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 and previous two years 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

	95-06	2007	2008	2009	Total
Submitted	51	7	5	0	63

Initial Evaluation

	95-06	2007	2008	2009	Total
Full[1]	83	14	13	1	111
Abridged/Generics	6	1	3	0	10
Withdrawals	11	0	1	0	12
Positive Opinions	69	9	13	2	93
Negative Opinions	1	0	0	0	1

Marketing Authorisations

	95-06	2007	2008	2009	Total
Granted	66	9	13	3	91
Withdrawals	1	0	1	0	2
Not renewed	1	1	0	0	2

Extensions - Annex II Applications[2]

	95-06	2007	2008	2009	Total
Submitted	47	9	4	2	62
Withdrawals	1	0	0	0	1
Positive Opinions	32	1	7	0	40
Negative Opinions	0	0	0	0	0

Variations – Applications submitted

	95-06	2007	2008	2009	Total
Type IA	238	29	23	4	344
Type IB		24	25	1	
Type II	111	47	52	7	217
Transfers	7	2	2	0	11

[1] Initial applications submitted and validated: 121 applications in total (full + abridged), comprising 62 immunologicals and 59 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

[2] Extensions applications submitted and validated: 58 line extensions in total, comprising 11 immunologicals and 47 pharmaceuticals; one opinion can cover a number of extensions

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Renewals					
	95-06	**2007**	**2008**	**2009**	**Total**
Submitted	29	14	7	3	53
Positive Opinions	29	11	8	2	50
Negative Opinions	0	0	0	0	0

Establishment of MRLs for new substances					
	95-06	**2007**	**2008**	**2009**	**Total**
Submitted	63	2	1	0	66
Withdrawals	5	0	0	0	5
Positive Opinions[3]	49	3	2	1	55
Negative Opinions[4]	6	0	1	0	7

Arbitrations and Community Referrals					
	95-06	**2007**	**2008**	**2009**	**Total**
Referrals Submitted	21	6	11	2	40
Opinions Reached	4	10	6	3	23

Extensions / Modifications/Extrapolations of MRLs					
	95-06	**2007**	**2008**	**2009**	**Total**
Submitted	95	1	2	1	99
Withdrawals	4	0	0	0	4
Positive Opinions[3]	107	4	2	1	114
Negative Opinions[4]	6	0	0	0	6
Extrapolations	45	0	5	0	50

[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 2009 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
• Netvax	Schering-Plough, UK	• Chickens • Necrotic enteritis	• 10/02/2007 • 11/02/2009 • 210 • 379	
• BTVPUR Alsap 8 • Inactivated adjuvanted vaccine	Mérial, France	• Sheep, cattle • Prevention of Blue Tongue virus serotype 8	• 25/03/2008 • 11/02/2009 • 175 • 149	

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 2009 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

Negative Opinions (Recommendation for inclusion in Annex IV or inability to recommend inclusion in any of the Annexes to Regulation 2377/90)

Substance INN	**Therapeutic area** ▪ Target species	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of regulation ▪ Official Journal

Arbitrations and Community Referrals in 2009

Type of referral	**Date of clock start / CVMP opinion**	▪ **Product name** ▪ **INN**
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008 15/01/2009	▪ ENRO-K 10% oral solution ▪ Enrofloxacin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008 15/01/2009	▪ Unisol (avifox) 10% oral solution ▪ Enrofloxacin
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	15/01/2009 (clock start re-examination)	▪ Pharmasin 100% w/w water soluble granules ▪ Tylosine tartrate
Referral under Art. 35 of Directive 2001/82/EC	16/01/2008 12/02/2009)	▪ Injectable veterinary medicinal products containing ivermectin indicated for use in cattle ▪ Ivermectin
Referral under Art. 35 of Directive 2001/82/EC	11/02/2009 (clock start)	▪ All strengths of water soluble powders and oral solutions containing doxycycline hyclate ▪ Doxycycline hyclate

Urgent procedures

Type of procedure	CVMP opinion	Product name

Guidelines and Working Documents in 2009

CVMP Efficacy

Reference number	Document title	Status

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMEA/CVMP/ERA/10043/2009-CONSULTATION	Concept paper on the fate of veterinary medicinal products in manure	Adopted for consultation, February 2009 (End of consultation: May 2009)

CVMP Immunologicals

Reference number	Document title	Status

CVMP Pharmacovigilance

Reference number	Document title	Status
SOP-EMEA/599270/2007	SOP on Handling of pharmacovigilance Rapid Alerts (RAs) and Non Urgent Informaion (NUI)for veterinary use	Endorsed, January 2009
EMEA/CVMP/10418/2009	Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted, February 2009

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMEA/CVMP/QWP/544461/2007	Guideline on the quality aspects of single-dose veterinary spot-on products	Adopted, January 2009
EMEA/CHMP/CVMP/QWP/663093/2008	Question and Answer document on Plastic Immediate Packaging Materials	Adopted, January 2009

EMEA/CHMP/CVMP/QWP/17760 /2009-Rev.1-CONSULTATION	Revised Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations	Adopted for consultation, February 2009 (End of consultation: August 2009)
EMEA/555991/2007	New Question and Answers which aim to clarify several issues associated with the use of Process Analytical Technology (PAT),	Adopted, February 2009

CVMP Safety

Reference number	Document title	Status

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/SAGAM/81730/20 06	Revised Reflection Paper on the use of 3rd and 4th generation cephalosporins in food producing animals in the European Union: development of resistance and impact on human and animal health.	Adopted, February 2009

CVMP General

Reference number	Document title	Status
EMEA/INS/GCP/390778/2008	Procedure for the preparation of a risk-based programme for routine PhV Inspections of MAHs connected with Veterinary Centrally Authorised Products (CAPs)	Adopted, January 2009
EMEA/INS/GCP/85059/2008	Procedure for coordination of pharmacovigilance inspections requests by the CVMP	Adopted, January 2009