



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 August 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 July 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	13	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	14	123
Withdrawals	2	0	4	0	6
Not renewed	2	0	0	0	2

Extensions					
	95-08	2009	2010	2011	Total
Submitted	60	12	3	3	77
Withdrawals	2	1	1	0	4
Positive opinions	40	7	8	3	58
Negative opinions	0	0	0	0	0



Variations – applications submitted					
	95-08	2009	2010	2011	Total
Type IA	339	32	76	71	670
Type IB		41	63	48	
Type II	210	40	26	13	289
Transfers	11	3	8	3	25

Renewals					
	95-08	2009	2010	2011	Total
Submitted	50	18	7	10	85
Positive opinions	48	17	8	7	80
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-08	2009	2010	2011	Total
Referrals submitted	38	9	12	9	68
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	4	4
Agreed	7	7
Scientific advice recommended	0	0

MUMS/ Limited market classification		
	2011	Total
Positive with financial incentives	6	6
Positive without financial incentives	9	9
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	4	114
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	Marketing authorisation holder	Therapeutic area	EMA/CVMP	European Commission
<ul style="list-style-type: none"> Invented name INN 		<ul style="list-style-type: none"> Target species Summary of indication 	<ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	<ul style="list-style-type: none"> Opinion received Date of decision Notification Official Journal
<ul style="list-style-type: none"> CaniLeish 	<ul style="list-style-type: none"> Virbac S.A. 	<ul style="list-style-type: none"> Dogs Vaccine against Leishmania infection 	<ul style="list-style-type: none"> 17/03/2010 12/01/2011 210 91 	<ul style="list-style-type: none"> 13/01/2011 14/03/2011 17/03/2011 OJ C 184/15
<ul style="list-style-type: none"> ZULVAC 1 + 8 Ovis 	<ul style="list-style-type: none"> Pfizer Limited 	<ul style="list-style-type: none"> Sheep Vaccine for prevention of viraemia caused by Bluetongue Virus serotypes 1 and 8 	<ul style="list-style-type: none"> 18/03/2010 12/01/2011 180 119 	<ul style="list-style-type: none"> 13/01/2011 14/03/2011 17/03/2011 OJ C 184/15
<ul style="list-style-type: none"> BLUEVAC BTv8 	<ul style="list-style-type: none"> CZ Veterinaria S.A 	<ul style="list-style-type: none"> Cattle, sheep Vaccine for active immunisation against bluetongue disease 	<ul style="list-style-type: none"> 17/01/2009 09/02/2011 210 543 	<ul style="list-style-type: none"> 10/02/2011 14/04/2011 18/04/2011 OJ C 184/15
<ul style="list-style-type: none"> Procox Emodepside and toltrazuril 	<ul style="list-style-type: none"> Bayer Animal Health GmbH 	<ul style="list-style-type: none"> Dogs Treatment of dogs when mixed parasitic infections, caused by certain specific roundworms and coccidia are suspected or demonstrated 	<ul style="list-style-type: none"> 16/02/2010 09/02/2011 210 148 	<ul style="list-style-type: none"> 11/02/2011 20/04/2011 28/04/2011 OJ C 184/15
<ul style="list-style-type: none"> Veraflox Pradofloxacin 	<ul style="list-style-type: none"> Bayer Animal Health GmbH 	<ul style="list-style-type: none"> Dogs, cats Treatment for dogs and cats with particular infections caused by certain specific and susceptible pathogens 	<ul style="list-style-type: none"> 19/05/2009 14/07/2010 205 217 09/02/2011 (re-consideration) 	<ul style="list-style-type: none"> 11/02/2011 12/04/2011 14/04/2011 OJ C 184/15
<ul style="list-style-type: none"> Zuprevo Tildipirosin 	<ul style="list-style-type: none"> Intervet International BV 	<ul style="list-style-type: none"> Pigs, cattle Treatment of bacterial infections in the respiratory tract in pigs and cattle 	<ul style="list-style-type: none"> 16/02/2010 08/03/2011 210 177 	<ul style="list-style-type: none"> 10/03/2011 06/05/2011
<ul style="list-style-type: none"> CERTIFECT Fipronil, (S)-methoprene, amitraz 	<ul style="list-style-type: none"> MERIAL SAS 	<ul style="list-style-type: none"> Dogs Treatment and prevention of infestations with ticks, alone or in association with fleas and/or chewing lice 	<ul style="list-style-type: none"> 16/03/2010 09/03/2011 210 148 	<ul style="list-style-type: none"> 10/03/2011 06/05/2011

