The European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 15-17 April 2009

CVMP Opinions on Veterinary Medicinal Products

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

Advocate – addition of ferrets as a new target species for the prevention and treatment of flea infestations and also for the prevention of heartworm infection

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

Ingelvac CircoFLEX - a scale-up of PCV-2 ORF-2 antigen production;

Vaxxitek HVT + IBD - for the implementation of Ph. Eur. General chapter 2.6.25 Avian live virus vaccines-tests for extraneous agents in batches of finished product, including the use of specific nucleic acid amplification techniques (PCR techniques).

Zactran - deletion of a test in the release specifications of the finished product;

Econor - the deletion of a contraindication for use of the product in rabbits;

Onsior - update to the quality part of the dossier (specifications of an excipient and the final product, extension of the shelf-life, storage conditions, change in blister size of the cat tablets) as well as a minor change (correction) to the SPC of the dog tablets.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Previcox**. 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.

Community Referrals

The Committee started a referral procedure for veterinary medicinal formulations containing **colistin** at 2MIU/ml and intended for administration via drinking water to any food producing species. The matter was referred to the CVMP by the United Kingdom, under Article 35(4) of Directive 2001/82/EC, on the basis that it is in the interest of the Community to consider concerns that differences in the posology and withdrawal period may present a potential serious risk to public and animal health.

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Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the extension of the current Annex I entry of Council Regulation (EEC) No. 2377/90 for **valnemulin** to rabbits. The substance has already maximum residue limits established for porcine species.

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

The Committee adopted a revised list of substances not falling within the scope of the Council Regulation (EEC) No 2377/90, in order to include **polymyxin B** for use as an endotoxin neutralising agent in vaccines at doses of not more than 60 µg/dose (approximately 500 IU per dose) or not more than 6 µg/kg bw (approximately 50 IU/kg bw), whichever is the lower. The decision stems from a request from the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDv) following variation applications submitted at national level. Based on the data available the CVMP considered that, following administration at the dose specified above, polymyxin B residues can be considered to be without pharmacological activity.

The document is available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/mrls/background.htm

Pharmacovigilance

The Committee reviewed the PSURs for **Draxxin**, **Meloxivet**, **Nobilis Influenza H5N2**, **Nobilis Influenza H7N1**, **Poulvac Flufend H5N3 RG**, **PRILACTONE**, **Virbagen Omega** and **Yarvitan** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

General

The Committee adopted a document on Sampling and Testing of Centrally Authorised products: Proposal for development of risk based approach for the selection of veterinary medicinal products (EMEA/INS/S&T/75010/2009). The document has been developed to extend the risk-based approach for the selection of centrally authorised products for post-authorisation testing in accordance with Article 57 (r) of Regulation (EC) 726/2004 to veterinary medicinal products taking into account of risk factors specific to these products.

Pharmacovigilance

The Committee adopted a revised SOP for Management of Period Safety Update Reports (PSURs) for Centrally Authorised Products (CAPs) and Annex I – Contact details of national competent authorities for PSUR submission (SOP/V/4023-Rev.1). The revision encourages Rapporteurs to delegate PSUR assessment to their corresponding PhVWP-V members more on a routine basis for more efficient utilisation of resources.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/general/sop/sop.htm#Vets

The Committee adopted a revised mandate for the Pharmacovigilance Working Party (EMEA/CVMP/PhVWP/133883/2004-Rev.2). The mandate, which was revised following the standard 3-year review cycle, now specifies the expertise necessary in the Working Party. As the Working Party reports both to CVMP and the EU Member States, the mandate will also be submitted to the Heads of Medicines Agencies - Veterinary for endorsement. The publication of the mandate will take place following the endorsement by the Heads of Medicines Agencies – Veterinary.

Efficacy

The Committee adopted a "*Guideline on dossier requirements for anticancer medicinal products for dogs and cats*" (EMEA/CVMP/28510/2008) following the close of public consultation. The guideline has been developed by the CVMP Efficacy Working Party in co-operation with the Working Parties on Quality, Safety and Environmental Risk Assessment. The aim is to provide guidance on special dossier requirements for veterinary oncology products with regard to the quality, safety and efficacy documentation.

