



**PRESS RELEASE**  
**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE**  
**Meeting of 10 to 12 October 2006**

The Committee elected Dr Anja Holm from Denmark as vice-chair of the Committee following the resignation of Dr Johannes Hoogland as member of the Committee in September 2006. The scientific profile of Dr. Holm can be found on the EMEA website at the following address: [http://www.emea.europa.eu/pdfs/general/contacts/aholm\\_CV.pdf](http://www.emea.europa.eu/pdfs/general/contacts/aholm_CV.pdf)

**CVMP Opinions on Veterinary Medicinal Products**

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **PRAC-TIC** (pyriprole), from Novartis Animal Sanidad, intended for the treatment and prevention of flea and tick infestations in dogs.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Promeris** (metaflumizone), from Fort Dodge Animal Health, intended for the treatment and prevention of flea infestations in cats.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Promeris Duo** (metaflumizone and amitraz), from Fort Dodge Animal Health, intended for the treatment and prevention of infestations by fleas and ticks in dogs.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Medicinal Oxygen** (oxygen), from Air Liquide Santé International, intended for oxygen supplementation and as a carrier gas during inhalation anaesthesia and for oxygen supplementation during recovery.

*The summary opinions are available on the EMEA web site: <http://www.emea.europa.eu>*

The Committee adopted by consensus a positive opinion for a Type II variation for **Pirsue** regarding various changes to the quality part of the dossier.

The Committee adopted by consensus a positive opinion for a Type II variation for **Previcox** regarding a change to the storage restrictions.

**Maximum Residue Limits**

The Committee adopted by consensus a positive opinion recommending the inclusion of **firocoxib** in Annex I of Council Regulation (EEC) No. 2377/90 for *Equidae* further to the CVMP recommendation for the establishment of provisional MRLs.

*The Summary opinion will be available on Monday 16 October 2006 on the EMEA web site:  
<http://www.emea.europa.eu>*

## Pharmacovigilance

The Committee reviewed a Periodic Safety Update Report (PSURs) for **Gonazon** and concluded that no further action or changes to the product literature of the product were required.

## Concept Papers, Guidelines and SOPs

### Efficacy

The Committee adopted a revision of the guideline on “*Testing and evaluation of the efficacy of antiparasitic substances for the treatment of tick and flea infestations in dogs and cats*”(EMEA/CVMP/EWP/005//00-CONSULTATION) for release for a 6-month period of public consultation. The revision mainly concerns the extension of the current scope (recommendations for products for systemic use against flea infestations and for insect-growth regulators) and provides further clarification on some areas of the existing guideline.

The Committee endorsed the recommendation from the Efficacy Working that there was no need at this stage to revise the “*Guideline for the conduct of efficacy studies for NSAIDs*”.

### Quality

The Committee adopted a “*Guideline on Parametric Release*” further to the close of the consultation period (EMEA/CVMP/QWP/339588/2005). This guideline outlines the requirements for applications in which the (optional) use of parametric release might be proposed. This guideline is very similar to the guideline for human medicines on the same subject. No comments had been received during the consultation period.

*The documents will be available on Monday 16 October 2006 on the EMEA web site:  
<http://www.emea.europa.eu>*

## Organisational Matters

The Committee endorsed the work programmes for 2007 for the CVMP Scientific Advice, Safety, Efficacy, Immunologicals, Pharmacovigilance and Environmental Risk Assessment working parties as well as for the Scientific Advisory Group on Antimicrobials.

*The documents will be available on Monday 16 October 2006 on the EMEA web site:  
<http://www.emea.europa.eu>*

The Committee also endorsed the work programme for the joint CHMP/CVMP Quality Working Party, which will be published on the EMEA website following its adoption by the CHMP foreseen for the meeting to be held on 16-19 October 2006.

The Committee welcomed introductory presentations from two new Interested Parties, the European Federation of Honey Packers and Distributors (FEEDM) and International Council on Animal Protection at ICH (ICAPI) and looked forward to fruitful collaboration in the future.

The CVMP meeting was followed by a Focus Group meeting with Interested Parties as well as representatives of the national authorities to discuss the comments received during the consultation period on the CVMP “*Reflection paper on the use of fluoroquinolones in food producing animals*” (EMEA/CVMP/SAGAM/184651/05). A separate Press Release for this meeting will be published on the EMEA web site: <http://www.emea.europa.eu>.

The next meeting of the CVMP will be held on 7-9 November 2006.

<p>David Mackay Head, Veterinary Medicines and Inspections Unit This press release and other documents are available on the Internet at the following address: <a href="http://www.emea.europa.eu">http://www.emea.europa.eu</a></p>
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