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 16-18 July 2019

CVMP concludes referral procedure and recommends suspension of veterinary medicines containing paromomycin to be administered parenterally to pigs

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Simparica Trio** (*sarolaner, moxidectin and pyrantel*), from Zoetis Belgium SA, a new antiparasitic product for dogs for the treatment of flea and tick infestations, gastrointestinal roundworm and hookworm infections and for the prevention of heartworm disease and angiostrongylosis.

The Committee adopted by consensus positive opinions for type II variation applications to add new therapeutic indications for **NexGard**, **Nexgard Spectra** and **Broadline**. The Committee also adopted by consensus a positive opinion for a grouped type II variation application for **MS-H Vaccine** concerning quality changes.

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

Renewals of marketing authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Porcilis PCV M Hyo**. 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.

Community referrals and related procedures

The Committee started a procedure for **Ketamine 100 mg/ml solution for injection** from Bela-Pharm GmbH & Co. KH. 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 started a procedure for **Adjusol and its associated names (sulfadiazine and trimethoprim)** from Virbac. The matter was referred to the Committee by the European Commission, under Article 34 of Directive 2001/82/EC due to divergent decisions taken by Member States resulting in differences in the product information.

The Committee concluded the referral procedure for **veterinary medicinal products containing paromomycin to be administered parenterally to pigs**. The matter was referred to the Committee by Belgium under Article 35 of Directive 2001/82/EC due to concerns related to the appropriateness of the indications, posology and withdrawal periods. The Committee adopted, by consensus, an opinion concluding that the benefit-risk balance for the concerned veterinary medicinal products is negative as there were inadequate data to support efficacy of these products for the proposed indications at the recommended treatment dose and that this deficiency poses a risk of ineffective treatment and antimicrobial resistance development. The CVMP recommended the suspension of the marketing authorisations for the concerned veterinary medicinal products.

Maximum residue limits

The Committee agreed to modify the entry for DEAE-dextran in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 and adopted a revised list (EMA/CVMP/519714/2009-Rev.40).

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

Scientific advice

The Committee adopted 2 separate scientific advice reports further to requests for:

- initial advice on efficacy issues for a new veterinary medicinal product acting on the reproductive system in pigs;
- initial advice on quality, safety and efficacy issues for a new veterinary medicinal product for a general indication for 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 (Nervous system) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The product is not eligible for financial incentives in line with the Guidance on the classification of veterinary medicinal products indicated for minor use minor species MUMS/ limited market (EMA/CVMP/388694/2014).

Following the Committee's review of three requests for reclassification under the MUMS/limited market policy, the CVMP:

- Reclassified two products for horses (Respiratory system and Musculo-skeletal system) as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. The products are not eligible for financial incentives in line with the Guidance on the classification of veterinary medicinal products indicated for minor use minor species MUMS/ limited market (EMA/CVMP/388694/2014).

- Did not reclassify a product for cattle (Immunomodulating Agents) as indicated for MUMS/limited market.

Pharmacovigilance

The Committee reviewed the PSURs for **Broadline**, **Credelio** and **Suprelorin**, and recommended amendments to the product information.

The Committee also reviewed the PSURs for **Cepedex**, **Coliprotec F4/F18**, **Dexdomitor**, **Emdocam**, **Innovax ND IBD**, **Melosus**, **Nobilis Influenza H5N2**, **Porcilis PCV ID**, **Proteq West Nile**, **Sedadex**, **Semintra**, **Stronghold Plus**, **Suvaxyn Circo**, **Suvaxyn PRRS MLV**, **UpCard** and **Vepured**, and concluded that no further action or changes to their product information were required.

Working parties

The Committee elected Sylvie Louet as vice-chair of the Scientific Advice Working Party for a 3-year mandate.

Regulatory

Further to the request of the European Commission the Committee adopted three scientific advices in relation to implementing and delegated acts to Regulation 2019/6 concerning:

- The list of variations not requiring assessment;
- Revision of Annex II of the Regulation;
- Collection of data for antimicrobials used in animals.

The documents will be sent to the European Commission and published on the Agency's website in due course.

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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