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

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EMEA/CVMP/071/03

# PRESS RELEASE
# COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

## Meeting of 14 to 16 January 2003

The Committee met for the first time under the chairmanship of Gérard Moulin.

## CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by majority, two positive opinions on extension applications for new indications to the marketing authorisation for **Metacam 20 mg/ml solution for injection** from Boehringer Ingelheim Vetmedica. The new indications cover adjunctive therapy in the treatment of acute mastitis in cows and use in non-infectious locomotor disorders as well as adjunctive therapy in the treatment of puerperal septicaemia and toxaemia with appropriate antibiotic therapy in pigs. The application procedures were initiated on 11 March 2002 and 19 December 2001 and the opinions were adopted on 15 January 2003 with an active review time of 150 days and 204 days respectively.

The Committee adopted by consensus a positive opinion for a type II variation for **Bayovac CFS E2** regarding compliance with the required standardised safety warning for veterinary medicinal products containing mineral oil with regard to operator safety. With this opinion, the Committee has concluded the evaluation of the variation applications submitted to comply with the safety warning agreed by the Committee regarding veterinary medicinal products containing mineral oil. The Committee awaits variation applications for two remaining vaccines from one marketing authorisation holder.

## Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **cypermethrin** in Annex I of Council Regulation (EEC) No. 2377/90 for *Salmonidae* further to establishment of provisional MRLs. The application procedure was initiated on 1 July 1996 and an opinion recommending the establishment of provisional MRLs for cypermethrin in *Salmonidae* was adopted on 6 May 1998 with an active review time of 162 days. The assessment of the response to the outstanding questions was initiated on 19 October 2002 and the opinion adopted on 15 January 2003 with an active review time of 89 days.

The Committee adopted an opinion recommending the extension of the current Annex II entry of Council Regulation (EEC) No. 2377/90 for **acetylsalicylic acid, sodium acetylsalicylate, acetylsalicylic acid DL-lysine and carbasalate calcium** to **all food producing species, except fish** (not for use in animals from which milk or eggs are produced for human consumption) further to a request from a company. This recommendation was made in accordance with the review of the risk assessment approach for the establishment of maximum residue limits with a view to establishing a more pragmatic approach in securing the provision of medicines for treating animals especially those classed as minor species.

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

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## Community Referrals

*Referral under Article 20 of Directive 81/851/EEC (now Article 35 of Directive 2001/82/EEC)*

The Committee considered the Grounds for Appeal against the opinion adopted in October 2002 on long acting injectable veterinary medicinal products containing **benzathine benzylpenicillin** and concluded that the previous recommendation of the Committee should stand. Therefore the Committee adopted unanimously an opinion confirming its previous recommendation to suspend the Marketing Authorisations for all benzathine benzylpenicillin injectable veterinary medicinal products intended for administration to food producing species. The opinion will be forwarded to the European Commission.

The Committee will review the opinion for suspension within one year or as soon as new data is submitted to the Committee for evaluation.

*Referral under Article 33 of Council Directive 2001/82/EC*

The Committee adopted by consensus an opinion regarding the referral from two Concerned Member States under Article 33 of Directive 2001/82/EC for arbitration on a Mutual Recognition Procedure concerning the proposed recommended dose of orbifloxacin for the treatment of skin and soft tissue infections in dogs. The Committee agreed that the recommended dose proposed by the Applicant was sufficient to ensure appropriate treatment of skin infections in dogs. The objections of the Concerned Member States who initiated the referral were overruled. The opinion will be forwarded to the Commission.

## Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) on **Bayovac CSF E2**, **Eurifel RCP FeLV**, **Locatim**, **Doxirobe Gel** and **Econor** and concluded that the information available did not create a need for further action or changes to the product literature of the products.

## International harmonisation

The Committee was informed on the first Workshop to take place in the context of the PERF III activities. The Workshop will focus on immunologicals and will take place in Strasbourg on 22-24 January 2003.

