EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2010
EMA/CVMP/64865/2010
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Monthly report of application procedures, guidelines and related documents January 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	3	77

Initial Evaluation

	95-07	2008	2009	2010	Total
Full	97	13	14	0	124
Abridged/ Generics	7	3	1	0	11
Withdrawals	11	1	0	0	12
Positive Opinions	78	13	13	0	104
Negative Opinions	1	0	0	0	1

Marketing Authorisations

	95-07	2008	2009	2010	Total
Granted	75	13	12	3	103
Withdrawals	1	0	1	0	2
Not renewed	2	0	0	0	2

Extensions - Annex II Applications

	95-07	2008	2009	2010	Total
Submitted	56	4	12	0	72
Withdrawals	1	1	1	0	3
Positive Opinions	33	7	7	1	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					
	95-07	2008	2009	2010	Total
Type IA	291	23	32	3	416
Type IB		25	41	1	
Type II	158	52	40	3	253
Transfers	9	2	3	0	14

Renewals					
	95-07	2008	2009	2010	Total
Submitted	43	7	18	4	72
Positive Opinions	40	8	15	1	64
Negative Opinions	0	0	0	0	0

Arbitrations and Community Referrals					
	95-07	2008	2009	2010	Total
Referrals Submitted	27	11	9	0	47
Opinions Reached	14	6	14	0	34

Establishment of MRLs for new substances					
	95-07	2008	2009	2010	Total
Submitted	65	1	4	0	70
Withdrawals	5	0	0	0	5
Positive Opinions[1]	52	2	2	0	56
Negative Opinions[2]	6	1	0	0	7

Extensions / Modifications/Extrapolations of MRLs					
	95-07	2008	2009	2010	Total
Submitted	96	2	2	0	100
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

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	• 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 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	12/11/2008 11/11/2009 (under re-examination)	• Tildren 500 mg • Tiludronic acid (as disodium salt)
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

Guidelines and Working Documents in 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)