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

	95-05	2006	2007	2008	Total
Submitted	37	14	7	1	59

Initial Evaluation

	95-05	2006	2007	2008	Total
Full[1]	78	5	14	1	98
Abridged/Generics	3	3	1	1	8
Withdrawals	11	0	0	0	11
Positive Opinions	56	13	9	0	78
Negative Opinions	0	1	0	0	1

Marketing Authorisations

	95-05	2006	2007	2008	Total
Granted	56	10	9	1	76
Withdrawals	1	0	0	0	1
Not renewed	1	0	1	0	2

Extensions - Annex II Applications[2]

	95-05	2006	2007	2008	Total
Submitted	47	0	9	0	56
Withdrawals	1	0	0	0	1
Positive Opinions	30	2	1	0	33
Negative Opinions	0	0	0	0	0

Variations – Applications submitted

	95-05	2006	2007	2008	Total
Type IA	207	18	29	5	304
Type IB		13	24	8	
Type II	86	25	47	2	160
Transfers	6	1	2	0	9

[1] Initial applications submitted and validated: 106 applications in total (full + abridged), comprising 52 immunologicals and 54 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

[2] Extensions applications submitted and validated: 56 line extensions in total, comprising 11 immunologicals and 45 pharmaceuticals; one opinion can cover a number of extensions

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Renewals					
	95-05	**2006**	**2007**	**2008**	**Total**
Submitted	27	2	14	1	44
Positive Opinions	24	5	11	1	41
Negative Opinions	0	0	0	0	0

Establishment of MRLs for new substances					
	95-05	**2006**	**2007**	**2008**	**Total**
Submitted	60	3	2		65
Withdrawals	5	0	0		5
Positive Opinions[3]	44	5	3	1	53
Negative Opinions[4]	6	0	0		6

Arbitrations and Community Referrals					
	95-05	**2006**	**2007**	**2008**	**Total**
Referrals Submitted	11	10	6	2	29
Opinions Reached	-	4	10	0	14

Extensions / Modifications/Extrapolations of MRLs					
	95-05	**2006**	**2007**	**2008**	**Total**
Submitted	92	3	1		96
Withdrawals	4	0	0		4
Positive Opinions[3]	101	6	4		111
Negative Opinions[4]	5	1	0		6
Extrapolations	40	5	0	1	46

[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 2008 on Medicinal Products for Veterinary Use

Positive Opinions

Product ▪ Brand name ▪ INN	**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
▪	▪	▪	▪	▪

Negative Opinions

Product ▪ Brand name ▪ INN	**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	**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 2008 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
▪ Lectin	▪ Porcine	▪ 18.10.2007 ▪ 16.01.2008 ▪ 90 days ▪ 0 days	▪

Arbitrations and Community Referrals in 2008

Type of referral	Date of CVMP opinion	▪ **Product name** ▪ **INN**
Referral under – Art. 35 of Directive 2001/82/EC	16/01/2008 (clock start)	▪ Injectable veterinary medicinal products containing ivermectin indicated for use in cattle ▪ Ivermectin
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	16/01/2008 (clock start)	▪ Compagel gel for horses ▪ Heparin sodium, levomenthol, hydroxyethyl salicylate

Guidelines and Working Documents in 2008

CVMP Efficacy

Reference number	Document title	Status

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status

CVMP Immunologicals

Reference number	Document title	Status

CVMP Pharmacovigilance

Reference number	Document title	Status

Joint CHMP/CVMP Quality

Reference number	Document title	Status

CVMP Safety

Reference number	Document title	Status

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/SAGAM/428938/2007-CONSULTATION	Reflection paper on antimicrobials resistance surveillance as post-marketing authorisation commitment	Adopted for consultation, January 2008. (End of consultation: April 2008)

CVMP General

Reference number	Document title	Status
EMEA/CVMP/28510/2008-CONSULTATION	Guideline on Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats	Adopted for consultation, January 2008. (End of consultation: July 2008)
EMEA/328/98-Rev.3	Guidline on the acceptability of names for veterinary medicinal products processed through the centralised procedure	Adopted, January 2008