European Medicines Agency
Veterinary Medicines and Inspections

London, 30 September 2007
Doc. Ref. EMEA/504391/2007

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

	95-04	2005	2006	2007	Total
Submitted	27	10	14	5	56

Initial Evaluation

	95-04	2005	2006	2007	Total
Full[1]	67	11	5	13	96
Abridged/Generics	3	0	3	1	7
Withdrawals	10	1	0	0	11
Positive Opinions	51	5	13	7	76
Negative Opinions	0	0	1	0	1

Marketing Authorisations

	95-04	2005	2006	2007	Total
Granted	45	11	10	8	74
Withdrawals	1	0	0	0	1
Not renewed	1	0	0	1	2

Extensions - Annex II Applications[2]

	95-04	2005	2006	2007	Total
Submitted	39	8	0	8	55
Withdrawals	1	0	0	0	1
Positive Opinions	24	6	2	1	33
Negative Opinions	0	0	0	0	0

Variations – Applications submitted

	95-04	2005	2006	2007	Total
Type IA	166	14	18	25	278
Type IB		27	13	15	
Type II	65	21	25	30	141
Transfers	5	1	1	1	8

[1] Initial applications submitted and validated: 103 applications in total (full + abridged), comprising 51 immunologicals and 52 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

[2] Extensions applications submitted and validated: 54 line extensions in total, comprising 11 immunologicals and 43 pharmaceuticals; one opinion can cover a number of extensions

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.europa.eu http://www.emea.europa.eu

Renewals					
	95-04	**2005**	**2006**	**2007**	**Total**
Submitted	18	9	2	11	40
Positive Opinions	14	10	5	5	34
Negative Opinions	0	0	0	0	0

Establishment of MRLs for new substances					
	95-04	**2005**	**2006**	**2007**	**Total**
Submitted	57	3	3	1	64
Withdrawals	5	0	0	0	5
Positive Opinions[3]	41	3	5	3	52
Negative Opinions[4]	6	0	0	0	6

Arbitrations and Community Referrals					
	95-04	**2005**	**2006**	**2007**	**Total**
Referrals Submitted	10	1	10	2	23
Opinions Reached	-	-	4	6	10

Extensions / Modifications/Extrapolations of MRLs					
	95-04	**2005**	**2006**	**2007**	**Total**
Submitted	87	5	3	1	96
Withdrawals	4	0	0	0	4
Positive Opinions[3]	93	8	6	3	110
Negative Opinions[4]	5	0	1	0	6
Extrapolations	34	6	5	0	45

[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 2007 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
▪ Slentrol ▪ Dirlotapide	▪ Pfizer	▪ Dogs ▪ Obesity ATC code	▪ 21/02/2006 ▪ 14/02/2007 ▪ 209 ▪ 148	▪ 19/02/2007 ▪ 13/04/2007
▪ Suprelorin ▪ Deslorelin ▪ Part B	▪ Cyton Biosciences Ltd	▪ Dogs ▪ temporary infertility in male dogs	▪ 20/09/2005 ▪ 15/05/2007 ▪ 211 ▪ 301	▪ 12/062007 ▪ 10/07/2007
▪ Nobilis Influenza H7N1 ▪ Vaccine ▪ Art. 3	▪ Intervet International bv	▪ Chickens ▪ Vaccine against avian influenza	▪ 18/10/2006 ▪ 14/03/2007 ▪ 120 ▪ 28	▪ 15/03/2007 ▪ 14/05/2007
▪ Prilactone ▪ Spironolactone ▪ Part B	▪ Ceva Sante Animale	▪ a) Dogs ▪ b) Heart failure	▪ 07/06/2005 ▪ 17/04/2007 ▪ 210 ▪ 469	▪ 22/05/2007 ▪ 20/06/2007
▪ Circovac ▪ Inactivated vaccine ▪ Article 3	▪ Merial	▪ Pigs ▪ b) passive immunity against porcine circovirus type 2.	▪ 21/12/2005 ▪ 17/04/2007 ▪ 210 ▪ 274	▪ 15/05/2007 ▪ 21/06/2007

