17 December 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 2010

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					
	95-07	2008	2009	2010	Total
Submitted	58	5	11	21	95

Initial evaluation					
	95-07	2008	2009	2010	Total
Full (Submitted)	97	13	14	16	140
Abridged/ generics (Submitted)	7	3	1	2	13
Withdrawals	11	1	0	1	13
Positive opinions	78	13	13	14	118
Negative opinions	1	0	0	0	1

Marketing authorisations					
	95-07	2008	2009	2010	Total
Granted	75	13	12	9	109
Withdrawals	1	1	0	4	6
Not renewed	2	0	0	0	2

Extensions					
	95-07	2008	2009	2010	Total
Submitted	56	4	12	3	73
Withdrawals	1	1	1	1	4
Positive opinions	33	7	7	8	55
Negative opinions	0	0	0	0	0

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Variations – applications submitted					
	95-07	2008	2009	2010	Total
Type IA	291	23	32	76	551
Type IB		25	41	63	
Type II	158	52	40	26	276
Transfers	9	2	3	8	22

Renewals					
	95-07	2008	2009	2010	Total
Submitted	43	7	18	7	75
Positive opinions	40	8	17	8	73
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-07	2008	2009	2010	Total
Referrals submitted	27	11	9	11	57
Opinions reached	14	6	14	4	43

Establishment of MRLs for new substances					
	95-07	2008	2009	2010	Total
Submitted	65	1	4	3	73
Withdrawals	5	0	0	0	5
Positive opinions[1]	52	2	2	2	58
Negative opinions[2]	6	1	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-07	2008	2009	2010	Total
Submitted	96	2	2	10	110
Withdrawals	4	0	0	0	4
Positive opinions[3]	111	2	3	3	119
Negative opinions[4]	6	0	0	0	6
Extrapolations	45	5	0	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 2010 on medicinal products for veterinary use

Positive opinions

Product • Invented name • INN	• Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Bovilis BTV 8	• Intervet International BV	• Cattle, sheep • Inactivated vaccine against Bluetongue virus serotype 8	• 22/04/2008 • 16/06/2010 • 197 • 589	• 17/06/2010 • 06/09/2010
• BTVPUR AlSap 2-4	• Merial S.A.S.	• Sheep • Inactivated vaccine against Bluetongue virus serotypes 2 and 4	• 18/12/2007 • 14/07/2010 • 209 • 728	• 15/07/2010 • 05/11/2010
• Veraflox	• Bayer Animal Health GmbH	• Dogs, cats • Infections caused by certain specified and susceptible pathogens	• 19/05/2009 • 14/07/2010 • 202 • 218	• 15/07/2010
• RHINISENG	• Laboratorios Hipra S.A.	• Pigs • Inactivated vaccine to prevent non-progressive atropic rhinitis in pigs	• 16/06/2009 • 14/07/2010 • 209 • 181	• 15/07/2010 • 16/09/2010
• COXEVAC	• Ceva Sante Animale	• Cattle, goats • Inactivated coxiella burnetti vaccine	• 17/12/2008 • 14/07/2010 • 203 • 370	• 15/07/2010 • 30/09/2010
• Meloxoral • Meloxicam	• LeVet B.V.	• Dogs, cats • Alleviation of inflammation and pain	• 17/06/2008 • 14/09/2010 • 210 • 609	• 16/09/2010 • 19/11/2010
• BTVPUR AlSAP 1	• Merial	• Sheep, cattle • Inactivated vaccine against Bluetongue virus serotypes 1	• 10/12/2009 • 13/10/2010 • 180 • 126	• 14/10/2010
• BTVPUR AlSAP 1-8	• Merial	• Sheep, cattle • Inactivated vaccine against Bluetongue virus	• 10/12/2009 • 13/10/2010 • 180 • 126	• 14/10/2010

