29 June 2012
EMA/343346/2012
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Monthly report of application procedures, guidelines and related documents

June 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	15	142
Advice given	73	18	24	12	127

Initial evaluation

	95-09	2010	2011	2012	Total
Full (Submitted)	124	16	8	3	151
Abridged/ generics (Submitted)	11	2	3	0	16
Withdrawals	12	1	0	1	14
Positive opinions	104	14	19	5	142
Negative opinions	1	0	0	0	1

Marketing authorisations

	95-09	2010	2011	2012	Total
Granted	100	9	22	3	134
Withdrawals	2	4	1	0	7
Not renewed	2	0	0	0	2

Extensions

	95-09	2010	2011	2012	Total
Submitted	72	3	7	4	86
Withdrawals	3	1	0	0	4
Positive opinions	47	8	4	7	66
Negative opinions	0	0	0	0	0

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Variations – applications submitted					
	95-09	2010	2011	2012	Total
Type IA	412	76	125	38	836
Type IB		63	87	35	
Type II	250	26	45	30	351
Transfers	14	8	3	2	27

Renewals					
	95-09	2010	2011	2012	Total
Submitted	68	7	14	0	89
Positive opinions	65	8	12	6	91
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-09	2010	2011	2012	Total
Referrals submitted	47	12	12	4	75
Opinions reached[1]	35 (5)	11 (1)	10	9 (1)	65 (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	0	7
Agreed	9	2	11
Scientific advice recommended	0	0	0

MUMS/ Limited market classification			
	2011	2012	Total
Positive with financial incentives	8	8	16
Positive without financial incentives	12	2	14
Negative	1	0	1

Establishment of MRLs for new substances					
	95-09	2010	2011	2012	Total
Submitted	70	3	1	0	74
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	2	125
Withdrawals	4	0	2	0	6
Positive opinions[2]	116	3	12	7 (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
• 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
• 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
• 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
• 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

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
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

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	• N/a • Dapsone
Procedure 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 • Florfenicol
Procedure under Article 35 of Directive 2001/82/EC	• 12/10/2011 • 13/04/2012	• Hipralona Enro-S and its generics • Enrofloxacin

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Procedure 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
Procedure 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
Procedure under Article 33(4) of Directive 2001/82/EC	• 15/05/2012	• Florgane 300 mg/ml suspension for injection for cattle and pigs • Florfenicol

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	Draft guideline on the approach to establish a pharmacological ADI.	Adopted for consultation, January 2012 (End of consultation 31 July 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)

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

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

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

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 animals and humans to veterinary medicinal products	Adopted June 2012
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

General

Reference number	Document title	Status
EMA/899273/2011	Revised list of target species	Adopted February 2012