European Medicines Agency
Veterinary Medicines and Inspections

London, 10 November 2006
EMEA/CVMP/430553/2006-Rev.1

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 7 - 9 November 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on a new marketing authorisation application for **Cortavance** (hydrocortisone aceponate), from Virbac S.A., intended for symptomatic treatment of inflammatory and pruritic dermatoses in dogs.

The Committee adopted by consensus a positive opinion on a new marketing authorisation application for **Ypozane** (osaterone acetate), from Virbac S.A., intended for the treatment of benign prostatic hypertrophy (BPH) in male dogs.

The Committee adopted by consensus a positive opinion on a new marketing authorisation application for **Meloxicam CEVA**, from CEVA Santé Animale. Meloxicam CEVA is a generic product containing meloxicam. It is intended for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

The Committee adopted by consensus a positive opinion on an extension application for **Gonazon** (azagly-nafarlin), from Intervet International BV. The extension concerns a new pharmaceutical form (implant), new target species (dogs) and a new indication (prevention of gonadal function in bitches via long term blockade of gonadotrophin synthesis).

Summary opinions for these medicinal products are 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 **Vaxxitek HVT+ IBD,** regarding an increase in batch size of frozen suspension.

Community Referrals

The Committee concluded the referral procedure for **Dolovet vet** and **Rifen** (ketoprofen). The procedure was referred to the Committee by the Reference Member State in the Mutual Recognition Procedure, Finland under Article 33 of Directive 2001/82/EC due to concerns raised by the Concerned Member States, Belgium and Norway that efficacy of the product was not sufficiently substantiated in the dossier. The Committee adopted by consensus an opinion concluding that the efficacy was sufficiently demonstrated in view of the entire available data and there were no concerns that the products would represent a potential serious risk to animals. The opinion will now be forwarded to the European Commission.

The Committee started a referral under Article 33 of Directive 2001/82/EC for **Bovilis BVD-MD**, The referral was initiated by the Reference Member State in the Mutual Recognition Procedure, Germany, to resolve disagreement following concerns from Denmark regarding the testing requirements to assure freedom from extraneous agents and lack of interference with national disease control programmes. A Rapporteur and Co-Rapporteur were appointed and a list of questions to be responded to by the Marketing Authorisation Holder was agreed.

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Scientific advice

The Committee agreed scientific advice regarding safety and clinical data requirements for extensions of an existing marketing authorisation to minor species.

Pharmacovigilance

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

Upon review of a PSUR for **Advocate**, the Committee recommended an amendment of product literature, to include local hypersensitivity as a new adverse reaction.

Further to its review of a PSUR for **Equilis StrepE**, the Committee amended its previous recommendation to vary the marketing authorisation to include new adverse reactions to the product literature requiring now also their incidence to be included.

Antimicrobial resistance

The CVMP reviewed the conclusions of the recent Focus Group on the CVMP reflection paper on use of fluoroquinolones in food producing animals. The CVMP also reviewed the recommendations from the CVMP Scientific Advisory Group on antimicrobials (SAGAM) taking into account the conclusions of the Focus Group. The Committee agreed on standard precautionary phrases for inclusion in the SPCs for (fluoro)quinolones which will be forwarded to the Heads of Medicines Agencies (veterinary) and Interested Parties for consideration and discussion of implementation measures.

Guidelines, SOPs and Position Papers

Immunologicals

The Committee adopted a concept paper on the need for revision of the position paper on "*Compliance of veterinary vaccines with veterinary vaccine monographs of the PhEur*" (EMEA/CVMP/IWP/229679/2006). While the existing position paper has been very useful in providing an interpretation of different aspects of the need for compliance with monographs, experience over the last seven years shows that there remain some areas where differences of interpretation exist and where a revision of the position paper could, therefore, be useful for all stakeholders.

The document will be available on Monday 13 November 2006 on the EMEA web site:
http://www.emea.europa.eu

International Harmonisation

The Committee adopted the draft VICH GL43: Guideline on Target Animal Safety for Pharmaceuticals at step 4 of the VICH procedure (EMEA/CVMP/VICH/393388/2006-CONSULTATION) for release for a 6-month period of public consultation. The guideline addresses target animals safety requirements for bovine, ovine, caprine, feline, canine, porcine, equine species and poultry.

