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

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Press release 11/10/2019

**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](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/marketing-authorisation-application) for **Mirataz**, from Aniserve GmbH, a new product for bodyweight gain in [cats](https://www.ema.europa.eu/en/glossary/cat) experiencing poor appetite and weight loss resulting from chronic medical conditions.

The Committee adopted by consensus positive opinions for [type II variation](https://www.ema.europa.eu/en/glossary/type-ii-variation) applications for**Exzolt** and for **Suvaxyn Circo and Suvaxyn Circo+MH RTU**(subject to a [worksharing](https://www.ema.europa.eu/en/glossary/worksharing" \t "_blank" \o "The submission of a single application for a variation that affects more than one marketing authorisation from the same marketing authorisation holder.   More information can be found under 'Worksharing -  questions and answers'.) procedure), both concerning quality changes.

The Committee also adopted by consensus a positive opinion for a [type IB variation](https://www.ema.europa.eu/en/glossary/type-ib-variation) application (subject to a [worksharing](https://www.ema.europa.eu/en/glossary/worksharing" \t "_blank" \o "The submission of a single application for a variation that affects more than one marketing authorisation from the same marketing authorisation holder.   More information can be found under 'Worksharing -  questions and answers'.) procedure) for **Meloxidolor, Novaquin,** **Sedadex** and **Prevomax**, concerning a new [pharmacovigilance](https://www.ema.europa.eu/en/glossary/pharmacovigilance) system.

More information about the above-mentioned medicines, including their full [indications](https://www.ema.europa.eu/en/glossary/indication), 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](https://www.ema.europa.eu/en/glossary/referral) procedure concerns the appropriateness of the current [withdrawal periods](https://www.ema.europa.eu/en/glossary/withdrawal-period) (meat and offal) in pigs for the aforementioned veterinary [medicinal products](https://www.ema.europa.eu/en/glossary/medicinal-product).

**Maximum residue limits**

The Committee adopted by consensus a positive opinion recommending that the current [maximum residue limits](https://www.ema.europa.eu/en/glossary/maximum-residue-limit) 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](https://www.ema.europa.eu/en/glossary/excipient) and adopted a revised list (EMA/[CVMP](https://www.ema.europa.eu/en/glossary/cvmp)/519714/2009-Rev. 41). This decision followed the Committee’s review of two requests that were submitted in accordance with the relevant [CVMP](https://www.ema.europa.eu/en/glossary/cvmp) guidance.

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

**Scientific advice**

The Committee adopted two separate [scientific advice](https://www.ema.europa.eu/en/glossary/scientific-advice) reports further to requests for:

* initial advice on [efficacy](https://www.ema.europa.eu/en/glossary/efficacy) issues for an antimicrobial veterinary [medicinal product](https://www.ema.europa.eu/en/glossary/medicinal-product) for pigs;
* initial advice on quality issues for an immunological veterinary [medicinal product](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/medicinal-product) indicated for minor use minor species/limited market (EMA/[CVMP](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/medicinal-product) indicated for minor use minor species / limited market (EMA/[CVMP](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/product-information) were required.

A petition by concerned citizens regarding the safety of **Bravecto** was presented to the [CVMP](https://www.ema.europa.eu/en/glossary/cvmp), which considered it along with a video and [list of questions](https://www.ema.europa.eu/en/glossary/list-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](https://www.ema.europa.eu/en/glossary/cvmp) draft [reflection paper](https://www.ema.europa.eu/en/glossary/reflection-paper) on ‘Promoting the authorisation of alternatives to antimicrobials in the EU’ (EMA/[CVMP](https://www.ema.europa.eu/en/glossary/cvmp)/461776/2017) for release for a 6-month period of public consultation. This [reflection paper](https://www.ema.europa.eu/en/glossary/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](https://www.ema.europa.eu/en/glossary/marketing-authorisation-application) for veterinary pharmaceutical and immunological products will be updated within the next few days on the [EMA website](https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/application-guidance). These checklists are used by the Agency to validate initial [marketing authorisation applications](https://www.ema.europa.eu/en/glossary/marketing-authorisation-application) 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](https://www.ema.europa.eu/en/glossary/variation) 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](https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/variations/type-ia-variations-questions-answers) and [type IB](https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/variations/type-ib-variations-questions-answers) procedures.