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Press Office

**Press release**

# Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 04-06 October 2016

## CVMP opinions on veterinary medicinal products

The Committee adopted by consensus positive opinions for initial marketing authorisation applications for:

**HALAGON** (*halofuginone*), from Emdoka BVBA, a generic antiparasitic product for the reduction and prevention of diarrhoea due to infection with *Cryptosporidiium parvum* in newborn calves; and

**Cepedex** (*dexmedetomidine*), from CP-Pharma Handelsgesellschaft mbH, a generic psycholeptic product for sedation and analgesia in dogs and cats.

The Committee adopted by majority a positive opinion for the initial marketing authorisation application for **VarroMed** (*oxalic acid dihydrate/formic acid*), from BeeVital GmbH, an antiparasitic product for in-hive use for the treatment of varroosis in honey bees.

The Committee adopted by consensus a positive opinion for a type IB variation application (subject to a worksharing procedure) for **Virbagen Omega** and **CaniLeish** regarding quality changes.

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

## Renewals of marketing authorisation

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Activyl Tick Plus** and **ZULVAC 1 + 8 Bovis**. The Committee, having re-assessed the benefit-risk balance of these products, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

## Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits for **fluralaner** in chicken tissues and eggs. Furthermore, and with reference to Article 5

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of Regulation (EC) No 470/2009, the Committee agreed to extrapolate the maximum residue limits recommended in chicken tissues and eggs to tissues and eggs of other poultry species.

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

## Scientific advice

The Committee adopted a scientific advice report further to a request for an initial advice on efficacy, quality, safety and MRL issues for an immunomodulating veterinary medicinal product for dairy cows.

## Minor use, minor species (MUMS) / limited market

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

- Classified a veterinary medicinal product with a musculoskeletal system indication for use in guinea pigs as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in non-food producing species (guinea pigs); and
- Reclassified a veterinary medicinal product with an oncology indication for dogs as indicated for MUMS/limited market and eligible for reduced data requirements. The product is not eligible for financial incentives as it is intended for use in non-food producing species (dogs).

## Pharmacovigilance

The Committee reviewed the PSURs for **Advocate**, **APOQUEL**, **BLUEVAC BTV8**, **Comfortis**, **EQUIP WNV**, **MS-H Vaccine**, **Naxcel**, **Porcilis PCV M Hyo**, **RevitaCam, Simparica**, **Suvaxyn Circo MH RTU and Zycortal** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSURs for **Certifect** and **Porcilis PCV M Hyo** and recommended amendments to their product literature.

## Concept papers, guidelines and SOPs

### Quality

The Committee adopted Questions and Answers on the deletion of a non-significant specification parameter.

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

## Working Parties

The Committee adopted the revised CVMP strategy on antimicrobials for the period 2016-2020 (EMA/CVMP/209189/2015). The CVMP vision on antimicrobials aims to ensure the availability of effective antimicrobial medicines for the treatment of infectious diseases of animals while, at the same time, minimising the risks to animals or humans arising from their use. The strategy intends to strengthen the benefit-risk assessment for antimicrobial veterinary medicinal products in a One Health context.

The document together with the overview of comments (EMA/CVMP/185871/2016) will be published on the Agency's website.

## Organisational matters

The Committee re-appointed the following two co-opted members for a further 3-year mandate to complement its expertise:

- Rory Breathnach as a veterinarian with specific expertise in large and small animal clinical practice.
- Wilhelm Schlumbohm as an expert with specific expertise in the quality of veterinary medicinal products.

The Committee appointed Gerrit Johan Schefferlie as a co-opted member with specific expertise in residue metabolism, pharmacokinetics and MRL assessment for a 3-year mandate.

The Committee elected Frida Hasslung Wikström as vice-chair of the Scientific Advice working party (SAWP-V) for a 3-year mandate.

## Procedural announcement

### Reminder of mandatory use of eSubmission Gateway for veterinary submissions as of 1 January 2017

The European Medicines Agency (the Agency) reminds its stakeholders that as of 1 January 2017 the EMA eSubmission Gateway will become the mandatory submission channel for all veterinary submissions to the Agency.

On 1 April 2014 the Agency extended the use of the eSubmission Gateway and the Web Client to all veterinary medicines submissions including veterinary referrals. For veterinary procedures, submissions on physical media (CD/DVD) or by Eudralink have continued to be accepted as an alternative method of use to the Gateway as an interim measure, although applicants have been encouraged to register to use the eSubmission Gateway or the free web-based Web Client solution as soon as possible.

As of 1 January 2017, use of these alternative channels will no longer be accepted for veterinary procedural submissions to the Agency, including:

- Initial marketing authorisation (MA) and extension applications;
- Applications for variations to the MA, renewals, transfers, annual reassessments, post-authorisation measures and other post-authorisation applications;
- Veterinary referrals assessed by the CVMP;
- Maximum Residue Limits applications;
- Submissions of new or updated Active Substance Master Files (ASMF) in relation to veterinary centrally authorised products; and
- Submission of Pharmacovigilance Safety Update Reports (PSURs) for veterinary centrally authorised products

Between January and March 2017 the Agency will operate a flexible approach for submissions of PSURs for cases where successful registration with Gateway is not possible for reasons outside applicants'

control. The Agency will also maintain a flexible approach in case submission via Gateway/Web Client is not possible due to unexpected technical failures of the system.

Applicants who have not done so already are reminded to complete the necessary registration process (see “Related information”).

For the time being applicants will be able to provide their submissions using either the previous filenaming convention method or the new XML delivery file technology. The filenaming convention will be phased out for veterinary submissions at a later date, which will be communicated in the future.

Tutorials and guidance materials for veterinary applicants on how to register with Gateway / Web Client solution as well as concerning the use of the system are available on the Veterinary eSubmission Website: http://esubmission.ema.europa.eu/tiges/vetesub.htm

***Related information***

- Procedural announcement - Mandatory use of Gateway for veterinary submissions as of 1 January 2017
- Statement of intent for use of xml delivery files for submissions via Gateway / Web Client
- Use of eSubmission Gateway / Web Client extended to new procedure types from 1st of April 2014
- eSubmission Gateway and Web Client information website
- Veterinary eSubmission Website
- eSubmission Registration
- eSubmission Gateway and Web Client online registration guidance
- eSubmission Web Client

## 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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