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

The CVMP Monthly Report includes statistical data for the current year and the previous two ones on Scientific Advice, Initial Evaluations, 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.

### Applications for Medicinal Products for Veterinary Use and Maximum Residue Limits (MRLs)

**Scientific Advice Requests**

| | 95-05 | 2006 | 2007 | 2008 | Total |
|---|---|---|---|---|---|
| Submitted | 37 | 14 | 7 | 2 | 60 |

**Initial Evaluation**

| | 95-05 | 2006 | 2007 | 2008 | Total |
|---|---|---|---|---|---|
| Full[1] | 78 | 5 | 14 | 7 | 104 |
| Abridged/Generics | 3 | 3 | 1 | 2 | 9 |
| Withdrawals | 11 | 0 | 0 | 0 | 11 |
| Positive Opinions | 56 | 13 | 9 | 2 | 80 |
| Negative Opinions | 0 | 1 | 0 | 0 | 1 |

**Marketing Authorisations**

| | 95-05 | 2006 | 2007 | 2008 | Total |
|---|---|---|---|---|---|
| Granted | 56 | 10 | 9 | 3 | 78 |
| Withdrawals | 1 | 0 | 0 | 1 | 2 |
| Not renewed | 1 | 0 | 1 | 0 | 2 |

**Extensions - Annex II Applications[2]**

| | 95-05 | 2006 | 2007 | 2008 | Total |
|---|---|---|---|---|---|
| Submitted | 47 | 0 | 9 | 0 | 56 |
| Withdrawals | 1 | 0 | 0 | 0 | 1 |
| Positive Opinions | 30 | 2 | 1 | 3 | 36 |
| Negative Opinions | 0 | 0 | 0 | 0 | 0 |

**Variations – Applications submitted**

| | 95-05 | 2006 | 2007 | 2008 | Total |
|---|---|---|---|---|---|
| Type IA | 207 | 18 | 29 | 7 | 310 |
| Type IB | | 13 | 24 | 12 | |
| Type II | 86 | 25 | 47 | 10 | 168 |
| Transfers | 6 | 1 | 2 | 0 | 9 |

[1] Initial applications submitted and validated: 113 applications in total (full + abridged), comprising 58 immunologicals and 55 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

[2] Extensions applications submitted and validated: 56 line extensions in total, comprising 11 immunologicals and 45 pharmaceuticals; one opinion can cover a number of extensions

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| Renewals | | | | | |
|---|---|---|---|---|---|
| | **95-05** | **2006** | **2007** | **2008** | **Total** |
| Submitted | 27 | 2 | 14 | 3 | 46 |
| Positive Opinions | 24 | 5 | 11 | 4 | 44 |
| Negative Opinions | 0 | 0 | 0 | 0 | 0 |

| Establishment of MRLs for new substances | | | | | |
|---|---|---|---|---|---|
| | **95-05** | **2006** | **2007** | **2008** | **Total** |
| Submitted | 60 | 3 | 2 | 0 | 65 |
| Withdrawals | 5 | 0 | 0 | 0 | 5 |
| Positive Opinions[3] | 44 | 5 | 3 | 1 | 53 |
| Negative Opinions[4] | 6 | 0 | 0 | 0 | 6 |

| Arbitrations and Community Referrals | | | | | |
|---|---|---|---|---|---|
| | **95-05** | **2006** | **2007** | **2008** | **Total** |
| Referrals Submitted | 11 | 10 | 6 | 2 | 29 |
| Opinions Reached | - | 4 | 10 | 2 | 16 |

| Extensions / Modifications/Extrapolations of MRLs | | | | | |
|---|---|---|---|---|---|
| | **95-05** | **2006** | **2007** | **2008** | **Total** |
| Submitted | 92 | 3 | 1 | 0 | 96 |
| Withdrawals | 4 | 0 | 0 | 0 | 4 |
| Positive Opinions[3] | 101 | 6 | 4 | 2 | 113 |
| Negative Opinions[4] | 5 | 1 | 0 | 0 | 6 |
| Extrapolations | 40 | 5 | 0 | 3 | 48 |

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

## CVMP Opinions in 2008 on Medicinal Products for Veterinary Use

Positive Opinions

| **Product**<br>▪ Brand name<br>▪ INN | **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 |
|---|---|---|---|---|
| ▪ Reconcile<br>▪ fluoxetine (as fluoxetine HCl) | ▪ Elanco | ▪ Dogs<br>▪ Behavioural problems | ▪ 15/05/2007<br>▪ 16/04/2008<br>▪ 210<br>▪ 127 | ▪ |
| ▪ Posatex<br>▪ orbifloxacin, mometasone furoate and posaconazole | ▪ Schering Plough Animal Health | ▪ Dogs<br>▪ Treatment of acute and recurrent otitis externa | ▪ 17/10/2006<br>▪ 210<br>▪ 334<br>▪ 15/04/2008 | ▪ |

