European Medicines Agency
Veterinary Medicines and Inspections

London, 15 February 2008
EMEA/CVMP/58014/2008

PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12-14 February 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a type II variation for **SevoFlo** regarding quality changes to the product.

The Committee adopted by consensus a positive opinion for a type II variation for **Stronghold** regarding amendment of the SPC and product literature.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the amendment of the current entries in Annex I and II of Council Regulation (EEC) No. 2377/90 for **rifaximin** to cover buffalo.

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

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Clomicalm**. The Committee, having re-assessed the benefit-risk balance of the product, concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation. A new warning regarding hepato-biliary disorders was added following the reporting of adverse reactions.

Community Referrals

The Committee concluded the referral procedure for **Compagel** (***heparin sodium, levomenthol, hydroxyethyl salicylate***), gel for horses from Boehringer Ingelheim Vetmedica GmbH. The procedure was referred to the Committee by the reference Member State in the mutual recognition procedure, Germany, under Article 33(4) of Directive 2001/82/EC due to concerns raised by France and Sweden regarding the efficacy of the product. The Committee adopted by consensus an opinion concluding that Compagel gel for horses is essentially similar to the reference product. Therefore, the same conclusions on efficacy apply equally to both products and the objections raised by France and Sweden should not prevent the granting of a marketing authorisation.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

The Committee concluded the referral procedure for **Solacyl (*sodium salicylate*)**, powder for oral solution for calves and pigs, from Eurovet Animal Health B.V. The procedure was referred to the Committee by the reference Member State in the decentralised procedure, The Netherlands, due to concerns raised by Ireland regarding the efficacy of the product. The Committee adopted by consensus an opinion concluding that Solacyl is essentially similar to the reference product. Therefore, the same conclusions on efficacy apply equally to both products and the objections raised by Ireland should not prevent the granting of a marketing authorisation.

Scientific advice

The Committee agreed scientific advice regarding the safety and clinical development of a veterinary medicinal product for the control of pyrexia and inflammation.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Cerenia, Dexdomitor, Equilis StrepE, Flexicam** and **Ibraxion,** and concluded that no further action or changes to the products literature were required.

The Committee adopted the EMEA public bulletin on veterinary pharmacovigilance for 2007 summarising the EMEA activities regarding pharmacovigilance for veterinary medicinal products during the past year (EMEA/CVMP/PhVWP/72829/2007). Annual public bulletins on veterinary pharmacovigilance are being produced by the EMEA with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU. The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2007.

The Committee endorsed a report for release for publication from the workshop on Pharmacovigilance Systems and Inspections concerning veterinary medicinal products (EMEA/575883/2007) held on 4 December 2007. This workshop was arranged by the Agency for regulators and industry in follow up to the publication of the "*Guideline on monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections for veterinary medicinal products*" by the European Commission in April 2007.

The documents will be available on the EMEA web site: http://www.emea.europa.eu

The Committee discussed information provided by companies in relation to the detection of DNA from a feline retrovirus in cell substrates of feline origin used for the production of some veterinary vaccines and in the vaccines produced from them. The Committee concluded that the DNA of the virus concerned, RD114, was endogenous to cats being present in the genome of all domestic cats and therefore in cells originating from them. The Committee considered that further information should be sought from marketing authorisation holders, from relevant experts and from other international regulatory authorities. The Committee referred the issue to the Immunologicals Working Party to provide advice on any potential implications that this finding might have for the quality of vaccines produced from cell lines derived from cats and endorsed the continuation of an ad hoc group of experts convened to provide specialist advice on this topic.

Concept Papers, Guidelines and SOPs

Quality

The Committee adopted a "*Reflection paper on the acceptability of water for injections prepared by reverse osmosis*" (EMEA/CHMP/CVMP/QWP/28271/2008). This reflection paper aims to stimulate discussion on the acceptability of using reverse osmosis for the production of water for injections and will be published following its adoption by the Committee for Medicinal Products for Human Use (CHMP), which is foreseen for its next meeting on 18-21 February 2008.

Biologics

The Committee adopted a "*Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*" (EMEA/410/01-Rev.4). This note has been updated to take into account advancement of science in the area of transmissible encephalopathies and the evolving situation regarding Bovine Spongiform Encephalopathy (BSE) across the world. The Note for guidance has been revised making reference to the World Organisation for Animal Health (OIE) classification of countries or regions according to their BSE risk, thereby replacing the previous GBR classification. Criteria for the sourcing and processing of gelatin and bovine blood derivatives used in the manufacture of medicinal products for human or veterinary use have been updated, and a new subsection on Peptones has been introduced.

The revised guideline will be submitted to the European Commission for release for consultation following the adoption by the Committee for Medicinal Products for Human Use (CHMP), which is foreseen for its next meeting on 18-21 February 2008.

Antimicrobials

The Committee adopted a "*Reflection paper on the use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union: development of resistance and impact on human and animal health*" (EMEA/CVMP/SAGAM/81730/2006-CONSULTATION) for release for a 6-month period of public consultation. The reflection paper critically reviews recent information on the use of cephalosporins of the 3rd and 4th generation in food-producing animals in the EU, its effect on development of resistance to this category of antimicrobial agents in bacterial species that are of importance for human and animal health, and the potential impact on human and animal health and provides recommendations for action.

The document will be available on the EMEA web site: http://www.emea.europa.eu

International Harmonisation

The Committee adopted a new "*VICH guideline (GL45) on Quality: Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products*", after sign-off by the VICH Steering Committee at Step 4 (EMEA/CVMP/VICH/581467/2007-CONSULTATION) for release for a 6-month period of public consultation. This guideline addresses recommendations on the application of bracketing and matrixing to stability studies conducted in accordance with principles outlined in the VICH GL 3 (R) on stability testing.

The document will be available on the EMEA web site: http://www.emea.europa.eu

Organisational Issues

The Committee considered preliminary comments from IFAH-Europe on the draft CVMP "*Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products*" in preparation for the EMEA/IFAH Infoday on 13-14 March 2008.

Withdrawal of Marketing Authorisation

The Committee noted that on 6 February 2008 the European Commission issued a decision to withdraw the marketing authorisation for **Advasure**. Pursuant to this decision the European Public Assessment Report for Advasure will be updated to reflect that the marketing authorisation is no longer valid. The marketing authorisation holder responsible for Advasure is Pfizer Animal Health. Advasure (previously called Bayovac CSF E2) is used to immunise pigs from the age of 2 weeks onwards to prevent death and to reduce clinical signs of classical swine fever. It is also used to reduce infection with classical swine fever and excretion of classic swine fever virus into the environment.

The European Commission was notified by the marketing authorisation holder on the 4 January 2008, of its decision to voluntarily withdraw the marketing authorisation for Advasure for commercial reasons. Therapeutic alternatives are available throughout the European Union.

The next meeting of the CVMP will be held on 11-13 March 2008

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