14 May 2013
EMA/249895/2013
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Monthly report of application procedures, guidelines and related documents

April 2013

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

	95-10	2011	2012	2013	Total
Submitted	101	26	28	11	166
Advice given	91	24	29	8	152

Initial evaluation

	95-10	2011	2012	2013	Total
Full (Submitted)	140	8	12	6	163
Abridged/ generics (Submitted)	13	3	0	0	16
Withdrawals	13	0	1	0	14
Positive opinions	118	19	9	4	150
Negative opinions	1	0	0	0	1

Marketing authorisations

	95-10	2011	2012	2013	Total
Granted	111	24	8	4	144
Withdrawals	6	1	3	0	10
Not renewed	2	0	0	0	2

Extensions

	95-10	2011	2012	2013	Total
Submitted	75	7	8	1	91
Withdrawals	4	0	1	0	5
Positive opinions	55	4	10	3	71
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					
	95-10	2011	2012	2013	Total
Type IA	551	120	104	19	998
Type IB		101	96	24	
Type II	276	45	52	12	378
Transfers	22	3	2	24	51

Renewals					
	95-10	2011	2012	2013	Total
Submitted	75	14	10	5	104
Positive opinions	73	12	10	4	96
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-10	2011	2012	2013	Total
Referrals submitted	59	12	12	5	88
Opinions reached[1]	46 (6)	10	11 (1)	4 (1)	71 (8)

[1] Re-examination of opinions in brackets

Substances considered as not falling within the scope of Regulation (EC) No 470/2009					
	2010	2011	2012	2013	Total
Submitted	5	5	9	5	24
Agreed	0	10	6	4	20
Scientific advice recommended	0	0	0	1	0

MUMS/ Limited market classification				
	2011	2012	2013	Total
Positive with financial incentives	8	16	3	26
Positive without financial incentives	12	5	5	22
Negative	1	1	1	3

Establishment of MRLs for new substances					
	95-10	2011	2012	2013	Total
Submitted	73	1	1	2	77
Withdrawals	5	0	0	2	7
Positive opinions[2]	58	4	1	0	63
Negative opinions[3]	7	0	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-10	2011	2012	2013	Total
Submitted	110	13	5	2	129
Withdrawals	4	2	0	0	6
Positive opinions[2]	119	12	8 (2)	1	140
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 2013 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**
• **Meloxidolor** • M*eloxicam*	• Le Vet Beheer B.V.	• Dogs, cats, cattle, pigs and horses • Anti-inflammatory and anti-rheumatic	• 15/12/2012 • 07/02/2013 • 210 • 212	• 07/02/2013 •
• **ECOPORC Shiga**	• IDT Biologika GmbH	• Piglets • Vaccine for the active immunisation to reduce the mortality and clinical sings of oedema disease	• 15/12/2012 • 07/02/2013 • 210 • 212	• 08/02/2013 • 10/04/2013
• **Oncept IL-2**	• MERIAL	• Cats • Immunotherapy product to be used in addition to surgery and radiotherapy with fibrosarcoma without metastasis or lymph node involvement	• 09/11/2012 • 07/03/2013 • 205 • 280	• 07/03/2013
• **Equilis West Nile**	• Intervet International BV	• Horses • For the active immunisation of horses against West Nile virus (WNV) to prevent virus viraemia and to reduce clinical symptoms of disease and lesions in the brain.	• 17/01/2012 • 11/04/2013 • 208 • 240	

CVMP opinions in 2013 on establishment of MRLs

Positive opinions

• **Substance**	• **Target species**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Opinion received** • **Date of regulation** • **Official Journal**
• Diclazuril	• Rabbits	• 12/09/2012 • 07/02/2013 • 148 • 0	• 18/02/2013

