



12 June 2013
EMA/249895/2013
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Monthly report of application procedures, guidelines and related documents

May 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	15	170
Advice given	91	24	29	11	155

Initial evaluation					
	95-10	2011	2012	2013	Total
Full (Submitted)	140	8	12	9	169
Abridged/ generics (Submitted)	13	3	0	0	16
Withdrawals	13	0	1	0	14
Positive opinions	118	19	9	6	152
Negative opinions	1	0	0	0	1

Marketing authorisations					
	95-10	2011	2012	2013	Total
Granted	111	24	8	6	149
Withdrawals	6	1	3	1	11
Not renewed	2	0	0	0	2

Extensions					
	95-10	2011	2012	2013	Total
Submitted	75	7	8	2	92
Withdrawals	4	0	1	0	5
Positive opinions	55	4	10	3	72
Negative opinions	0	0	0	0	0



Variations – applications submitted					
	95-10	2011	2012	2013	Total
Type IA	551	120	104	41	1052
Type IB		101	96	39	
Type II	276	45	52	14	387
Transfers	22	3	2	24	51

Renewals					
	95-10	2011	2012	2013	Total
Submitted	75	14	10	5	104
Positive opinions	73	12	10	6	101
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-10	2011	2012	2013	Total
Referrals submitted	59	12	12	9	92
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	10	29
Agreed	0	10	6	6	22
Scientific advice recommended	0	0	0	2	2

MUMS/ Limited market classification				
	2011	2012	2013	Total
Positive with financial incentives	8	16	7	31
Positive without financial incentives	12	5	6	23
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	3	131
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 <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"> Meloxidolor <i>Meloxicam</i> 	<ul style="list-style-type: none"> Le Vet Beheer B.V. 	<ul style="list-style-type: none"> Dogs, cats, cattle, pigs and horses Anti-inflammatory and anti-rheumatic 	<ul style="list-style-type: none"> 15/12/2012 07/02/2013 210 212 	<ul style="list-style-type: none"> 07/02/2013 22/04/2013 24/04/2013 C 156 of 31/05/2013
<ul style="list-style-type: none"> ECOPORC Shiga 	<ul style="list-style-type: none"> IDT Biologika GmbH 	<ul style="list-style-type: none"> Piglets Vaccine for the active immunisation to reduce the mortality and clinical signs of oedema disease 	<ul style="list-style-type: none"> 15/12/2012 07/02/2013 210 212 	<ul style="list-style-type: none"> 08/02/2013 10/04/2013 12/04/2013 C 156 of 31/05/2013
<ul style="list-style-type: none"> Oncept IL-2 	<ul style="list-style-type: none"> MERIAL 	<ul style="list-style-type: none"> Cats Immunotherapy product to be used in addition to surgery and radiotherapy with fibrosarcoma without metastasis or lymph node involvement 	<ul style="list-style-type: none"> 09/11/2012 07/03/2013 205 280 	<ul style="list-style-type: none"> 07/03/2013 03/05/2013
<ul style="list-style-type: none"> Equilis West Nile 	<ul style="list-style-type: none"> Intervet International BV 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 17/01/2012 11/04/2013 208 240 	<ul style="list-style-type: none"> 11/04/2013
<ul style="list-style-type: none"> ProZinc Insulin (human) 	<ul style="list-style-type: none"> Boehringer Ingelheim Vetmedica GmbH 	<ul style="list-style-type: none"> Cats For the treatment of diabetes mellitus to achieve reduction of 	<ul style="list-style-type: none"> 15/03/2012 16/05/2013 210 218 	<ul style="list-style-type: none"> 16/05/2013

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
		hyperglycaemia and improvement of associated clinical signs		
<ul style="list-style-type: none"> Aftovaxpur DOE 	<ul style="list-style-type: none"> MERIAL 	<ul style="list-style-type: none"> Cattle, sheep, pigs Vaccine containing a maximum of three inactivated, purified foot-and-mouth-disease (FMD) virus strains out of seven authorised strains 	<ul style="list-style-type: none"> 12/10/2012 16/05/2013 210 737 	<ul style="list-style-type: none"> 16/05/2013

CVMP opinions in 2013 on establishment of MRLs

Positive opinions

Substance	Target species	EMA/CVMP	European Commission
		<ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	<ul style="list-style-type: none"> Opinion received Date of regulation Official Journal
<ul style="list-style-type: none"> Diclazuril 	<ul style="list-style-type: none"> Rabbits 	<ul style="list-style-type: none"> 12/09/2012 07/02/2013 148 0 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 15/09/2011 11/04/2013 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 12/10/2011 13/06/2012 07/02/2013 (re-examination) 	<ul style="list-style-type: none"> Nuflor Swine Once 450 mg/ml Florfenicol

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 Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 12/04/2012 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/05/2012 	<ul style="list-style-type: none"> • Micotil 300 Injectie and associated names • Tilmicosin
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 15/05/2012 • 07/03/2013 	<ul style="list-style-type: none"> • Florgane 300 mg/ml suspension for injection for cattle and pigs • Florfenicol
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 11/07/2012 • 10/04/2013 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 12/09/2012 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 12/09/2012 	<ul style="list-style-type: none"> • Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications • Dexamethasone
Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 10/10/2012 	<ul style="list-style-type: none"> • Linco-Spectin 100 and its associated names • Lincomycin, spectinomycin
Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 07/11/2012 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 07/11/2012 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 07/11/2012 • 07/03/2013 	<ul style="list-style-type: none"> • Soludox 500 mg/g powder for use in drinking water for pigs and chickens • Doxycycline hyclate
Referral under Article 30(3) of Regulation	<ul style="list-style-type: none"> • 10/01/2013 	<ul style="list-style-type: none"> • Lidocaine

Type of referral	<ul style="list-style-type: none"> • Date of clock start • CVMP opinion 	<ul style="list-style-type: none"> • Product name • INN
726/2004		<ul style="list-style-type: none"> • Lidocaine
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 07/03/2013 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 07/03/2013 	<ul style="list-style-type: none"> • Suifertil 4 mg/ml Oral Solution for Pigs • Altrenogest
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 10/04/2013 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 10/04/2013 	<ul style="list-style-type: none"> • Cydectin TriclaMox pour-on solution for use in cattle • Triclabendazole and moxidectin
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 16/05/2013 	<ul style="list-style-type: none"> • Norbonex 5-mg/ml pour-on solution for beef and dairy cattle • Eprinomectin
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 16/05/2013 	<ul style="list-style-type: none"> • 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
Referral under Article 13 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 16/05/2013 	<ul style="list-style-type: none"> • Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products • Enrofloxacin
Referral under Article 45 of Regulation (EC) No. 726/2004	<ul style="list-style-type: none"> • 16/05/2013 	<ul style="list-style-type: none"> • Suvaxyn PCV (inactivated vaccine)

Guidelines and working documents in 2013

CVMP Quality

Reference number	Document title	Status
EMA/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

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 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	Adopted for consultation, May 2013 (End of consultation 30 November 2013)

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/VICH/463/2002	VICH GL34: Biologicals: Testing for	Adopted March 2013

Reference number	Document title	Status
	the detection of Mycoplasma contamination	
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)

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