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Media and Public Relations

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 13-15 March 2018

CVMP recommends modification of the MRL for diflubenzuron in *Salmonidae*

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Bravecto Plus** (*fluralaner/moxidectin*), from Intervet International B.V., a new combination product for the treatment of tick and flea infestations and nematodes in cats.

The Committee adopted by consensus a positive opinion for an extension of the existing authorisation for **Semintra** (*telmisartan*) oral solution, from Boehringer Ingelheim Vetmedica GmbH, concerning the addition of a new strength (10 mg/ml), and a new indication for the treatment of systemic hypertension in cats.

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

The Committee adopted by majority a positive opinion for a type II variation application for **Activyl Tick Plus** to change conditions regarding supply and use from prescription-only to non-prescription.

The Committee adopted by consensus a positive opinion for a type II variation application, subject to a worksharing procedure, for **Naxcel** (and related nationally-authorised products) regarding changes in the Active Substance Master File (ASMF).

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Onsior** to add a new therapeutic indication and to implement significant changes in the product information due to new preclinical data on the interchangeable use of tablets and solution for injection, interaction with other substances and accidental intravenous use.

The Committee adopted by consensus a positive opinion for a grouped type II variation application for **Zolvix** regarding quality changes.

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

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Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Meloxidolor**. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the indefinite renewal of the marketing authorisation.

Community referrals and related procedures

The Committee started a procedure under Article 30(3) of Regulation (EC) No 726/2004, to prepare a scientific opinion for diethanolamine, used as an excipient in some veterinary medicinal products. The matter was referred to the Committee by Belgium following the removal of diethanolamine from the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009. The Committee will consider the potential risk to the consumer resulting from the use of diethanolamine in veterinary medicinal products for food-producing species and whether its use as an excipient should be subject to a maximum residue limit evaluation. In the context of this procedure the CVMP invites all interested parties such as the pharmaceutical industry, learned societies, governmental institutions and European Union and European Economic Area-European Free Trade Association Member States to respond to a public consultation and to submit any relevant scientific data, which may be used in preparation of the scientific opinion.

More information about the call for data will be published on the Agency's website.

Maximum residue limits

The Committee adopted by consensus a positive opinion recommending the extension of maximum residue limits for **isoflurane** to porcine species.

Further to a request from the European Commission under Article 11 of Regulation (EC) No 470/2009 for the review of the MRL for **diflubenzuron** due to concerns relating to the genotoxic potential of the metabolite 4-chloroaniline, the Committee adopted by consensus an opinion recommending the modification of the current entry in table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 for diflubenzuron in *Salmonidae*.

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

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 veterinary medicinal product (antineoplastic and immunomodulating agent) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as it is intended for use in non-food producing species (dogs).
- Classified a veterinary medicinal product (immunological) for turkeys as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable. No financial incentives will apply as an authorised product exists in the EU for the indication.
- Did not classify a veterinary medicinal product (immunological) for dogs as indicated for MUMS/limited market and therefore the product is also not eligible for financial incentives.

Pharmacovigilance

The Committee reviewed the PSURs for **CYTOPOINT, Evalon, LETIFEND, NexGard, Rabigen SAG2** and **Vectormune ND**, and concluded that no further action or changes to their product information were required.

The Committee reviewed the PSUR for **Bravecto**, and recommended amendments to the product information of Bravecto spot on solution.

The Committee adopted the **public bulletin on veterinary pharmacovigilance for 2017** summarising the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMA/697615/2017). Annual public bulletins on veterinary pharmacovigilance are published by the Agency with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2017.

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

Procedural clarification

Clarification regarding eligibility requests for fixed combinations of known active substances

The Agency would like to raise applicants' awareness regarding eligibility criteria for access to the centralised procedure for fixed combination veterinary medicinal products containing known active substances.

To date, new fixed combinations of known active substances were, for the purpose of reviewing eligibility to the centralised procedure, considered the same as new active substances and therefore eligible to the centralised procedure under the optional scope, Article 3(2)a of Regulation (EC) No 726/2004.

From the date of the publication of this press release, for new eligibility requests where the product falls outside the **mandatory scope** criterion (Article 3(1) of Regulation (EC) No 726/2004), applicants are asked to justify their request for access to the centralised procedure for fixed combinations of known active substances under the optional scope, Article 3(2)b of Regulation (EC) No 726/2004, under either significant therapeutic, technical, scientific innovation or in the interest of animal health at Community level. The pre-submission guidance has been updated accordingly.

Procedural announcement

Stepwise implementation towards mandatory use of the Common Repository for veterinary submissions

The use of the Common Repository by National Competent Authorities (NCAs) to retrieve veterinary submissions will be mandatory from **1st June 2018**. Until this time, a **transition period** is ongoing, whereby the use of the Common Repository is being implemented in a stepwise approach, with the following 2 possible options, as indicated in the Dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency and to members of the Committee for Medicinal Products for Veterinary use (CVMP) (EMA/466102/2007):

Option 1) For **NCAs ready to receive submissions via the Common Repository only** as indicated with “Yes” in the column “Access to Common repository **from 19 March 2018**”, the following process is applicable:

- the applicant sends their dossier via the EMA Gateway;
- the submitted dossier is made available in the Common Repository;
- for CVMP members, no further submissions via any other channels is necessary, as they will retrieve the dossier via the Common Repository.

Option 2) For **NCAs NOT yet ready to receive submissions via the Common Repository** as indicated with “No” in the column “Access to Common repository **from 19 March 2018**”, the following process is applicable:

- the applicant sends their dossier via the EMA Gateway;
- the submitted dossier is made available in the Common Repository;
- for CVMP members, **additional submission** via the recommended channel stated in the column “Submission Portal” is necessary, as they will NOT yet retrieve any submission via the Common Repository. Applicants are encouraged to submit applications via CESP as a first option. Where CESP is not accepted as a submission channel, Eudralink should be used or CD/DVD. Use of multiple submission channels to the same authority (e.g. CESP **and** Eudralink or CESP **and** CD/DVD) is not allowed.

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

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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