Arbitrations and Community referrals in 2013

Type of referral	• **Date of clock start** • **CVMP opinion**	• **Product name** • **INN**
Referral under Article 35 of Directive 2001/82/EC	• 15/09/2011 • 11/04/2013	• All long acting formulations for injection containing barium selenate for all food producing species • Barium selenate
Referral under Article 33(4) of Directive 2001/82/EC	• 12/10/2011 • 13/06/2012 • 07/02/2013 (re-examination)	• Nuflor Swine Once 450 mg/ml • 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 food-producing 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 • 07/03/2013	• 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 • 10/04/2013	• 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

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
		• 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 • 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 • 07/03/2013	• Soludox 500 mg/g powder for use in drinking water for pigs and chickens • Doxycycline hyclate
Referral under Article 30(3) of Regulation 726/2004	• 10/01/2013	• Lidocaine • Lidocaine
Referral under Article 33(4) of Directive 2001/82/EC	• 07/03/2013	• Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle • Deltamethrin
Referral under Article 33(4) of Directive 2001/82/EC	• 07/03/2013	• Suifertil 4 mg/ml Oral Solution for Pigs • Altrenogest
Referral under Article 35 of Directive 2001/82/EC	• 10/04/2013	• All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses • Altrenogest
Referral under Article 13 of Regulation (EC) No. 1234/2008	• 10/04/2013	• Cydectin TriclaMox pour-on solution for use in cattle • Triclabendazole and moxidectin

Guidelines and working documents in 2013

CVMP Quality

Reference number	Document title	Status
EMEA/CVMP/511/03-Rev.1	Annexes to: CPMP/ICH/283/95 Impurities: Guideline for residual solvents & CVMP/VICH/509/99 Guideline on impurities: residual solvents.	Adopted February 2013
EMA/CVMP/VICH/858875/2011	VIVH GL 51: Quality: Statistical evaluation of stability data	Adopted March 2013

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/398880/2012	Concept paper on genotoxic impurities	Adopted for consultation, January 2013 (End of consultation 30 April 2013)
EMA/CVMP/VICH/526/2000	VICH GL 23(R) Safety: Studies to evaluate the safety of residues of veterinary drugs in human food: Genotoxicity testing	Adopted for consultation, January 2013 (End of consultation 31 March 2013)

CVMP Environmental Risk Assessment

EMA/CVMP/ERA/718229/2012	Draft Concept paper on assessing the toxicological risk to humans and the environment of veterinary pharmaceuticals in groundwater	Adopted for consultation, April 2013 (End of consultation 30 June 2013)

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/VICH/463/2002	VICH GL34:Biologicals: Testing for the detection of Mycoplasma contamination	Adopted March 2013
EMA/CVMP/VICH/582610/2009	VICH GL 50: Biologicals: Harmonisation of criteria to waive Target Animal Batch Safety Testing (TABST) for inactivated vaccines for veterinary use	Adopted March 2013
EMA/CVMP/IWP/97961/2013	Draft guideline on the compliance of authorised equine influenza vaccines with OIE requirements	Adopted for consultation, April 2013 (End of consultation 31 October 2013)

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/536313/2011	Draft Reflection paper on pharmacovigilance communication concerning veterinary medicinal products	Adopted for consultation, February 2013 (End of consultation 31 May 2013)
EMA/CVMP/PhVWP/552/2003–Rev.1	Draft revised Recommendation on harmonising the approach to causality assessment for adverse events to veterinary medicinal products	Adopted for consultation, February 2013 (End of consultation 31 May 2013)
EMA/CVMP/VICH/123940/2006	VICH GL 35 on Pharmacovigilance: Electronic standards for transfer of data	Adopted March 2013
EMA/CVMP/PhVWP/126661/2009-Rev.3	Q&A on Serious non-fatal adverse events and reporting rules	Adopted April 2013
EMA/CVMP/PhVWP/303762/2012	Q&A on PSUR preparation, management and assessment	Adopted April 2013
EMA/CVMP/PhVWP/145186/2013	Q&A on Adverse event reporting	Adopted April 2013

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/680258/2012	Concept paper on the development of a guideline on antimicrobial risk assessment	Adopted for consultation, January 2013 (End of consultation 30 April 2013)