EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 8-10 December 2015

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an extension of the existing marketing authorisation for **Zactran** (*gamithromycin*), from Mérial, concerning the addition of a new food-producing species (pigs) for the treatment of swine respiratory disease (SRD).

The Committee adopted by majority a negative opinion for an extension application for **Bravecto** (*fluralaner*), from Intervet International B. V., concerning the addition of a new pharmaceutical form (spot-on solution) for dogs and a new target species (cats) for this pharmaceutical form.

The Committee adopted by consensus positive opinions for type II variation applications for **Porcilis PCV M Hyo** and **Versican Plus DHPPi/L4, Versican Plus DHPPi/L4R, Versican Plus Pi/L4R, Versican Plus DHPPi, Versican Plus Pi, Versican Plus Pi/L4** (subject to a worksharing procedure) 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 **BLUEVAC BTV8**. 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. The authorisation was originally granted under exceptional circumstances and since the specific obligations for BLUEVAC BTV8 are now fulfilled the Committee also recommended the conversion to a standard marketing authorisation for this product.

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Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **copper carbonate** in all food producing animals.

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **eprinomectin** in ovine and caprine species, further to the establishment of provisional maximum residue limits. Furthermore, the Committee agreed to extrapolate these maximum residue limits to all ruminants species.

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

The Committee agreed to include **N-(2-deoxy-2-L-leucylamino-ß-D-glucopyranosyl)-N-octadecyl-dodecanoylamide hydroacetate** 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 excipients and adopted a revised list (EMA/CVMP/519714/2009-Rev.32). This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

The Committee adopted two separate scientific advice reports concerning:

- Initial advice related to quality and safety for a new veterinary medicinal product for use in a musculoskeletal condition in dogs; and
- Initial advice on MRL issues for a new hormonal veterinary medicinal product for rabbits.

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 medicinal product for poultry. The CVMP considered that the product was not indicated for MUMS/limited market and was not therefore eligible for financial incentives.
- An immunological veterinary medicinal product for horses as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives in line with the Guidance on the classification of veterinary medicinal products indicated for MUMS/limited market (EMA/CVMP/388694/2014) and due to the existence of currently authorised alternative products in the EU.
- A hormonal veterinary medicinal product for rabbits as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives due to the existence of a currently authorised alternative product in the EU.

Pharmacovigilance

The Committee reviewed the PSURs for **Cimalgex**, **ECOPORC SHIGA**, **NEXGARD SPECTRA**, **ProZinc**, **Reconcile**, **Rheumocam**, **Suvaxyn PCV** and **Versican Plus L4** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Advocate** and **Vectra 3D** and recommended amendments to their product information.

Concept papers, guidelines and SOPs

Immunologicals

The Committee adopted a new concept paper on guidance on statistical principles for clinical trials for veterinary immunological medicinal products (EMA/CVMP/IWP/309514/2015) for a three-month period of public consultation. The concept paper was developed to address the need to provide guidance on the approach to statistical principles and interpretation of data from the small scale safety and efficacy studies commonly conducted for immunological veterinary medicinal products.

Quality

The Committee adopted a new Question and Answer on the use of powders and granules in medicinal products composed of 100% active substance.

Pharmacovigilance

The Committee adopted revised Questions and Answers on adverse event reporting.

Antimicrobial resistance

Following the recent discovery of a gene (called mcr-1) in China that can be transferred between different types of bacteria, causing them to become resistant to the antibiotic colistin, the Committee agreed on the need to update the 2013 advice on the substance. As the original advice was produced following a request from the European Commission, the Agency is now seeking a formal mandate to undertake this work from the Commission. The Committee also requested to re-convene the Antimicrobial Advice Ad Hoc Expert Group (AMEG), who prepared the 2013 advice.

General

The Committee adopted a new guideline on the principles for preparing assessment reports for veterinary medicinal products (EMA/CVMP/450781/2015). The guideline applies for pharmaceutical and immunological veterinary medicines and provides general guidance to assessors preparing assessment reports regarding procedures for veterinary medicinal products to facilitate consistency and coherence in the assessment of dossiers in the European Union independent of the application procedure.

The Committee adopted a Question and Answer document on solvents in the centralised procedure for a three-month period of public consultation.

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

Working Parties

The Committee re-elected Helen Jukes as chair of the CVMP Antimicrobials Working Party and Baukje Schat as vice-chair for the CVMP Pharmacovigilance Working Party for a further three-year mandate.

The Committee reviewed and adopted revised mandates for the CVMP Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009), Antimicrobials Working Party (EMA/CVMP/AWP/749774/2012), Immunologicals Working Party (EMA/CVMP/IWP/208689/2004) and the Joint CHMP/CVMP Quality Working Party (EMA/CHMP/CVMP/QWP/80473/2014) for another period of three years.

Organisational matters

The Committee re-appointed Keith Baptiste as a co-opted member for a further three-year mandate to complement its expertise in antimicrobials and antimicrobial resistance.

The Committee appointed Jason Weeks as a co-opted member for a three-year mandate to complement its expertise in environmental risk assessment.

Notes

1. 'MUMS' stands for minor use minor species.
2. 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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