10 December 2010
EMA/CVMP/760118/2010
Press Office

**Press release**

# Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 7-9 December 2010

## CVMP opinions on veterinary medicinal products

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Cimalgex** (cimicoxib), from Vétoquinol SA, for the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, in dogs.

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Comfortis** (spinosad), from Eli Lilly and Company Ltd, for the treatment and prevention of flea infestations (*Ctenocephalides felis*) in dogs.

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **ACTIVYL** (indoxacarb), from Intervet International BV, for the treatment and prevention of flea infestations (*Ctenocephalides felis*) in cats and dogs.

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Purevax Rabies** (vaccine containing the recombinant canarypox virus (vCP65) expressing the rabies glycoprotein G), from MERIAL, for the active immunisation of cats to prevent mortality due to rabies infection.

The Committee adopted by consensus a positive opinion for a marketing authorisation application for **Melosus** (meloxicam), from CP-Pharma Handelsgesellschaft mbH, for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs and the alleviation of inflammation and pain in chronic musculo-skeletal disorders in cats.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
**E-mail** press@ema.europa.eu **Website** www.ema.europa.eu

The Committee also adopted by consensus a positive opinion for a type II variation application for:

**Zulvac 8 Ovis** (inactivated blue tongue virus, serotype 8) **-** revision of sections 4.2 and 4.9 of the SPC in order to provide precise information on the duration of immunity.

The Committee also adopted by majority a positive opinion for a type II variation application for:

**ZOLVIX** (monepantel) – change of indication to include inhibited larvae of various parasites and change of SPC wording on interactions/ incompatibilities with other veterinary medicinal products;

The Committee also adopted by consensus a negative opinion for a type II variation application for:

**Masivet** (masitinib) – new indication: treatment of dogs with atopic dermatitis.

More information about the above mentioned veterinary medicines can be found on the Agency's website.

## Scientific advice

The Committee agreed scientific advice concerning the establishment of an MRL for horses as a follow-up request to advice previously given. The Committee also agreed scientific advice for review of dossier requirements in line with the MUMS guidelines for an immunological product for sheep and goats.

## MUMS / Limited markets

Following the Committee's review of a request for classification under the MUMS/limited markets policy, which concerned an antimicrobial product for rabbits, the CVMP considered that the product was indicated for MUMS but was not eligible for financial incentives as alternative authorised products already exist for the same indication in rabbits.

## Pharmacovigilance

The Committee reviewed the PSURs for **Clomicalm**, **Cortavance**, **Melovem**, **Neocolipor**, **Profender**, **Rheumocam**, **Startvac**, **Zactran**, **Zulvac 8 Bovis** and **Zulvac 8 Ovis** and concluded that no further action or changes to their product literature were required.

## Concept papers, guidelines and SOPs

### Safety

The Committee adopted a concept paper on revision of the note for guidance for the determination of withdrawal periods for milk (EMA/CVMP/SWP/736014/2010) for release for a 3-month period of public consultation. This concept paper proposes the revision of the note for guidance in order to better address the establishment of withdrawal periods for veterinary medicinal products administered to cows during the dry period.

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

### Quality

The Committee adopted a template for the Qualified Person's declaration concerning GMP compliance of the active substance used as a starting material, and verification of its supply chain for release for a 3-month period of public consultation. This "QP Declaration template" is intended for use for both

human and veterinary medicines applications. Further information is available in the “Questions and Answers” document which was also adopted and will also be available on the Agency’s website.

**Antimicrobials**

The Committee adopted the CVMP Strategy on Antimicrobials 2011-2015 (EMA/CVMP/287420/2010) for release for a 3-month period of public consultation. This strategy is the third CVMP document on its strategy for antimicrobials since 2005. The CVMP strategy seeks to promote the continued availability of effective antimicrobials for use in animals whilst at the same time acting to minimise risks to animals or man arising from their use and sets out intentions for direct action by the Committee during the next 5 years.

The document above will be available on the Agency’s website.

## CVMP Working Parties

The Committee elected chairpersons for working parties for which the 3-year mandate had been completed. The following chairs were elected:

Johan Schefferlie - Safety Working Party

Jean-Claude Rouby - Immunologicals Working Party

Joop de Knecht - Environmental Risk Assessment Working Party

Peter Ekström - Pharmacovigilance Working Party.

The Committee also reviewed and adopted the mandate for the CVMP Safety Working Party (EMA/CVMP/131613/2004-Rev.2) for another period of 3 years. The content of the mandate remains unchanged.

The document above will be available on the Agency’s website.

## Organisational matters

The Committee appointed Claire Chauvin, an expert in antimicrobials and antimicrobial resistance, as the fifth co-opted member to complement its expertise.

## International harmonisation

The Committee agreed that the public consultation of the draft VICH guideline GL34 on mycoplasma contamination (EMA/CVMP/VICH/463/02) be re-opened for release for a 3-month period of public consultation. Draft VICH GL34 was published for consultation first in 2002. Following a 12 months it was agreed to suspend the consultation to wait for the testing of reference strains. The consultation is now re-opened to allow submission to any further comments.

The document above will be available 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

## Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu