EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Monthly report of application procedures, guidelines and related documents

November 2009

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	8	71

Initial Evaluation

	95-06	2007	2008	2009	Total
Full	83	14	13	8	118
Abridged/ Generics	6	1	3	0	10
Withdrawals	11	0	1	0	12
Positive Opinions	69	9	13	13	104
Negative Opinions	1	0	0	0	1

Marketing Authorisations

	95-06	2007	2008	2009	Total
Granted	66	9	13	12	100
Withdrawals	1	0	1	0	2
Not renewed	1	1	0	0	2

Extensions - Annex II Applications

	95-06	2007	2008	2009	Total
Submitted	47	9	4	12	72
Withdrawals	1	0	1	1	3
Positive Opinions	32	1	7	7	48
Negative Opinions	0	0	0	0	0

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Variations – Applications submitted					
	95-06	2007	2008	2009	Total
Type IA	238	29	23	32	410
Type IB		24	25	39	
Type II	111	47	52	38	248
Transfers	7	2	2	3	14

Renewals					
	95-06	2007	2008	2009	Total
Submitted	29	14	7	17	66
Positive Opinions	29	11	8	14	62
Negative Opinions	0	0	0	0	0

Arbitrations and Community Referrals					
	95-06	2007	2008	2009	Total
Referrals Submitted	21	6	11	9	47
Opinions Reached	4	10	6	12	32

Establishment of MRLs for new substances					
	95-06	2007	2008	2009	Total
Submitted	63	2	1	4	70
Withdrawals	5	0	0	0	5
Positive Opinions[1]	49	3	2	1	55
Negative Opinions[2]	6	0	1	0	7

Extensions / Modifications/Extrapolations of MRLs					
	95-06	2007	2008	2009	Total
Submitted	95	1	2	2	100
Withdrawals	4	0	0	0	4
Positive Opinions[3]	107	4	2	3	116
Negative Opinions[4]	6	0	0	0	6
Extrapolations	45	0	5	0	50

[1] Including opinions recommending definitive MRLs for substances with previously provisional maximum residue limits
[2] 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 • **Invented name** • **INN/Common name**	**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 • Clostridium perfringens type A toxoid	• Schering-Plough, United Kingdom	• Chickens • Necrotic enteritis	• 10/02/2007 • 11/02/2009 • 210 • 379	• 16/03/2009 • 16/04/2009 • 20/04/2009 • OJ C 121/12
• BTVPUR Alsap 8 • Blutongue virus serotype 8 antigen	• Mérial, France	• Sheep, cattle • Prevention of Blue Tongue virus serotype 8	• 25/03/2008 • 11/02/2009 • 175 • 149	• 12/02/2009 • 17/03/2009 • 19/03/2009 • OJ C 101/12
• Improvac • GnRF analogue-protein conjugate	• Pfizer, United Kingdom	• Male pigs • Control of boar taint	• 14/08/2007 • 11/03/2009 • 210 • 365	• 08/04/2009 • 11/05/2009 • 13/05/2009 • OJ C 146/13
• Leucofeligen FeLV/RCP • vaccine against feline calicivirosis, feline viral rhinotrachietis, feline panleucopenia and feline leukaemia	• Virbac France	• Cats • Immunisation against against feline calicivirosis, viral rhinotracheitis, panleucopenia ad leukaemia	• 18/03/2008 • 11/03/2009 • 210 • 147	• 20/05/2009 • 25/06/2009 • 29/06/2009 • OJ C 178/22
• Leucogen • inactivated feline leukaemia virus	• Virbac • France	• Cats • Immunisation against feline leukaemia	• 18/03/2008 • 11/03/2008 • 210 • 147	• 20/05/2009 • 17/06/2009 • 19/06/2009 • OJ C 178/22
• Melovem • meloxicam	• Dopharma, The Netherlands	• Cattle, pigs • Musculo-skeletal	• 15/07/2008 • 13/05/2009 • 155 • 119	• 10/06/2009 • 07/07/2009 • 09/07/2009 • OJ C 231/16
• Suvaxyn PCV • inactivated porcine cirovirus recombinant virus (cPCV) 1-2	• Fort Dodge • United Kingdom	• Piglets • Vaccine to reduce PCV-2 viraemia	• 20/05/2008 • 13/05/2008 • 184 • 147	• 18/05/2009 • 24/07/2009 • 30/07/2009 • OJ C 231/16