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
▪ Nobilis Influenza H5N6 ▪ Vaccine ▪ Art. 32(2)	▪ Intervet International BV	▪ Birds ▪ Prevention of avian influenza	▪ 13/02/2007 ▪ 11/07/2007 ▪ 90 ▪ 28	▪
▪ Meloxivet ▪ Meloxicam generic	▪ Janssen Pharmaceutica N.V.	▪ Dogs ▪ Musculo-skeletal	▪ 19/12/2006 ▪ 12/09/2007 ▪ 210 ▪ 57	▪

Negative 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
▪	▪	▪	▪	▪

Withdrawals prior to opinion

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
▪		▪	▪	▪

CVMP Opinions in 2007 on establishment of MRLs for new substances

Positive Opinions

Substance INN	**Therapeutic area** ▪ Target species	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Avilamycin	▪ Pigs, poultry and rabbits	▪ 13/01/2005 ▪ 14/04/2007 ▪ 120 ▪ 670	▪ 30/03/2007
▪ Monensin	▪ Dairy Cattle	▪ 17/02/2005 ▪ 15/05/2007 ▪ 119 ▪ 698	▪
▪ Gamithromycin	▪ Bovine	▪ 10/08/2006 ▪ 11/07/2007 ▪ 117 ▪ 215	▪

Arbitrations and Community Referrals in 2007

Type of referral	Date of CVMP opinion	International non-proprietary name (INN)
Referral for arbitration – art. 33(4) Directive 2001/82/EC	17/1/2007	Ivermectin (Equimectin 12mg/g)
Referral for arbitration – art.40 Directive 2001/82/EC	17/01/2007	Suvaxyn Parvo E
Referral for arbitration – art.40 Directive 2001/82/EC	17/01/2007	Suvaxyn Ery
Referral for arbitration – art. 33(4) Directive 2001/82/EC	14/02/2007	Doxyprex 100 mr/g
Referral for arbitration – art. 33(4) Directive 2001/82/EC	17/04/2007	Bovilis BVD
Referral for arbitration – art. 33(4) Directive 2001/82/EC	18/04/2007	Enurace 50
Referral for arbitration - art. 33(4) Directive 2001/82/EC	11/072007 (clock start)	Ecomectin (ivermectin)
Referral for arbitration – art. 35 of Directive 2001/82/EC	11/07/2007 (clock start)	Tribrissen oral paste for horses and generics (trimethoprim and sulfadiazine)

Guidelines and Working Documents in 2007

CVMP Efficacy

Reference number	Document title	Status
EMEA/CVMP/EWP/170208/2005	Guideline on the summary of product characteristics for anthelmintics	Adopted July 2007
EMEA/CVMP/EWP/362275/2007-CONSULTATION	Concept paper for the revision of the guideline on "Veterinary medicinal products controlling *Varroa destructor* and *Acarapis woodi* parasitosis in bees"	Adopted for consultation September 2007. (End of consultation: March 2008)

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMEA/CVMP/ERA/418282/2005	Guideline on Environmental Impact Assessment for VMPs in support of the VICH guidelines GL6 and GL38	Adopted April 2007

CVMP Immunologicals

Reference number	Document title	Status
EMEA/CVMP/IWP/23332/2006	Guideline on user safety for immunological veterinary medicinal products”	Adopted April 2007
EMEA/CVMP/IWP/222624/2006	Guideline on data requirements for an authorisation under exceptional circumstances for vaccines in birds against avian influenza”	Adopted April 2007
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 April 2007
EMEA/CVMP/IWP/105008/2007	Reflection paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue”	Adopted April 2007
EMEA/CVMP/IWP/501304/2006	Concept paper on the need for requiring data to demonstrate the influence of maternally derived antibody on the vaccination of very young animals”	Adopted April 2007
EMEA/CVMP/IWP/90459/2007	Concept paper on requirements for multi-strain dossiers”	Adopted April 2007
EMEA/CVMP/IWP/123243/2007	Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species/limited markets	Adopted July 2007

