The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Inspections

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EMEA/CVMP/1129/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 9 to 10 December 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on the granting of a Community marketing authorisation for **Novem 5 mg/ml** (***meloxicam)***, from Boehringer Ingelheim VetMedica. The product is an anti-inflammatory indicated for the treatment of acute respiratory infection in calves and young cattle in combination with appropriate antibiotic therapy. The application procedure was initiated on 15 October 2003 and the opinion adopted on 10 December 2003 with an active review time of 57 days.

The Committee adopted by consensus a positive opinion on the granting of a Community marketing authorisation for **Novem 20 mg/ml** (***meloxicam)*** from Boehringer Ingelheim VetMedica. The product is an anti-inflammatory indicated for the treatment of acute respiratory infection in cattle in combination with appropriate antibiotic therapy, diarrhoea in calves and non-lactating cattle in combination with oral re-hydration, and acute mastitis in lactating cattle in combination with appropriate antibiotic therapy. In pigs the product is indicated for the treatment of non-infectious locomotor disorders and puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy. The application procedure was initiated on 15 October 2003 and the opinion was adopted on 10 December 2003 with an active review time of 57 days.

The Committee also adopted by consensus a positive opinion for an extension to the Marketing Authorisation for **Metacam** (***meloxicam)*** to 5mg/ml solution for injection for the treatment of non-infectious locomotor disorders in pigs. The application procedure was initiated on 15 October 2003 and the opinion was adopted on 10 December 2003 with an active review time of 57 days.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of provisional maximum residue limits for **oxolinic acid** in **cattle**. The application procedure was initiated on 27 October 2003 and the opinion was adopted on 10 December 2003 with an active review time of 90 days.

The Committee adopted by consensus a positive opinion recommending the inclusion of **oxalic acid** in Annex II of Council Regulation 2377/90 for **honeybees**. The application procedure was initiated on 27 October 2003 and the opinion was adopted on 10 December 2003 with an active review time of 90 days. The application benefited from a fee waiver granted by the EMEA's Executive Director following the advice of the Committee considering the substance essential in the treatment of *Varroosis* in honeybees.

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In the context of the current CVMP exercise to improve the availability of veterinary medicinal products, and recognising that insufficient veterinary medicines are available for the treatment of ectoparasites and/or endoparasites in sheep and goats, the CVMP agreed to extrapolate the existing MRLs in cattle and/or sheep to further ruminant species for certain substances identified as essential. These same substances are considered as fulfilling certain criteria in accordance with the Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin (EMEA/CVMP/187/00-FINAL) and the Position Paper regarding Availability of Veterinary Medicines - Extrapolation of MRLs (EMEA/CVMP/457/03-Post CONSULTATION). Having also considered comments received during public consultation the Committee adopted by consensus positive opinions recommending the extrapolation of existing MRLs for the following substances:

- Albendazole: Extrapolation of existing MRLs to all ruminants including milk
- Febantel: Extrapolation of existing MRLs to all ruminants including milk
- Fenbendazole: Extrapolation of existing MRLs to all ruminants including milk
- Oxfendazole: Extrapolation of existing MRLs to all ruminants including milk
- Oxyclozanide: Extrapolation of existing MRLs to all ruminants including milk
- Thiabendazole: Extrapolation of existing MRLs to goats including milk
- Amitraz: Extrapolation of existing MRLs to goats including milk
- Cypermethrin: Extrapolation of existing MRLs to all ruminants including milk
- Deltamethrin: Extrapolation to all ruminants including milk

In addition and in accordance with the same guideline and criteria the CVMP agreed to recommend the extrapolation of dexamethasone to goats including milk.

For further details please see the summary opinions available on the EMEA web site: http://www.emea.eu.int

Scientific advice

The Committee noted a request for scientific advice in relation to development of a feline vaccine and appointed a coordinator for the procedure.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSUR) for **Eurican Herpes 205, Proteq Flu** and **Proteq Flu Te** and concluded that no changes to the product literature or other regulatory actions were required.

