European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 11-13 September 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Meloxivet** (meloxicam), from Janssen Pharmaceutica N.V., intended for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

The summary of opinion is 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 **ProteqFlu-Te** regarding a decrease in the target formulation titre and deletion of freeze dried presentations.

The Committee adopted by consensus a positive opinion for a Type II variation for **Purevax FeLV** regarding an amendment of the compatibilities and interactions sections of the product literature and deletion of the freeze dried presentations.

Renewals of Marketing Authorisations

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Quadrisol** and **SevoFlo**. The Committee having re-assessed the benefit-risk balance of the products concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Cerenia**, **Nobivac Piro**, **Poulvac Flufend**, **ProteqFlu**, **ProteqFlu-Te**, **Flexicam**, **Yarvitan**, **Halocur** and **Pruban** and concluded that no further action or changes to the products literature were required. The Committee also reviewed a PSUR for **Stronghold** and concluded that there was a need to include information on new adverse reactions in the product literature.

Concept Papers, Guidelines and SOPs

Efficacy

The Committee adopted a concept paper for the revision of the guideline on "Veterinary medicinal products controlling *Varroa destructor* and *Acarapis woodi* parasitosis in bees" (EMEA/CVMP/EWP/362275/2007-CONSULTATION) for release for a 6-month period of public consultation. This concept paper was prepared since a revision of methods and standards as mentioned in the current guideline was considered necessary.

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

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General Guidance

The Committee adopted a "*Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products*" (EMEA/CVMP/248499/2007-CONSULTATION) for release for a 6-month period of public consultation. The guideline is addressed to assessors and applicants/Marketing Authorisation Holders. The purpose of this guideline is to provide a more systematic approach for evaluating benefit-risk analyses, hence improving the consistency and transparency of decisions taken at CVMP level, and also by CMD(v) and Member States. The proposed guideline is not intended to introduce new requirements but rather to provide guidance on the elaboration of all assessment documents that include a section on the evaluation of the benefit-risk balance.

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

International Harmonisation

The Committee adopted the "*VICH GL41 Target animal safety: examination of live veterinary vaccines in target animals for absence of reversion to virulence*" at step 7 of the VICH procedure (EMEA/CVMP/VICH/1052/2004). The guideline establishes internationally agreed criteria and requirements for the conduct of studies that examine the potential for reversion to or increase in virulence of live veterinary vaccines in target animals. The guideline will be implemented by 1 July 2008.

The Committee adopted the "*VICH GL44 Guideline Target Animal Safety for veterinary live and inactivated vaccines*" at step 4 of the VICH procedure (EMEA/CVMP/VICH/359665/2005-CONSULTATION) for release for a 6-month period of public consultation. The guideline is intended to establish internationally harmonised criteria and requirements for the conduct of studies that evaluate the safety of final formulations of veterinary live and inactivated vaccines in the target animals.

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

Regulatory Issues

The Committee adopted the following concept paper and guidelines:

- "*Guideline on procedures for re-examination of CVMP opinions*" (EMEA/CVMP/2128/2007) for implementation following the close of public consultation. The overview of the comments received during the public consultation of this guideline (EMEA/CVMP/248860/2007) is also available on the EMEA web site.

- Concept paper on the classification of veterinary medicinal products authorised by the Community (EMEA/358850/2007-CONSULTATION) for release for a 2-month period of public consultation. The concept paper recommends that a guideline be developed and that a mechanism to change the classification of a centrally authorised veterinary medicinal product be established.

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

The Committee adopted a template for the Overview of Scientific Data, Overall conclusions and List of Questions (EMEA/CVMP/353958/2007) for initial and extension applications at day 120. The revision provides standard wording to indicate whether a product under assessment (a) is approvable, (b) could be approvable subject to concerns being satisfactorily addressed, or (c) is not approvable at the present time due to major objections requiring resolution before a recommendation for a marketing authorisation could be made.

Availability of Veterinary Medicines

The Committee agreed a series of actions proposed by EMEA/CVMP in response to the HMA Task Force on Availability of Veterinary Medicines, which will be discussed with HMA at their next meeting.

Organisational Matters

The Committee elected Professor Stane Srčič from Slovenia as vice-Chairman of the Scientific Advice Working Party for a 3-year mandate. Professor Srčič has been a member of the Committee and of the Scientific Advice Working Party since 2004.

The Committee reviewed the "*Mandate, objectives and rules of procedures for the CVMP Scientific Advice Working Party*" and confirmed the mandate and objectives of the working party. The Committee updated the rules of procedure part of the document to bring it in line with the recent revision of the "*CVMP Rules of procedure*" (EMEA/CVMP/765/04-Rev.2).

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

The next meeting of the CVMP will be held on 9-11 October 2007

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http://www.emea.europa.eu