European Medicines Agency
Veterinary Medicines and Inspections

London, 31 March 2005
EMEA/CVMP/103137/2005

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.

Peter G.H. Jones
Head, Veterinary Medicines Evaluation Unit
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	2	**53**
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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

Scientific Advice

	1995-2002	2003	2004	2005	Total
Requests received	20	2	5	3	**30**

Extensions (Annex II applications)

	1995-2002	2003	2004	2005	Total
Applications submitted	32	2	5	5	**44**[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	4	**175**
Type IB			5	5	
Transfers	2	2	1	1	**6**
Type II	37	12	16	8	**73**

Renewals of marketing authorisations

	1995-2002	2003	2004	2005	Total
Applications submitted	7	4	7	2	**20**
Positive opinions	5	4	5	4	**18**
Negative opinions	0	0	0	0	**0**

[b] Applications submitted and validated: overall total 41 line extensions, comprising 8 immunologicals and 36 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	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	1	**88**
Withdrawals	4	0	0	0	**4**
Positive opinions [c]	79	6	8	5	**98**
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 ▪ 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	▪ ... ▪ ... ▪ ... ▪ ...
▪ Profender ▪ Emodepside praziquantel ▪ Part B	Bayer Health Care	▪ Cats ▪ Antiparasitic	▪ 16.03.2004 ▪ 09.03.2005 ▪ 204 ▪ 155	▪ ... ▪ ... ▪ ... ▪ …

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 ▪ 453 days	▪ 02.02.2005 ▪ ... ▪ ...
▪ 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	▪ … ▪ … ▪ …

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

Substance INN	Target species	EMEA/CVMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Fluazuron	Cattle	▪ 09.12.2004 ▪ 09.03.2005 ▪ 90 days ▪ 0 days	▪ … ▪ … ▪ …

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	Guidelines 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

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/1034/04-Consultation	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