



**PRESS RELEASE**  
**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE**  
**Meeting of 11-13 March 2008**

**CVMP Opinions on Veterinary Medicinal Products**

The Committee adopted by consensus a positive opinion for **Aivlosin** regarding an extension of the existing marketing authorisation to include granules for oral solution for medicated drinking water for chickens.

The Committee adopted by consensus a positive opinion for **Rabigen** regarding an extension of the indication 'for the active immunisation of red foxes to prevent infection by rabies virus' to include raccoon dogs as a target species.

*Summary of opinions will be available on the EMEA web site: <http://www.emea.europa.eu>*

The Committee adopted by consensus positive opinions for type II variations for:

- **Proteq Flu and Proteq Flu Te** - substitution of vCP1529 (Kentucky) strain with the vCP2242 (Ohio) strain;
- **Previcox Chewable Tablets for Dogs** - additional indication for the relief of post-operative pain and inflammation associated with soft-tissue surgery in dogs for both strengths of tablet presentations (57mg and 227mg);
- **Eurican Herpes 205** - removal of routine safety batch testing;
- **Ibraxion** - removal of routine safety batch testing;
- **Virbagen Omega** - replacement of the stoppers used to close the freeze dried fraction, adjustment step during the product bulk formulation and additional control to guarantee the absence of virus plant contaminant in the active ingredient of the product.

**Maximum Residue Limits**

The Committee agreed that corn oil does not fall within the scope of Council Regulation (EEC) No 2377/90. This conclusion follows a request from a company to use the substance as excipient. The list of substances not falling within the scope will be revised accordingly.

*The document will be 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 **Nobilis IB4-91**. 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.

## Scientific advice

The Committee agreed scientific advice regarding quality issues for the development of a veterinary medicinal product for ketosis in cattle.

## Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Pruban**, **Nobilis Influenza H7N1** and **Rabigen SAG**, and concluded that no further action or changes to the products literature were required.

## Concept Papers, Guidelines and SOPs

### Safety

The Committee adopted a Report of the Focus group meeting on user safety guideline (EMEA/CVMP/27466/2008). The guideline came into effect on 13 July 2005 and since that time industry representatives have raised a number of concerns over the guideline. The meeting was arranged to discuss these concerns further.

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

### Immunologicals

The Committee adopted a “*Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus*”, following the close of the public consultation (EMEA/CVMP/IWP/205351/2006). This guideline has been updated following comments received from IFAH Europe. The guideline will be implemented by 1 October 2008.

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/37534/2007).

The Committee adopted a “*Guideline on the requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs)*” (EMEA/CVMP/IWP/105504/2007-CONSULTATION) for release for a 6-month period of public consultation. This guideline deals with the specific requirements for the replacement of an antigen (e.g. virus, bacteria, fungus) master seed by a master seed of the same origin. It also applies to the replacement of the master cell seed used to produce a vaccine organism by a master cell seed of the same origin.

The Committee adopted a “*Concept paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue*”, for release for a 2-month period of public consultation (EMEA/CVMP/IWP/37267/2008-CONSULTATION). This concept paper has been developed as a consequence of the reflection paper on the same topic published in April last year and is intended to lead to a guideline to be released for consultation by July 2008.

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

## Quality

The Committee adopted a “*Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products*” (EMEA/HMPC/CHMP/CVMP/214869/2006) for implementation from 1 October 2008, following the close of the public consultation. The purpose of this guideline is to outline approaches for the identification and quantitative determination of herbal substances and/or herbal preparations in combination herbal medicinal products, taking into account their complex composition and the potential for interference in analysis by the other herbal substances/preparations present.

The guideline and overview of the comments (EMEA/HMPC/559281/2007) will be published on the EMEA website following its adoption by the Committee for Medicinal Products for Human Use (CHMP), which is foreseen for its next meeting on 17-19 March 2008.

## International Harmonisation

The Committee adopted the “*VICH guideline (GL24) on Management of Adverse Event Reports*” following sign-off by the VICH Steering Committee at its 20<sup>th</sup> meeting on 17-18 October 2007 (EMEA/CVMP/VICH/547/00). This guideline includes the definitions for the different types of adverse events and describes the general obligations for the MAH as well as the regulatory authority for the management of adverse events.

The implementation date of this guideline will be determined at a later stage.

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

## Regulatory Issues

The Committee adopted a “*CVMP Reflection Paper regarding the assessment of environmental risks of veterinary medicinal products*” (EMEA/CVMP/182112/2006) for release for a 3-month period of public consultation. This reflection paper addresses the implementation of Directive 2001/82/EC, as amended, in respect to the requirements for the environmental risks assessment of veterinary medicinal products, describing the CVMP considerations based on the legal interpretation of the provisions by the European Commission and the advice by its Environmental Risk Assessment Working Party, and consultations with the CMD(v).

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

## Organisational matters

The CVMP meeting was followed by an EMEA/IFAH-Europe Infoday on 13-14 March under the theme “Balancing the benefits and risks of veterinary medicinal products”. The programme of the meeting is attached to this Press Release.

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

*2008 EMEA/IFAH-Europe Info Day*

**'BALANCING THE BENEFITS AND RISKS OF VETERINARY  
MEDICINAL PRODUCTS'**

*13-14 March 2008, EMEA, London*

**Programme**

**Thursday 13<sup>th</sup> March 2008**

13:45	Registration	
14:00	Introduction and Welcome	David Mackay (EMEA)
<b>Session I: The benefit:risk assessment</b>		
	<u>Chair:</u> David Mackay, Head of Vet. Unit and Inspections, EMEA Background and status of the CVMP Benefit:Risk Guideline	David Mackay
14:15	<b>The industry reaction to the benefit:risk guideline</b>	Neil Craven (Pfizer)
14:45	<b>How to do a robust benefit:risk assessment</b> • Including a response to industry's initial comments	Gérard Moulin (Chairman of the CVMP)
15:15	1.1.1.1. Discussion	
15:45	Tea and Coffee	
<b>Session II: Outcome of recent discussions on new safety guidelines</b>		
16:15	<b>User safety guideline: conclusions of the December focus group meeting</b>	Kevin Woodward (Schering-Plough), Johan Schefferlie (CVMP)
16:45	Discussion	
17:00	<b>Environmental Risk Assessment</b>  • <b>ERA Technical Guidance Document: conclusions of the January focus group meeting on developing a common understanding on its use and interpretation</b>  • <b>Requirements for ERA under Dir 2001/82/EC, as amended.</b> Development of guidance for all applications, including for generics, variations, renewals and extensions	Joop De Knecht (Chairman of the ERA WP), Leo van Leemput (Janssen)  Kornelia Grein (EMEA)
17:30	Discussion	
18:00	Close of the session by the chairman	
18:15	Cocktail reception, followed by supper at 18:45, EMEA canteen	

**Friday 14<sup>th</sup> March 2008**

**Session III: Update on Pharmacovigilance**

Chair: Kornelia Grein, EMEA

09:00	<b>Perspective of the veterinary practitioner</b>	Jan Vaarten (FVE)
09:20	<b>Progress with pharmacovigilance</b> <ul style="list-style-type: none"><li>• Volume 9: status and content (what is changing)</li><li>• Status of EudraVigilance Veterinary</li><li>• Signal detection and related possible regulatory actions</li><li>• Feedback from the December workshop on detailed description of Pharmacovigilance system and Pharmacovigilance inspections</li></ul>	Cornelia Ibrahim (Chairperson, CVMP Pharmacovigilance WP) and Fia Westerholm (EMEA)
09:50	<b>Industry perspective on the future of veterinary pharmacovigilance</b> , including follow-up to the December workshop	Bob Cornez (Alpharma)
10:10	Discussion	
10:30	Tea and coffee	

**Session IV: Referrals**

Chair: Jill Ashley-Smith, EMEA

10:50	Initial results from industry survey (article 33 referrals)	Sylvie Meillerais (IFAH-Europe)
11:05	Recent experience of referrals at CVMP	Gabriel Beechinor (IMB, and CVMP)
11:20	Recent experience of referrals at CMD(v)	Esther Werner (Chairperson, CMD-v)
11:35	Questions	

**Session V: EMEA Bulletin board**

Chair: Melanie Leivers, EMEA

11:45	EMEA/CVMP activities <ul style="list-style-type: none"><li>• Medicines availability</li><li>• CVMP response to IFAH-Europe Benchmarking</li></ul>	David Mackay
12:00	E-presentations – update	Melanie Leivers
12:15	EMEA Cooperation agreement with FDA	Kornelia Grein
12:30	Questions and answers session to Vet Unit senior management and CVMP Chairman following a list of key points on CP functioning presented by industry	David Mackay, Kornelia Grein, Jill Ashley-Smith, Gérard Moulin, Melanie Leivers
13:00	Close of the meeting	David Mackay