EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2010
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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 December 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	11	74

Initial Evaluation					
	95-06	2007	2008	2009	Total
Full	83	14	13	14	124
Abridged/Generics	6	1	3	1	11
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

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Variations – Applications submitted					
	95-06	2007	2008	2009	Total
Type IA	238	29	23	32	412
Type IB		24	25	41	
Type II	111	47	52	40	250
Transfers	7	2	2	3	14

Renewals					
	95-06	2007	2008	2009	Total
Submitted	29	14	7	18	67
Positive Opinions	29	11	8	15	63
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	14	34

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	2	56
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 Medical 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 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	11/08/2009 04/11/2009

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**
			92	
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 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/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**

Withdrawals prior to opinion

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

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
Tildipirosin	• Cattle • Pigs	• 19/03/2009 • 10/12/2009 • 119 • 146	• 22/12/2009

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 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	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	16/09/2008 13/05/2009	Pulmotil AC and associated names Tilmicosin

Type of referral	Date of clock start / CVMP opinion	• **Product name** • **INN**
2001/82/EC		
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 (under re-examination)	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 09/12/2009	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
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	12/11/2008 11/11/2009 (under 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 08/12/2009	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	Adopted, September 2009

Reference number	Document title	Status
	Environmental Impact Assessment for Veterinary Medicinal Products in Support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	
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 Information (NUI)for veterinary use	Endorsed, January 2009
EMEA/CVMP/10418/2009	Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in	Adopted, February 2009

Reference number	Document title	Status
	animals and humans to veterinary medicinal products	
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	Adopted for consultation, February 2009

Reference number	Document title	Status
	pharmaceutical industry and the data requirements for new submissions and variations	(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
EMEA/HMPC/CHMP/CVMP/287539/2005-Rev.1	Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/ traditional herbal medicinal products	Adopted, December 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)
EMEA/CVMP/VICH/463072/2009	VICH GL46: Metabolism study to determine the quantity and identify the nature of residues	Adopted for consultation, December 2009 (End of consultation, May 2010)
EMEA/CVMP/VICH/463104/2009	VICH GL47: Comparative metabolism studies in laboratory animals	Adopted for consultation, December 2009 (End of consultation, May 2010)
EMEA/CVMP/VICH/463199/2009	VICH GL48: Marker residue depletion studies to establish product withdrawal periods	Adopted for consultation, December 2009 (End of consultation, May

Reference number	Document title	Status
		2010)
EMEA/CVMP/VICH/463202/2009	VICH GL49: Validation of analytical methods used in residue depletion studies	Adopted for consultation, December 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-	Reflection paper on publication of	Adopted, June 2009

Reference number	Document title	Status
Rev.1	withdrawals of Marketing Authorisation applications for veterinary medicinal products	
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)