European Medicines Agency
Veterinary Medicines and Inspections

London, 10 December 2004
EMEA/CVMP/1163/04-corrigendum[1]

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 7 to 9 December 2004

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an extension application for **Eurifel FeLV**, a vaccine against feline leukaemia from Mérial to add a suspension for injection formulation. The application procedure was initiated on 19 April 2004 and the opinion was adopted on 8 December 2004 with an active review time of 177 days.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the extension of the current Annex I entry of Council Regulation (EEC) No. 2377/90 for **penethamate** to all mammalian food-producing species**,** further to a request from a company. This recommendation was made taking into account that MRLs were already established for benzylpenicillin in all food producing species and for which the same marker residue has been identified and the CVMP risk assessment approach for extrapolating existing maximum residue limits to further species.

For further details please see the Summary opinions which will be available on Monday 13 December 2004 on the EMEA web site: http://www.emea.eu.int

Community Referrals

The Committee finalised its evaluation of the referral from France concerning national marketing authorisations existing in several EU Member States for Micotil 300 (tilmicosin). The referral was initiated by France under Article 35 of Council Directive 2001/82/EC in the interest of the Community to investigate concerns regarding user safety. This followed the receipt of a report about a fatal accidental injection in a human being in the USA during treatment of animals earlier this year. The Committee concluded by majority that the benefits of Micotil under appropriate use as detailed in the revised user safety warnings outweigh the potential risks to the user, especially in conjunction with the additional measures recommended by the Committee. These measures include recommendation of restriction to use by veterinarians, a group of persons who by nature of their training and their job are experienced in handling potentially lethal medicinal products, and better guidance on advisable courses of treatment should accidental administration occur.

An appeal against this opinion may be launched by the companies concerned within the deadlines provided by legislation.

[1] Correction introduced on 6 January 2005 in the reference to the annex entry for penethamate (Annex I instead of Annex II)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

The Committee considered the grounds for appeal against the CVMP opinion adopted on 8 September 2004 with regard to the referral for **Dectomax 1%** injectable solution (doramectin). The referral was initiated by the United Kingdom in order to harmonise the different withdrawal periods established by Member States with respect to sheep. The Committee, having considered the grounds for appeal provided by the Marketing Authorisation Holder confirmed its previous opinion concluding that a withdrawal period of 70 days following intramuscular administration should be established. The Committee also confirmed that for subcutaneous administration no withdrawal period ensuring residues levels below MRLs could be established and therefore this route should be removed from the product literature. The Committee adopted by consensus a final opinion on the referral accordingly.

Pharmacovigilance

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

Guidelines, SOPs and Position Papers

Pharmacovigilance

The Committee adopted a guideline on additional controlled terminology for electronic submission of reports on adverse reactions to veterinary medicinal products, following the close of the consultation period (EMEA/CVMP/556/04-FINAL). This guideline describes controlled terminology that will be implemented in the electronic system in the EU for reporting adverse reactions, EudraVigilance. The guideline will become effective as of 1 January 2005, since no suggestions for amendments were received during the consultation period and electronic reporting of suspected adverse reaction to veterinary medicines by Competent Authorities will begin on that date.

Immunologicals

The Committee adopted a guideline on live recombinant vector vaccines for veterinary use further to the consideration of the comments received during the public consultation (EMEA/CVMP/004/04-FINAL). This guideline defines the requirements for the quality, safety and efficacy part of applications for marketing authorisations for vector vaccines, with particular emphasis on the properties of live recombinant vector vaccines in the target and non-target species including the natural host of the parental organism, where relevant. The guideline will particularly provide advice where the vector itself is an immunogen.

The Committee adopted a concept paper on the need to revise the note for guidance on requirements for combined vaccines, prepared by the Immunologicals Working Party further to the consideration of comments received during the consultation period and gave the mandate to the Immunologicals Working Party to initiate the work on the revision of the guideline.

The documents will be available on the EMEA web site on 13 December 2004: http://www.emea.eu.int

Availability of Medicines

The Committee adopted a proposal for a list of substances essential for the treatment of horses further to the request from the European Commission. The list was prepared following consultation with the Federation of European Veterinarians (FVE) and the European Association for Veterinary Pharmacology and Toxicology (EAVPT). The list will now be submitted to the Commission for adoption by the Standing Committee in accordance in Article 10 (3) of Directive 2001/82/EC as amended. Once adopted, the list will eventually provide for the use of products by veterinarians in the horse under the conditions of the "cascade" containing the listed substances for which no MRLs are established, providing a minimal withdrawal period of 6 months is applied.

Organisational issues

CVMP Working Parties

The Committee elected the Chairpersons of the standing and temporary working parties as follows:

- Efficacy Working Party: Michael Holzhauser-Alberti
- Immunologicals Working Party: Jean-Claude Rouby
- Pharmacovigilance Working Party: Cornelia Ibrahim
- Safety Working Party: Christian Friis
- Environmental Risk Assessment Working Party: Johannes Hoogland

The election of the chair of the joint Quality Working Party will first take place at the CHMP and then submitted for confirmation to the CVMP.

Rory Breathnach was elected vice-chair of the Scientific Advice Working Party; the Chairperson, Reinhard Kroker had been elected back in July 2004.

Elections of any vice-chairs of the remaining working parties will take place at a later stage following decisions of the working parties whether they wish to have a vice-chair.

Notice for Applicants: Guidance on genetically modified organisms (GMOs)

The Committee adopted for release for consultation an updated guideline on the Environmental Risk Assessment for veterinary medicinal products containing or consisting of GMOs (current guidance forms Annex I to Volume 6B of the European Commission's Notice to Applicants).

The updated document combines the three existing guidelines, in order to create guidance for Applicants which is easier to follow. The guidance is released for a three month period of consultation and, after finalisation, will be included in Volume 6C of the Notice to Applicants.

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

Informal CVMP meeting

The Committee had an initial report of the Informal CVMP meeting held on 1-2 December in Rotterdam, the Netherlands

CVMP Audit

The Committee reviewed in detail the Report of the CVMP Audit that took place on 8-12 October 2004 and the Opportunity for Improvement (OFI) in respect to certain aspects of functioning of the Committee and agreed on proposed actions based on the recommendations of the Informal CVMP meeting.

The next meeting of the CVMP will be held on 11-13 January 2005

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

Marketing Authorisations

	1995-2003	2004	Overall Total
Applications submitted[2]	60	7	67
Withdrawals	9	1	10
Positive CVMP opinions	42	10	52
Negative CVMP opinions[3]	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I[1]	146	19	165
Variations type II[1]	49	14	63
Transfers	4	1	5

Extensions

	1995-2003	2004	Overall Total
Extensions (Annex II applications) submitted[1]	35	5	40
Withdrawals	1	0	1
Positive opinions	21	3	24
Negative opinions	0	0	0

[2] Applications submitted and validated at the time of going to press
[3] In case of appeal the opinion will not be counted twice

Renewals of marketing authorisations

	1995-2003	2004	Overall Total
Renewal applications submitted[1]	11	5	16
Renewal positive opinions	9	5	14
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted[1]	22	5	27

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted[1]	52	81	133	4	7	11	144
Withdrawals	5	4	9	0	0	0	9
Positive opinions[*]	37	86	123	8	8	16	137
Negative opinions[**]	5	5	10	1	0	1	11

[*] Including 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

	1995-2003	2004	Overall Total
Referrals	8	2	10