EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 17-19 July 2018

CVMP adopts draft revised guidance on assessment of the risk to public health from resistance due to use of antimicrobials in food-producing animals

CVMP opinions on veterinary medicinal products

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

The Committee adopted also by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Inflacam** and **Rheumocam** concerning quality changes.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Broadline**. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the indefinite renewal of the marketing authorisation.

Community referrals and related procedures

The Committee concluded a procedure concerning the risk to the consumer and the need for a maximum residue limit (MRL) evaluation for **diethanolamine**, an excipient included in a number of veterinary medicinal products for food producing animals. The procedure responds to a request from Belgium for the Committee to give a scientific opinion under Article 30 of Regulation (EC) No. 726/2004 due to concerns over the toxicity of diethanolamine. The Committee adopted by consensus an opinion responding to specific questions raised by Belgium and concluded that, on the basis of the

[1]The press release has been updated on 8 August to include document reference numbers for VICH GL56 and GL58, and to correct the reference number for the draft reflection paper on dose optimisation of established veterinary antibiotics in the context of summary of product characteristics (SPC) harmonisation.

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information available, it is not possible to rule out a risk for consumers of food produced from animals treated with veterinary medicinal products containing diethanolamine, thus confirming that the substance is not appropriate for inclusion in the list of substances considered as not falling within the scope of Regulation 470/2009 (the 'out of scope' list). In order to allow further consideration of the consumer safety associated with the use of diethanolamine in veterinary medicinal products for food producing animals, an application for the establishment of MRLs would be needed.

The opinion and assessment report will be published on the Agency's website.

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits, in accordance with Regulation (EC) No 470/2009, for **ovotransferrin** in chicken tissues and eggs. Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in chicken tissues to tissues of other poultry species.

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

Scientific advice

The Committee adopted five scientific advice reports further to requests for:

- initial advice on quality and safety issues for an immunological veterinary medicinal product for red foxes and racoon dogs;
- initial advice on quality and safety issues for an immunological veterinary medicinal product for calves;
- initial advice on efficacy issues for an anti-inflammatory and analgesic veterinary medicinal product for dogs;
- initial advice on quality, safety and efficacy issues for an anti-parasitic veterinary medicinal product for dogs;
- initial advice on safety and efficacy issues for a pharmaceutical veterinary medicinal product for alimentary track disorders in dogs.

Minor use, minor species (MUMS) / limited market

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

- A product (musculo-skeletal system) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as it is intended for use in non-food producing species.
- A product (antiparasitic products, insecticides and repellents) for cats as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as it is intended for use in non-food producing species.
- A product (musculo-skeletal system) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply, as according to the MUMS policy, products for horses are generally not eligible for fee incentives.

- A product (antiparasitic products, insecticides and repellents) for fish as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable, and confirmed that it is eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Canigen L4/Nobivac L4**, **Coliprotec F4/F18**, **Equilis Te**, **Imrestor**, **Purevax RCP**, **Purevax RCPCh**, **Sedadex**, **Stronghold Plus**, **Suvaxyn PRRS MLV, UpCard**, **Ypozane** and **ZACTRAN**, and concluded that no further action or changes to their product information were required.

The Committee also reviewed the PSURs for **ERYSENG** and **ERYSENG PARVO** and recommended amendments to their product information.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a draft guideline on the quality of water for pharmaceutical use (EMA/CHMP/CVMP/QWP/383481/2018) for a 6-month period of public consultation. The guideline replaces the Note for guidance on quality of water for pharmaceutical use (CPMP/QWP/158/01, EMEA/CVMP/115/01) and the CPMP Position statement on the quality of water used in the production of vaccines for parenteral use (EMEA/CPMP/BWP/1571/02-Rev.1). The new draft guideline reflects a number of changes made to European Pharmacopoeia monographs on quality of water.

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

The Committee adopted a Question and Answer on the control of content of active substance in a veterinary medicinal product where there can be batch to batch variability in the potency of the active substance.

The Question and Answer will be published on the Agency's website.

Efficacy

The Committee adopted a draft guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector-borne diseases in dogs and cats (EMA/CVMP/EWP/278031/2015) for a 12-month period of public consultation. The guideline provides recommendations for the design and conduct of studies to support the efficacy of veterinary medicinal products intended for the prevention of transmission of vector-borne pathogens in dogs and cats, which can be transferred by blood-feeding arthropods, and outlines the requirements for laboratory and field studies.

Antimicrobial resistance

The Committee adopted a draft revised guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (EMA/CVMP/AWP/706442/2013) for release for a second period of public consultation for 3 months. This guideline provides advice in regards to applications for marketing authorisations for antimicrobial veterinary medicinal products on the data required and the methodology to be used for performing an assessment of the risk to public health from antimicrobial resistance due to use of the product.

The guideline together with the overview of comments from the first public consultation (EMA/CVMP/AWP/598285/2015) will be published on the Agency's website.

The Committee adopted a draft reflection paper on dose optimisation of established veterinary antibiotics in the context of summary of product characteristics (SPC) harmonisation (EMA/CVMP/849775/2017) for a 6-month period of public consultation. The reflection paper follows consideration of the report from a pilot project aimed at developing and testing non-experimental approaches for dose optimisation and evaluating the consequences for withdrawal periods, target animal safety and environmental risk assessment. The overall objective of the project is to develop practical methodologies that can be used for dose optimisation and harmonisation of SPCs of old veterinary antibiotics.

International harmonisation

The Committee adopted the following VICH guidelines following sign-off by the VICH Steering Committee:

- VICH GL56 on Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods (EMA/CVMP/VICH/176637/2014), for implementation in the EU, at step 7 of the VICH process;
- VICH GL58 on Stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV (EMA/CVMP/VICH/335918/2016), for a 5-month consultation period.

The guidelines 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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