European Medicines Agency
*Veterinary Medicines and Inspections*

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# PRESS RELEASE

# COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

## Meeting of 16-18 June 2009

## CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Palladia** (*toceranib*), from Pfizer Ltd., intended for the treatment of non-resectable Patniak grade II (intermediate grade) or III (high grade), recurrent, cutaneous mast cell tumours in dogs**.**

*The summary opinion is available on the EMEA web site:*
*http://www.emea.europa.eu/htms/vet/opinion/opinion.htm*

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

**PRILACTONE** – additional information added to the Summary of Product Characteristics (SPC) concerning the reduction in the relative risk of mortality in treated dogs;

**Zactran –** addition of new packaging, updates to the product literature;

**Reconcile -** minor changes in the detailed description of the pharmacovigilance system.

## Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Aivlosin**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

## Annual Reassessment of Marketing Authorisations

The Committee adopted an opinion on the annual reassessment for **Nobilis Influenza H5N2**, further to the evaluation of the data submitted by Intervet. The Committee recommended the continuation of the Community Marketing Authorisation under exceptional circumstances for the veterinary medicinal product.

The Committee adopted an opinion on the annual reassessment for **Nobilis Influenza H5N6,** further to the evaluation of the data submitted by Intervet. The Committee recommended the continuation of the Community Marketing Authorisation under exceptional circumstances for the veterinary medicinal product.

The Committee adopted an opinion on the annual reassessment for **Nobilis Influenza H7N1,** further to the evaluation of the data submitted by Intervet. The Committee recommended the continuation of the Community Marketing Authorisation under exceptional circumstances for the veterinary medicinal product.

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## Community Referrals

The Committee noted the report on the outcome of the written procedure for the adoption of the re-examination opinion concerning the Article 35 referral procedure for injectable veterinary medicinal products containing **ivermectin** indicated for use in cattle at a dose rate of 200µg ivermectin/kg bodyweight.

The Committee on 5 June 2009 adopted by consensus the final opinion concluding that its opinion of 11 February 2009 should be revised and that a withdrawal period of 66 days should be established for all concerned injectable products for cattle containing ivermectin in combination with clorsulon as a second active ingredient. The Committee confirmed that a withdrawal period of 49 days should be established for all concerned injectable products for cattle containing ivermectin as a single active ingredient. The withdrawal period of 49 days for cattle also applies for all concerned injectable products containing ivermectin in combination with closantel as a second active ingredient. Therefore, the Committee recommended the variation of the existing marketing authorisations accordingly.

The Committee noted a request for re-examination of the CVMP opinion adopted during the May 2009 meeting concerning the Article 33 referral procedure for **Clavobay Lactating Cow**. The procedure will be initiated once the grounds for the re-examination are submitted.

## Scientific advice

The Committee agreed scientific advice regarding quality aspects of an immunological for poultry.

## Pharmacovigilance

The Committee reviewed the PSURs for **Cortavance**, **EQUIOXX**, **Porcilis Porcoli**, **Profender**, **Reconcile**, **Rheumocam**, **Suprelorin**, **Ypozane** and **Zactran** and concluded that no further action or changes to the product literatures were required.

## Concept Papers, Guidelines and SOPs

### General

The Committee adopted a revised "*Reflection paper on publication of withdrawals of Marketing Authorisation applications for veterinary medicinal products*" (EMEA/CVMP/425558/2006-Rev.1). Minor changes have been made to the reflection paper to provide clearer information and to introduce some editorial amendments.

*The document will be available on the EMEA web site:*
*http://www.emea.europa.eu/htms/vet/withdraw/background.htm*

### Pharmacovigilance

The Committee adopted the following standard lists used for electronic reporting of suspected adverse reactions following the yearly review and update*:*

- Combined VeDDRA List of Clinical Terms for Reporting Suspected Adverse Reactions in Animals and Humans (EMEA/CVMP/10418/2009-Rev.1);
- Revised List of Species and Breeds for Electronic Reporting of Suspected Adverse Reactions in Veterinary Pharmacovigilance (EMEA/CVMP/553/03-Rev.4).

The Committee also adopted the following list for implementation of the Combined VeDDRA List in EudraVigilance Veterinary:

- Deprecated Veddra Recoded Term List for Implementation of the Combined VeDDRA List (EMEA/CVMP/353015/2009)

These lists will be published on the EMEA website in due course. The implementation of these lists in EudraVigilance Veterinary is provisionally scheduled for 30 December 2009.

*The documents will be available on the EMEA web site:*
http://www.emea.europa.eu/htms/vet/phvwp/eudravigilance.htm

**Efficacy**

The Committee adopted a "*Concept paper on the revision of the guideline on statistical principles for veterinary clinical trials*" (EMEA/CVMP/EWP/37388/2009-CONSULTATION) for a 3-month period of public consultation. Based on experience in the past years, it was considered necessary to revise the current guideline to provide clearer guidance on a number of issues.

*The document will be available on the EMEA web site:*
http://www.emea.europa.eu/htms/vet/vetguidelines/efficacy.htm

**Immunologicals**

The Committee adopted a Question and Answer document on inactivation kinetics studies (EMEA/CVMP/340494/2009). This document answers the question on whether it is possible to extrapolate pre-inactivation titres as part of validation of an inactivation process.

*The document will be available on the EMEA web site:*
http://www.emea.europa.eu/htms/vet/vetguidelines/immunologicals.htm

**Antibacterials**

The Committee adopted a "*Concept paper on the use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health"* (EMEA/CVMP/SAGAM/113420/2009-CONSULTATION) for a 2-month period of public consultation. This Concept paper has been prepared to allow for comments on the proposal to prepare a scientific report, including recommendations for action, on macrolides, lincosamides and streptogramins in food-producing animals. This report will follow previous CVMP reports on quinolones and cephalosporins (3$^{rd}$ and 4$^{th}$ generation).

*The document will be available on the EMEA web site:*
http://www.emea.europa.eu/htms/vet/vetguidelines/safety.htm

## Organisational Issues

**Interested Parties**

The Committee held a meeting with the interested parties on 17 June 2009 attended by representatives of International Federation of Animal Health Europe (IFAH-Europe), International Council on Animal Protection in Pharmaceutical Programs (ICAPPP), European Federation of Honey Packers and Distributors (F.E.E.D.M.), and the European Association for Veterinary Pharmacology and Toxicology (EAVPT).

The topics discussed concerned:

- Review of working relationship between CVMP and interested parties
- Review of 2009 EMEA/IFAH-Europe Infoday and proposals for a 2010 Infoday
- Shelf-life of multi-dose containers
- Update on EMEA/CVMP activities to promote the 3Rs
- Update on the changes to OECD test guidelines on carcinogenicity, chronic toxicity and reproductive toxicity and suggestions for corresponding VICH updates
- Update on EMEA and VICH activity related to animal testing for veterinary products, incl. update on the progress with waiving the Target Animal Batch Safety Test at VICH
- Feedback from Informal CVMP 27/28 April 2009: for information to stakeholders
- Follow-up of the HMA/EMEA stakeholder meeting on antimicrobials: for discussion
- Update on Commission review of legislation
- Update on EMEA activities and plans in relation to products for bees.

The next meeting of the CVMP will be held on 14-16 July 2009

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http://www.emea.europa.eu