14 January 2014
EMA/778335/2013
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Monthly report of application procedures, guidelines and related documents

December 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	40	195
Advice given	91	24	29	34	178

Initial evaluation

	95-10	2011	2012	2013	Total
Full (Submitted)	140	8	12	23	183
Abridged/ generics (Submitted)	13	3	0	0	16
Withdrawals	13	0	1	0	14
Positive opinions	118	19	9	12	158
Negative opinions	1	0	0	0	1

Marketing authorisations

	95-10	2011	2012	2013	Total
Granted	111	24	8	13	156
Withdrawals	6	1	3	3	13
Not renewed	2	0	0	0	2

Extensions

	95-10	2011	2012	2013	Total
Submitted	75	7	8	5	95
Withdrawals	4	0	1	0	5
Positive opinions	55	4	10	9	78
Negative opinions	0	0	0	0	0

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Variations – applications submitted					
	95-10	2011	2012	2013	Total
Type IA	551	120	104	175	1255
Type IB		101	96	108	
Type II	276	45	52	32	405
Transfers	22	3	2	24	51

Renewals					
	95-10	2011	2012	2013	Total
Submitted	75	14	10	16	115
Positive opinions	73	12	10	14	109
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-10	2011	2012	2013	Total
Referrals submitted	59	12	12	10	93
Opinions reached[1]	46 (6)	10	11 (1)	13 (3)	80 (10)

[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	16	35
Agreed	0	10	6	9	25
Scientific advice recommended	0	0	0	3	3

MUMS/ Limited market classification				
	2011	2012	2013	Total
Positive with financial incentives	8	16	10	34
Positive without financial incentives	12	5	10	27
Negative	1	1	2	4

Establishment of MRLs for new substances					
	95-10	2011	2012	2013	Total
Submitted	73	1	1	7	82
Withdrawals	5	0	0	2	7
Positive opinions[2]	58	4	1	4	67
Negative opinions[3]	7	0	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-10	2011	2012	2013	Total
Submitted	110	13	5	6	134
Withdrawals	4	2	0	0	6
Positive opinions[2]	119	12	8 (2)	8	147
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** • **Decision** • **Notification** • **Official Journal**
• **Meloxidolor** • M*eloxicam*	• Le Vet Beheer B.V.	• Dogs, cats, cattle, pigs and horses • Anti-inflammatory and anti-rheumatic	• 15/12/2011 • 07/02/2013 • 210 • 212	• 07/02/2013 • 22/04/2013 • 24/04/2013 • C 156 of 31/05/2013
• **ECOPORC Shiga**	• IDT Biologika GmbH	• Piglets • Vaccine for the active immunisation to reduce the mortality and clinical sings of oedema disease	• 15/12/2011 • 07/02/2013 • 210 • 212	• 08/02/2013 • 10/04/2013 • 12/04/2013 • C 156 of 31/05/2013
• **Oncept IL-2**	• MERIAL	• Cats • Immunotherapy product to be used in addition to surgery and radiotherapy with fibrosarcoma without metastasis or lymph node involvement	• 09/11/2011 • 07/03/2013 • 205 • 280	• 07/03/2013 • 03/05/2013 • 07/05/2013 • C 184 of 28/06/2013
• **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	• 11/04/2013 • 06/06/2013 • 16/07/2013 • C 250 of 30/08/2013