The document will be available on Monday 13 November 2006 on the EMEA web site:
http://www.emea.europa.eu

Organisational matters

The Committee received a presentation from the International Federation for Animal Health (Global) as a recognised Interested Party. The presentation reflected on the priorities for the organisation, the current and future prospects for the animal health industry in terms of access to market for new and existing veterinary medicines and how medicines regulation affects these prospects. The Committee was grateful for the information received and looked forward to continuing a useful dialogue with IFAH in the future.

The CVMP meeting was followed by an EMEA/IFAH-Europe Infoday on 9-10 November 2006 under the theme "Stimulating innovation and managing risk in market access to the veterinary sector". The programme of the meeting is attached to this Press Release.

The next meeting of the CVMP will be held on 12-14 December 2006.

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

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Europe IFAH
Representing the European Animal Health Industry

2006 EMEA/IFAH-Europe Info Day

'STIMULATING INNOVATION AND MANAGING RISK IN MARKET ACCESS TO THE VETERINARY SECTOR'

9-10 November 2006, EMEA, London

Programme

Thursday 9th November 2006

13:15	Registration	
13:45	Introduction and Welcome	Thomas Lönngren, Executive Director, EMEA

Session I: Risk:benefit assessment appropriate for the veterinary sector

Chair: David Mackay, Head of Vet. Unit and Inspections EMEA

Notes: Participants will be seated in 6 discussion groups of 10-12 people for Session 1 with a cross representation of interested parties in each group. The groups will remain the same for all three discussions. Speakers will be asked as part of their presentation to identify a small number of key topics for debate by each of the six groups (i.e. each group will discuss the same points). Nominated individuals will report back the main conclusions of their group. There will be a plenary discussion at the end of the session.

14:00	**The importance of differentiating between the human and veterinary sectors** • Presentation, culminating in a short list of discussion points	Rick Clayton, IFAH-Europe
14:20	**Discussion of the points in small groups**	
14:50	**How to do a robust risk:benefit assessment** • Presentation, culminating in a short list of discussion points	Gérard Moulin, Chairman of the CVMP
15:20	**Discussion of the points in small groups**	
15:50	Tea and Coffee	
16:10	**Better Regulation - a key element for implementing the Lisbon Agenda** • Presentation, culminating in a short list of discussion points	Karin Krauss, European Commission
16:40	**Discussion of the points in small groups**	
17:10	**Plenary session, presentation of main conclusions of each group and discussion of these conclusions**	
17:50	**Close of first day**	
18:00	Cocktail reception and supper, EMEA canteen	

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Europe IFAH
Representing the European Animal Health Industry

Friday 10th November 2006

Session II: Risk:benefit with specific safety topics

Chair: Leo van Leemput, IFAH-Europe/Janssen Animal Health

08:45	**Environmental risk assessment (ERA): how to implement?** • Implementation of the legal requirements	Kornelia Grein, EMEA
09:00	• Phase 2 Technical guidance document – Authorities' view	Joop A. de Knecht, CVMP ad hoc group on ERA
09:20	• Phase 2 Technical guidance document – Industry's view	Audrey Kelly, Elanco,
09:40	• Discussion	
	User safety guidelines: how to implement the legal requirements – are guidelines needed for pharmaceuticals and immunologicals, and what should they contain	
09:50	• Industry's perspective	Kevin Woodward, Schering Plough
10:10	• What does the CVMP expect	Professor Reinhard Kroker, CVMP
10:20	• User Safety Guidelines for Immunologicals	Maria Tollis, CVMP
10:35	• Discussion (i) Pharmaceuticals (ii) Immunologicals	
10:45	Tea and coffee	

Session III: EMEA Bulletin board / Progress with the EMEA Road Map

Chair: Melanie Leivers, EMEA

11:15	**Progress with the EMEA Road Map**	David Mackay, EMEA
11:30	**New procedures: accelerated assessment, and relation to existing procedures, exceptional circumstances** (e.g. for avian influenza)	Jill Ashley-Smith, EMEA
11:55	**Transparency: new readable EPARS for the public**	Karen Quigley, EMEA
12:10	**CVMP reflections on 3Rs policy and alternatives to animal testing**	Kornelia Grein, EMEA
12:30	**Sunset clause**	Jill Ashley-Smith, EMEA
12:45	Questions	
13:00	Close of the meeting	