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 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	1	**68**
Abridged Applications	1	1	1	0	**3**
Withdrawals	8	1	1	0	**10**
Positive opinions	38	3	10	5	**56**
Negative opinions	0	0	0	0	**0**

Scientific Advice

	1995-2002	2003	2004	2005	Total
Requests received	20	2	5	6	**33**

[a] Applications submitted and validated: overall total 71 applications (full + abridged), comprising 39 immunologicals and 32 pharmaceuticals.
Negative opinions: in case of appeals, the opinion will not be counted twice.

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Extensions (Annex II applications)

	1995-2002	2003	2004	2005	Total
Applications submitted	32	2	5	6	**45**[b]
Withdrawals	1	0	0	0	**1**
Positive opinions	15	6	3	1	**25**
Negative opinions	0	0	0	0	**0**

Variations

	1995-2002	2003	2004	2005	Total
Type IA	99	48	14	6	**180**
Type IB			5	8	
Transfers	2	2	1	1	**6**
Type II	37	12	16	16	**81**

Renewals of marketing authorisations

	1995-2002	2003	2004	2005	Total
Applications submitted	7	4	7	2	**20**
Positive opinions	5	4	5	6	**20**
Negative opinions	0	0	0	0	**0**

Arbitrations and Community Referrals

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

[b] Applications submitted and validated: overall total 45 line extensions, comprising 8 immunologicals and 37 pharmaceuticals; 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	2	**59**
Withdrawals	5	0	0	0	**5**
Positive opinions [c]	36	1	4	1	**42**
Negative opinions [d]	5	0	1	0	**6**

Extensions / Modifications of MRLs

	1995-2002	2003	2004	2005	Total
Applications submitted	73	7	7	2	**89**
Withdrawals	4	0	0	0	**4**
Positive opinions [c]	79	6	8	5	**98**
Negative opinions [d]	5	0	0	0	**5**

[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 ▪ Brand name ▪ INN ▪ Part A or B	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Naxcel ▪ Ceftiofur ▪ Part B	Pfizer	▪ Pigs ▪ Respiratory disease	▪ 12.11.2002 ▪ 11.01.2005 ▪ 210 ▪ 506	▪ 15.02.2005 ▪ 19.05.2005 ▪ ... ▪ ...
▪ Profender ▪ Emodepside praziquantel ▪ Part B	Bayer Health Care	▪ Cats ▪ Antiparasitic	▪ 16.03.2004 ▪ 18.05.2005[f] ▪ 204 ▪ 155	▪ ... ▪ ... ▪ ... ▪ …
▪ Equilis Prequenza-Te ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Equine influenza and tetanus	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ ... ▪ ... ▪ …
▪ Equilis Prequenza ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Immunity against influenza	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ ... ▪ ... ▪ …
▪ Equilis Te ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Immunity against tetanus	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ ... ▪ ... ▪ …
▪ Metacam 0.5 mg/ml oral suspension for dogs (extension new strength)	Boehringer Ingelheim Vetmedica GmbH	▪ Dogs	▪ 05.08.2004 ▪ 18.05.2005 ▪ 187 ▪ 99	▪ 01.06.2005 ▪ ... ▪ ... ▪ ...

CVMP Opinions in 2005 on establishment of MRLs for new substances

Positive Opinions

Substance INN	**Target species**	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Phenoxymethylpenicillin (extension)	Poultry	▪ 12.02.2004 ▪ 12.01.2005 ▪ 120 days ▪ 214 days	▪ 02.02.2005 ▪ … ▪ …
▪ Thiamphenicol (extension)	Pigs	▪ 19.06.2003 ▪ 12.01.2005 ▪ 119 days	▪ 02.02.2005 ▪ ... ▪ ...

