10 December 2012
EMA/792274/2012
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Monthly report of application procedures, guidelines and related documents

November 2012

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

	95-09	2010	2011	2012	Total
Submitted	80	21	26	24	151
Advice given	73	18	24	23	138

Initial evaluation

	95-09	2010	2011	2012	Total
Full (Submitted)	124	16	8	9	157
Abridged/ generics (Submitted)	11	2	3	0	16
Withdrawals	12	1	0	1	14
Positive opinions	104	14	19	7	144
Negative opinions	1	0	0	0	1

Marketing authorisations

	95-09	2010	2011	2012	Total
Granted	100	9	22	7	138
Withdrawals	2	4	1	0	7
Not renewed	2	0	0	2	4

Extensions

	95-09	2010	2011	2012	Total
Submitted	72	3	7	7	89
Withdrawals	3	1	0	0	4
Positive opinions	47	8	4	10	69
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					
	95-09	2010	2011	2012	Total
Type IA	412	76	125	112	954
Type IB		63	87	79	
Type II	250	26	45	40	361
Transfers	14	8	3	2	27

Renewals					
	95-09	2010	2011	2012	Total
Submitted	68	7	14	8	97
Positive opinions	65	8	12	10	95
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-09	2010	2011	2012	Total
Referrals submitted	47	12	12	12	83
Opinions reached[1]	35 (5)	11 (1)	10	11 (1)	66 (7)

[1] Re-examination of opinions in brackets

Substances considered as not falling within the scope of Regulation (EC) No 470/2009			
	2011	2012	Total
Submitted	7	2	7
Agreed	9	4	13
Scientific advice recommended	0	0	0

MUMS/ Limited market classification			
	2011	2012	Total
Positive with financial incentives	8	12	20
Positive without financial incentives	12	5	17
Negative	1	1	2

Establishment of MRLs for new substances					
	95-09	2010	2011	2012	Total
Submitted	70	3	1	1	75
Withdrawals	5	0	0	0	5
Positive opinions[2]	56	2	4	1	63
Negative opinions[3]	7	0	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-09	2010	2011	2012	Total
Submitted	100	10	13	5	128
Withdrawals	4	0	2	0	6
Positive opinions[2]	116	3	12	8 (2)	139
Negative opinions	6	0	0	0	6

[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances with previously provisional maximum residue limits. Re-examination of opinions are indicated in brackets.

[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 2012 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**
• Zulvac 1+8 Bovis • Inactivated Bluetongue virus, serotype 1 and 8, strain BTV-1	• Pfizer Limited	• Cattle • Vaccine for the active immunisation of cattle for the prevention of viraemia caused by Bluetongue Virus, serotype 1 and 8.	• 04/02/2011 • 12/01/2012 • 152 • 191	• 12/01/2012 • 08/03/2012 • 12/03/2012 • 27/04/2012
• Poulvac E. Coli	• Pfizer Limited	• Chickens • Vaccine for the active immunisation to reduce mortality and lesions associated with E. Coli serotype 078	• 09/02/2011 • 11/04/2012 • 210 • 219	• 13/04/2012 • 15/06/2012 • 20/06/2012 • 27/07/2012
• Porcilis ColiClos	• Intervet Internatinal B.V.	• Piglets • Vaccine for the passive immunisation against E. Coli and C. perfringens	• 12/10/2010 • 11/04/2012 • 210 • 339	• 16/04/2012 • 14/06/2012 • 17/06/2012 • 27/07/2012
• Cardalis tablets • Benazepril and spironolactone	• Ceva Santé Animale	• Dogs • Indicated for the treatment of congestive heart failure caused by chronic degenerative valvular disease	• 13/07/2011 • 16/05/2012 • 208 • 99	• 16/05/2012 • 23/07/2012 • 25/07/2012 • 31/08/2012
• Nobivac L4	• Intervet Internatinal B.V.	• Dogs • Vaccine containing inactivated Leptospira strains and indicated for the active immunisation of dogs to reduce infection and/or urinary excretion caused by Leptospira strains.	• 04/01/2012 • 16/05/2012 • 201 • 256	• 16/05/2012 • 16/07/2012 • 18/07/2012 • 31/08/2012

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**
• Contacera	• Pfizer Limited	• Cattle, pigs and horses. • Anti-inflammatory and anti-rheumatic	• 12/10/2011 • 11/10/2012 • 210 • 156	• 11/10/2012
• Kexxtone	• Eli Lilly and Company Limited	• Cattle • reduction of the incidence of ketosis in the periparturient dairy cow/heifer	• 12/10/2011 • 08/11/2012 • 210 • 185	• 08/11/2012

