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. The CVMP Monthly Report will be updated at the end of each month.

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

(*) CVMP opinions (p.4-5): the table has been updated with details of four extensions' opinions

Scientific Advice

	1995-2002	2003	2004	2005	Total
Requests received	20	2	5	10	**37**

Initial Evaluation[a]

	1995-2002	2003	2004	2005	Total
Full Applications	50	10	7	11	**78**
Abridged Applications	1	1	1	0	**3**
Withdrawals	8	1	1	1	**11**
Positive opinions	38	3	10	5	**56**
Negative opinions	0	0	0	0	**0**

[a] Applications submitted and validated: overall total 81 applications (full + abridged), comprising 40 immunologicals and 41 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	8	**47**[b]
Withdrawals	1	0	0	0	**1**
Positive opinions	15	6	3	6	**30**
Negative opinions	0	0	0	0	**0**

Variations

	1995-2002	2003	2004	2005	Total
Type IA	99	48	14	14	**207**
Type IB			5	27	
Transfers	2	2	1	1	**6**
Type II	37	12	16	21	**86**

Renewals of marketing authorisations

	1995-2002	2003	2004	2005	Total
Applications submitted	7	4	7	9	**27**
Positive opinions	5	4	5	10	**24**
Negative opinions	0	0	0	0	**0**

Arbitrations and Community Referrals

	1995-2003	2003	2004	2005	Total
Submitted	7	1	2	1	**11**

[b] Applications submitted and validated: overall total 47 line extensions, comprising 8 immunologicals and 39 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	3	**60**
Withdrawals	5	0	0	0	**5**
Positive opinions[c]	36	1	4	3	**44**
Negative opinions[d]	5	0	1	0	**6**

Extensions / Modifications of MRLs

	1995-2002	2003	2004	2005	Total
Applications submitted	73	7	7	5	**92**
Withdrawals	4	0	0	0	**4**
Positive opinions[c]	79	6	8	8	**101**
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 on Initial Applications and Extensions

Product ▪ Brand name ▪ INN ▪ Part A or B	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ ▪ ▪ ▪	**European Commission** ▪ ▪ ▪ ▪
▪ Naxcel ▪ Ceftiofur ▪ Part B	Pfizer	▪ Pigs ▪ Respiratory disease	▪ 12.11.2002 ▪ 11.01.2005 ▪ 210 ▪ 506	▪ 15.02.2005 ▪ 19.05.2005 ▪ 24.05.2005 ▪ OJ C 153, 24.06.2005, p.5
▪ Profender ▪ Emodepside praziquantel ▪ Part B	Bayer Health Care	▪ Cats ▪ Antiparasitic	▪ 16.03.2004 ▪ 18.05.2005[f] ▪ 204 ▪ 155	▪ 16.06.2005 ▪ 27.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Equilis Prequenza-Te ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Equine influenza and tetanus	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ 08.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Equilis Prequenza ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Immunity against influenza	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ 08.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Equilis Te ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Immunity against tetanus	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ 08.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ 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 ▪ 01.08.2005 ▪ 03.08.2005 ▪ OJ C 241, 30.09.2005, p.4
▪ Novem 5mg/ml (extension to new targer species)	Boehringer Ingelheim Vetmedica GmbH	▪ Pigs ▪ Musculo-skeletal disorder	▪ 15.03.2005 ▪ 15.06.2005 ▪ 92 ▪ 0	▪ n/a ▪ 25.08.2005 ▪ 29.08.2005 ▪ OJ C 241, 30.09.2005, p.4
▪ Aivlosin (extension to new strength)	ECO Animal Health	▪ Pigs ▪ Premix for medicated feed	▪ 18.01.2005 ▪ 08.11.2005 ▪ 215 ▪ 78	▪ …. ▪ ..... ▪ ..... ▪ .....
▪ Aivlosin (extension new pharmaceutical form)	ECO Animal Health	▪ Pigs ▪ Premix for medicated feed	▪ 15.02.2005 ▪ 09.11.2005 ▪ 209 ▪ 50	▪ …. ▪ ..... ▪ ..... ▪ .....
▪ Proteq Flu (extension new pharmaceutical form)	Merial	▪ Horses ▪ Equine Influenza + tetanus	▪ 15.03.2005 ▪ 07.12.2005 ▪ 210 ▪ 57	▪ …. ▪ ..... ▪ ..... ▪ .....

