



PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
Meeting of 6 to 8 December 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus positive opinions on extension applications for **Proteq Flu** and **Proteq Flu-Te** concerning a new pharmaceutical form (suspension for injection).

The summary opinion is available on the EMA web site: <http://www.emea.eu.int>

The Committee adopted by consensus a positive opinion for a type II variation for **Clomicalm** regarding an extension of shelf life from 2 to 4 years and other quality changes.

The Committee adopted by consensus a positive opinion for a type II variation for **Metacam** regarding an additional indication in horses for the relief of pain associated with colic.

Renewals of Marketing Authorisations

The Committee adopted, by consensus, positive opinions for the renewal of the marketing authorisations for **Advasure** and **Pirsue**. The Committee concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and therefore recommended the renewal of the marketing authorisations.

Scientific Advice

The Committee adopted scientific advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning safety issues in the development of a vaccine intended for cancer treatment in dogs.

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Report (PSUR) for **Eurifel RCP FeLV** following the receipt of further details requested previously and recommended that the SPC point 5.3 "Undesirable effects" is reworded to better describe the reactions at the injection site.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee gave the mandate to the Pharmacovigilance Working Party to develop a guideline on the assessment of Periodic Safety Update Reports (PSURs) for veterinary medicinal products following consideration of the comments received during the public consultation on the concept paper on the subject (EMEA/CVMP/PhVWP/145320/2005).

Immunologicals

The Committee adopted a concept paper on the need for a procedure to be followed when a batch of a vaccine is suspected to be contaminated with bovine viral diarrhoea (BVD) virus for release for a 2-month period of public consultation (EMEA/CVMP/IWP/268282/2005-CONSULTATION).

*The documents will be available on Monday 12 December 2005 on the EMEA web site:
<http://www.emea.eu.int>*

International harmonisation

The Committee endorsed comments prepared by its Safety Working Party concerning the Joint FAO/WHO Expert Committee on Food Additives (JECFA) proposal for statistical methods for the estimation of MRLs expressing a general support for statistical methods for the estimation of MRLs (EMEA/CVMP/367651/2005).

*The document will be available on Monday 12 December 2005 on the EMEA web site:
<http://www.emea.eu.int>*

The next meeting of the CVMP will be held on 17-19 January 2006

CVMP Secretariat
Veterinary Medicines and Inspections Unit
This press release and other documents are available on the Internet at the following address:
<http://www.emea.eu.int>