31 January 2011
EMA/CVMP/37837/2011
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Monthly report of application procedures, guidelines and related documents January 2011

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					
	95-08	2009	2010	2011	Total
Submitted	63	11	21	2	97

Initial evaluation					
	95-08	2009	2010	2011	Total
Full (Submitted)	110	14	16	0	140
Abridged/ generics (Submitted)	10	1	2	0	13
Withdrawals	12	0	1	0	13
Positive opinions	91	13	14	2	120
Negative opinions	1	0	0	0	1

Marketing authorisations					
	95-08	2009	2010	2011	Total
Granted	88	12	9	0	109
Withdrawals	2	0	4	0	6
Not renewed	2	0	0	0	2

Extensions					
	95-08	2009	2010	2011	Total
Submitted	60	12	3	1	76
Withdrawals	2	1	1	0	4
Positive opinions	40	7	8	0	55
Negative opinions	0	0	0	0	0

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Variations – applications submitted					
	95-08	2009	2010	2011	Total
Type IA	339	32	76	4	557
Type IB		41	63	2	
Type II	210	40	26	1	277
Transfers	11	3	8	0	22

Renewals					
	95-08	2009	2010	2011	Total
Submitted	50	18	7	0	75
Positive opinions	48	17	8	1	74
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-08	2009	2010	2011	Total
Referrals submitted	38	9	12	0	59
Opinions reached[1]	20	15 (5)	11 (1)	0	46 (6)

[1] Re-examination of opinions in brackets

Establishment of MRLs for new substances					
	95-08	2009	2010	2011	Total
Submitted	66	4	3	1	74
Withdrawals	5	0	0	0	5
Positive opinions[2]	54	2	2	0	58
Negative opinions[3]	7	0	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-08	2009	2010	2011	Total
Submitted	98	2	10	1	111
Withdrawals	4	0	0	0	4
Positive opinions[3]	113	3	3	1	120
Negative opinions[4]	6	0	0	0	6
Extrapolations	50	0	0	0	50

[2] Including opinions recommending definitive MRLs for substances with previously provisional maximum residue limits

[3] Including one opinion concluding that final MRL could not be established for a substance with provisional maximum residue limits previously established

CVMP opinions in 2011 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
• CaniLeish	• Virbac S.A.	• Dogs • Vaccine against Leishmania infection	• 17/03/2010 • 12/01/2011 • 210 • 91	• 13/01/2011
• ZULVAC 1 + 8 Ovis	• Pfizer Limited	• Sheep • Vaccine for prevention of viraemia caused by Bluetongue Virus serotypes 1 and 8	• 18/03/2010 • 12/01/2011 • 180 • 119	• 13/01/2011

CVMP opinions in 2011 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
• Methylpredni – solone (after provisional MRLs)	• Bovine	• n/a • 12/01/2011 • 90 • 0	

Arbitrations and Community referrals in 2011

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
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	• 14/04/2010	• Synulox Lactating Cow and associated names • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Combimox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art.	• 14/07/2010	• Nisamox Lactating Cow

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
33(4) of Directive 2001/82/EC		• 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
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010	• Doxyfar 50% WSP and associated names • Doxycycline hyclate
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 2011

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/736964/2009	Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius* (MRSP)	Adopted January 2011