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Press Office

**Press release**

# Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 11-13 December 2012

## CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for:

**Semintra** (*telmisartan*), from Boehringer Ingelheim Vetmedica GmbH, for chronic kidney disease in cats.

The Committee adopted by majority a positive opinion for an initial marketing authorisation application for:

**Pexion** (*imepitoin*), from Boehringer Ingelheim Vetmedica GmbH, for the control of epilepsy in dogs.

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

The Committee adopted by consensus positive opinions for type II variation applications for:

**Prac-tic** concerning the change from prescription only to non-prescription status for the indications for tick and flea infestations.

**Purevax RC, Purevac RCP and Purevax RCPCh** concerning the addition of a manufacturing site,

**Panacur AquaSol** concerning the addition of a new therapeutic indication for treatment and control of gastro-intestinal nematodes in pigs,

**Profender** (tablets for dogs) amending the indication for the treatment of *Trichuris vulpis* in dogs to include L4 larvae, and removing the advice against using the product during pregnancy and lactation,

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**Profender** (spot-on solution for cats) concerning the revision of some precautions, and improvement of the dosage table in the SPC and product information,

**Previcox and Equioxx** concerning quality changes,

**Porcilis PCV** concerning the addition of a new manufacturing site.

## Annual reassessment of marketing authorisations

The Committee adopted an opinion on the annual reassessments for **BTVPUR AlSap 2-4**, **Zulvac 1 Bovis** and **Zulvac 1 Ovis**, further to the evaluation of the data submitted by the marketing authorisation holders. The Committee recommended the continuation of the Community marketing authorisation under exceptional circumstances for **BTVPUR AlSap 2-4.** Since the specific obligations for **Zulvac 1 Bovis** and **Zulvac 1 Ovis** have been fulfilled the Committee recommended the conversion of the Community marketing authorisations from under exceptional circumstances to a normal status for these two products.

## Scientific advice

The Committee responded to four separate scientific advice requests concerning quality, safety and efficacy requirements for a product against mastitis in cattle; safety and efficacy requirements for an antiparasitic product for cats; safety and efficacy requirements for an immunological product for dogs and safety requirements for a cardiovascular product for dogs.

## MUMS / Limited markets

Following the Committee's review of two requests for classification under the MUMS/Limited markets policy, which concerned an antidote product for dogs and a product with musculoskeletal indication for horses; the CVMP considered that both products were indicated for MUMS/Limited markets and were eligible for reduced financial incentives as no alternatives are authorised for the same target species for the same indication.

## Pharmacovigilance

The Committee reviewed the PSURs for **BTVPUR AlSap 1-8**, **Circovac**, **EQUIOXX and Previcox oral paste for horses**, **Melosus**, **Porcilis Porcoli**, **RESPIPORC FLU3**, **Rheumocam**, **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis** and concluded that no further action or changes to their product literature were required.

The Committee also reviewed the PSUR for **CERTIFECT** and recommended amendments to the product information to add new adverse reactions.

# Concept papers, guidelines and SOPs

**Antimicrobials**

The Committee adopted a draft reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/SAGAM/119489/2012-CONSULTATION) for a 6-month period of public consultation. This reflection paper has been developed to summarise current knowledge on resistance development and the potential impact of this resistance on animal and human health as detailed in a previous concept paper on the topic (EMA/CVMP/SAGAM/435644/2011).

The Committee noted a draft reflection paper from the Agency project for European Surveillance of Veterinary Antimicrobial Consumption on collecting data on consumption of antimicrobial agents per animal species, on technical units of measurement and indicators for reporting consumption of antimicrobial agents in animals (EMA/286416/2012-CONSULTATION). This reflection paper has been developed to discuss how to establish systems for the collection of reliable and standardised data on consumption of antimicrobial agents by animal species for the ESVAC database and to report the data taking into account the differences in dosing between the various antimicrobial agents as well as the animal population at risk for treatment. The document will be released for a 3-month period of public consultation.

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

# Working Parties

The Committee elected Baukje Schat as vice-chair of the Pharmacovigilance Working Party for a 3-year mandate.

The Committee reviewed and adopted the mandate, objectives and rules of procedure for the CVMP Environmental Risk Assessment Working Party (EMA/CVMP/ERA/705470/2009-Rev.1) for a period of 3 years.

The Committee reviewed and adopted the mandate, objectives and rules of procedure for a new CVMP Antimicrobials Working Party (EMA/CVMP/749774/2012), which will progress the work carried out by the former CVMP Scientific Advisory Group on Antimicrobials (SAGAM). This Working Party will, similar as previously SAGAM, provide advice to the Committee on all issues relating to antimicrobials, including matters related to guidelines, communication, recommendations, product evaluation, referral procedures, scientific and regulatory developments in the area of antimicrobials and in particular resistance development, cooperation within the European Union and on international level. The status change to a working party instead of a scientific advisory group was considered appropriate to bring the group in line with the Agency's policy on scientific advisory groups and to better reflect the role of the group.

The Committee endorsed the work plan for 2013 for the CVMP Antimicrobials Working Party (EMA/CVMP/758417/2012), including activities initiated by the former CVMP Scientific Advisory Group on Antimicrobials (SAGAM).

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

## Notes

1. ‘MUMS’ stands for minor use minor species.
2. 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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