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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 6-8 November 2018

CVMP recommends two new veterinary medicines, incl. one new vaccine

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Isemid** (torasemide), from CEVA Santé Animale, a new cardiovascular product intended for treatment of clinical signs related to congestive heart failure in dogs, including pulmonary oedema.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Syvazul BTV**, from LABORATORIOS SYVA, S.A.U., a vaccine for the active immunisation of sheep to prevent viraemia and reduce clinical signs and lesions caused by bluetongue virus serotypes 1 and/or 8, and/or to reduce viraemia and clinical signs caused by bluetongue virus serotype 4; and of cattle to prevent viraemia caused by bluetongue virus serotypes 1 and/or 8 and/or to reduce viraemia caused by bluetongue virus serotype 4.

The Committee adopted by consensus a positive opinion for a type II variation application for **AFTOVAXPUR DOE** concerning a change to the onset of immunity in cattle and sheep.

More information about the above mentioned medicines, including their full indications, 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 **Loxicom** and **Parvoduk**. 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 renewals of the marketing authorisations. Based on pharmacovigilance grounds (limited data) the Committee concluded that a further 5-year renewal was necessary for Parvoduk. An indefinite authorisation was recommended for Loxicom.

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Community referrals and related procedures

The Committee concluded a procedure concerning the need for inclusion of a maximum limit for histamine in the active substance and/or finished product specifications for **veterinary medicinal products containing gentamicin for parenteral administration to horses**. The procedure responds to a request from the European Medicines Agency Executive Director for the Committee to give a scientific opinion under Article 30(3) of Regulation 726/2004 in connection with adverse reactions seen in horses following use of gentamicin solution for injection. The adverse reactions were considered to be linked to histamine residues present in the active substance. The Committee adopted by consensus an opinion concluding that, where relevant, a maximum limit for histamine should be included in the specification for the active substance gentamicin. In addition, the Committee has made recommendations to the European Directorate for the Quality of Medicines (EDQM), active substance manufacturers and marketing authorisation holders.

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

Scientific advice

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

- Initial advice on quality, safety and efficacy issues for a new immunological veterinary medicinal product for dogs;
- Initial advice on safety and efficacy issues for a new immunological veterinary medicinal product for chickens.

Minor use, minor species (MUMS)/limited market

Following the Committee's review of a request for classification under the MUMS/limited market policy, the CVMP classified an indication in a veterinary medicinal product (antiparasitics, insecticides and repellents) 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 non-food producing species.

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP reclassified an immunological product for foxes and raccoon dogs as intended for a MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **Acticam**, **EQUIOXX**, **Fevaxyn Pentofel**, **Halagon**, **Rabitec**, **Trifexis**, **Velactis**, **Versican Plus DHPPI L4 and Versican Plus DHPPi L4R** and concluded that no changes to their product information or other regulatory action were required.

The Committee also reviewed the PSURs for **MiPet Easecto, Simparica** and **Zycortal** and recommended amendments to the product information.

Concept papers, guidelines and SOPs

Quality

The Committee adopted a draft reflection paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) for public consultation until 31 August 2019. This new reflection paper has been developed to address the requirements to control elemental impurities in veterinary medicinal products, as a result of updates in the European Pharmacopoeia General Monograph 2619 for pharmaceutical preparations. The Committee also adopted revised timelines for the implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017).

Both the draft reflection paper and the timelines for implementation document will be published on the Agency's website.

The Committee adopted the revised guideline on active substance master file procedure (EMEA/CVMP/134/02 Rev 4). The update is intended to clarify the responsibilities of the applicant/marketing authorisation holder in the provision of information related to active substances.

The revised guideline will be published on the Agency's website.

The Committee adopted a question and answer on requirements for selection and justification of starting materials for the manufacture of chemical active substances in veterinary medicinal products.

The question and answer will be published on the Agency's website.

Environmental Risk Assessment

The Committee adopted a draft reflection paper (EMA/CVMP/ERA/632109/2014) on antimicrobial resistance in the environment for a 9-month period of public consultation. This draft reflection paper has examined key sources and pathways relevant to the release of antimicrobials in the environment from the use of antimicrobial veterinary medicinal products, including the potential transport of antimicrobial resistance genes. The paper considers the suitability of the current environmental risk assessment for characterising the potential risks posed by antimicrobial resistance genes, and concludes in a series of recommendations to improve the understanding of the impact to animal and human health of antimicrobials in the environment resulting from the use of veterinary medicinal products.

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

Antimicrobials

The Committee adopted a reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union (EMA/CVMP/AWP/237294/2017). The reflection paper aims to explore the potential risks related to antimicrobial resistance (AMR) associated with the use of antimicrobial in veterinary medicine which does not comply with the approved summary of product characteristics.

The reflection paper together with the overview of comments (EMA/CVMP/EWP/30098/2018) 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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