Product <ul style="list-style-type: none"> Invented name INN 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> Target species Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	European Commission <ul style="list-style-type: none"> Opinion received Date of decision Notification Official Journal
<ul style="list-style-type: none"> MS-H Vaccine <i>Mycoplasma synoviae</i> strain MS-H 	<ul style="list-style-type: none"> Pharmsure Ltd 	<ul style="list-style-type: none"> Chickens Vaccine to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by <i>Mycoplasma synoviae</i> 	<ul style="list-style-type: none"> 15/12/2009 07/04/2011 206 271 	<ul style="list-style-type: none"> 08/04/2011 14/06/2011
<ul style="list-style-type: none"> Recuvyra Fentanyl 	<ul style="list-style-type: none"> Nexcyon Pharmaceuticals Ltd 	<ul style="list-style-type: none"> Dogs Control of post-operative pain associated with major orthopaedic and soft tissue surgery 	<ul style="list-style-type: none"> 16/12/2009 04/05/2011 210 294 	<ul style="list-style-type: none"> 05/05/2011
<ul style="list-style-type: none"> Emdocam Meloxicam 	<ul style="list-style-type: none"> Emdoka bvba 	<ul style="list-style-type: none"> 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 toxemia in pigs. In horses for treatment in musculo-skeletal disorders as well for the relief of pain in equine colic. 	<ul style="list-style-type: none"> 18/05/2010 09/06/2011 175 211 	<ul style="list-style-type: none"> 09/06/2011
<ul style="list-style-type: none"> Proteq West Nile West Nile recombinant canarypox virus (vCP2017 virus) 	<ul style="list-style-type: none"> MERIAL 	<ul style="list-style-type: none"> Horses Vaccine for the active immunisation of horses against West Nile disease 	<ul style="list-style-type: none"> 18/05/2010 09/06/2011 196 190 	<ul style="list-style-type: none"> 09/06/2011
<ul style="list-style-type: none"> Zulvac 1 Bovis Inactivated Bluetongue virus, serotype 1, strain BTV-1 	<ul style="list-style-type: none"> Pfizer Limited 	<ul style="list-style-type: none"> Cattle Active immunisation of cattle for the prevention of viraemia caused by Bluetongue Virus, serotype 1 	<ul style="list-style-type: none"> 12/08/2010 09/06/2011 180 120 	<ul style="list-style-type: none"> 06/07/2011

Product <ul style="list-style-type: none"> Invented name INN 	<ul style="list-style-type: none"> Marketing authorisation holder 	Therapeutic area <ul style="list-style-type: none"> Target species Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	European Commission <ul style="list-style-type: none"> Opinion received Date of decision Notification Official Journal
<ul style="list-style-type: none"> Zulvac 1 Ovis Inactivated Bluetongue Virus, serotype 1, strain BTV-1 	<ul style="list-style-type: none"> Pfizer Limited 	<ul style="list-style-type: none"> Sheep Active immunisation of sheep for the prevention of viraemia caused by Bluetongue Virus, serotype 1 	<ul style="list-style-type: none"> 15/07/2010 09/06/2011 179 148 	<ul style="list-style-type: none"> 06/07/2011
<ul style="list-style-type: none"> Nobivac Myxo-RHD Live myxoma vectored RHD virus strain 009 	<ul style="list-style-type: none"> Intervet International BV, 	<ul style="list-style-type: none"> Rabbits Active immunisation of rabbits to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease 	<ul style="list-style-type: none"> 16/02/2010 14/07/2011 210 302 	<ul style="list-style-type: none"> 15/07/2011
<ul style="list-style-type: none"> Recocam Meloxicam 	<ul style="list-style-type: none"> CF Pharma 	<ul style="list-style-type: none"> 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 toxemia in pigs. In horses for treatment in musculo-skeletal disorders as well for the relief of pain in equine colic. 	<ul style="list-style-type: none"> 16/03/2010 14/07/2011 210 274 	<ul style="list-style-type: none"> 14/07/2011