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 • Decision • Notification • Official Journal
• **ProZinc** • Insulin (human)	• Boehringer Ingelheim Vetmedica GmbH	• Cats • For the treatment of diabetes mellitus to achieve reduction of hyperglycaemia and improvement of associated clinical signs	• 15/03/2012 • 16/05/2013 • 210 • 218	• 16/05/2013 • 12/07/2013 • 16/07/2013 • C 250 of 30/08/2013
• **AFTOVAXPURDOE**	• MERIAL	• Cattle, sheep, pigs • Vaccine containing a maximum of three inactivated, purified foot-and-mouth-disease (FMD) virus strains out of seven authorised strains	• 12/10/2012 • 16/05/2013 • 210 • 737	• 16/05/2013 • 15/07/2013 • 17/07/2013 • C 250 of 30/08/2013
• **APOQUEL** • Oclacitinib maleate	• Zoetis Belgium SA	• Dogs • Treatment of clinical manifestations of pruritus associated with allergic dermatitis in dogs and treatment of clinical manifestations of atopic dermatitis in dogs.	• 15/08/2012 • 18/07/2013 • 210 • 127	• 18/07/2013 • 12/09/2013 • 16/09/2013 • C 311 of 25/10/2013
• **Trifexis** • Spinosad / milbemycin oxime	• Eli Lilly & Co Ltd	• Dogs • Treatment and prevention of flea infestations in dogs when the concurrent prevention of heartworm disease and/or treatment of specified gastrointestinal nematode infections is indicated.	• 15/02/2012 • 17/07/2013 • 210 • 308	• 18/07/2013 • 19/09/2013 • 23/09/2013 • C 311 of 25/10/2013

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 • Decision • Notification • Official Journal
• **Broadline** • **Fipronil/eprinomectin/praziquantel/(s)-methoprene**	• MERIAL	• Cats • For cats with existing, or at risk from, mixed parasitic infections	• 10/10/2012 • 10/10/2013 • 210 • 155	• 10/10/2013 • 04/12/2013
• **Vectra 3D** • **Dinotefuran/pyriproxyfen/permethrin**	• CEVA Santé Animale	• Dogs • Treatment and prevention of infestations by certain specified fleas and ticks. It is also intended for the prevention of bites from sand flies, mosquitoes and stable flies.	• 12/10/2011 • 10/10/2013 • 203 • 526	• 10/10/2013 • 04/12/2013
• **Bravecto** • **Fluralaner**	• Intervet International B.V.	• Dog • For the treatment and prevention of tick (Ixodes ricinus, Ixodes hexagonus, Ixodes scapularis, Dermacentor reticulatus, Dermacentor variabilis and Rhipicephalus sanguineus) and flea (Ctenocephalides felis) infestations in dogs.	• 12/12/2012 • 12/12/2013 • 210 • 155	• 12/12/2013
• **NexGard** • **Afoxolaner**	• MERIAL	• Dog • Treatment and prevention of flea infestation in dogs	• 08/11/2012 • 12/12/2013 • 210 • 190	• 12/12/2013

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** • **Regulation** • **Official Journal**
• Diclazuril	• Rabbits	• 12/09/2012 • 07/02/2013 • 148 • 0	• 18/02/2013
• Butafosfan	• All mammalian food producing species	• 16/01/2013 • 13/06/2013 • 148 • 0	• 26/06/2013
• Chloroform	• All mammalian food producing species	• 11/10/2013 • 13/06/2013 • 175 • 71	• 26/06/2013
• Triptorelin acetate	• Porcine species	• 13/02/2013 • 18/07/2013 • 155 • 0	• 18/07/2013
• Tulathromycin (modification of ADI and MRLs)	• Bovine and porcine species	• 16/02/2012 • 10/10/2013 • 208 • 212	• 24/10/2013
• Triclabendazole (after provisional MRLs)	• All ruminants (milk)	• N/a • 07/11/2013 • 90 • 0	• 15/11/2013
• Cabergoline	• Bovine species	• 10/10/2012 • 12/12/2013 • 209 • 218	• 18/12/2013
• Lufenuron	• Fin fish	• 20/03/2013 • 12/12/2013 • 210 • 57	• 18/12/2013
• Clorsulon (after provisional MRLs)	• Bovine milk	• N/a • 12/12/2013 • 77 • 0	• 18/12/2013
• Closantel (after provisional MRLs)	• Bovine and ovine milk	• N/a • 12/12/2013 • 77 • 0	• 18/12/2013

• Lasalocid	• Poultry	• 07/11/2012 • 12/12/2013 • 210 • 155	• 18/12/2013
• Rafoxanide	• Bovine and ovine milk	• N/a • 12/12/2013 • 173 • 673	• 18/12/2013

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 • 18/07/2013 (re-examination)	• 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 • 12/06/2013	• 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 • 18/07/2013	• 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 • Spiramycin
Referral under Article 35 of Directive 2001/82/EC	• 12/09/2012 • 18/07/2013	• Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications • Dexamethasone

