30 June 2010
EMA/CVMP/404291/2010
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Monthly report of application procedures, guidelines and related documents June 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	14	88

Initial Evaluation

	95-07	2008	2009	2010	Total
Full (Submitted)	97	13	14	8	132
Abridged/ Generics (Submitted)	7	3	1	2	13
Withdrawals	11	1	0	0	12
Positive Opinions	78	13	13	1	105
Negative Opinions	1	0	0	0	1

Marketing Authorisations

	95-07	2008	2009	2010	Total
Granted	75	13	12	4	104
Withdrawals	1	1	0	4	6
Not renewed	2	0	0	0	2

Extensions - Annex II Applications

	95-07	2008	2009	2010	Total
Submitted	56	4	12	2	74
Withdrawals	1	1	1	1	4
Positive Opinions	33	7	7	5	52
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	43	482
Type IB		25	41	27	
Type II	158	52	40	15	265
Transfers	9	2	3	3	17

Renewals					
	95-07	2008	2009	2010	Total
Submitted	43	7	18	5	73
Positive Opinions	40	8	15	7	70
Negative Opinions	0	0	0	0	0

Arbitrations and Community Referrals					
	95-07	2008	2009	2010	Total
Referrals Submitted	27	11	9	4	51
Opinions Reached	14	6	14	6	40

Establishment of MRLs for new substances					
	95-07	2008	2009	2010	Total
Submitted	65	1	4	2	72
Withdrawals	5	0	0	0	5
Positive Opinions[1]	52	2	2	1	57
Negative Opinions[2]	6	1	0	0	7

Extensions / Modifications/Extrapolations of MRLs					
	95-07	2008	2009	2010	Total
Submitted	96	2	2	6	106
Withdrawals	4	0	0	0	4
Positive Opinions[3]	111	2	3	0	116
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	**EMEA/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 vaccines against Bluetongue virus sterotype 8	• 22/04/2008 • 16/06/2010 • 197 • 589	• 17/06/2010

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	

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

Type of referral	Date of clock start / CVMP opinion	• **Product name** • **INN**
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-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	• 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	• 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	• Suvaxyn PCV • Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein

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)

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)

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
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-	Guideline on data requirements for	Adopted, April 2010

Reference number	Document title	Status
Rev.2	immunological veterinary medicinal products intended for Minor Use or Minor Species/ Limited markets	

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)

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

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

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