24 May 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 May 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	69	11	21	6	107
Advice given	65	8	18	5	96

Initial evaluation					
	95-08	2009	2010	2011	Total
Full (Submitted)	110	14	16	2	142
Abridged/ generics (Submitted)	10	1	2	1	14
Withdrawals	12	0	1	0	13
Positive opinions	91	13	14	8	126
Negative opinions	1	0	0	0	1

Marketing authorisations					
	95-08	2009	2010	2011	Total
Granted	88	12	9	13	122
Withdrawals	2	0	4	0	6
Not renewed	2	0	0	0	2

Extensions					
	95-08	2009	2010	2011	Total
Submitted	60	12	3	2	77
Withdrawals	2	1	1	0	4
Positive opinions	40	7	8	2	57
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	28	603
Type IB		41	63	24	
Type II	210	40	26	8	280
Transfers	11	3	8	2	24

Renewals					
	95-08	2009	2010	2011	Total
Submitted	50	18	7	6	81
Positive opinions	48	17	8	3	76
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-08	2009	2010	2011	Total
Referrals submitted	38	9	12	7	66
Opinions reached[1]	20	15 (5)	11 (1)	5	51 (6)

[1] Re-examination of opinions in brackets

Substances considered as not falling within the scope of Regulation (EC) No 470/2009		
	2011	Total
Submitted	2	2
Agreed	6	6
Scientific advice recommended	0	0

MUMS/ Limited market classification		
	2011	Total
Positive with financial incentives	3	3
Positive without financial incentives	6	6
Negative	1	1

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	3	61
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[2]	113	3	3	3	121
Negative opinions	6	0	0	0	6
Extrapolations	50	0	0	0	50

[2] Including opinions recommending the extension of the expiry date for provisional MRLS or 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 • 14/03/2011
• 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 • 14/03/2011
• BLUEVAC BTV8	• CZ Veterinaria S.A	• Cattle, sheep • Vaccine for active immunisation against bluetongue disease	• 17/01/2009 • 09/02/2011 • 180 • 511	• 10/02/2011 • 14/04/2011
• Procox • Emodepside and toltrazuril	• Bayer Animal Health GmbH	• Dogs • Treatment of dogs when mixed parasitic infections, caused by certain specific roundworms and coccidia are suspected or demonstrated	• 16/02/2010 • 09/02/2011 • 210 • 148	• 11/02/2011 • 20/04/2011
• Veraflox • Pradofloxacin	• Bayer Animal Health GmbH	• Dogs, cats • Treatment for dogs and cats with particular infections caused by certain specific and susceptible pathogens	• 19/05/2009 • 14/07/2010 • 205 • 217 • 09/02/2011 (re-consideration)	• 11/02/2011 • 12/04/2011

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
• Zuprevo • Tildipirosin	• Intervet International BV	• Pigs, cattle • Treatment of bacterial infections in the respiratory tract in pigs and cattle	• 16/02/2010 • 08/03/2011 • 210 • 177	• 10/03/2011 • 06/05/2011
• CERTIFECT • Fipronil, (S)-methoprene, amitraz	• MERIAL SAS	• Dogs • Treatment and prevention of infestations with ticks, alone or in association with fleas and/or chewing lice	• 16/03/2010 • 09/03/2011 • 210 • 148	• 10/03/2011 • 06/05/2011
• MS-H Vaccine • *Mycoplasma synoviae* strain MS-H	• Pharmsure Ltd	• Chickens • Vaccine to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae*	• 15/12/2009 • 07/04/2011 • 206 • 271	• 08/04/2011
• Recuvyra • Fentanyl	• Nexcyon Pharmaceuticals Ltd	• Dogs • Control of post-operative pain associated with major orthopaedic and soft tissue surgery	• 16/12/2009 • 04/05/2011 • 210 •	• 05/05/2011

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	• 27/01/2011
• Octenidine dihydrochloride	• All mammalian food producing species	• 11/08/2009 • 08/02/2011 • 210 • 246	• 21/02/2011
• Monepantel (after provisional MRLs)	• Caprine	• n/a • 09/03/2011 • 90 • 0	• 25/03/2011
• Azamethiphos	• Fin fish	• 21/02/2011 • 07/04/2011 • 45 • 0	• 08/04/2011
• Pegylated bovine granulocyte colony stimulating factor	• Bovine	• 16/03/2010 • 05/05/2011 • 210 • 205	• 18/05/2011
• Lasalocid	• Bovine	• 10/08/2010 • 05/05/2011 • 210 • 58	• 18/05/2011

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

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010 • 07/04/2011	• Combimox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010 • 07/04/2011	• Nisamox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010 • 07/04/2011	• Combisyn Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010 • 04/05/2011	• Doxycycline 50% WSP and associated names • Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010 • 04/05/2011	• 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
Referral under Art. 33(4) of Directive 2001/82/EC	• 09/02/2011	• Clavudale 50 mg tablet for cats and dogs • Amoxicillin and clavulanic acid
Referral under Art. 35 of Directive 2001/82/EC	• 09/03/2011	• Veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk
Referral under Art. 35 of Directive 2001/82/EC	• 06/04/2011	• All veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins and intended for use in food producing species • Cefquinome and ceftiofur
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011	• Prontax 10 mg/ml solution for injection for sheep, cattle and pigs • Doramectin
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011	• Prontax 5 mg/ml pour-on solution for cattle • Doramectin
Referral under Art. 35 of Directive 2001/82/EC	• 04/05/2011	• All pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix • Tilmicosin

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Art. 78 of Directive 2001/82/EC	• 04/05/2011	• HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names • Inactivated *Mannheimia haemolytica* and *Histophilus somni*

Guidelines and working documents in 2011

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/016/00-Rev.2	Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted April 2011
EMA/CVMP/760764/2010	Concept paper on the revision of the CVMP Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted for consultation, April 2011 (End of consultation 31 July 2011)
EMA/CVMP/EWP/459868/2008	Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish	Adopted May 2011

CVMP Environmental Risk Assessment

Reference number	Document title	Status
EMA/CVMP/ERA/147844/2011	Reflection paper on the testing strategy and risk assessment for plants	Adopted for consultation, March 2011 (End of consultation 30 June 2011)
EMA/CVMP/ERA/430327/2009	Guideline on determining the fate of veterinary medicinal products in manure	Adopted March 2011
EMA/CVMP/ERAWP/409328/2010	Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products	Adopted for consultation, May 2011 (End of consultation 31 August 2011)

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/206555/2010	Guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted for consultation, March 2011 (End of consultation 30 September 2011)
EMA/CVMP/IWP/314550/2010	Guideline on the design of studies	Adopted for consultation,

Reference number	Document title	Status
	to evaluate the safety and efficacy of fish vaccines	March 2011 (End of consultation 30 September 2011)

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/471721/2006	Recommendation on the basic surveillance of EudraVigilance Veterinary (EVVet) data	Adopted February 2011
EMA/CVMP/PhVWP/44873/2011	Public bulletin - Veterinary pharmacovigilance for 2010	Adopted February 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

General

Reference number	Document title	Status
EMA/347137/2010	Summary of procedures for consultation by CVMP of Scientific Advisory Groups (SAGs) and ad-hoc expert groups functioning as SAGs in relation to applications for authorisation for veterinary medicinal products	Adopted February 2011