CVMP opinions in 2011 on establishment of MRLs for new substances

Positive opinions

<ul style="list-style-type: none"> Substance INN 	<ul style="list-style-type: none"> Target species 	EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	European Commission <ul style="list-style-type: none"> Opinion received Date of regulation Official Journal
<ul style="list-style-type: none"> Methylpredni – solone (after provisional MRLs)	<ul style="list-style-type: none"> Bovine 	<ul style="list-style-type: none"> n/a 12/01/2011 90 0 	<ul style="list-style-type: none"> 27/01/2011
<ul style="list-style-type: none"> Octenidine dihydrochloride 	<ul style="list-style-type: none"> All mammalian food producing species 	<ul style="list-style-type: none"> 11/08/2009 08/02/2011 210 246 	<ul style="list-style-type: none"> 21/02/2011
<ul style="list-style-type: none"> Monepantel (after provisional MRLs)	<ul style="list-style-type: none"> Caprine 	<ul style="list-style-type: none"> n/a 09/03/2011 90 0 	<ul style="list-style-type: none"> 25/03/2011
<ul style="list-style-type: none"> Azamethiphos 	<ul style="list-style-type: none"> Fin fish 	<ul style="list-style-type: none"> 21/02/2011 07/04/2011 45 0 	<ul style="list-style-type: none"> 08/04/2011
<ul style="list-style-type: none"> Pegylated bovine granulocyte colony stimulating factor 	<ul style="list-style-type: none"> Bovine 	<ul style="list-style-type: none"> 16/03/2010 05/05/2011 210 205 	<ul style="list-style-type: none"> 18/05/2011
<ul style="list-style-type: none"> Lasalocid 	<ul style="list-style-type: none"> Bovine 	<ul style="list-style-type: none"> 10/08/2010 05/05/2011 210 58 	<ul style="list-style-type: none"> 18/05/2011
<ul style="list-style-type: none"> Ivermectin 	<ul style="list-style-type: none"> All mammalian food producing species 	<ul style="list-style-type: none"> n/a 09/06/2011 176 0 	<ul style="list-style-type: none"> 20/06/2011
<ul style="list-style-type: none"> Phenoxymethyl-penicillin 	<ul style="list-style-type: none"> Poultry eggs 	<ul style="list-style-type: none"> 12/10/2010 14/07/2011 210 65 	<ul style="list-style-type: none"> 22/07/2011

Arbitrations and Community referrals in 2011

Type of referral	<ul style="list-style-type: none"> Date of clock start CVMP opinion 	<ul style="list-style-type: none"> Product name INN
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> 11/11/2009 	<ul style="list-style-type: none"> Fortekor vet and associated names Benazepril hydrochloride
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> 14/04/2010 07/06/2011 	<ul style="list-style-type: none"> Synulox Lactating Cow and associated names Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> 14/07/2010 07/04/2011 	<ul style="list-style-type: none"> Combimox Lactating Cow Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> 14/07/2010 07/04/2011 	<ul style="list-style-type: none"> Nisamox Lactating Cow Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> 14/07/2010 07/04/2011 	<ul style="list-style-type: none"> Combisyn Lactating Cow Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> 14/07/2010 04/05/2011 	<ul style="list-style-type: none"> Doxycycline 50% WSP and associated names Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> 14/07/2010 04/05/2011 	<ul style="list-style-type: none"> Doxyfar 50% WSP and associated names Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> 09/11/2010 	<ul style="list-style-type: none"> Baytril 10% oral solution and associated names Enrofloxacin
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> 09/02/2011 08/06/2011 	<ul style="list-style-type: none"> Clavudale 50 mg tablet for cats and dogs Amoxicillin and clavulanic acid
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> 09/03/2011 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 06/04/2011 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 04/05/2011 	<ul style="list-style-type: none"> Prontax 10 mg/ml solution for injection for sheep, cattle and pigs Doramectin

Type of referral	<ul style="list-style-type: none"> • Date of clock start • CVMP opinion 	<ul style="list-style-type: none"> • Product name • INN
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 04/05/2011 	<ul style="list-style-type: none"> • Prontax 5 mg/ml pour-on solution for cattle • Doramectin
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 04/05/2011 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 04/05/2011 • 14/07/2011 	<ul style="list-style-type: none"> • HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names • Inactivated <i>Mannheimia haemolytica</i> and <i>Histophilus somni</i>

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)

Reference number	Document title	Status
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	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2011
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 <i>Staphylococcus pseudintermedius</i> (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