• Palladia • toceranib	• Pfizer • United Kingdom	• Dogs • Treatment of Patnaik grade II or III, recurrent, cutaneous tumours	• 20/05/2008 • 18/06/2009 • 174 • 157	• 14/07/2009 • 23/09/2009 • 25/09/2009 • OJ C 260/13
• Zolvix • monepantel	• Novartis • Denmark	• Sheep • Anthelmintic	• 16/09/2008 • 15/07/2009 • 119 • 92	• 11/08/2009 • 04/11/2009
• RESPIPORC FLU3 • Inactivated influenza A virus/ swine	• IDT Biologiak GmhB • Germany	• Pigs • Immunisation against swine influenza	• 12/08/2008 • 11/11/2009 • 210 • 246	• 06/11/2009 • 14/01/2010
• Gripovac 3 • Inactivated influenza A virus/ swine	• Mérial S.A.S. • France	• Pigs • Immunisation against swine influenza	• 09/03/2009 • 11/11/2009 • 156 • 92	• 06/11/2009 • 14/01/2010
• Zulvac 8 Bovis • Inactivated inactivated blue tongue virus, serotype 8	• Fort Dodge Animal Health • United Kingdom	• Cattle • Prevention of viraemia caused by Bluetongue Virus, serotype 8.	• 25/03/2008 • 11/11/2009 • 168 • 427	• 09/12/2009 • 15/01/2010
• Zulvac 8 Ovis • inactivated blue tongue virus, serotype 8	• Fort Dodge Animal Health • United Kingdom	• Sheep • Prevention of viraemia caused by Bluetongue Virus, serotype 8.	• 17/04/2008 • 11/11/2009 • 145 • 428	• 09/12/2009 • 15/01/2010

Negative Opinions

Product • **Invented 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 • **Invented 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**
Gamithromycin	• Bovine	• Following provisional MRLs • 14/01/2009 • 83 • -	• 29/01/2009 • 04/07/2009 • OJ L 175/3
Diclofenac	• Bovine (milk)	• 13/11/2008 • 11/02/2009 • 90 • 0	• 27/02/2009 • 04/07/2009 • OJ L 175/5
Valnemulin	• Rabbit	• 16/01/2009 • 16/04/2009 • 90 • 0	• 06/05/2009
Methylprednisolone	• Bovine (milk)	• 16/04/2009 • 15/07/2009 • 90 • 0	• 23/07/2009

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 2010

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	14/08/2008 11/03/2009 (after re-examination)	▪ Pharmasin 100% w/w water soluble granules ▪ Tylosine tartrate
Referral under Art. 35 of Directive 2001/82/EC	15/04/2009 05/06/2009 (after re-examination)	▪ Injectable veterinary medicinal products containing ivermectin indicated for use in cattle ▪ Ivermectin
Referral under Art. 35 of Directive 2001/82/EC	11/02/2009	▪ All strengths of water soluble powders and oral solutions containing doxycycline hyclate ▪ Doxycycline hyclate
Referral under Art. 35 of Directive 2001/82/EC	16/04/2009	▪ Veterinary medicinal formulations containing colistin at 2 MIU/ml and intended for administration in drinking water to any food producing species ▪ Colistin sulfate
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/09/2008 16/09/2009 (after re-examination)	▪ Clavobay Lactating Cow ▪ Amoxicillin and clavulanic acid
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/09/2008 13/05/2009	▪ Shotaflor 300 mg/ml ▪ Florfenicol
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	16/09/2008 13/05/2009	▪ Fenflor 300 mg/ml ▪ Florfenicol
Referral for arbitration – Art. 34(1) Directive 2001/82/EC	16/09/2008 13/05/2009	▪ Pulmotil AC and associated names ▪ Tilmicosin
Referral for arbitration – Art. 34(1) Directive 2001/82/EC	16/07/2008 13/05/2009	▪ Pulmotil 40/100/200 VET Premix ▪ Tilmicosin
Referral under Art. 35 of Directive 2001/82/EC	13/05/2009 11/11/2009	▪ Veterinary medicinal products containing quinolones or fluoroquinolones for all food-producing species ▪ Quinolones / fluoroquinolones
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	12/05/2009	▪ Cevazuril 50 mg/ml oral suspension for piglets ▪ Toltrazuril
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	15/10/2008 11/11/2009 (after re-examination)	▪ APPM Respipharm ▪ Strains of Actinobacillus pleuropneumoniae