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
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 • 07/11/2013	• 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 • 12/06/2013 (re-examination)	• 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 • 17/07/2013	• 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 • 18/07/2013	• 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 • 16/07/2013	• Cydectin TriclaMox pour-on solution for use in cattle • Triclabendazole and moxidectin
Referral under Article 33(4) of Directive 2001/82/EC	• 16/05/2013	• Norbonex 5-mg/ml pour-on solution for beef and dairy cattle • Eprinomectin
Referral under Article 33(4) of Directive 2001/82/EC	• 16/05/2013 • 11/12/2013	• Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs • Fipronil

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Article 35 of Directive 2001/82/EC	• 16/05/2013	• Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC • Enrofloxacin
Referral under Article 45 of Regulation (EC) No. 726/2004	• 16/05/2013 • 10/10/2013	• Suvaxyn PCV (inactivated vaccine)
Referral under Article 35 of Directive 2001/82/EC	• 06/11/2013	• All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs • Tylosin

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
N/a	Q&A on co-operation between assessors and inspectors when real-time release testing is applied.	Adopted May 2013
N/a	Q&A on setting specifications for impurities in veterinary medicinal products	Adopted June 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)
EMA/CVMP/520190/2007-Rev.1	Reflection paper on injection site residues	Adopted for consultation, October 2013 (End of consultation 30 April 2014)
EMA/CVMP/SWP/285070/2013	Concept paper proposing the review of the Note for Guidance on withdrawal time determination	Adopted for consultation, October 2013 (End of consultation 31 January 2014)

CVMP Environmental Risk Assessment

EMA/CVMP/ERA/718229/2012	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 Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/261180/2012	Draft Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (revision)	Adopted for consultation, May 2013 (End of consultation 30 November 2013)
CVMP/EWP/141272/2011	Draft Guideline on theConduct of efficacy studies for intramammary products for use in cattle (revision)	Adopted for consultation, October 2013 (End of consultation 30 Apr 2014)

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)
EMA/CVMP/IWP/594618/2010	Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs)	Adopted July 2013
EMA/CVMP/IWP/640481/2013	Public statement: Routes of administration of vaccines to poultry	Adopted November 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	Recommendation on harmonising the approach to causality assessment for adverse events to veterinary medicinal products	Adopted October 2013

Reference number	Document title	Status
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
EMA/CVMP/10418/2009-Rev.5	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2013
EMA/CVMP/PhVWP/288284/2007-Rev.6	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2013
EMA/123352/2001-Rev.7	Call for comments on standard lists for EudraVigilance Veterinary	Adopted June 2013
EMA/CVMP/PhVWP/536313/2011	Reflection paper on pharmacovigilance communication concerning veterinary medicinal products	Adopted December 2013
EMA/CVMP/PhVWP/901279/2011	Recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products	Adopted for consultation, December 2013 (End of consultation 30 June 2014)

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)
EMA/363834/2013	Request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals: Answer to the first request from the European Commission	Adopted July 2013
EMA/755938/2012	Use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health	Adopted July 2013

Reference number	Document title	Status
EMA/291760/2013	Use of glycylcyclines in animals in the European Union: development of resistance and possible impact on human and animal health	Adopted July 2013
EMA/CVMP/AWP/401740/2013	Reflection paper on the risk of antimicrobial resistance transfer from companion animals	Adopted for consultation, October 2013 (End of consultation 31 January 2014)
EMA/CVMP/AWP/119489/2012	Reflection paper on use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted November 2013

Joint CVMP/ CHMP AHEG on the application of the 3Rs (replacement, refinement and reduction) in regulatory testing of medicinal products

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/746429/2013	Recommendation to marketing authorisation holders for veterinary vaccines, highlighting the need to update marketing authorisations to remove the target animal batch safety test (TABST) following removal of the requirement from the European Pharmacopoeia monographs	Adopted May 2013
EMA/CHMP/CVMP/JEG-3Rs/704685/2012-draft 2	Concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products	Adopted for consultation, December 2013 (Three months public consultation, subject to adoption by CHMP)