Product • Invented name • INN	• Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
		serotypes 1 and 8		
• Hiprabovis IBR Marker Live	• Laboratorios Hipra S.A.	• Cattle • A live vaccine against infectious bovine rhinotracheitis (IBR)	• 17/03/2009 • 10/11/2010 • 204 • 398	• 11/11/2010
• Cimalgex • Cimicoxib	• Vétoquinol SA	• Dogs • Alleviation of inflammation and pain	• 10/11/2009 • 07/12/2010 • 210 • 180	• 09/12/2010
• Comfortis • Spinosad	• Eli Lilly and Company Ltd	• Dogs • Treatment and prevention of flea infestations	• 15/12/2009 • 08/12/2010 • 210 • 147	• 09/12/2010
• ACTIVYL • Indoxacarb	• Intervet International BV	• Cats, dogs • Treatment and prevention of flea infestations	• 10/11/2009 • 08/12/2010 • 198 • 195	• 09/12/2010
• Purevax Rabies	• Merial	• Cats • vaccine containing the recombinant canarypox virus (vCP65) expressing the rabies glycoprotein G	• 15/12/2009 • 08/12/2010 • 210 • 147	• 10/12/2010
• Melosus • Meloxicam	CP-Pharma Handels-gesellschaft mbH	• Cats • Alleviation of inflammation and pain	• 15/12/2009 • 08/12/2010 • 175 • 183	• 09/12/2010

CVMP opinions in 2010 on establishment of MRLs for new substances

Positive opinions

• Substance • INN	• Therapeutic area • Target species	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Date of regulation • Official Journal
• Derquantel	• Ovine	• 18/06/2009 • 19/05/2010 • 119 • 206	• 07/06/2010
• Monepantel (extension of provisional MRLs)	• Caprine	• N/a • 15/09/2010 • N/a • N/a	• 29/09/2010
• Isoeugenol	• Fin fish	• 17/09/2009 • 15/09/2010 • 209 • 218	• 29/09/2010
• Closantel (Procedure under Article 9(1b) of Regulation 470/2009)	• Bovine and ovine milk	• N/a • 15/09/2010 • 97 • 0	• 29/09/2010
• Triclabendazole (Procedure under Article 9(1b) of Regulation 470/2009)	• Milk of all ruminants	• N/a • 10/11/2010 • 152 • 0	• 16/11/2010

Arbitrations and Community referrals in 2010

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Art. 35 of Directive 2001/82/EC	• 11/02/2009 • 10/02/2010	• 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 • 10/02/2010	• Veterinary medicinal formulations containing colistin at 2 MIU/ml and intended for administration in drinking water to any food producing species • Colistin sulfate
Referral under Art. 35 of Directive 2001/82/EC	• 13/05/2009 • 10/03/2010 (after re-examination)	• Veterinary medicinal products containing quinolones or fluoroquinolones for all food-

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
		producing species • Quinolones / fluoroquinolones
Referral under 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 under Art. 6(12) of Regulation (EC) No 1084/2003	• 14/10/2009 • 19/05/2010	• Porcilis PRRS • Live attenuated PRRS virus strain DV
Referral under Art. 6(12) of Regulation (EC) No 1084/2003	• 14/10/2009 • 19/05/2010	• Porcilis M Hyo • Inactivated whole cell concentrate of Mycoplasma hyopneumoniae strain 11
Referral under Art. 34 of Directive 2001/82/EC	• 11/11/2009	• Fortekor vet and associated names • Benazepril hydrochloride
Referral under Art. 34 of Directive 2001/82/EC	• 15/10/2008 • 10/03/2010	• Tiamutin premix • Tiamulin fumarate
Referral under Art. 34 of Directive 2001/82/EC	• 14/04/2010	• Synulox Lactating Cow and associated names • Amoxicillin, clavulanic acid, prednisolone
Procedure under Art. 78 of Directive 2001/82/EC	• 19/05/2010 • 14/07/2010	• Pregsure BVD and associated names • Inactivated Bovine Viral Diarrhoea (BVD) type 1 virus
Procedure under Art. 30(3) of Regulation 726/2004	• 19/05/2010 • 15/09/2010	• Retrovirus RD114 in relation to live attenuated vaccines for use in dogs and cats • N/a
Procedure under Art. 45 of Regulation (EC) No 726/2004	• 16/06/2010 • 14/07/2010	• Suvaxyn PCV • Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Combimox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Nisamox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Combisyn Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010	• Doxycycline 50% WSP and associated names • Doxycycline hyclate

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010	• Doxyfar 50% WSP and associated names • Doxycycline hyclate
Procedure under Art. 45 of Regulation (EC) No 726/2004	• 13/07/2010 • 14/07/2010	• Flexicam 1.5 mg/ml Suspension for Dogs • Meloxicam
Procedure under Art. 45 of Regulation (EC) No 726/2004	• 14/09/2010 • 15/09/2010	• Acticam 1.5 mg/ml Oral Suspension for Dogs • Meloxicam
Referral under Art. 34 of Directive 2001/82/EC	• 09/11/2010	• Baytril 10% oral solution and associated names • Enrofloxacin

