The European Medicines Agency
Veterinary Medicines and Inspections

London, 13 March 2009
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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 10-12 March 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for the vaccine **Improvac**, from Pfizer Ltd., intended for the active immunisation of male pigs as an alternative to surgical castration for the reduction of boar taint.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for the vaccine **Leucofeligen FeLV/RCP**, from Virbac S.A., intended for the active immunisation of cats against feline calicivirosis, feline rhinotracheitis virus, feline leukaemia and feline panleucopenia virus.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for the vaccine **Leucogen**, from Virbac S.A., intended for the active immunisation of cats against feline leukaemia. The corresponding existing nationally authorised product (authorised via the concertation procedure) will be withdrawn once a Commission Decision has been granted.

The Committee adopted by consensus a positive opinion for **Aivlosin** regarding an extension of the existing marketing authorisation for a new pharmaceutical form (granules for oral solution for medicated drinking water) for the treatment of Porcine Proliferative Enteropathy (PPE) in pigs.

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

Community Referrals

The Committee considered the grounds for appeal against the opinion adopted during its December 2008 meeting concerning **Pharmasin 100% W/W Water Soluble Granules** in the context of an Article 33 arbitration procedure. The Committee concluded that the previous recommendation of the Committee should stand as the application does not satisfy the criteria for authorisation in respect of environmental risk. Therefore, the Committee adopted by consensus an opinion concluding that the marketing authorisation applications for Pharmasin 100% W/W Water Soluble Granules and its associated names should be refused by the Member States. Furthermore, the CVMP recommends that the existing Marketing Authorisations should be revoked. The Committee limited its considerations to the data presented by the Applicant in the dossier for this product in line with the restrictions in legislation with respect to data on environmental risk. No consideration was given nor conclusion drawn regarding the applicability of the conclusions to other licensed products containing the same active ingredient.

The Committee noted a request for re-examination of the CVMP opinion adopted during the February 2009 meeting concerning the Article 35 referral procedure for injectable veterinary medicinal products containing **ivermectin** indicated for use in cattle at a dose rate of 200µg ivermectin/kg bodyweight. The procedure will be initiated once the grounds for the re-examination are submitted.

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Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin** and **Eurican Herpes 205** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Efficacy

The Committee adopted a revision of the "*Guideline on the conduct of bioequivalence studies for veterinary medicinal products*" (EMEA/CVMP/016/00-Rev.1-CONSULTATION) for a 6-month period of public consultation. The guideline has been revised to clarify the wording of the guideline and to harmonise the dossier requirements in line with the human guideline e.g. by adding a new annex listing BCS-based biowavers.

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

During the public consultation, the EMEA will hold a Focus Group meeting to provide Interested Parties with the possibility to discuss the revised guideline. The meeting is scheduled for 6 May 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

The Committee adopted a Question and Answer document in relation to CVMP Guideline on "*Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats*" (EMEA/CVMP/EWP/82829/2009). This document provides clarification in regard to the data requirements for generic ectoparasitic spot-on product applications for dogs and cats, which do not act systemically.

The document will be linked to the current guideline and be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/vetguidelines/background.htm

Immunologicals

The Committee adopted a "*Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot-and-mouth disease*" (EMEA/CVMP/IWP/105506/2007-CONSULTATION) for a 6-month period of public consultation. These vaccines represent a special case in terms of the need for rapid and constant change in the strains included and therefore do not fit well within the general regulatory model for vaccines. Following experience with the authorisation of avian influenza vaccines, the concept of a multi-strain dossier approach has been included in the Commission Directive 2009/9/EC and in the revised Variation Regulation (EC) 1234/2008. This guideline applies to new applications for authorisation of vaccines defined in multi-strain dossiers and variations concerning the addition or replacement of strains of inactivated vaccines intended for use against avian influenza, bluetongue and foot-and-mouth disease. It describes the requirements that should be presented in the analytical, safety and efficacy part of the multi-strain dossier.

The Committee adopted a "*Reflection paper on the demonstration of a possible impact of maternally derived antibodies on vaccine efficacy in young animals*" (EMEA/CVMP/IWP/439467/2007-CONSULTATION) for a 6-month period of public consultation. The reflection paper has been developed as the next step in the process of developing a guideline on how to demonstrate the extent to which Maternally Derived Antibodies (MDAs) may have an impact on the efficacy of vaccines administered to animals at an age at which maternally acquired immunity is still present.

The Committee adopted a "*Guideline on data requirements to support in-use stability claims for veterinary vaccines*" (EMEA/CVMP/IWP/250147/2008-CONSULTATION) for a 6-month period of public consultation. The guideline has been developed to outline the data that should be provided in support of in-use shelf-life claims for veterinary vaccines.

The Committee adopted a revised "*Guideline on data requirements for immunological veterinary medicinal products intended for Minor Use or Minor Species/ Limited markets*" (EMEA/CVMP/IWP/123243/2006-Rev.1-CONSULTATION) for a 3-month period of public consultation. The guideline has been revised to take into account data that supported the inclusion *M. synoviae* in chickens in Table 2 listing the diseases and animal species currently considered as limited markets. A shortened period of consultation is therefore considered appropriate.