The Committee endorsed the mandate for the pharmacovigilance working party.

Quality

The Committee adopted a Concept Paper on the development of a guideline on the stability test data to be submitted for variation applications to a Marketing Authorisation (EMEA/CVMP/1027/03). The document is being released for a 2-month period of consultation.

The document is available on the EMEA web site: http://www.emea.eu.int

Availability of Medicines

In addition to the adoption of the above mentioned opinions extrapolating MRLs to further ruminant species the CVMP adopted the revised Position Paper regarding Availability of Veterinary Medicinal Products – Extrapolation of MRLs (EMEA/CVMP/457/03-Post CONSULTATION) having considered the comments received on its proposals regarding facilitation of MRLs for essential MUMS products during the public consultation. The CVMP's next activities in this field will concern extrapolation of MRLs from chicken to poultry, the review of data requirements for the establishment of MRLs for veterinary medicines for use in apiculture and the availability of MRLs for substances suitable for treatment of histomoniasis in poultry, particularly in turkeys.

Enlargement

To facilitate a smooth transition for the CVMP Observers of the New Member States with regard to ongoing applications for Maximum Residue Limits and Marketing Authorisations, the Committee endorsed a procedural announcement (see attached Annex) concerning the transitional requirements for such applications for the New Member States. Applicants are requested to submit MRL applications and Part I of their Marketing Authorisation applications to the nominated contact points of the New Member States in accordance with the defined procedure.

The next meeting of the CVMP will be held on 13-15 January 2004

Peter G.H. Jones
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This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Procedural announcement

Maximum Residue Limit (MRL) applications and Marketing Authorisation applications (MAAs) - transitional arrangements for the New Member States

In view of the EU Enlargement that will come into force as of 1st May 2004, and in order to facilitate a smooth transitional phase for the evaluation activities of the CVMP, the EMEA requests Applicants to also submit MRL applications and Part I of their MA applications, to the Contact Points of the New Member States that can be found in the attached table. This will enable the CVMP Observers of the Accession Countries to have an increased awareness of the supporting documentation that will be discussed by the CVMP during their monthly meetings between now and the 1st May 2004.

The EMEA proposes the following:

MRL applications (including those for extensions and modifications to the MRL, under Article 2 of Commission Regulation (EC) No 1085/2003):

After positive validation of the MRL application, in addition to the normal submission to the CVMP Members (as per the SOP on MRL applications), the MRL dossier can be presented to the contact points of each of the new Member States (see attached Table).

CENTRALISED PROCEDURE for MARKETING AUTHORISATION APPLICATIONS:

New Full Applications
(including those under Annex II of Commission Regulation (EC) No 1085/2003):
After positive validation of the MAA, in addition to the normal submission to the CVMP Members, as per the published EMEA dossier requirements, Part I (electronically and/or hard copies) can be presented to the Contact Points of the New Member States* (see attached Table).

Ongoing Full Applications
(including those under Annex II of Commission Regulation (EC) No 1085/2003):
It is preferable to stage the supply of these MAAs at specific milestones in the centralised procedure as follows:

- At the time of submission of the Responses to Day 120 List of Questions, Part I should be forwarded to the Contact Points of the New Member States*
- At the time of submission of the Responses to Day 180 List of Outstanding Issues, Part I should be forwarded to the Contact Points of the New Member States*

Type II variations concerning changes to/addition of therapeutic indications or changes to/addition of a non-food producing target species:
After positive validation of the variation application, in addition to the normal submission to the CVMP Members, as per the published EMEA Post-Authorisation guide, Part I can be presented to the Contact Points of the New Member States*.

In parallel with the above process, which applicants are recommended to follow, the EMEA will also forward the relevant Rapporteurs' assessment reports to the Nominated CVMP Observers. If there are any queries regarding this proposed process, please forward them to: Kornelia.Grein@emea.eu.int for MRL applications and Jill.Ashley@emea.eu.int for Centralised Procedures.