Type of referral	Date of clock start / CVMP opinion	▪ **Product name** ▪ **INN**
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	12/11/2008 11/11/2009 (after re-examination)	▪ Tildren 500 mg ▪ Tiludronic acid (as disodium salt)
Referral for arbitration – Art. 6(12) of Commission Regulation 2001/82/EC	14/07/2009	▪ Vasotop (1.25, 2.5 and 0.625 mg) ▪ Ramipril
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	14/07/2009 14/10/2009	▪ Poulvac Bursa Plus ▪ Live infectious Bursal Disease Virus, strain V877
Referral for arbitration – Art. 6(12) of Regulation (EC) No 1084/2003	14/10/2009	▪ Porcilis PRRS ▪ Live attenuated PRRS virus strain DV
Referral for arbitration – Art. 6(12) of Regulation (EC) No 1084/2003	14/10/2009	▪ Porcilis M Hyo ▪ Inactivated whole cell concentrate of Mycoplasma hyopneumoniae strain 11
Referral for arbitration – Art. 34 of Directive 2001/82/EC	11/11/2009	▪ Fortekor vet and associated names ▪ Benazepril hydrochloride

Urgent procedures

Type of procedure	CVMP opinion	Product name

Guidelines and Working Documents in 2009

CVMP Efficacy

Reference number	Document title	Status
EMEA/CVMP/016/00-Rev.1-CONSULTATION	Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted for consultation, March 2009 (End of consultation: September 2009)
EMEA/CVMP/EWP/82829/2009	Question and Answer document in relation to CVMP Guideline on "Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats"	Adopted, March 2009

EMEA/CVMP/28510/2008	Guideline on dossier requirements for anticancer medicinal products for dogs and cats	Adopted, April 2009
EMEA/CVMP/EWP/37388/2009-CONSULTATION	Concept paper on the revision of the guideline on statistical principles for veterinary clinical trials	Adopted for consultation, June 2009 (End of consultation: September 2009)
EMEA/CVMP/EWP/459868/2008-CONSULTATION	(Revised) guideline on demonstration of target animal safety and efficacy of veterinary medicinal products for use in farmed fish	Adopted for consultation, October 2009 (End of consultation: April 2009)
EMEA/CVMP/EWP/459883/2008-CONSULTATION	Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees	Adopted for consultation, October 2009 (End of consultation: April 2009)

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, April 2009
EMEA/CVMP/ERA/172074/2008-Rev.1	Update of Question & Answer document on the implementation of the CVMP Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in Support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted, September 2009
EMEA/CVMP/ERA/12254/2009-CONSULTATION	Concept paper on higher tier testing of antiparasitics to dung organisms	Adopted for consultation, (End of consultation: November 2009)

CVMP Immunologicals

Reference number	Document title	Status
EMEA/CVMP/IWP/105506/2007-CONSULTATION	Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot-and-mouth disease	Adopted for consultation, March 2009 (End of consultation: September 2009)
EMEA/CVMP/IWP/439467/2007-CONSULTATION	Reflection paper on the demonstration of a possible impact of maternally derived antibodies on vaccine efficacy in young animals	Adopted for consultation, March 2009 (End of consultation: September 2009)
EMEA/CVMP/IWP/250147/2008-CONSULTATION	Guideline on data requirements to support in-use stability claims for veterinary vaccines	Adopted for consultation, March 2009 (End of consultation: September 2009)

EMEA/CVMP/IWP/123243/2006-Rev.1-CONSULTATION	Guideline on data requirements for immunological veterinary medicinal products intended for Minor Use or Minor Species/ Limited markets	Adopted for consultation, March 2009 (End of consultation: June 2009)
EMEA/CVMP/340494/2009	Question and Answer document on inactivation kinetics studies	Adopted, June 2009
EMEA/CVMP/IWP/105504/2007	Guideline on the requirements for the replacement of established Master Seeds (MS) already used in authorised immunological veterinary medicinal products	Adopted, July 2009

