European Medicines Agency
*Veterinary Medicines and Inspections*

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# PRESS RELEASE

# COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

**Meeting of 12 to 14 October 2004**

## CVMP Opinions on Veterinary Medicinal Products

The Committee adopted a positive opinion by consensus for a Type II variation for Neocolipor regarding the addition of othersmanufacturing sites.

## Maximum Residue Limits

The Committee adopted, by consensus, a positive opinion recommending the inclusion of lasalocid in Annex I of Council Regulation (EEC) No. 2377/90, as amended, for poultry. The application procedure was initiated on 13 February 2004 and the opinion was adopted on 13 October 2004 with an active review time of 120 days.

*For further details please see the Summary opinions which will be available on Monday 18 October 2004 on the EMEA web site: http://www.emea.eu.int*

## Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for Draxxin, Metacam & Novem, Porcilis Pesti, SevoFlo, and further to the receipt of additional clarification from the MAH, for Eurifel RCP FeLV and Proteq Flu-Te, and concluded that no further action or changes to the product literature of the products were required.

The Committee adopted a common EU form for reporting adverse drug reactions by veterinarians (EMEA/CVMP/893/04-CONSULTATION), for release for consultation. The intention of the form, which has been developed by the CVMP Pharmacovigilance Working Party, is to encourage and facilitate reporting of ADRs by veterinary practitioners throughout the EU in a harmonised format that is easy and straightforward to use.

The Committee also adopted the first revision of the VEDDRA list of clinical terms for reporting adverse reactions in animals to veterinary medicines (EMEA/CVMP/413/99-Rev.1). This controlled terminology is a core piece of the EU electronic reporting system for adverse reactions to veterinary medicinal products, EudraVigilance Veterinary, as it will allow presentation of reported adverse reactions in a standardised way that will facilitate comparison of reactions and analysis of the data. This list of terms shall be revised on an annual basis and therefore the Committee also adopted a call for comments for annual revision of VEDDRA (EMEA/CVMP/892/04). Furthermore, the Committee adopted the VEDDRA – draft terms for reporting reactions in human beings to veterinary medicines for release for consultation (EMEA/CVMP/891/04-CONSULTATION), an analogous list to the previously mentioned one with the specific purpose of coding reactions to veterinary medicines that occur in human beings. This draft terminology will already be available in EudraVigilance Veterinary,

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since it is expected that comments are likely to focus on the tems and their placement within the VEDDRA structure. Any revisions made to the human terms following the consultation period will be implemented in EudraVigilance Veterinary in the same manner as the annual revisions of the terminology.

*The documents will be available on the EMEA web site: http://www.emea.eu.int on Monday 18 October 2004*

*The VEDDRA terminology is also available in form of a database at www.veddra.org.*

## Safety of Medicines

The Committee adopted a revised guideline on injection site residues prepared by the Safety Working Party after consideration of comments received during the public consultation (EMEA/CVMP/542/03-FINAL). A summary of the comments received from Interested Parties during consultation including the CVMP considerations will be shortly published.
This guideline is a revision of and supersedes the Working Document prepared by the Safety of Residues Working Party and agreed by the CVMP in 1994 on principles concerning the assessment of injection site residues.

*The guideline will be available on the EMEA web site: http://www.emea.eu.int on Monday 18 October 2004*

## Availability of veterinary medicines

The Committee discussed with experts from FVE and EAVPT the first draft for a proposal for a list of essential substances for the treatment of horses that is being prepared by the CVMP further to the request from the Commission. Suggestions from the experts were discussed and another meeting is likely to take place in the margins of the CVMP meeting in December before the list is submitted to the Commission. Taking into account the proposal from the CVMP the Commission will then present a list for adoption by the Standing Committee in accordance with Article 10 (3) of Directive 2001/82/EC, as amended. The list, once adopted, 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.

