veterinary medicinal product with an anti-infectious indication for dogs; and
- Initial advice on quality issues for a veterinary medicinal product with a gastrointestinal indication for sheep.

Minor use, minor species (MUMS)/limited market

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

- Renewed the classification of the vaccine Coxevac as indicated for MUMS/limited market and confirmed that it remains eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Cerenia**, **Contacera**, **Nobilis OR inac**, **Porcilis PCV ID**, **Trifexis**, **Vectra 3D**, **Vectra Felis**, **Veraflox**, **Versican Plus Pi**, **Versican Plus Pi/L4R**, **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis**, and concluded that no further action or changes to their product literature were required.

Antimicrobial resistance

The CVMP adopted the updated advice on the use of colistin in animals prepared by the Antimicrobial Advice ad hoc Expert Group (AMEG). The initial advice was adopted in 2013 and the request from the European Commission for the update of the advice followed the discovery the gene *mcr-1* and the need to take into account the new information available. The updated advice will be submitted to the CHMP for adoption at their May meeting (scheduled for 23-26 May 2016) and subsequent release for a one week consultation period (anticipated to be 25 May 2016 – 2 June 2016). A press release will be published to raise awareness of the publication for consultation of the advice.

Concept papers, guidelines and SOPs

Environmental Risk Assessment

The Committee adopted a draft guideline on the plant testing strategy for veterinary medicinal products (EMA/CVMP/ERA/689041/2015) for a 6-month period of public consultation. The guideline was developed to provide guidance on the extent of plant species required for testing of veterinary pharmaceuticals.

Pharmacovigilance

The Committee adopted a draft reflection paper on non-spontaneous adverse event reports (EMA/CVMP/PhVWP/357539/2015) for a 3-month period of public consultation. The reflection paper outlines aspects of handling of adverse events reported in peer-reviewed literature and other non-spontaneous sources e.g. on the internet.

The 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

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu