European Medicines Agency
*Veterinary Medicines and Inspections*

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# COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

# MONTHLY REPORT OF APPLICATION PROCEDURES, GUIDELINES AND RELATED DOCUMENTS

As from January 2005 the statistics related to the status of CVMP procedures previously annexed to the CVMP Press Release, are now published as a stand alone document, the CVMP Monthly Report. The CVMP Monthly Report includes statistical data for the current year and the previous two ones on Initial Evaluations, Scientific Advice, Variations, Line Extensions, Renewals, MRLs Initial Evaluations and MRLs Extensions/Modifications and Arbitration and Referral procedures. In addition, the report includes a summary table of the opinions issued by the CVMP in the current year and a list of adopted Guidelines and other public documents. The CVMP Monthly Report will be updated at the end of each month.

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**The Monthly Report, the Press Release and other documents are available on the Internet at the following address: www.emea.eu.int**

## Initial Evaluation[a]

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Full Applications** | 50 | 10 | 7 | 0 | **67** |
| **Abridged Applications** | 1 | 1 | 1 | 0 | **3** |
| **Withdrawals** | 8 | 1 | 1 | 0 | **10** |
| **Positive opinions** | 38 | 3 | 10 | 1 | **52** |
| **Negative opinions** | 0 | 0 | 0 | 0 | **0** |

[a] Applications submitted and validated: overall total 70 applications (full + abridged), comprising 39 immunologicals and 31 pharmaceuticals.
Negative opinions: in case of appeals, the opinion will not be counted twice.

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## Scientific Advice

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Requests received** | 20 | 2 | 5 | 2 | **29** |

## Extensions (Annex II applications)

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Applications submitted** | 32 | 2 | 5 | 1 | **40**[b] |
| **Withdrawals** | 1 | 0 | 0 | 0 | **1** |
| **Positive opinions** | 15 | 6 | 3 | 0 | **24** |
| **Negative opinions** | 0 | 0 | 0 | 0 | **0** |

## Variations

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Type IA** | 99 | 48 | 14 | 1 | **159** |
| **Type IB** | | | 5 | 1 | **9** |
| **Transfers** | 2 | 2 | 1 | 0 | **5** |
| **Type II** | 37 | 12 | 16 | 2 | **67** |

## Renewals of marketing authorisations

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Applications submitted** | 7 | 4 | 7 | 0 | 18 |
| **Positive opinions** | 5 | 4 | 5 | 1 | 15 |
| **Negative opinions** | 0 | 0 | 0 | 0 | 0 |

[b] Applications submitted and validated: overall total 40 line extensions, comprising 6 immunologicals and 34 phamaceuticals; one opinion can cover a number of extensions.

## Establishment of maximum residue limits (MRLs) for new substances

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Applications submitted** | 50 | 1 | 6 | 1 | 58 |
| **Withdrawals** | 5 | 0 | 0 | 0 | 5 |
| **Positive opinions** [c] | 36 | 1 | 4 | 0 | 41 |
| **Negative opinions** [d] | 5 | 0 | 1 | 0 | 6 |

## Extensions / Modifications of MRLs

| | 1995-2002 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Applications submitted** | 73 | 7 | 7 | 0 | 87 |
| **Withdrawals** | 4 | 0 | 0 | 0 | 4 |
| **Positive opinions** [c] | 79 | 6 | 8 | 3 | 96 |
| **Negative opinions** [d] | 5 | 0 | 0 | 0 | 5 |

## Arbitrations and Community Referrals

| | 1995-2003 | 2003 | 2004 | 2005 | Total |
|---|---|---|---|---|---|
| **Submitted** | 7 | 1 | 2 | 0 | 10 |

[c] Including opinions recommending definitive MRLs for substances with previously provisional maximum residue limits
[d] Including one opinion concluding that final MRL could not be established for a substance with provisional maximum residue limits previously established

## CVMP Opinions in 2005 on Medicinal Products for Veterinary Use

Positive Opinions

| Product<br>▪ Brand name<br>▪ INN<br>▪ Part A or B | Marketing authorisation holder | Therapeutic area<br>▪ Target species<br>▪ Summary of indication | EMEA/CVMP<br>▪ Validation<br>▪ Opinion<br>▪ Active time<br>▪ Clock stop | European Commission<br>▪ Opinion received<br>▪ Date of decision<br>▪ Notification<br>▪ Official Journal |
|---|---|---|---|---|
| ▪ Naxcel<br>▪ Ceftiofur<br>▪ Part B | Pfizer | ▪ Pigs<br>▪ Respiratory disease | ▪ 12.11.2002<br>▪ 11.01.2005<br>▪ 210<br>▪ 506 | ▪ ...<br>▪ ...<br>▪ ...<br>▪ ... |

## CVMP Opinions in 2005 on establishment of MRLs for New Substances

Positive Opinions

| **Substance INN** | **Therapeutic area**<br>▪ Target species | **EMEA/CVMP**<br>▪ Validation<br>▪ Opinion<br>▪ Active time<br>▪ Clock stop | **European Commission**<br>▪ Opinion received<br>▪ Date of regulation<br>▪ Official Journal |
|---|---|---|---|
| ▪ Phenoxymethylpenicillin (extension) | Poultry | ▪ 12.02.2004<br>▪ 12.01.2005<br>▪ 120 days<br>▪ 214 days | ▪ …<br>▪ …<br>▪ … |
| ▪ Thiamphenicol (extension) | Pigs | ▪ 19.06.2003<br>▪ 12.01.2005<br>▪ 119 days<br>▪ 453 days | ▪ ...<br>▪ ...<br>▪ ... |
| ▪ Phoxim (extension) | Chickens | ▪ 17.10.2002<br>▪ 12.01.2005<br>▪ 180 days[e]<br>▪ 637 days | ▪ ...<br>▪ ...<br>▪ ... |

## Arbitrations and Community Referrals in 2005

Community harmonisation and pharmacovigilance referrals

| **Type of referral** | **Date of CVMP opinion** | **International non-proprietary name (INN)** |
|---|---|---|
| | | |

[e] Active time for the evaluation of the initial application and submission of responses to outstanding issues following the establishment of provisional MRLs.

# Guidelines and Working Documents in 2005

## CVMP Scientific Advice Working Party SAWP-V

| Reference number | Document title | Status |
|---|---|---|
| | | |

## CVMP Safety Working Party

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/543/03-FINAL | Guidelines on user safety for pharmaceutical veterinary medicinal products | Adopted January 2005<br>(coming into effect 13 July 2005) |
| EMEA/CVMP/209865/2004 | Overview of comments received on draft Guideline on Injection Site Residues (EMEA/CVMP/542/03) | Adopted January 2005 |

## CVMP Immunologicals Working Party

| Reference number | Document title | Status |
|---|---|---|
| | | |

## CVMP Efficacy Working Party

| Reference number | Document title | Status |
|---|---|---|
| | | |

## CVMP Temporary Environmental Risk Assessment Working Party

| Reference number | Document title | Status |
|---|---|---|
| | | |

## CVMP Pharmacovigilance Working Party (PhVWP-V)

| Reference number | Document title | Status |
|---|---|---|
| | | |

## Joint CHMP/CVMP Quality Working Party

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/511/03<br>Annex to: EMEA/CVMP/VICH/502/99 | Annexes to Guideline on Impurities Residual Solvents | Adopted January 2005 |

The documents are available on the EMEA website: http://www.emea.eu.int