## Scientific Advice Working Party

The Committee adopted the mandate for the Scientific Advice Working Party governing the main tasks and objectives of this group, which has now held its second meeting since the creation of the Working Party in September 2004. The mandate and composition of the Scientific Advice Working Party will be published on the EMEA website. The mandate reflects a more user-friendly approach to the provision of scientific advice, in response to feedback received from interested parties. Advice can now be requested on topics even where guidelines are available. Follow-up and enquiries are encouraged and provided for.

*The document will be available on the EMEA web site: http://www.emea.eu.int on Monday 18 October 2004*

## Organisational issues

The Committee endorsed the work programmes for 2005 for the CVMP Scientific Advice, Pharmacovigilance, Efficacy, Safety, Immunologicals, Quality, Biotech and Environmental Risk Assessment Working Parties and also for the Scientific Advisory Group on Antimicrobials. The work programmes will be summarised in the EMEA Work Programme for 2005, which will be published

later this year. The work programmes will be an item for discussion at the forthcoming joint infoday with IFAH Europe at EMEA on the 9/10 December. A programme for the infoday will be published soon.

The Committee endorsed the following revised Standard Operating Procedures (SOP):

- SOP on Submission and evaluation procedure for an application for the establishment of Maximum Residue Limits (MRLs) (EMEA/CVMP/819/99-Rev.3)
- SOP on Appeal against CVMP Opinions on the establishment of MRLs and provision of detailed grounds for appeal (EMEA/CVMP/931/00-Rev.2)
- External SOP on Submission of an Application for the Granting of a Community Marketing Authorisation (EMEA/CVMP/970/04)

The SOPs have been amended to take into account the implementation of the new pharmaceutical legislation in particular the new composition of the Committee

The Committee endorsed procedure to be followed to facilitate communication and dialogue between the CVMP and the interested parties following consideration of comments received during the public consultation (EMEA/CVMP/329/04_FINAL)

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

The next meeting of the CVMP will be held on 9-11 November 2004

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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** | 60 | 7 | 67 |
| **Withdrawals** | 9 | 1 | 10 |
| **Positive CVMP opinions** | 42 | 4 | 46 |
| **Negative CVMP opinions**[1] | 0 | 0 | 0 |

## Variations

| | 1995-2003 | 2004 | Overall Total |
|---|---|---|---|
| **Variations type I** | 146 | 16 | 162 |
| **Variations type II** | 49 | 8 | 57 |
| **Transfers** | 4 | 1 | 5 |

## Extensions

| | 1995-2003 | 2004 | Overall Total |
|---|---|---|---|
| **Extensions (Annex II applications) submitted** | 35 | 5 | 40 |
| **Withdrawals** | 1 | 0 | 1 |
| **Positive opinions** | 21 | 1 | 22 |
| **Negative opinions** | 0 | 0 | 0 |

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

## Renewals of marketing authorisations

| | 1995-2003 | 2004 | Overall Total |
|---|---|---|---|
| **Renewal applications submitted** | 11 | 3 | 14 |
| **Renewal positive opinions** | 9 | 5 | 14 |
| **Renewal negative opinions** | 0 | 0 | 0 |

## Scientific advice

| | 1995-2003 | 2004 | Overall Total |
|---|---|---|---|
| **Applications submitted** | 22 | 4 | 26 |

## Establishment of maximum residue limits

| | 1995-2003 | | | 2004 | | | Overall Total |
|---|---|---|---|---|---|---|---|
| | Full | Extension/ Modification | Total | Full | Extension/ Modification | Total | |
| **Applications submitted** | 52 | 81 | 133 | 4 | 6 | 10 | 143 |
| **Withdrawals** | 5 | 4 | 9 | 0 | 0 | 0 | 9 |
| **Positive opinions*** | 37 | 86 | 123 | 8 | 5 | 13 | 136 |
| **Negative opinions**** | 5 | 5 | 10 | 1 | 0 | 1 | 11 |

*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

| | 1995-2003 | 2004 | Overall Total |
|---|---|---|---|
| **Referrals** | 8 | 2 | 10 |