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

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EMEA/CVMP/595/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 17 to 19 June 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an extension application for a further species (horses) to the marketing authorisation for **Metacam 15 mg/ml oral suspension**, from Boehringer Ingelheim Vetmedica. The product is indicated for the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders. The application procedure was initiated on 13 November 2002 and the opinion was adopted on 18 June 2003 with an active review time of 210 days.

The Committee adopted by consensus a positive opinion for a Type I variation following a Type II procedure for **Fevaxyn Pentofel** for the amendment of the testing of some of the component antigens.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of provisional maximum residue limits in accordance with Council Regulation (EEC) No 2377/90, as amended, for **phoxim** for chicken. The application procedure was initiated on 18 October 2002 and the opinion was adopted on 18 June 2003 with an active review time of 120 days.

The Committee adopted by consensus two positive opinions recommending the inclusion of **alphacypermethrin** (bovine and ovine species) and **metamizole** (bovine, porcine and *Equidae* species) in Annex I of Council Regulation (EEC) No 2377/90, further to establishment of provisional MRLs. The applications were submitted under the procedure for the so-called "old substances" ("old" Article 7 of Council Regulation (EEC) No 2377/90) and the current provisional MRLs will expire on 1 July 2003.

The Committee considered an appeal in respect to the negative MRL opinion for **morantel** adopted on 12 March 2003. The Committee revised the previous opinion in light of the explanations by the applicant company and recommended by majority the inclusion of morantel in Annex II of Council Regulation (EEC) No 2377/90 for bovine and ovine species.

The Committee noted the Decision of the EMEA's Executive Director to grant a **fee waiver** for an application for the establishment of MRLs for a substance considered essential in the treatment of ***Varroosis* in honeybees**, further to the advice of the Committee.

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

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Antimicrobial Resistance

Further to the in depth discussions during the Informal CVMP held in Athens under the initiative of the Greek presidency of the European Union on 20 and 21 May 2003, the Committee reviewed the future strategy on antimicrobial resistance (EMEA/CVMP/558/03). In short, the Committee will in the future focus its effort on the **implementation of the recently approved guidelines on antimicrobial** substances, including the future organisation of a **workshop** with its interested parties on these guidelines, and on seeking information on **antimicrobial surveillance and consumption**.

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

The Committee took note of the Opinion of the Scientific Committee on veterinary measures relating to public health on the human health risk caused by the use of **fluoroquinolones** in animals and specifically the acknowledgement that the new CVMP guidelines are believed to further reduce fluoroquinolone resistance in livestock.

Availability of Medicines

The Committee adopted a Position Paper on **Availability of products for minor uses and minor species (MUMS)** (EMEA/CVMP/477/03-CONSULTATION). This extremely important paper considers the position today following the progress made since 1999-2000 and aims to define the problem in some depth and makes suggestions for possible solutions in a strategic action plan. In particular a more pragmatic approach is called for concerning the dossier requirements for minor uses and major species and further proposals for improving availability. The Position Paper is being released for a 6-month consultation period.

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

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Pirsue**, **Econor**, **Eurican Herpes 205** and **Rabigen SAG2**, and concluded that no changes to the product literature or other regulatory actions were required.

The Committee adopted the guideline on **Causality assessment** for adverse reactions to veterinary medicinal products, prepared by the Pharmacovigilance Working Party with input from pharmaceutical industry (EMEA/CVMP/552/03-CONSULTATION). The guideline is being released for a 6-month period of consultation. This guideline was one of the key recommendations of the Pharmacovigilance Madrid Conference in 2002 and is welcomed by the Committee.

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

Further to the adoption by CVMP of the revised **VEDDRA terminology** in September 2002, a VEDDRA database has been developed. Having been tested with the Competent Authorities of the Member States, the database is now being made publicly available. It can be accessed at http://www.veddra.org or http://193.130.35.17/veddra/ or via link from the EMEA web site.

Immunologicals

The Committee adopted a revised Position Paper on **indications for veterinary vaccines** following the close of the consultation period (EMEA/CVMP/042/97-Rev.1-FINAL) with immediate effect. This position paper, which was originally published in 1998, had been updated by the Immunologicals Working Party to reflect the experience gained with the application of the original position paper.

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

International harmonisation

The Committee was informed regarding ongoing **PERF III activities** in the context of the enlargement of the EU. An **Efficacy Workshop** held on 11-12 June 2003 in Riga, Latvia focussed on the clinical expert report, dossier assessment, bibliographical applications, bioequivalence, intramammary and non-steroidal anti-inflammatory products. An **Acquis communautaire Working Group** was held on 2-4 June 2003 in Warsaw, Poland. Marketing Authorisation Holders are now to be informed of the next actions to be taken in order to prepare for a smooth phasing in of Centralised Marketing Authorisations into the territory of the new Member States. The main message was that supporting elements (SPC, labelling, package leaflet templates) were available from the respective National Authorities and that companies should start with the translations of the product information into the new official languages as soon as possible. A Safety Workshop would take place on 23-24 June 2003 in London focussing on remaining issues regarding safety assessment and environmental risk assessment.

The Committee discussed the draft "**Glossary of Terms and Definitions**" to be included in the "Code of practice on antimicrobials" currently being prepared by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), which has been prepared by the US FDA, who is the rapporteur for this Codex activity. In preparation of the oncoming CCRVDF drafting group in July 2003, the Committee prepared comments on the glossary.

The Committee agreed on comments on the JECFA response to the CCRVDF regarding **risk assessment principles** for the establishment of maximum residue limits.

New topics

The Committee endorsed a concept paper for the development of guidance on the description of **target animal species in the SPC**, to be prepared by the Efficacy Working Party. This guidance would be incorporated into the existing SPC guidelines, possibly as an annex.

The next meeting of the CVMP will be held on 22-24 July 2003

The CVMP held a meeting with its **Interested Parties** on Wednesday 18 June where representatives of FVE, IFAH and AVC were in attendance. The main discussions focussed on the Availability of Medicines and the latest CVMP proposals in this regard, and preparation for enlargement of the European Union in the Veterinary Pharmaceutical sector under the PERF programme.

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

Annex I to CVMP Press Release June 2003

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	3	53
Withdrawals	8	1	9
Positive CVMP opinions	38	1	39
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2002	2003	Overall Total
Variations type I	98	22	120
Variations type II	37	4	41

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	1	34
Withdrawals	1	0	1
Positive opinions	15	3	18
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	2	9
Renewal positive opinions	5	4	9
Renewal negative opinions	0	0	0

Scientific advice

	1995-2002	2003	Overall Total
Applications submitted	20	1	21

Establishment of maximum residue limits

	1995-2002			2003			Overall Total
	Full	Extension/ Modification	Total	Full	Extension/ Modification	Total	
Applications submitted	50	73	123	0	5	5	128
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	0	2	2	117
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	8	0	8