



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 3-5 December 2019

CVMP adopts an updated advice on the categorisation of antibiotics in the European Union, and recommendations on the use of live attenuated PRRSV vaccines

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Onsior** to add a new therapeutic indication for the treatment of pain and inflammation associated with soft tissue surgery in dogs and to amend the product information due to new clinical data. The Committee also adopted by consensus a positive opinion for a grouped type II variation application for **Eravac** to extend the duration of immunity from 9 to 12 months. The Committee also adopted by consensus positive opinions for grouped type II variation applications for **Apoquel**, **Circovac** and **Zactran** concerning quality-related changes.

The Committee adopted by consensus a positive opinion for a type II variation application for **Nobilis IB 4-91** to include the claim for associated non-mixed use with Innovax-ND-IBD and to update the product information. The Committee also adopted by consensus positive opinions for type II variation applications for **Zulvac SBV** and for **Innovax ILT**, both concerning quality-related changes.

The Committee adopted by consensus positive opinions for type II variation applications (subject to worksharing procedures) for **Simparica** and **MiPet Easecto**, and for **Bravecto** and **Bravecto Plus**, both concerning quality-related changes.

The Committee adopted by consensus a negative final opinion for a type II variation application for **Velactis**, further to the re-examination of the opinion adopted during the Committee meeting in September 2019. In August 2016, the marketing authorisation for Velactis was suspended by the European Commission (C(2016)5480 (final)) because of target animal safety concerns. This variation was submitted with the intention to fulfil the conditions for the lifting of the suspension. However, the CVMP concluded that the overall benefit-risk balance remains negative and recommended that the suspension of the marketing authorisation of Velactis is maintained.



More information about the above-mentioned medicines, including their full indication, will be published on the Agency's website.

Community referrals and related procedures

The Committee concluded the referral procedure for **Ketabel 100 mg/ml solution for injection and associated names** (ketamine) from Bela-Pharm GmbH & Co. KG. The matter was referred to the Committee by France as the reference Member State in the decentralised procedure, under Article 33 (4) of Directive 2001/82/EC, due to concerns raised by Germany regarding the appropriateness of the withdrawal period when this veterinary medicinal product is administered via the intramuscular route to cattle, pigs, sheep and goats. The Committee adopted by consensus an opinion concluding that the objections raised by Germany during the decentralised procedure should not prevent the granting of a marketing authorisation.

The Committee concluded the referral procedure for **veterinary medicinal products containing tylosin base (as single active substance) presented as solutions for injection for intramuscular use in pigs**. The matter was referred to the Committee by France under Article 35 of Directive 2001/82/EC due to concerns relating to the appropriateness of the withdrawal periods in pigs. The Committee agreed that the maximum injection volume per site and the withdrawal periods for pig meat and offal should be amended to provide assurance for consumer safety. The Committee adopted by majority an opinion concluding that the marketing authorisations for the concerned products should be varied in order to amend the product information accordingly.

Maximum residue limits

The Committee agreed to include bovine casein hydrolysate in a list of biological substances considered as not requiring an MRL evaluation in accordance with Regulation (EU) No. 2018/782 and adopted this list (EMA/CVMP/572629/2009).

The document, following consultation with the EC, will be published on the Agency's website.

Scientific advice

The Committee adopted three separate scientific advice reports further to requests for:

- Initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for musculoskeletal disorder indications in dogs;
- Initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for musculoskeletal disorder indications in dogs;
- Initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for musculoskeletal disorder indications in horses.

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 classified a product (antineoplastic and immunomodulating agents) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives as it is intended for use in non-food producing species.

Pharmacovigilance

The Committee reviewed the PSURs for **Coliprotec F4/F18, NexGard Spectra, Rheumocam, UBAC, Versican Plus DHPPi, Versican Plus DHPPi L4R, Versican Plus L4, Versican Plus Pi, Versican Plus Pi L4** and **Versican Plus Pi L4R**, and concluded that no further action was required.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted the update of the scientific advice on the categorisation of antibiotics in the European Union prepared by the Antimicrobial Advice ad hoc Expert Group (AMEG) following the close of the public consultation. The initial scientific advice was adopted in 2014 and the request from the European Commission for the updated categorisation followed the need to take account of new information available and to refine the criteria applied. The comments received during the consultation procedure have been considered for the revision of the scientific advice and were also adopted for publication by the Committee.

Both documents, the revised advice and the comments received during consultation, will be published on the Agency's website after their adoption by CHMP which is foreseen for the December meeting of the CHMP on 9-12 December 2019.

International harmonisation

The Committee adopted the guideline VICH GL58 on stability testing of new veterinary drug substances and medicinal products in Climatic Zones III and IV for implementation at step 7 following the sign-off by the VICH Steering Committee

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

Organisational matters

The Committee adopted the CVMP work plan for 2020, which highlights the priority areas for the Committee in the coming year.

The CVMP work plan for 2020 will be published on the Agency's website.

CVMP recommendation on the use of live attenuated PRRSV vaccines

The CVMP is aware of a recombination event between two live attenuated Porcine Reproductive and Respiratory Syndrome virus (PRRSV) type 1 vaccine strains leading to a recombinant strain that has been associated with clinical signs of disease in PRRS-naïve herds in Denmark.

Recombination between strains of PRRS virus, including live type 1 PRRSV vaccine strains, is a known phenomenon that has been reported in the scientific literature. Therefore, recombinations of PRRSV strains similar to the one observed in Denmark may occur elsewhere at any time.

The CVMP makes the following recommendations concerning the use of live attenuated PRRSV vaccines:

- In order to limit the potential risk of recombination between vaccine strains, the simultaneous or consecutive use of different live attenuated PRRSV vaccines should be avoided as much as possible while continuing to protect animal health.
- Increased monitoring of any suspected adverse event relating to clinical signs of PRRS, including the occurrence of relevant clinical signs of the disease in vaccinated herds, is recommended. Any suspected adverse event should be reported to the national competent authority for veterinary medicines or the marketing authorisation holder. Clinical signs of PRRS include reduced fertility, increased rate of abortions, reduced appetite, increased piglet mortality and respiratory distress.
- It should be noted that sequence data indicating recombination between vaccine strains or between vaccine strains and wild types should be regarded as relevant pharmacovigilance data and therefore should be reported.

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 officers

Tel. +31 (0)88 781 8427

E-mail: press@ema.europa.eu

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