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
SOP/V/4023-Rev.1	Management of Period Safety Update Reports (PSURs) for Centrally Authorised Products (CAPs) and Annex I – Contact details of national competent authorities for PSUR submission	Adopted, April 2009
EMEA/CVMP/PhVWP/133883/2004-Rev.2	Mandate, Objectives and Rules of Procedure For The CVMP Pharmacovigilance Working Party (PhVWP-V)	Adopted, April 2009
EMEA/INS/PhV/85061/2008	Procedure for Reporting of Pharmacovigilance Inspections Requested by the CVMP	Adopted, April 2009
EMEA/CVMP/10418/2009-Rev.1	Combined VeDDRA List of Clinical Terms for Reporting Suspected Adverse Reactions in Animals and Humans	Adopted, June 2009
EMEA/CVMP/553/03-Rev.4	Revised List of Species and Breeds for Electronic Reporting of Suspected Adverse Reactions in Veterinary Pharmacovigilance	Adopted, June 2009
EMEA/CVMP/353015/2009	Deprecated Veddra Recoded Term List for Implementation of the Combined VeDDRA List	Adopted, June 2009
SOP/V/4052	SOP on procedure for Management of 15-day Suspected Adverse Reaction (SAR) reports to a centrally authorised veterinary medicinal product	Endorsed, July 2009

EMEA/CVMP/126726/2007-CONSULTATION	Reflection paper on Risk Management Plans for Centrally Authorised Veterinary Medicinal Products	Adopted for consultation, November 2009 (End of consultation: March 2010)

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
EMEA/CHMP/CVMP/QWP/160263/2009	Question and Answer documents on endotoxin/sterility testing during and at the end of shelf-life	Adopted, April 2009
EMEA/CHMP/CVMP/QWP/450653/2006	Recommendation on the Assessment of the quality of medicinal products containing existing/ known active substances	Adopted, April 2009

CVMP Safety

Reference number	Document title	Status
EMEA/CVMP/SWP/322484/2008-Rev.1-CONSULTATION	Guideline on user safety for pharmaceutical veterinary medicinal products	Adopted for consultation, April 2009 (End of consultation, August 2009)
EMEA/CVMP/VICH/486/02-Rev.2	VICH Guideline on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing	Adopted, April 2009
EMEA/CVMP/516817/2009-CONSULTATION	Guideline on data to be provided in support of a request to include substance in the list of substances considered as not falling within the scope of regulation (EC) No. 470/2009	Adopted for consultation, November 2009 (End of consultation, May 2010)

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/SAGAM/81730/2006	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, including recommendations	Adopted, March 2009
EMEA/CVMP/SAGAM/68290/2009	Reflection paper on MRSA in food producing and companion animals in the European Union: epidemiology and control options for human and animal health	Adopted, March 2009
EMEA/CVMP/SAGAM/113420/2009-CONSULTATION	Concept paper on the use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, June 2009 (End of consultation, August 2009)
EMEA/CVMP/SAGAM/386369/2009-CONSULTATION	Concept paper on meticillin-resistant Staphylococcus (pseud)intermedius	Adopted for consultation, July 2009 (End of consultation, March 2010)

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
EMEA/INS/S&T/75010/2009	Sampling and Testing of Centrally Authorised products	Adopted, April 2009
EMEA/CVMP/248499/2007-Rev.1	Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted, April 2009
EMEA/CVMP/425558/2006-Rev.1	Reflection paper on publication of withdrawals of Marketing Authorisation applications for veterinary medicinal products	Adopted, June 2009
EMEA/CVMP/430509/2009-CONSULTATION	Guideline on the change in classification of veterinary medicinal products authorised by the Community	Adopted for consultation, September 2009 (End of consultation, March 2010)

EMEA/CVMP/468877/2009	Appointment and responsibilities of rapporteur and co-rapporteur for procedures regarding veterinary medicinal products	Adopted, September 2009
EMEA/CVMP/2128/2007-Rev.1-CONSULTATION	Revised procedural advice on the re-examination of CVMP opinions	Adopted for consultation, September 2009 (End of consultation, November 2009)
EMEA/CVMP/626480/2009-CONSULTATION	Concept paper for the revision of the assessor guideline	Adopted for consultation, October 2009 (End of consultation, December 2009)