Guidelines and working documents in 2010

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/62867/2009	Concept Paper on proposed revision to the guideline for the conduct of efficacy studies for NSAIDs	Adopted for consultation, May 2010 (End of consultation 31 August 2010)
EMA/CVMP/330382/2007-Rev.2	Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted for 2nd consultation, July 2010 (End of consultation 31 October 2010
EMA/CVMP/EWP/459868/2008-CONSULTATION	Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish	Consultation period extended, July 2010 (End of consultation 31 October 2010)
EMA/CVMP/EWP/81976/2010	Guideline on statistical principles for veterinary clinical trials	Adopted for consultation, September 2010 (End of consultation 31 March 2011)
EMA/CVMP/EWP/87114/2010	Concept paper for the revision of the guideline on the Conduct of efficacy studies for intramammary products for use in cattle	Adopted for consultation, September 2010 (End of consultation 31 December 2010)
EMA/CVMP/EWP/62867/2009	Concept paper for the revision to the Guideline for the conduct of efficacy studies for NSAIDs	Adopted for consultation, May 2010 (End of consultation

Reference number	Document title	Status
		extended until 30 November 2010)
EMA/CVMP/EWP/81987/2010	Concept paper for a guideline on the demonstration of palatability of veterinary medicinal products	Adopted for consultation, November 2010 (End of consultation extended until 28 February 2011)
EMA/CVMP/EWP/459883/2009	Guideline on veterinary medicinal products controlling *Varroa destructor parasitosis* in bees	Adopted, November 2010

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMA/CVMP/ERA/430327/2009-CONSULTATION	Guideline on degradation of veterinary medicinal products in manure	Adopted for consultation, February 2010 (End of consultation, 31 August 2010)
EMA/CVMP/ERAWP/389867/2010	Concept paper on assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine	Adopted for consultation, July 2010 (End of consultation 1 September 2010
EMEA/CVMP/ERA/172074/2008-Rev.2	Questions and Answers (Q&A) document on the implementation of CVMP guideline on Environmental Impact Assessment for veterinary medicinal products in support of the VICH guidelines GL6 (PHASE I) and GL38 (PHASE II)	Adopted, July 2010

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/58879/2010	Reflection paper on data requirements for swine influenza vaccines against pandemic (H1N1) 2009 influenza	Adopted, February 2010
EMA/CVMP/IWP/105506/2007	Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted, March 2010
EMA/CVMP/IWP/43283/2010	Recommendation on the submission of multi-strain dossier applications for vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted, March 2010

Reference number	Document title	Status
EMA/CVMP/IWP/250147/2008	Guideline on data requirements to support in-use stability claims for veterinary vaccines	Adopted, March 2010
EMA/CVMP/IWP/582970/2009	Reflection paper on control of the active substance in the finished product for immunological veterinary medicinal products (IVMPs)	Adopted, March 2010
EMA/CVMP/IWP/439467/2007	Reflection paper on the demonstration of a possible impact of maternally derived antibodies on vaccine efficacy in young animals	Adopted, March 2010
EMA/CVMP/IWP/123243/2006-Rev.2	Guideline on data requirements for immunological veterinary medicinal products intended for Minor Use or Minor Species/ Limited markets	Adopted, April 2010
EMA/CVMP/IWP/596708/2010	Public statement on the number of tests required to control for complete inactivation in inactivated vaccines	Adopted, November 2010

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/729768/2009	Veterinary Pharmacovigilance 2009 Public Bulletin	Adopted, February 2010
EMA/CVMP/PhVWP/471721/2006	Recommendation for the basic surveillance of Eudravigilance Veterinary data	Adopted for consultation, May 2010 (End of consultation, 30 November 2010)
EMA/CVMP/10418/2009-Rev.2	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted, July 2010
EMA/CVMP/553/03-Rev.5	List of species and breeds for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance	Adopted, July 2010
EMA/CVMP/PhVWP/288284/2007-Rev.3	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted, July 2010
EMA/123352/2004-Rev.5	Revised call for comments on standard lists for EudraVigilance Veterinary	Adopted, July 2010
EMA/CVMP/VICH/647/2001	VICH GL30: Guideline on controlled list of terms	Adopted, September 2010
EMA/CVMP/VICH/123940/2006	VICH GL35: Guideline on pharmacovigilance of veterinary	Adopted, September 2010 (End of consultation,

	medicinal products: electronic standards for transfer of data	15 March 2011)
EMA/CVMP/VICH/355996/2005	VICH GL42: Data elements for submission of adverse event reports	Adopted, Sptember 2010