Negative Opinions

| **Product**<br>▪ Brand name<br>▪ INN | **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 |
|---|---|---|---|---|
| ▪ | ▪ | ▪ | ▪ | ▪ |

Withdrawals prior to opinion

| **Product**<br>▪ Brand name<br>▪ INN | **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 |
|---|---|---|---|---|
| ▪ | | ▪ | ▪ | ▪ |

## CVMP Opinions in 2008 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 |
|---|---|---|---|
| ▪ Lectin | ▪ Porcine | ▪ 18.10.2007<br>▪ 16.01.2008<br>▪ 90 days<br>▪ 0 days | ▪ |

## Arbitrations and Community Referrals in 2008

| **Type of referral** | **Date of clock start / CVMP opinion** | ▪ **Product name**<br>▪ **INN** |
|---|---|---|
| Referral under Art. 35 of Directive 2001/82/EC | 16/01/2008 (clock start) | ▪ Injectable veterinary medicinal products containing ivermectin indicated for use in cattle<br>▪ Ivermectin |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 13/02/2008 | ▪ Compagel gel for horses<br>▪ Heparin sodium, levomenthol, hydroxyethyl salicylate |
| Referral for arbitration – Art. 33(4) of Directive 2001/82/EC | 13/02/2008 | ▪ Solacyl<br>▪ Sodium salicylate |
| Referral under Art. 35 of Directive 2001/82/EC | 15/04/2008 (clock re-start) | ▪ Suramox 15% and Stabox 15%<br>▪ Amoxicillin |

## Guidelines and Working Documents in 2008

### CVMP Efficacy

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

## CVMP Environmental Risk Assessment (ERA)

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

## CVMP Immunologicals

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/IWP/205351/2006 | Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus | Adopted, March 2008<br>(This guideline has been updated following comments received from IFAH Europe) |
| EMEA/CVMP/IWP/105504/2007-CONSULTATION | Guideline on the requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs) | Adopted for consultation, March 2008<br>(End of consultation: September 2008) |
| EMEA/CVMP/IWP/37267/2008-CONSULTATION | Concept paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue | Adopted for consultation, March 2008<br>(End of consultation: May 2008) |

## CVMP Pharmacovigilance

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/PhVWP/72829/2007 | EMEA public bulletin 2007 on veterinary pharmacovigilance | Adopted, February 2008 |
| EMEA/CVMP/VICH/547/00 | VICH guideline (GL24) on Management of Adverse Event Reports | Adopted, March 2008 |

## Joint CHMP/CVMP Quality

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CHMP/CVMP/QWP/28271/2008 – CONSULTATION | Reflection paper on the acceptability of water for injections prepared by reverse osmosis | Adopted for consultation, February 2008 |
| EMEA/CVMP/VICH/581467/2007-CONSULTATION | VICH guideline (GL45) on Quality: Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products | Adopted for consultation, February 2008<br>(End of consultaion: August 2008) |
| EMEA/HMPC/CHMP/CVMP/214869/2006 | Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products | Adopted, March 2008 |

## CVMP Safety

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/27466/2008 | Report of the Focus group meeting on user safety guideline | Adopted , March 2008 |
| EMEA/CVMP/SWP/173804/2008-CONSULTATION | Concept paper for the revision of the Guideline on User Safety | Adopted for consultation, April 2008.<br>(end of consultation: May 2008) |

## CVMP Scientific Advisory Group on Antimicrobials

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/SAGAM/428938/2007-CONSULTATION | Reflection paper on antimicrobials resistance surveillance as post-marketing authorisation commitment | Adopted for consultation, January 2008.<br>(End of consultation: April 2008) |
| EMEA/CVMP/SAGAM/81730/2006-CONSULTATION | Reflection paper on the use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union: development of resistance and impact on human and animal health | Adopted for consultation, February 2008.<br>(End of consultation: August 2008) |

## CVMP General

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/28510/2008-CONSULTATION | Guideline on Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats | Adopted for consultation, January 2008.<br>(End of consultation: July 2008) |
| EMEA/328/98-Rev.3 | Guidline on the acceptability of names for veterinary medicinal products processed through the centralised procedure | Adopted, January 2008 |
| EMEA/410/01-Rev.4 | Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products | Adopted, February 2008 |
| EMEA/CVMP/182112/2006 | CVMP Reflection Paper regarding the assessment of environmental risks of veterinary medicinal products | Adopted for consultation, March 2008<br>(end of consultation: June 2008)) |