[f] Confirmation of positive opinion CVMP dated 09.03.2005

Product ▪ Brand name ▪ INN ▪ Part A or B	**Marketing authorisation holder**	**Therapeutic area** ▪ Summary of indication	**EMEA/CVMP** ▪ ▪ ▪ ▪	**European Commission** ▪ ▪ ▪ ▪
▪ Proteq Flu-Te (extension new pharmaceutical form)	Merial	▪ Horses ▪ Equine influenza	▪ 15.03.2005 ▪ 07.12.2005 ▪ 210 ▪ 57	▪ …. ▪ ..... ▪ ..... ▪ .....

CVMP Opinions in 2005 on establishment of MRLs for new substances

Positive Opinions

Substance INN	**Target species**	**EMEA/CVMP** ▪ ▪ ▪ ▪	**European Commission** ▪ ▪ ▪
▪ Phenoxymethylpenicillin (extension)	Poultry	▪ 12.02.2004 ▪ 12.01.2005 ▪ 120 days ▪ 214 days	▪ 02.02.2005 ▪ 08.08.2005 ▪ OJ L 206, 09.08.2005, p.6
▪ Thiamphenicol (extension)	Pigs	▪ 19.06.2003 ▪ 12.01.2005 ▪ 119 days ▪ 453 days	▪ 02.02.2005 ▪ 08.08.2005 ▪ OJ L 206, 09.08.2005, p.7
▪ Phoxim (extension)	Chickens	▪ 17.10.2002 ▪ 12.01.2005 ▪ 180 days[e] ▪ 637 days	▪ 02.02.2005 ▪ 08.08.2005 ▪ OJ L 206, 09.08.2005, p.6
▪ Oxolinic acid (extension)	Cattle (extrapolated to all food producing species)	▪ 11.09.2003 ▪ 09.02.2005 ▪ 180 days[e] ▪ 516 days	▪ 11.03.2005 ▪ 18.08.2005 ▪ OJ L 214, 19.08.2005, p.5
▪ Acetylisovaleryltylosin (extension)	Poultry	▪ 15.04.2004 ▪ 09.03.2005 ▪ 179 days[e] ▪ 149 days	▪ 06.04.2005 ▪ 19.09.2005 ▪ OJ L 244, 20.09.2005, p.12
▪ Fluazuron	Cattle	▪ 09.12.2004 ▪ 09.03.2005	▪ 06.04.2005 ▪ 19.09.2005

[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 ▪ ▪ ▪	European Commission ▪ ▪ ▪
		▪ 90 days ▪ 0 days	▪ OJ L 244, 20.09.2005, p.12
▪ Firocoxib	Horses	▪ 15.07.2004 ▪ 13.07.2005 ▪ 120 days ▪ 243 days	▪ 02.08.2005 ▪ … ▪ …
▪ **Piceae turiones recentes extractum *(Spruce-tips extract)***	All food producing	▪ 16.01.2004 ▪ 13.07.2005 ▪ 117 days ▪ 426 days	▪ 02.08.2005 ▪ … ▪ …
▪ Tosylchloramide Sodium (extension)	Horses	▪ 14.04.2005 ▪ 13.07.2005 ▪ 90 days ▪ 0 days	▪ 02.08.2005 ▪ … ▪ …
▪ Toltrazuril (extension)	Calves	▪ 18.03.2004 ▪ 07.09.2005 ▪ 180 days[e] ▪ 358	▪ 06.10.2005 ▪ … ▪ …
▪ Triclabendazole (extension)	Cattle and sheep	▪ 14.10.2004 ▪ 05.10.2005 ▪ 120 days ▪ 236 days	▪ 04.11.2005 ▪ … ▪ …

Arbitrations and Community Referrals in 2005

Community harmonisation and pharmacovigilance referrals

Type of referral	Date of CVMP opinion	International non-proprietary name (INN)
Article 35	November 2005	Micotil[g]

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

[g] Revised opinion to consider new data; initial opinion was adopted in December 2004

