19 February 2014
EMA/68959/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Monthly report of application procedures, guidelines and related documents

January 2014

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

	95-11	2012	2013	2014	Total
Submitted	127	28	40	4	199
Advice given	115	29	34	4	182

Initial evaluation

	95-11	2012	2013	2014	Total
Full (Submitted)	148	12	23	0	183
Abridged/ generics (Submitted)	16	0	0	0	16
Withdrawals	13	1	0	0	14
Positive opinions	137	9	12	2	160
Negative opinions	1	0	0	0	1

Marketing authorisations

	95-11	2012	2013	2014	Total
Granted	135	8	13	0	156
Withdrawals	7	3	3	0	13
Not renewed	2	0	0	0	2

Extensions

	95-11	2012	2013	2014	Total
Submitted	82	8	5	0	95
Withdrawals	4	1	0	1	6
Positive opinions	59	10	9	1	79
Negative opinions	0	0	0	0	0

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Variations – applications submitted					
	95-11	2012	2013	2014	Total
Type IA	772	104	175	15	1275
Type IB		96	108	5	
Type II	321	52	32	0	405
Transfers	25	2	24	0	51

Renewals					
	95-11	2012	2013	2014	Total
Submitted	89	10	16	2	117
Positive opinions	85	10	14	2	111
Negative opinions	0	0	0	0	0

Arbitrations and Community referrals					
	95-11	2012	2013	2014	Total
Referrals submitted	76	12	10	0	98
Opinions reached[1]	66 (10)	11 (1)	13 (3)	1	91 (14)

[1] Re-examination of opinions in brackets

Substances considered as not falling within the scope of Regulation (EC) No 470/2009					
	2010-11	2012	2013	2014	Total
Submitted	10	9	16	0	35
Agreed	10	6	9	2	27
Scientific advice recommended	0	0	6	0	6

MUMS/ Limited market classification					
	2011	2012	2013	2014	Total
Positive with financial incentives	8	16	10	0	34
Positive without financial incentives	12	5	10	0	27
Negative	1	1	2	0	4

Establishment of MRLs for new substances					
	95-11	2012	2013	2014	Total
Submitted	74	1	7	0	82
Withdrawals	5	1	1	0	7
Positive opinions[2]	62	1	4	0	67
Negative opinions[3]	7	0	0	0	7

Extensions / modifications/extrapolations of MRLs					
	95-11	2012	2013	2014	Total
Submitted	123	5	6	0	134
Withdrawals	6	0	0	0	6
Positive opinions[2]	131	8 (2)	8	0	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 2014 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**
• **Fungitraxx** • Itraconazole	• Avimedical B.V.	• Ornamental bird • For the treatment of aspergillosis and candidiasis in companion birds	• 07/11/2012 • 16/01/2014 • 231 • 225	• 16/01/2014 •
• **Equisolon** • Prednisolone	• LE VET B.V.	• Horse • Alleviation of inflammatory and clinical parameters associated with recurrent airway obstruction (RAO) in horses, in combination with environmental control.	• 10/10/2012 • 16/01/2014 • 210 • 253	• 16/01/2014 •

CVMP opinions in 2014 on establishment of MRLs

Positive opinions

• Substance	• Target species	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Regulation • Official Journal
•	•		

Arbitrations and Community referrals in 2014

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
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 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 30(3) of Regulation 726/2004	• 10/01/2013	• Lidocaine • Lidocaine
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 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 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

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
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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 30(3) of Regulation 726/2004	• 10/01/2013	• Lidocaine • Lidocaine
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 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 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
Referral under Article 33(4) of Directive 2001/82/EC	• 16/05/2013 • 15/01/2014	• Norbonex 5-mg/ml pour-on solution for beef and dairy cattle • Eprinomectin
Referral under Article 33(4) of Directive 2001/82/EC (under re-examination)	• 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

Guidelines and working documents in 2014

CVMP Quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/70278/2012-Rev.1	Guideline on process validation for finished products: Information and data to be provided in regulatory submissions.	Adopted January 2014 (End of consultation 31 October 2012)
EMA/CHMP/CVMP/QWP/441071/2011	Guideline on stability testing for applications for variations to a marketing authorisation	Adopted January 2014 (End of consultation 31 January 2012)
[Published on EMA website]	Revised Q&A on Limits for microbiological quality for premixes for medicated feeding stuffs which contain excipients of natural origin	Adopted January 2014

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/513162/2013	Guideline on the conduct of efficacy studies for non-steroidal anti-inflammatory drugs (NSAID) (Revised).	Adopted January 2014 (End of consultation 31 May 2013)