CVMP opinions in 2012 on establishment of MRLs

Positive opinions

• **Substance** • **INN**	• **Target species**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Opinion received** • **Date of regulation** • **Official Journal**
Sodium salicylate (After provisional MRLs)	• Turkeys	• n/a • 09/02/2012 • 90 • 0	• 15/02/2012 • 12/10/2012 • 13/10/2012
Prednisolone	• Horses	• 12/10/2011 • 08/03/2012; *14/06/2012 (Re-examination)* • 148 • 0	• 20/06/2012
Monensin	• Bovine species	• 15/06/2011 • 08/03/2012 • 205 • 63	• 21/03/2012
Phoxim	• All food producing except fin fish	• 04/01/2010 • 08/03/2012 • 210 • 220	• 21/03/2012
Diclazuril	• Poultry	• 09/11/2011 • 13/04/2012 • 156 • 0	• 20/04/2012
Double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of Israel Acute Paralysis Virus	• Bees	• 09/10/2010 • 13/04/2012 • 210 • 312	• 20/04/2012
Eprinomectin	• Ovine and caprine	• 18/05/2010 • 13/04/2012 • 183 • 515	• 20/04/2012
Monepantel	• Ovine and caprine milk	• 13/09/2011 • 16/05/2012 • 210 • 36	• 25/05/2012

Manganese carbonate	• All food producing species	• 15/02/2012 • 12/07/2012 • 148 • 0	• 25/07/2012

Arbitrations and Community referrals in 2012

Type of referral	• **Date of clock start** • **CVMP opinion**	• **Product name** • **INN**
Referral under Art. 34 of Directive 2001/82/EC	• 09/11/2010 • 13/06/2012	• Baytril 10% oral solution and associated names • Enrofloxacin
Referral under Art. 35 of Directive 2001/82/EC	• 09/03/2011 • 08/03/2012 • 13/06/2012 (re-examination)	• Veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk and which are intended for use in ruminants producing milk for human consumption
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011 • 08/02/2012	• Prontax 5 mg/ml pour-on solution for cattle • Doramectin
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011 • 08/02/2012	• Prontax 10 mg/ml solution for injection for sheep, cattle and pigs • Doramectin
Referral under Art. 35 of Directive 2001/82/EC	• 04/05/2011 • 08/03/2012	• All pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix • Tilmicosin
Referral under Art. 34 of Directive 2001/82/EC	• 14/09/2011 • 08/03/2012	• 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 • 11/07/2012	• N/a • Dapsone
Referral under Article 33(4) of Directive 2001/82/EC	• 12/10/2011 • 13/06/2012	• Nuflor 300 mg/ml solution for injection for cattle and sheep

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
		• Florfenicol
Referral under Article 35 of Directive 2001/82/EC	• 12/10/2011 • 13/04/2012	• Hipralona Enro-S and its generics • Enrofloxacin
Referral under Article 33(4) of Directive 2001/82/EC	• 10/01/2012 • 13/06/2012	• Nuflor Swine Once 450 mg/ml solution for injection • Florfenicol
Referral under Article 35 of Directive 2001/82/EC	• 12/04/2012	• All injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian foodproducing species • Doramectin
Referral under Art. 34 of Directive 2001/82/EC	• 15/05/2012	• Micotil 300 Injectie and associated names • Tilmicosin
Referral under Article 33(4) of Directive 2001/82/EC	• 15/05/2012	• Florgane 300 mg/ml suspension for injection for cattle and pigs • Florfenicol
Referral under Article 33(4) of Directive 2001/82/EC	• 11/07/2012 • 08/11/2012	• Melosolute 40 mg/ml solution for injection for cattle, pigs and horses • Meloxicam
Referral under Article 33(4) of Directive 2001/82/EC	• 11/07/2012	• Strenzen 500/125 mg/g powder for use in drinking water for pigs • Amoxicillin/clavulanic acid
Referral under Article 35 of Directive 2001/82/EC	• 12/09/2012	• Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications • Spiramycin
Referral under Article 35 of Directive 2001/82/EC	• 12/09/2012	• Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications • Dexamethasone
Referral under Article 34 of Directive 2001/82/EC	• 10/10/2012	• Linco-Spectin 100 and its associated names • Lincomycin, spectinomycin
Referral under Article 34 of Directive 2001/82/EC	• 07/11/2012	• Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
		• Enrofloxacin
Referral under Article 35 of Directive 2001/82/EC	• 07/11/2012	• All veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys • Enrofloxacin
Referral under Article 13 of Regulation (EC) No. 1234/2008	• 07/11/2012	• Soludox 500 mg/g powder for use in drinking water for pigs and chickens • Doxycycline hyclate

Guidelines and working documents in 2012

CVMP Quality

Reference number	Document title	Status
EMEA/CVMP/134/02-Rev.3/CHMP/QWP/277/02-Rev.3	Draft guideline on the Active Substance Master File Procedure	Adopted June 2012
EMEA/CHMP/CVMP/QWP/17760/2009-Rev.1	Draft guideline on the Use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations	Adopted for consultation, January 2012 (End of consultation 30 April 2012)
EMA/CHMP/CVMP/QWP/70278/2012-Rev.1	Draft guideline on process validation	Adopted for consultation, March 2012 (End of consultation September 2012)
EMA/705532/2011	Questions and Answers on Post Approval Change Management Protocols	Adopted March 2012
Not applicable	Questions and Answers on the Uniformity of Dosage Units	Adopted April 2012
EMA/CHMP/CVMP/QWP/199250/2009	Guideline on setting specifications for related impurities in antibiotics	Adopted June 2012

