EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2019
EMA/CVMP/535058/2019
Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 8-10 October 2019

CVMP recommends two new veterinary medicines for companion animals

CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Neptra**, from Bayer Animal Health GmbH, a new product for the treatment of canine otitis externa caused by susceptible strains of bacteria sensitive to florfenicol and fungi sensitive to terbinafine.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Miratаz**, from Aniserve GmbH, a new product for bodyweight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions.

The Committee adopted by consensus positive opinions for type II variation applications for **Exzolt** and for **Suvaxyn Circo and Suvaxyn Circo+MH RTU** (subject to a worksharing procedure), both concerning quality changes.

The Committee also adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Meloxidolor, Novaquin, Sedadex** and **Prevomax**, concerning a new pharmacovigilance system.

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

Community referrals and related procedures

The Committee started a procedure for **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof** (azaperone). The matter was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC. This referral procedure concerns the appropriateness of the current withdrawal periods (meat and offal) in pigs for the aforementioned veterinary medicinal products.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending that the current maximum residue limits for **dicyclanil** in sheep remain unchanged.

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

The Committee agreed to include **ethoxylated nonylphenol** with an average of 9–10 ethylene oxide moieties and **ethoxylated octylphenol** with an average of 7–9 ethylene oxide moieties 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. 41). This decision followed the Committee's review of two requests that were submitted in accordance with the relevant CVMP guidance.

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

Scientific advice

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

- initial advice on efficacy issues for an antimicrobial veterinary medicinal product for pigs;
- initial advice on quality issues for an immunological veterinary medicinal product for horses.

Minor use, minor species (MUMS)/limited market

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

- A product (ATCvet therapeutic category QV: Various) 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;
- A product (ATCvet blood and blood forming organs) for horses 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/limited market (EMA/CVMP/388694/2014) which indicates products for horses as generally not eligible;
- An immunological product for horses 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 / limited market (EMA/CVMP/388694/2014) which indicates products for horses as generally not eligible.

Following the Committee's review of a request for reclassification under the MUMS/limited market policy, the CVMP reclassified an immunological product 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 **Easotic**, **EQUIP WNV**, **Halocur**, **MS-H vaccine**, **Naxcel**, **Nobivac Myxo RHD**, **Porcilis PCV M Hyo** and **Zeleris**, and concluded that no further action or changes to their product information were required.

A petition by concerned citizens regarding the safety of **Bravecto** was presented to the CVMP, which considered it along with a video and list of questions that were received with the petition. A response to the questions posed will be drafted for adoption at an upcoming meeting of the Committee.

Concept papers, guidelines and SOPs

Antimicrobials

The Committee adopted a CVMP draft reflection paper on 'Promoting the authorisation of alternatives to antimicrobials in the EU' (EMA/CVMP/461776/2017) for release for a 6-month period of public consultation. This reflection paper has been developed to identify additional measures that could be taken to promote the authorisation of alternatives to antimicrobials in the EU.

Regulatory

Further to a request of the European Commission, the Committee adopted one report in relation to implementing and delegated acts to Regulation 2019/6 concerning the criteria to designate antimicrobials for human use.

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

Procedural Announcement

Validation checklists for initial marketing authorisation applications for veterinary pharmaceutical and immunological products will be updated within the next few days on the EMA website. These checklists are used by the Agency to validate initial marketing authorisation applications for pharmaceuticals and immunologicals and applicants should use them as a means to review in advance of their submission that standard requirements are fulfilled.

MAHs are encouraged to avoid submitting Type I variations shortly before or during the Agency holiday periods (e.g. Christmas). This is in line with the information published in the Agency's post-authorisation Q&A's for type IA and type IB procedures.

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
Follow us on Twitter @EMA_News