* **It is important to clearly state the purpose of such a submission in a letter accompanying the documentation.**

Contact details for submission of dossiers to New Member States

Country	Name	Address	Telephone	Fax	e-mail
Cyprus	Dr Kleitos Andreou/ Dr Phedias Loucaides	Ministry of Agriculture, Natural Resources and Environment Veterinary Services CY-1417 Nicosia	+357 228 05 200 +357 228 05 201	+357 223 32 803	director@vs.moa.gov.cy
Czech Republic	Vice professor Alfred Hera, DVM, PhD	Institute for the State Control of Veterinary Biologicals and Medicaments Hudcova Str. 56A CZ-621 00 Brno – Medlanky	+420 541 210 022-4 +420 541 321 203	+420 541 210 026	hera@uskvbl.cz
Estonia	Dr Birgit Aasmäe/ Dr Ave-Ly Toomvap	State Agency of Medicines 19 Ravila Street EE-50411 Tartu	+372 7 374 140 +372 7 374 143	+372 7 374 142 +372 7 374 152	Birgit.Aasmae@sam.ee Birgit@sam.ee Ave-Ly.Toomvap@sam.ee
Hungary	Dr Tibor Soós	Institute for Veterinary Medicinal Products Szállás utca 8 H-1107 Budapest X POB 318 H-1475 Budapest 10	+36 1 433 0345	+36 1 262 2839	soost@oai.hu
Latvia	To be advised				
Lithuania	Dr Laimis Jodkonis/ Dr Juozas Jokimas	Lithuanian State Inspection on Veterinary Preparations Savanoriu pr. 287 LT-3009 Kaunas	+370 37 312 568 +370 37 311 558	+370 37 312 531	laijod@vet.lt vet.prep.lab@vet.lt

Country	Name	Address	Telephone	Fax	e-mail
Malta	Mr Kenneth Mifsud	Department of Food and Veterinary Services Albertown M-Marsa	+356 9984 5587	+356 21 23 81 05	kenneth.mifsud@gov.mt
Poland	Ms Dorota Papierska	Office for Medicinal Products, Medical Devices and Biocides 30/34 Chelmska St. PL-00-725 Warsaw	+48 22 452 06 39 +48 22 851 43 81	tel.(48-22) 452 06 39 fax.(48-22) 452 06 34	dorota.papierska@urpl.gov.pl
Slovak Republic	Dr Judita Hederová/ Dr Milan Šajgalík	Institute for State Control of Veterinary Biologicals and Medicaments Biovetská 34 SK-949 01 Nitra	+421 37 6515 501-5	+421 37 6517 915	uskvbl@flynet.sk
Slovenia	To be advised				

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	10	60
Withdrawals	8	1	9
Positive CVMP opinions	38	4	42
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2002	2003	Overall Total
Variations type I	98	48	146
Variations type II	37	12	49

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	2	35
Withdrawals	1	0	1
Positive opinions	15	6	21
Negative opinions	0	0	0

[1] In case of appeal the opinion will not be counted twice

Renewals of marketing authorisations

	1995-2002	2003	Overall Total
Renewal applications submitted	7	4	11
Renewal positive opinions	5	4	9
Renewal negative opinions	0	0	0

Scientific advice

	1995-2002	2003	Overall Total
Applications submitted	20	2	22

Establishment of maximum residue limits

	1995-2002			2003			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	50	73	123	2	8	10	133
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	1	7	8	123
Negative opinions**	5	5	10	0	0	0	10

*Including 16 opinions recommending definitive MRLs for substances with previously provisional maximum residue limits

**Including 2 opinions (1 full, 1 extension) concluding that final maximum residue limits could not be established for substances with provisional maximum residue limits previously established

Referrals

	1995-2002	2003	Overall Total
Referrals	7	1	8