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
EMEA/CVMP/SWP/139646/2005-CONSULTATION	Concept Paper on Guidance on the approach on how to demonstrate whether a substance is capable of pharmalogical action or not	Released for consultation November 2005 (end of consultation 21 February 2006)
EMEA/CVMP/223005/2005	Approaches on how to consider the excipients in the context of Council Regulation 2377/90	Adopted November 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)
EMEA/CVMP/67951/2005-CONSULTATION	Concept Paper on revision of the current guideline on the SPC for antimicrobial products (EMEA/CVMP/612/01-FINAL)	Released for consultation June 2005 (end of consultation 31 August 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)

Reference number	Document title	Status
EMEA/CVMP/815/00-Rev.1	Guideline on Specifications: Test procedures and acceptance criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products	Released for consultation June 2005 (end of consultation 15 September 2005)
CVMP/VICH/837/99-Rev.1-CONSULTATION	VICH Topic GL10(R) Quality: Impurities in new veterinary drug substances	Released for consultation June 2005 (end of consultation 1 September 2005)
CVMP/VICH/838/99-Rev.1-CONSULTATION	VICH Topic GL11(R) Quality: Impurities in new veterinary medicinal products	Released for consultation June 2005 (end of consultation 1 September 2005)
EMEA/CVMP/814/00-Rev.1	Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Product	Released for consultation July 2005 (end of consultation 30 September 2005)
EMEA/CVMP/VICH/899/99-Rev.1-CONSULTATION	VICH Topic GL3(R): Stability testing guidelines: New veterinary drug substances and medicinal products	Released for consultation October 2005 (end of consultation 5 January 2006)
CVMP/VICH/810/04-FINAL	VICH Topic GL39 Step 7 Guideline on Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances (	Adopted November 2005
CVMP/VICH/811/04-FINAL	VICH Topic GL40 Step 7 Guideline on Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products	Adopted November 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)
EMEA/CVMP/893/04	Guideline on EU Veterinary Suspected Adverse Reaction report form for veterinarians and health professionals	Adopted June 2005
EMEA/CVMP/SOP/693/99-Rev.1	Procedure for Management of 15-day Suspected Adverse Reaction (SAR) reports to a centrally authorised veterinary medicinal product	Adopted June 2005
EMEA/CVMP/PhVWP/145320/2005-CONSULTATION	Concept Paper on a Periodic Safety Update Report (PSUR) assessment guideline for veterinary medicinal products	Released for consultation July 2005 (end of consultation 30 September 2005)
CVMP/VICH/547/00-CONSULTATION	VICH Topic GL24 Step 4 Pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs)	Released for consultation November 2005
CVMP/VICH/355996/05-CONSULTATION	VICH Topic GL42 Step 4 Guideline on Pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports	Released for consultation November 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)
EMEA/CVMP/EWP/79590/2005-CONSULTATION	Concept Paper on Dossier Requirements for Oncology Porducts	Released for consultation June 2005 (end of consultation 30 September 2005)
EMEA/CVMP/EWP/202810/2005-CONSULTATION	Concept Paper on Revision of the Guideline for the Testing and Evaluation of the Efficacy of Antiparasitic Substances for the Treatment and Prevention of Tick and Flea Infestations in Dogs and Cats	Released for consultation September 2005 (end of consultation 31 December 2005)
EMEA/CVMP/83804/2005-CONSULTATION	Fixed combinations of veterinary pharmaceutical products	Released for consultation October 2005 (end of consultation 30 April 2006)

CVMP Immunologicals Working Party

Reference number	Document title	Status
EMEA/CVMP/743/00-Rev.2	Revised guideline on requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products	Adopted November 2005 (coming into effect 1 January 2006)
EMEA/CVMP/IWP/268282/2005-CONSULTATION	Concept paper on the need for a procedure to be followed when a batch of a vaccine is suspected to be contaminated with bovince viral diarrhoea (BVD) virus	Released for consultation December 2005 (end of consultation 28 February 2006)

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
EMEA/CVMP/064/05	Guideline on the Summary of Product Characteristics for Immunological Veterinary Medicinal Products	Released for consultation September 2005 (end of consultation 31 December 2005)
EMEA/CVMP/065/05	Guideline on the summary of product characteristics for Pharmaceutical Veterinary Medicinal Products	Released for consultation September 2005 (end of consultation 31 December 2005)