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/809114/ 2009	Concept paper on the revision of the guideline on process validation	Adopted for consultation, January 2010 (End of consultation, April 2010)
EMA/63033/2010	Concept Paper on the need for revision of the guideline on stability testing for applications for variations to a marketing authorisation	Adopted for consultation, February 2010 (End of consultation, 30 April 2010)
EMEA/CHMP/CVMP/QWP/80386/ 2010	Questions and Answers concerning stability issues of pharmaceutical bulk products used in the manufacture of drug products	Adopted, February 2010
EMA/CVMP/VICH/502/1999-Rev.1	VICH GL 18 residual solvents in new veterinary medicinal products, active substances and excipients	Adopted for consultation, May 2010 (End of consultation 31 October 2010)
EMA/CVMP/VICH/581467/2007	VICH GL 45 quality: bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products	Adopted, May 2010
EMA/CHMP/CVMP/QWP/300039/ 2010	Question and Answer document on GMP compliance documentation that should be submitted in case of sterilisation of an active substance	Adopted, June 2010
EMA/CHMP/CVMP/QWP/199250/ 2009	Guideline on setting specifications for related impurities in antibiotics	Adopted for consultation, July 2010 (End of consultation 31 January 2011)
EMA/CVMP/QWP/565528/2010	Question and Answer document on the microbiological quality of veterinary premixes containing excipients of natural origin	Adopted, October 2010
EMA/CVMP/QWP/565529/2010	Question and Answer document on rubber stopper testing	Adopted, October 2010
EMA/CVMP/QWP/574579/2010	Question and Answer document on veterinary powders for use in drinking water	Adopted, October 2010
EMA/CVMP/QWP/565531/2010	Question and Answer document which clarifies the regulatory issues concerning whether or not it is permitted to authorise a multi-dose	Adopted, October 2010

Reference number	Document title	Status
	(parenteral) veterinary medicinal product for use both as an intramuscular injection and also an intramammary preparation	
EMA/CHMP/CVMP/QWP/586330/2010	Question and Answers document on post-approval change management protocols	Adopted, October 2010
EMA/CHMP/CVMP/QWP/586385/2010	Question and Answer document on Variation B.II.b.4 (change of batch size of the finished product)	Adopted, October 2010
QP Declaration template	Template for the Qualified Person's declaration concerning GMP compliance of the active substance used as a starting material, and verification of its supply chain	

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/543/03-Rev.1	Guideline on user safety for pharmaceutical veterinary medicinal products	Adopted, March 2010
EMA/CVMP/516817/2009	Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009	Adopted, November 2010
EMA/CVMP/SWP/736014/2010	Concept paper on revision of the note for guidance for the determination of withdrawal periods for Milk	Adopted for conusltation, December 2010 (End of consultation 31 March 2011)

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/736964/2009	Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius*	Adopted for consultation, September 2010 (End of consultation 30 November 2010)
EMEA/CVMP/SAGAM/741087/2009	Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European	Adopted for consultation, November 2010 (End of consultation 28

	Union: development of resistance and impact on human and animal health	February 2011)
EMA/CVMP/287420/2010	CVMP Strategy on Antimicrobials 2011-2015	Adopted for consultation, December 2010 (End of consultation 28 February 2011)

General

Reference number	Document title	Status
SOP/EMA/85634/2006-Rev.1	Standard Operating Procedure (SOP) on Evaluation procedure for applications and requests for the establishment of Maximum Residue Limits (MRLs) under Articles 3, 9, 10 and 15 of Regulation (EC) 470/2009	Adopted, February 2010
EMA/CVMP/38660/2010	Analysis of the functioning of the current veterinary legislation and proposals for its evolution to provide clarification on its views and additional areas for consideration by the European Commission	Adopted, July 2010
EMA/CVMP/VICH/463/02	VICH GL34 on mycoplasma contamination	Consultation re-opened, December 2010 (End of consultation 31 March 2011)