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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 4-6 November 2015

CVMP opinions on veterinary medicinal products

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

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

Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Activyl**, **CaniLeish**, **Cimalgex**, **Comfortis**, **Melosus**, **Procox**, **Veraflox** and **ZULVAC 1+8 Ovis**. 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 started a procedure for **all veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses**. The matter was referred to the Committee by Germany, under Article 35 of Directive 2001/82/EC, due to concerns that moxidectin may have persistent bioaccumulative and toxic (PBT) properties and consequently a potential serious risk to the environment may arise from the use of products containing the substance.

The Committee concluded the referral procedure for **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys** (amoxicillin) from Eurovet Animal Health B.V. The matter was referred to the Committee by the United Kingdom as the reference Member State in the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns raised by Denmark related to the demonstration of bioequivalence of the product with the reference product and also advice on prudent use in the product information. The Committee adopted by majority an opinion concluding that the objections raised by Denmark during the decentralised procedure should not

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prevent the granting of a marketing authorisation subject to changes in the product information concerning additional information on solubility and advice on prudent use.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending a 2-year extension to the provisional maximum residue limit status for **rafoxanide** in bovine and ovine milk in order to allow for the completion of the ongoing work for the validation of the analytical method for monitoring of residues in milk.

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

The Committee agreed to include **di-n-butyl-adipate**, **didodecyl 3,3'-sulfanediyldipropanoate**, **dolomite, erucamide, pentaerythrityl tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]**, **poly(ethylene-vinyl acetate)**, **polypropylene and styrene-butadiene block copolymer** as new entries 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.31). This decision followed the Committee's review of requests submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

The Committee adopted seven separate scientific advice reports concerning:

- Initial advice related to safety and efficacy for a respiratory veterinary medicinal product for horses;
- Initial advice related to safety and efficacy for an anti-parasitic veterinary medicinal product for dogs;
- Initial advice on MUMS data requirements related to quality, safety and efficacy for an immunological product for foxes and raccoon dogs;
- Initial advice on whether an excipient can be considered as not falling within the scope of Regulation (EC) No 470/2000;
- Initial advice related to quality for an anti-parasitic veterinary medicinal product for bees;
- Initial advice related to quality for an immunostimulant veterinary medicinal product for dogs, cattle and pigs; and
- Initial advice related to safety for an analgesic veterinary medicinal product for cats.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam**, **Broadline**, **Cerenia**, **Certifect**, **ERYSENG**, **ERYSENG PARVO**, **Hiprabovis IBR Marker Live**, **Inflacam**, **Porcilis Porcoli Diluvac Forte**, **Practic**, **RevitaCAM**, **Trifexis**, **Versican Plus DHPPi**, **Versican Plus Pi**, **Versican Plus Pi/L4**, **Versican Plus Pi/L4R**, **ZULVAC 8 BOVIS** and **ZULVAV 8 OVIS** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Pharmacovigilance

The Committee adopted a concept paper on revision of the recommendation for the basic surveillance of data contained in EudraVigilance Veterinary (EMA/CVMP/PhVWP/590073/2015) for a 3-month period of public consultation. The concept paper describes and discusses the need to revise the CVMP recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data (EMA/CVMP/PhVWP/471721/2006) for centrally authorised products (CAPs) taking into account the recent adoption of the recommendation on pharmacovigilance surveillance and providing a comprehensive and streamlined surveillance process involving periodic safety update report (PSUR) assessment and signal detection within the framework of the current legislation.

Antimicrobial resistance

The Committee adopted the CVMP Strategy on Antimicrobials 2016-2020 (EMA/CVMP/209189/2015) for release for a 3-month period of public consultation. This strategy is the fourth CVMP document on its strategy for antimicrobials. The CVMP strategy seeks to promote the continued availability of effective antimicrobials for use in animals whilst at the same time acting to minimise risks to animals or humans arising from their use and sets out intentions for direct action by the Committee during the next 5 years. To celebrate the World Antibiotic Awareness Week, the Strategy on Antimicrobials will be published in the week of 16-22 November 2015.

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

Working Parties

The Committee reviewed and adopted the revised mandate for the CVMP Efficacy Working Party (EMA/CVMP/208686/2004-Rev.3) for another period of 3 years, including changes concerning the expertise required for the group to better reflect the work anticipated for the forthcoming years.

The Committee endorsed the work plans for 2016 for the CVMP Working Parties on Scientific Advice, Safety, Environmental Risk Assessment, Efficacy, Immunologicals, Antimicrobials and Pharmacovigilance as well as for the Joint CHMP/CVMP Quality Working Party and the ad hoc veterinary expert group on novel therapies (ADVENT).

The work plans will be published on the Agency's website.

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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