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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

September 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	16	117
Advice given	65	8	18	19	104

Initial evaluation					
	95-08	2009	2010	2011	Total
Full (Submitted)	110	14	16	3	143
Abridged/ generics (Submitted)	10	1	2	1	14
Withdrawals	12	0	1	0	13
Positive opinions	91	13	14	14	132
Negative opinions	1	0	0	0	1

Marketing authorisations					
	95-08	2009	2010	2011	Total
Granted	88	12	9	20	129
Withdrawals	2	0	4	1	7
Not renewed	2	0	0	0	2

Extensions					
	95-08	2009	2010	2011	Total
Submitted	60	12	3	2	76
Withdrawals	2	1	1	0	4
Positive opinions	40	7	8	3	58
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	82	693
Type IB		41	63	60	
Type II	210	40	26	22	298
Transfers	11	3	8	3	25

Renewals					
	95-08	2009	2010	2011	Total
Submitted	50	18	7	10	85
Positive opinions	48	17	8	10	83
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-08	2009	2010	2011	Total
Referrals submitted	38	9	12	12	71
Opinions reached[1]	20	15 (5)	11 (1)	8	54 (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	6	6
Agreed	8	8
Scientific advice recommended	0	0

MUMS/ Limited market classification		
	2011	Total
Positive with financial incentives	6	6
Positive without financial incentives	11	11
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	4	62
Negative opinions[3]	7	0	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-08	2009	2010	2011	Total
Submitted	98	2	10	5	115
Withdrawals	4	0	0	0	4
Positive opinions[2]	113	3	3	5	124
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 • 17/03/2011 • OJ C 184/15
• 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 • 17/03/2011 • OJ C 184/15
• BLUEVAC BTV8	• CZ Veterinaria S.A	• Cattle, sheep • Vaccine for active immunisation against bluetongue disease	• 17/01/2009 • 09/02/2011 • 210 • 543	• 10/02/2011 • 14/04/2011 • 18/04/2011 • OJ C 184/15
• 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 • 28/04/2011 • OJ C 184/15
• 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 • 14/04/2011 • OJ C 184/15
• 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 • 06/05/2011 • OJ C 250/16
• 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 • 06/05/2011 • OJ C 250/16

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
• 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 • 14/06/2011 • 14/06/2011 • OJ C 250/16
• 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 • 294	• 05/05/2011
• Emdocam • Meloxicam	• Emdoka bvba	• Cattle, pigs, horses • For treatment in respiratory infections, diarrhoea and mastitis in cattle. For treatment in non-infectious locomotor disorders and in puerperal septicaemia and toxaemia in pigs. In horses for treatment in musculo-skeletal disorders as well for the relief of pain in equine colic.	• 18/05/2010 • 09/06/2011 • 175 • 211	• 09/06/2011 • 18/08/2011
• Proteq West Nile • West Nile recombinant canarypox virus (vCP2017 virus)	• MERIAL	• Horses • Vaccine for the active immunisation of horses against West Nile disease	• 18/05/2010 • 09/06/2011 • 196 • 190	• 09/06/2011 • 05/08/2011
• Zulvac 1 Bovis • Inactivated Bluetongue virus, serotype 1, strain BTV-1	• Pfizer Limited	• Cattle • Active immunisation of cattle for the prevention of viraemia caused by Bluetongue Virus, serotype 1	• 12/08/2010 • 09/06/2011 • 180 • 120	• 06/07/2011 • 05/08/2011

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
• Zulvac 1 Ovis • Inactivated Bluetongue Virus, serotype 1, strain BTV-1	• Pfizer Limited	• Sheep • Active immunisation of sheep for the prevention of viraemia caused by Bluetongue Virus, serotype 1	• 15/07/2010 • 09/06/2011 • 179 • 148	• 06/07/2011 • 05/08/2011
• Nobivac Myxo-RHD • Live myxoma vectored RHD virus strain 009	• Intervet International BV,	• Rabbits • Active immunisation of rabbits to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease	• 16/02/2010 • 14/07/2011 • 210 • 302	• 15/07/2011 • 07/09/2011
• Recocam • Meloxicam	• CF Pharma	• Cattle, pigs, horses • For treatment in respiratory infections, diarrhoea and mastitis in cattle. For treatment in non-infectious locomotor disorders and in puerperal septicaemia and toxaemia in pigs. In horses for treatment in musculo-skeletal disorders as well for the relief of pain in equine colic.	• 16/03/2010 • 14/07/2011 • 210 • 274	• 14/07/2011 • 13/09/2011

CVMP opinions in 2011 on establishment of MRLs for new substances

Positive opinions

• Substance • INN	• 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
• Ivermectin	• All mammalian food producing species	• n/a • 09/06/2011 • 176 • 0	• 20/06/2011
• Phenoxymethyl-penicillin	• Poultry eggs	• 12/10/2010 • 14/07/2011 • 210 • 65	• 22/07/2011
• Tildipirosin (after provisional MRLs)	• Bovine, porcine and caprine	• n/a • 15/09/2011 • 90 • n/a	• 29/09/2011

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 • 07/06/2011	• Synulox Lactating Cow and associated names • Amoxicillin, clavulanic acid, prednisolone
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 • 08/06/2011	• 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 5 mg/ml pour-on solution for cattle • Doramectin

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
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
Referral under Art. 78 of Directive 2001/82/EC	• 04/05/2011 • 14/07/2011	• HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names • Inactivated *Mannheimia haemolytica* and *Histophilus somni*
Referral under Art. 34 of Directive 2001/82/EC	• 14/09/2011	• Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names • Praziquantel, pyrantel and febantel
Referral under Art. 35 of Directive 2001/82/EC	• 15/09/2011	• All long acting formulations for injection containing barium selenate for all food producing species • barium selenate
Procedure under Art. 30(3) of Regulation (EC) No 726/2004	• 15/09/2011	• N/a • Dapsone

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

Reference number	Document title	Status
		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)
EMA/CVMP/ERA/172074/2008-Rev.3	Questions and answers document on implementation of ERA Guideline in support of VICH guidelines (GL 6 and GL 38)	Adopted July 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 to evaluate the safety and efficacy of fish vaccines	Adopted for consultation, 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
EMA/CVMP/10418/2009-Rev.3	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2011
EMA/CVMP/PhVWP/377827/2011	List of species and breeds for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance	Adopted June 2011
EMA/CVMP/PhVWP/288284/2007-Rev.4	Quidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in	Adopted June 2011

Reference number	Document title	Status
	animals and humans	
SOP/V/4019	Standard operating procedure - Annual review of standard lists to be used in EudraVigilance Veterinary	Adopted June 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
EMA/CVMP/287420/2010	CVMP Strategy on antimicrobials 2011-2015	Adopted July 2011
EMA/CVMP/414812/2011	Question and answer document on the CVMP guideline on the SPC for antimicrobial products	Adopted July 2011
EMA/CVMP/VICH/502/1999-Rev.1	VICH GL18(R) on residual solvents in new veterinary medicinal products, active substances and excipients	Adopted September 2011
EMA/CVMP/814/00-Rev.2	HMPC Guideline on quality of herbal medicinal products/traditional herbal medicinal products	Adopted September 2011
EMA/HMPC/162241/2005-Rev.2	Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products	Adopted September 2011