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/355689/2006	Guideline on the approach to establish a pharmacological ADI.	Adopted November 2012
EMA/CVMP/SWP/878228/2011	Concept paper introducing a review and update of existing EU guidelines on residues studies to bring these into line with the VICH metabolism and residues guidelines VICH 46-49	Adopted for consultation, February 2012 (End of consultation 31 May 2012)

Reference number	Document title	Status
EMA/CHMP/CVMP/SWP/169430/2012-CONSULTATION	Draft guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities	November 2012 (End of consultation 31 May 2013)

CVMP Environmental Risk Assessment

Reference number	Document title	Status
EMA/CVMP/ERA/409328/2010	Reflection paper on mitigation measures related to the environmental risk assessment of veterinary medicinal products testing	Adopted March 2012
EMA/CVMP/ERA/52740/2012	Draft guidance on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine	Adopted for consultation, July 2012 (End of consultation 01 September 2012)
EMA/CVMP/ERA/172074/2008 – Rev.4	Q&A document on the implementation of the CVMP Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted September 2012

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/81976/2010 replacing EMEA/CVMP/816/00	Guideline on Statistical principles for veterinary clinical trials.	Adopted January 2012
EMA/CVMP/EWP/82829/2009-Rev.2	Revised Questions and Answers on: Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats	Adopted July 2012
EMA/CVMP/EWP/206024/2011-CONSULTATION	Draft guideline on demonstration of palatability of veterinary medicinal products	Adopted for consultation, November 2012 (End of consultation 31 May 2013)
EMA/CVMP/EWP/1061/2011-CONSULTATION	Draft revised guideline on conduct of efficacy studies for non-steroidal anti-inflammatory drugs (NSAID)	Adopted for consultation, November 2012 (End of consultation 31 May

Reference number	Document title	Status
		2013)

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/810769/2011 replacing EMEA/CVMP/865/03/final	Guideline on data requirements for removing the target animal batch safety test for immunological veterinary medicinal products in the EU	Adopted January 2012
EMA/CVMP/IWP/4199/2012	Concept paper on the need of revision of the Note for Guidance on the Harmonisation of requirements for equine influenza vaccines	Adopted for consultation, March 2012 (End of consultation 31 May 2012)
EMA/CVMP/IWP/206555/2010	Guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted April 2012 Adoption of the revised version June 2012
EMA/CVMP/IWP/594618/2010-CONSULTATION	Draft guideline on the requirements for combined vaccines and association of immunological veterinary medicinal products	Adopted for consultation, November 2012 (End of consultation 31 Jan 2013)
EMA/CVMP/IWP/105112/2011-CONSULTATION	Draft table of extraneous agents to be tested for in relation to the Guideline on Requirements for the Production and Control of Immunological Veterinary Medicinal Products	Adopted for consultation, November 2012 (End of consultation 31 May 2013)

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/126726/2007-Rev.1	Reflection paper on risk management plans for centrally authorised veterinary medicinal products	Adopted February 2012
EMA/CVMP/PhVWP/987984/2011	Public bulletin on veterinary pharmacovigilance for 2011	Adopted February 2012
EMA/SOP/V/4025	Procedure in accordance with Article 78 of Directive 2001/82/EC related to pharmacovigilance measures for veterinary medicinal products authorised in the European Union	Adopted April 2012
EMA/CVMP/10418/2009-Rev.4	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in	Adopted June 2012

Reference number	Document title	Status
	animals and humans to veterinary medicinal products	
EMA/CVMP/PhVWP/288284/2007-Rev.5	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2012
EMA/123352/2004-Rev.6	Call for comments on standard lists for EudraVigilance Veterinary	Adopted June 2012
EMA/CVMP/PhVWP/5507/2011	Concept paper for the revision of the CVMP guideline on harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products	Adopted for consultation, July 2012 (End of consultation 31 October 2012)

Application of 3Rs (Replacement, Refinement and Reduction) in testing

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/252137/2012	Recommendation to marketing authorisation holders, highlighting the need to ensure compliance with 3Rs methods described in the European Pharmacopoeia	Adopted July 2012
EMA/CHMP/CVMP/JEG-3Rs/169839/2011-Rev.1	Concept paper on the need for revision of the position on the replacement of animal studies by *in vitro* models	Adopted for consultation, July 2012 (End of consultation 31 October 2012)

General

Reference number	Document title	Status
EMA/899273/2011	Revised list of target species for use in SPCs	Adopted February 2012
EMA/SOP/V/4003	Incident management for medicines for veterinary	Endorsed September 2012