## Organisational issues

The Committee reviewed its policy regarding the appointment of Rapporteurs for the evaluation of the different procedures considering the experience gained and the recommendations on this topic from the last two informal CVMP meetings. The revised approach aims to facilitate the appointment of Rapporteurs and a more balanced distribution of rapporteurship between members

*For further details please see Document EMEA/CVMP/928/02-Final available on the EMEA web site: http://www.emea.eu.int*

The Committee noted the following procedural announcement regarding mock-ups and specimens for new applications taking account the implementation of the revised linguistic review process:

**PROCEDURAL ANOUNCEMENT**

**MOCK-UP & SPECIMEN REQUIREMENTS FOR NEW APPLICATIONS**

Further to the implementation of the "New product information linguistic review process" (http://www.emea.eu.int/pdfs/human/regaffair/554202en.pdf), the EMEA would like to clarify the mock-up and specimen requirements for new applications in the Centralised Procedure.

**At submission (Day 0):**
One English mock-up (preferably in colour) and one multi-lingual mock-up ("worst-case") of the outer and inner packaging for each pharmaceutical form in the smallest pack-size must be included in Part I of the application.

**After adoption of the CVMP opinion (Day 210)**
A reduced mock-up package and package insert will have to be submitted by Day 260 for every country where marketing is proposed. At this stage, the linguistic checking procedure will be finalised and the Applicant is expected to reflect the latest agreed translations, incorporating all comments made, into the mock-ups. The EMEA will perform the mock-up check in 30 days in parallel to the Standing Committee consultation.

Mock-ups must be submitted for the smallest pack-size of each strength and pharmaceutical form, for each container type (e.g. vial) for all Member States, based on the latest version of the product information, together with a commitment that all other pack-sizes will be identical -except for pack-size specific information- and that EMEA comments will also be implemented in the other pack-sizes.

**Before launch**
Once the medicinal product is authorised and in all cases before the medicinal product is placed on the market, specimens of the final outer and inner packaging and the package leaflet must be submitted for review to the EMEA within a timeframe agreed between the EMEA and the Marketing Authorisation Holder.

The next meeting of the CVMP will be held on 11-13 February 2003

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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 January 2003**

## Marketing Authorisations

| | 1995-2002 | 2003 | Overall Total |
|---|---|---|---|
| **Applications submitted** | 50 | 1 | 51 |
| **Withdrawals** | 8 | 0 | 8 |
| **Positive CVMP opinions** | 38 | 0 | 38 |
| **Negative CVMP opinions**[1] | 0 | 0 | 0 |

## Variations

| | 1995-2002 | 2003 | Overall Total |
|---|---|---|---|
| **Variations type I** | 98 | 1 | 99 |
| **Variations type II** | 37 | 0 | 37 |

## Extensions

| | 1995-2002 | 2003 | Overall Total |
|---|---|---|---|
| **Extensions (Annex II applications) submitted** | 33 | 0 | 33 |
| **Withdrawals** | 1 | 0 | 1 |
| **Positive opinions** | 15 | 2 | 17 |
| **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 | 0 | 7 |
| **Renewal positive opinions** | 5 | 0 | 5 |
| **Renewal negative opinions** | 0 | 0 | 0 |

## Scientific advice

| | 1995-2002 | 2003 | Overall Total |
|---|---|---|---|
| **Applications submitted** | 20 | 0 | 20 |

## Establishment of maximum residue limits

| | 1995-2002 | | | 2003 | | | Overall Total |
|---|---|---|---|---|---|---|---|
| | **Full** | **Extension/ Modification** | **Total** | **Full** | **Extension/ Modification** | **Total** | |
| **Applications submitted** | 50 | 73 | 123 | 0 | 0 | 0 | 123 |
| **Withdrawals** | 5 | 4 | 9 | 0 | 0 | 0 | 9 |
| **Positive opinions*** | 36 | 79 | 115 | 0 | 1 | 0 | 116 |
| **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 |