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

	95-04	2005	2006	2007	Total
Submitted	27	10	14	3	54

Initial Evaluation

	95-04	2005	2006	2007	Total
Full[1]	67	11	5	9	92
Abridged/Generics	3	0	3	0	6
Withdrawals	10	1	0	0	11
Positive Opinions	51	5	13	5	74
Negative Opinions	0	0	1	0	1

Marketing Authorisations

	95-04	2005	2006	2007	Total
Granted	45	11	10	5	71
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	2	49
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	16	264
Type IB		27	13	10	
Type II	65	21	25	12	123
Transfers	5	1	1	0	7

[1] Initial applications submitted and validated: 98 applications in total (full + abridged), comprising 47 immunologicals and 51 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

[2] Extensions applications submitted and validated: 49 line extensions in total, comprising 8 immunologicals and 41 pharmaceuticals; one opinion can cover a number of extensions

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Renewals					
	95-04	**2005**	**2006**	**2007**	**Total**
Submitted	18	9	2	3	32
Positive Opinions	14	10	5	1	30
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	2	51
Negative Opinions[4]	6	0	0	0	6

Arbitrations and Community Referrals					
	95-04	**2005**	**2006**	**2007**	**Total**
Referrals Submitted	10	1	10	0	21
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	1	108
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	▪
▪ Suprelorin ▪ Deslorelin ▪ Part B	▪ Cyton Biosciences Ltd	▪ Dogs ▪ temporary infertility in male dogs	▪ 20/09/2005 ▪ 14/03/2007 ▪ 211 ▪ 301	▪
▪ Nobilis Influenza H7N1 ▪ Vaccine ▪ Art. 3	▪ Intervet Internationa l bv	▪ Chickens ▪ Vaccine against avian influenza	▪ 18/10/2006 ▪ 14/03/2007 ▪ 120 ▪ 28	▪
▪ Prilactone ▪ Spironolactone ▪ Part B	▪ Ceva Sante Animale	▪ a) Dogs ▪ b) Heart failure	▪ 07/06/2005 ▪ 17/04/2007 ▪ 210 ▪ 469	▪
▪ Circovac ▪ Inactivated vaccine ▪ Article 3	▪ Merial	▪ Pigs ▪ b) passive immunity against porcine circovirus type 2.	▪ 21/12/2005 ▪ 17/04/2007 ▪ 210 ▪ 274	▪

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	▪

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	14/02/2007	Doxyprex 100 mr/g

Type of referral	Date of CVMP opinion	International non-proprietary name (INN)
arbitration – art. 33(4) Directive 2001/82/EC		
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

Guidelines and Working Documents in 2007

CVMP Efficacy

Reference number	Document title	Status

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

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

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

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)

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