CVMP Pharmacovigilance

Reference number	Document title	Status
EMEA/CVMP/PhVWP/73213/2007	EMEA Public Bulletin 2006 on Veterinary Pharmacovigilance on activities regarding pharmacovigilance for veterinary medicinal products during the past year	Adopted February 2007
EMEA/INS/PhV/47075/2007	Guideline on monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections	Adopted February 2007. Published on the European Commission website on 4 April 2007
SOP/V/4023	Procedure for management of Periodic Safety Update Reports (PSURs) for centrally authorised products	Adopted March 2007
EMEA/CVMP/413/99-Rev.4	VEDDRA list of clinical terms for adverse reactions in animals	Adopted June 2007
EMEA/CVMP/891/04-Rev.2	VEDDRA list of clinical terms for adverse reactions in humans	Adopted June 2007
EMEA/CVMP/553/03-Rev.2	List of species and breeds	Adopted June 2007
Published by the European Commission's EudraLex	Phamacovigilance for Veterinary Medicinal Products – Procedures for Marketing Authorisation Holders	Adopted June 2007

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMEA/CVMP/VICH/899/99-Rev.1	Stability testing of new veterinary drug substances and medicinal products	Adopted February 2007
EMEA/CVMP/VICH/837/99-Rev.1	Impurities in new veterinary drug substances	Adopted February 2007
EMEA/CVMP/VICH/838/99-Rev.1	Impurities in new veterinary medicinal products	Adopted February 2007
EMEA/CVMP/QWP/103377/2007	Concept Paper on the revision of the CVMP guideline on stability testing of existing active substances and related finished products	Adopted April 2007
EMEA/HMPC/CHMP/CVMP/287539/2005	Guideline on the Declaration of Herbal Substances in the SPC	Adopted July 2007
EMEA/CHMP/CVMP/QWP/221930/2007-CONSULTATION	Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products	Adopted for consultation July 2007 (end of consultation October 2007)

CVMP Safety

Reference number	Document title	Status
EMEA/CVMP/95682/2007-CONSULTATION	Reflection paper on assessment of bioavailability of bound residues in food commodities of animal origin in the context of Council Regulation (EEC) No 2377/90	Adopted for consultation May 2007 (end of consultation November 2007)
EMEA/CVMP/VICH/1052/2004	"VICH GL41 Target animal safety: examination of live veterinary vaccines in target animals for absence of reversion to virulence"	Adopted September 2007 (Implementation: July 2008)
EMEA/CVMP/VICH/359665/2005-CONSULTATION	"VICH GL44 Guideline Target Animal Safety for veterinary live and inactivated vaccines"	Adopted for consultation September 2007 (end of consultation: March 2008)

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/SAGAM/383441/2005-CONSULTATION	Revised guideline on the SPC for antimicrobial products	Adopted for consultation January 2007 (end of consultation: June 2007)
EMEA/CVMP/SAGAM/184651/2005	Public statement on the use of (fluoro)quinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted February 2007

CVMP General

Reference number	Document title	Status
EMEA/CVMP/422/04-Rev.1	Revised CVMP rules of procedure	Adopted in February 2007
EMEA/4789/2007	Procedure for the nomination and appointment of co-opted members of the Committee	Adopted March 2007
SOP/INSP/2019	Coordination of pre-approval GxP Inspections	Adopted April 2007
EMEA/328/98-Rev.3-CONSULTATION	The acceptability of names for veterinary medicinal products processed through the centralised procedure	Adopted for consultation June 2007 (end of consultation: September 2007)
EMEA/CVMP/425558/2006	Reflection paper on Withdrawals of Marketing Authorisation Applications for Veterinary Medicinal Products	Adopted July 2007

EMEA/CVMP/459912/2006	Reflection paper on the publication of the CVMP's Negative Opinion and Refusal to Recommend the granting of a Marketing Authorisation for Veterinary Medicinal Products	Adopted July 2007
EMEA/CVMP/248499/2007-CONSULTATION	Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted for consultation September 2007. (end of consultation March 2008)
EMEA/CVMP/2128/2007	Guideline on procedures for re-examination of CVMP opinions	Adopted September 2007
EMEA/358850/2007-CONSULTATION	Concept paper on the classification of veterinary medicinal products authorised by the Community	Adopted for consultation September 2007. (end of consultation: November 2007)