[f] Confirmation of positive opinion CVMP dated 09.03.2005

Substance INN	Target species	EMEA/CVMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of regulation ▪ Official Journal
		▪ 453 days	
▪ Phoxim (extension)	Chickens	▪ 17.10.2002 ▪ 12.01.2005 ▪ 180 days[e] ▪ 637 days	▪ 02.02.2005 ▪ ... ▪ ...
▪ Oxolinic acid (extension)	Cattle (extrapolated to all food producing species)	▪ 11.09.2003 ▪ 09.02.2005 ▪ 180 days[e] ▪ 516 days	▪ 11.03.2005 ▪ ... ▪ ...
▪ Acetylisovaleryltylosin (extension)	Poultry	▪ 15.04.2004 ▪ 09.03.2005 ▪ 179 days[e] ▪ 149 days	▪ 06.04.2005 ▪ … ▪ …
▪ Fluazuron	Cattle	▪ 09.12.2004 ▪ 09.03.2005 ▪ 90 days ▪ 0 days	▪ 06.04.2005 ▪ … ▪ …

Arbitrations and Community Referrals in 2005

Community harmonisation and pharmacovigilance referrals

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

Guidelines and Working Documents in 2005

CVMP Safety Working Party

Reference number	Document title	Status
EMEA/CVMP/543/03-FINAL	Guideline on user safety for pharmaceutical veterinary medicinal products	Adopted January 2005 (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
EMEA/CVMP/41180/2005	Summary of the comments received on draft guideline on user safety for pharmaceutical veterinary medicinal products (EMEA/CVMP/543/03-CONSULTATION)	Adopted April 2005

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

Reference number	Document title	Status
EMEA/CVMP/66781/2005-CONSULTATION	Guideline on Safety and Residue Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Released for consultation April 2005 (end of consultation 31 October 2005)
EMEA/CVMP/SWP/122154/2005-CONSULTATION	Concept Paper on a Guideline on the Assessment of pharmacological/pharmacodynamic data to establish a pharmacological ADI	Released for consultation May 2005 (end of consultation 31 July 2005)
CVMP/VICH/645/01-Rev.1-FINAL	VICH Topic GL 28: "Studies to evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing	Adopted May 2005

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/1034/04-Consultation	Concept paper on further guidance on interpretation of the data from VICH GL27	Released for consultation March 2005 (end of consultation 9 June 2005)

Joint CHMP/CVMP Quality Working Party

Reference number	Document title	Status
EMEA/CVMP/511/03 Annex to: EMEA/CVMP/VICH/502/99	Annexes to Guideline on Impurities Residual Solvents	Adopted January 2005
EMEA/CVMP/134/02-Rev.1	Guideline on Active substance Master File Procedure	Adopted April 2005
EMEA/CVMP/QWP/114420/2005-CONSULTATION	Concept Paper on the development of a Guideline on Parametric Release	Released for consultation April 2005 (end of consultation 31 July 2005)
EMEA/CVMP/QWP/128710/2004-CONSULTATION	Guideline on Quality Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Released for consultation April 2005 (end of consultation 31 October 2005)
EMEA/CVMP/205/04-FINAL	Guideline on plastic primary packaging materials	Adopted May 2005 (coming into effect 1 December 2005)
EMEA/CVMP/373/04-FINAL	Guideline on stability testing for applications for variations to a marketing authorisation	Adopted May 2005 (coming into effect 1 December 2005)

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMEA/CVMP/900/03-FINAL	Guideline on Strategy for Triggering Investigations preceding Regulatory Actions by EU Competent Authorities	Adopted April 2005 (coming into effect 1 November 2005)
EMEA/CVMP/PhVWP/110607/2005-CONSULTATION	Veterinary Pharmacovigilance in the EU – A simple guide to reporting adverse reactions	Released for consultation April 2005 (end of consultation 18 October 2005)

CVMP Efficacy Working Party

Reference number	Document title	Status
EMEA/CVMP/EWP/117899/2004-CONSULTATION	Guideline on Efficacy and Target Animal Safety Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Released for consultation April 2005 (end of consultation 31 October 2005)

CVMP General

Reference number	Document title	Status
EMEA/CVMP/115769/2005	Guideline For An Assessor Preparing Assessment Reports For Veterinary Medicinal Products	Adopted May 2005