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

Antimicrobials

The Committee adopted the Recommendations for action in relation to the published "*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), adopted by the CVMP at the March 2009 meeting. The recommendations have been integrated into the published revised Reflection Paper, and an update of the Reflection Paper will be published shortly. The Committee will consult with stakeholders over the coming months in relation to how best these recommendations can be implemented.

The Committee adopted a "*Reflection paper on MRSA in Companion and Food producing Animals in the European Union: epidemiology and control options for human and animal*" (EMEA/CVMP/SAGAM/68290/2009). This reflection paper has been developed to provide a preliminary risk profile for the use of antimicrobials in animals in relation to the risk of meticillin resistant *Staphylococcus aureus* (MRSA) infection and colonisation in animals (livestock and companion). The paper assesses the impact of the use of antimicrobials in livestock and companion animals on the risk of colonisation or infection with MRSA and provides advice on options for management of MRSA in animals. Coordination will now take place with the European Food Safety Authority (EFSA) whose Panel on Biological Hazards has also adopted an opinion on MRSA with a view of producing a synthesis of recommendations of the two committees.

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

Other Activities

The CVMP meeting was followed by an EMEA/IFAH-Europe Infoday on 12-13 March 2009 under the theme "The latest developments in scientific review, legislation and marketing authorisation procedures". The programme of the meeting is attached to this Press Release.

The next meeting of the CVMP will be held on 15-17 April 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

The European Medicines Agency
Veterinary Medicines and Inspections

2009 EMEA/IFAH-Europe Info Day

'THE LATEST DEVELOPMENTS'
IN SCIENTIFIC REVIEW, LEGISLATION AND MARKETING AUTHORISATION PROCEDURES

12-13 March 2009, EMEA, London

Programme

Thursday 12th March 2009		
13:30	*Registration open*	
14:00	Introduction and Welcome	Thomas Lönngren, EMEA
Session I:	**Scientific Developments**	Chair: Kornelia Grein, EMEA
14:10	**An analysis of the changes to Annex I and their impact** • Title I: Part 1 (Summary) and Part 2 (Pharmaceutical Quality) • Title I: Part 3 (Safety and residue tests) and Part 4 (Clinical) and Title III (Specific marketing authorisations) • Title II (Immunologicals) and Title IV (particular products – immunologicals)	Wilhelm Schlumbohm, CVMP Ray Harding, Cyton Nikolaus Križ, EMEA
15:10	Discussion	
15:30	**Review of main conclusions from recent scientific discussions**: • Oncology guideline for cats and dogs • PK/PD modelling	Barbara Cyrus, EMEA Barbara Cyrus, EMEA
15:55	Tea and Coffee	
16:15	**Biologicals** - Developments in scientific requirements and procedures	Jean-Claude Rouby, IWP Chair
16:40	**ERA Requirements** - Clarification of requirements and procedures	Alex Tait, ERA WP Vice Chair
17:05	Discussion	
17:25	**VICH**: an update on developments following the 22nd Steering Committee meeting in February 2009	Kornelia Grein, EMEA
17:45	Close of the session by the chairman	
18:00	Cocktail reception, followed by supper at 18:30, EMEA canteen	

Friday 13th March 2009

Session II:	**EMEA Bulletin board and procedures**	Chair: David Mackay, EMEA
09:00	**Review of priorities for CVMP and its working parties for 2009,** including plans for interactions with stakeholders	Anja Holm, CVMP Vice Chair
09:30	**Update on the Centralised Procedure** • Renewals and sunset clause: practical tips for compliance • E-presentations	Melanie Leivers, EMEA
09:45	**Survey of the centralized procedure**	
	• Industry perspective	Sylvie Meillerais, IFAH-Europe
	• EMEA perspective	Veronica Picciafuoco, EMEA
10:10	**MRL Regulation – where we are now**	Isaura Duarte, EMEA
10:30	Tea and coffee	
Session III:	**Legislation Developments**	Chair: Declan O'Brien, IFAH-Europe
10:50	**Variations Regulation**	
	• Are we on the right track	Jacques Cuvelier, IFAH-Europe Variations Task Force
	• Implementation proposal for the variation Regulation	Melanie Leivers, EMEA
11:20	Discussion	
11:30	**Pharmacovigilance**: how should the current challenge be met? • Update on Volume 9B • Detailed description of pharmacovigilance • Streamlining PSURs	Fia Westerholm, EMEA
11:50	**Pharmacovigilance**: industry perspective on how the veterinary chapter should be reviewed	Bob Cornez, IFAH-Europe Pharmacovigilance Working Group
12:10	Questions	
12:20	**The 2010 Review**: IFAH-Europe proposals for optimising veterinary medicines legislation	Rick Clayton, IFAH-Europe
12:40	Questions	
12:50	Close of the meeting	Declan O'Brien and David Mackay