The overview of comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/EWP/512902/2008).

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

Safety

The Committee adopted a revised "*Guideline on user safety for pharmaceutical veterinary medicinal products*" (EMEA/CVMP/SWP/322484/2008-Rev.1-CONSULTATION) for a 4-month period of public consultation. This guideline was reviewed following concerns raised by industry and as a result of that process a number of amendments have been made with the aim of improving the clarity of the document.

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

Environmental Risk Assessment

Following the adoption of the CVMP Concept paper on fate of veterinary medicinal products in manure (EMEA/CVMP/ERA/10043/2009-CONSULTATION) (http://www.emea.europa.eu/pdfs/vet/era/1004309en.pdf), which is currently under consultation until 30 April 2009, the EMEA announces to hold a Focus Group meeting on the subject. The aim of the meeting is to give Interested Parties the possibility to provide early input to the preparation of the guideline. The meeting is scheduled for 23 June 2009.

The draft agenda and a registration form for the Focus Group Meeting will be available on the EMEA web site: http://www.emea.europa.eu/meetings/conference.htm

Quality

The Committee adopted two Question and Answer documents on endotoxin/sterility testing during and at the end of shelf-life (EMEA/CHMP/CVMP/QWP/160263/2009) which aim to clarify the need for, and timing of, these tests in the case of parenteral products.

The Committee adopted a paper on the assessment of products containing existing/known active substances (EMEA/CHMP/CVMP/450653/2006) which is intended to provide guidance for quality assessors in the case of applications containing existing or known active substances. It was adopted by the CHMP at their March 2009 meeting.

The documents will be available on the EMEA web site:
http://www.emea.europa.eu/Inspections/qwp/list.htm and
http://www.emea.europa.eu/Inspections/QWPhome.html, respectively

International harmonisation

The Committee adopted a revised guideline "*VICH GL33 on Safety: studies to evaluate the safety of residues of veterinary drugs in human food: general approach to testing*" (EMEA/CVMP/VICH/486/02-Rev.2) following sign-off by the VICH Steering Committee at its 22nd meeting on 25-26 February 2009. The revision includes a reference to the 3 R's Principle (Refine, Reduce and Replace) highlighting the VICH adherence to the goal of minimising animal testing.

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

The Committee agreed on comments on draft MRLs for consideration by the 18th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) to be held on 11-15 May 2009. The MRLs concern the substances avilamycin, dexamethasone, monensin, tilmicosin, triclabendazole and tylosin.

Regulatory issues

The Committee adopted a "*Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products*" (EMEA/CVMP/248499/2007-Rev.1) following the close of the second public consultation. This recommendation has been updated to take account the comments received during the public consultation.

The overview of the comments received during the second public consultation will be published on the EMEA website (EMEA/CVMP/66531/2009).

The documents will be available on the EMEA web site:
http://www.emea.europa.eu/htms/general/direct/legislation/legislationvet.htm

Organisational matters

The Committee adopted the Procedure for reporting of Pharmacovigilance inspections requested by the CVMP (EMEA/INS/PhV/85061/2008) prepared by the Ad hoc Pharmacovigilance Inspectors Working Group. This procedure describes the different steps for the reporting of pharmacovigilance inspections requested by the CVMP, from the preparation of the inspection reports, submission to EMEA, circulation to the CVMP, assessors and MAH and considerations for follow up, if needed, after the inspection.

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

The Committee finalised the preparation of the Informal CVMP and Joint CVMP/CMDv meetings to be held under the Czech Presidency of the EU, on 27-28 April 2009. The discussions will focus on:

- Antimicrobial Resistance
- Functioning of the CVMP
- Implementation of the new MRL regulation
- Treatment of bees

The next meeting of the CVMP will be held on 12-14 May 2009

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This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu