The European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/312958/2005
London, 7 October 2005

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 4 to 6 October 2005

Maximum Residue Limits

The Committee adopted by majority a positive opinion recommending the modification of the existing maximum residue limits (MRLs) for **triclabendazole**. Triclabendazole had maximum residue limits previously established for bovine and ovine species and therefore at this occasion of reconsidering the MRLs, in application of the CVMP guidance on extrapolation of MRLs, a recommendation for all ruminants was now made.

The Summary opinion will be available on Monday 10 October 2005 on the on the EMEA web site:
http://www.emea.eu.int

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Draxxin** and **Virbagen Omega** and concluded that no further action or changes to the product literature of the products were required.

Concept Papers, Guidelines and SOPs

Efficacy and Safety

The Committee adopted a revision of the guideline on "Fixed combinations of veterinary pharmaceutical products" (EMEA/CVMP/83804/2005-CONSULTATION) for release for a 6-month period of public consultation.

The document will be available on Monday 10 October 2005 on the EMEA web site:
http://www.emea.eu.int

International Harmonisation

The Committee adopted the revised VICH Quality guideline GL3(R): Stability Testing of New Veterinary Drug Substances and Medicinal Products for release for a 3-month public consultation (EMEA/CVMP/VICH/899/99-Rev.1-CONSULTATION).

The document will be available on Monday 10 October 2005 on the EMEA web site:
http://www.emea.eu.int

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Organisational Matters

CVMP Working Parties

Antoni Kamphuis was elected vice-chair of the Pharmacovigilance Working Party.

The Committee endorsed the work programmes for 2006 for the CVMP Scientific Advice, Quality, Safety, Efficacy, Immunologicals, Pharmacovigilance and Environmental Risk Assessment working parties and also for the Scientific Advisory Group on Antimicrobials. The work programmes will be published soon on the EMEA website.

Informal CVMP meeting

The Committee received an initial report of the informal CVMP meeting held on 20-21 September 2005 in Windsor, United Kingdom, and endorsed the recommendations made at the meeting.

Interested Parties

With a view to increase its dialogue with parties concerned with the use of medicines, in particular users of medicines and veterinarians, the CVMP gave for the first time the opportunity to the Federation of Veterinarians of Europe (FVE) to address the Committee and discuss issues of common interest. The following topics were addressed:

- Directive 2004/28/EC and its implementation
- Availability of Veterinary Medicinal Products
- Responsible use of Veterinary Medicinal Products

The meeting between the Committee and the FVE representatives was in accordance with the rules introduced by the CVMP to facilitate communication and dialogue between the CVMP and the interested parties. This procedure can be found here.

The CVMP meeting was followed by an EMEA/IFAH - Europe Infoday on 6-7 October 2005 under the theme “Nurturing innovation and sustainability in the European animal health sector”. The programme of the meeting is attached to this Press Release.

The next meeting of the CVMP will be held on 8-10 November 2005

CVMP Secretariat
Veterinary Medicines and Inspections Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Doc Ref: EMEA/CVMP/312958/2005

EMEA / IFAH-Europe Infoday

Nurturing innovation and sustainability in the European animal health sector

Thursday-Friday 6-7 October 2005, EMEA, London

Programme

Thursday 6th October 2005

13:15	Registration	
13:45	Introduction and Welcome	Thomas Lönngren, Executive Director, EMEA
Session I:	**Preparation for the focus group session**	Chair: J. Gabriel Beechinor, CVMP
14:00	**Medicines availability** (in its broadest sense) • Latest developments update (MUMS GLs, Annex 1) • Issues and proposals for next steps from the interested parties (IFAH-Europe, AVC, FVE) • Labelling and packaging and small markets • Suggested discussion points for the focus group	Kornelia Grein, EMEA (10') Bill Vandaele, Interested parties (10') Karin Krauss, European Commission (10') Hans Hoogland, CVMP (10')
14:40	**The development and benefits of CVMP guidelines** • Introduction: procedure for developing guidelines • What are the overall benefits of guidelines; proposals	Emer Cooke, EMEA (10') Anja Holm, CVMP (10')
15:00	**The impact of guidelines on innovation and sustainability** • Need for guidelines for predictability/consistency • Results of IFAH-Europe survey; examples of good and poor guidelines, advantages and disadvantages • Proposals and suggested discussion points for the focus group	Rob Joosten, EGGVP (10') Andrew Fleetwood, IFAH-Europe (20') Brigitte Boenisch, IFAH-Europe (10')
15:40	Tea and Coffee	
Session II:	**Focus group session**	
16:10	Parallel Focus group meetings 1. Medicines availability – • *[discussion points]* 2. Impact of guidelines – • *[discussion points]*	Chair: Hans Hoogland, CVMP Chair: Brigitte Boenisch, IFAH-Europe
18:00	Close of first day	
	Cocktail reception and supper, EMEA canteen	

Friday 7th October 2005

08.30	Plenary report: 1. Conclusions of focus group on medicines availability 2. Conclusions of focus group on impact of guidelines	 Hans Hoogland, CVMP (20') Brigitte Boenisch, IFAH-Europe (20')
09:10	Discussion of recommendations	30'

Session III: Pharmacovigilance — Chair: Erik De Ridder, IFAH-Europe

09:40	Pharmacovigilance: an update	Jos Olaerts, EMEA (20')
10:00	Pharmacovigilance issues for marketing authorisation holders	Bob Cornez, IFAH-Europe (20')
10:20	IT/Eudravigilance	Olivier Simoen, EMEA (20')
10:40	Discussion	
10:50	Tea and coffee	

Session IV: EMEA bulletin board — Chair: Jill Ashley-Smith (EMEA)

11:20	• Update on 'implementation measures' • Centralised Procedure – proposals for improvement • CVMP work plan for 2006	Jill Ashley-Smith, EMEA (20') Sylvie Meillerais, IFAH-Europe (20') Kornelia Grein, EMEA (20')
12:20	Questions and discussion	
12:30	Closing remarks	Declan O'Brien, IFAH-Europe Managing Director
12:45	Close	