



17 August 2012  
EMA/483316/2012  
Committee for Medicinal Products for Veterinary Use (CVMP)

## CVMP Monthly report of application procedures, guidelines and related documents

July 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	19	146
Advice given	73	18	24	15	130

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	5	136
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



<b>Variations – applications submitted</b>					
	95-09	2010	2011	2012	Total
Type IA	412	76	125	58	862
Type IB		63	87	41	
Type II	250	26	45	33	354
Transfers	14	8	3	2	27

<b>Renewals</b>					
	95-09	2010	2011	2012	Total
Submitted	68	7	14	5	89
Positive opinions	65	8	12	6	91
Negative opinions	0	0	0	0	0

<b>Arbitrations and Community referrals</b>					
	95-09	2010	2011	2012	Total
Referrals submitted	47	12	12	6	77
Opinions reached <sup>1</sup>	35 (5)	11 (1)	10	9 (1)	65 (7)

<sup>1</sup> Re-examination of opinions in brackets

<b>Substances considered as not falling within the scope of Regulation (EC) No 470/2009</b>			
	2011	2012	Total
Submitted	7	2	7
Agreed	9	2	11
Scientific advice recommended	0	0	0

<b>MUMS/ Limited market classification</b>			
	2011	2012	Total
Positive with financial incentives	8	9	17
Positive without financial incentives	12	2	14
Negative	1	0	1

<b>Establishment of MRLs for new substances</b>					
	95-09	2010	2011	2012	Total
Submitted	70	3	1	0	74
Withdrawals	5	0	0	0	5
Positive opinions <sup>2</sup>	56	2	4	1	63
Negative opinions <sup>3</sup>	7	0	0	0	7

<b>Extensions / modifications/extrapolations of MRLs</b>					
	95-09	2010	2011	2012	Total
Submitted	100	10	13	2	125
Withdrawals	4	0	2	0	6
Positive opinions <sup>2</sup>	116	3	12	8 (2)	140
Negative opinions	6	0	0	0	6

<sup>2</sup> 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.

<sup>3</sup> 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

<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Marketing authorisation holder</b></li> </ul>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• Zulvac 1+8 Bovis</li> <li>• Inactivated Bluetongue virus, serotype 1 and 8, strain BTV-1</li> </ul>	<ul style="list-style-type: none"> <li>• Pfizer Limited</li> </ul>	<ul style="list-style-type: none"> <li>• Cattle</li> <li>• Vaccine for the active immunisation of cattle for the prevention of viraemia caused by Bluetongue Virus, serotype 1 and 8.</li> </ul>	<ul style="list-style-type: none"> <li>• 04/02/2011</li> <li>• 12/01/2012</li> <li>• 152</li> <li>• 191</li> </ul>	<ul style="list-style-type: none"> <li>• 12/01/2012</li> <li>• 08/03/2012</li> <li>• 12/03/2012</li> <li>• 27/04/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Poulvac E. Coli</li> </ul>	<ul style="list-style-type: none"> <li>• Pfizer Limited</li> </ul>	<ul style="list-style-type: none"> <li>• Chickens</li> <li>• Vaccine for the active immunisation to reduce mortality and lesions associated with E. Coli serotype 078</li> </ul>	<ul style="list-style-type: none"> <li>• 09/02/2011</li> <li>• 11/04/2012</li> <li>• 210</li> <li>• 219</li> </ul>	<ul style="list-style-type: none"> <li>• 13/04/2012</li> <li>• 15/06/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Porcilis ColiClos</li> </ul>	<ul style="list-style-type: none"> <li>• Intervet Internatinal B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• Piglets</li> <li>• Vaccine for the passive immunisation against E. Coli and C. perfringens</li> </ul>	<ul style="list-style-type: none"> <li>• 12/10/2010</li> <li>• 11/04/2012</li> <li>• 210</li> <li>• 339</li> </ul>	<ul style="list-style-type: none"> <li>• 16/04/2012</li> <li>• 14/06/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Cardalis tablets</li> <li>• Benazepril and spironolactone</li> </ul>	<ul style="list-style-type: none"> <li>• Ceva Santé Animale</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• Indicated for the treatment of congestive heart failure caused by chronic degenerative valvular disease</li> </ul>	<ul style="list-style-type: none"> <li>• 13/07/2011</li> <li>• 16/05/2012</li> <li>• 208</li> <li>• 99</li> </ul>	<ul style="list-style-type: none"> <li>• 16/05/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Nobivac L4</li> </ul>	<ul style="list-style-type: none"> <li>• Intervet Internatinal B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• Vaccine containing inactivated Leptospira strains and indicated for the active immunisation of dogs to reduce infection and/or urinary excretion caused by Leptospira strains.</li> </ul>	<ul style="list-style-type: none"> <li>• 04/01/2012</li> <li>• 16/05/2012</li> <li>• 201</li> <li>• 256</li> </ul>	<ul style="list-style-type: none"> <li>• 16/05/2012</li> </ul>

## CVMP opinions in 2012 on establishment of MRLs

### Positive opinions

<ul style="list-style-type: none"> <li>• <b>Substance</b></li> <li>• <b>INN</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Target species</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Date of regulation</b></li> <li>• <b>Official Journal</b></li> </ul>
Sodium salicylate (After provisional MRLs)	<ul style="list-style-type: none"> <li>• Turkeys</li> </ul>	<ul style="list-style-type: none"> <li>• n/a</li> <li>• 09/02/2012</li> <li>• 90</li> <li>• 0</li> </ul>	<ul style="list-style-type: none"> <li>• 15/02/2012</li> </ul>
Prednisolone	<ul style="list-style-type: none"> <li>• Horses</li> </ul>	<ul style="list-style-type: none"> <li>• 12/10/2011</li> <li>• 08/03/2012; 14/06/2012 (<i>Re-examination</i>)</li> <li>• 148</li> <li>• 0</li> </ul>	<ul style="list-style-type: none"> <li>• 20/06/2012</li> </ul>
Monensin	<ul style="list-style-type: none"> <li>• Bovine species</li> </ul>	<ul style="list-style-type: none"> <li>• 15/06/2011</li> <li>• 08/03/2012</li> <li>• 205</li> <li>• 63</li> </ul>	<ul style="list-style-type: none"> <li>• 21/03/2012</li> </ul>
Phoxim	<ul style="list-style-type: none"> <li>• All food producing except fin fish</li> </ul>	<ul style="list-style-type: none"> <li>• 04/01/2010</li> <li>• 08/03/2012</li> <li>• 210</li> <li>• 220</li> </ul>	<ul style="list-style-type: none"> <li>• 21/03/2012</li> </ul>
Diclazuril	<ul style="list-style-type: none"> <li>• Poultry</li> </ul>	<ul style="list-style-type: none"> <li>• 09/11/2011</li> <li>• 13/04/2012</li> <li>• 156</li> <li>• 0</li> </ul>	<ul style="list-style-type: none"> <li>• 20/04/2012</li> </ul>
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	<ul style="list-style-type: none"> <li>• Bees</li> </ul>	<ul style="list-style-type: none"> <li>• 09/10/2010</li> <li>• 13/04/2012</li> <li>• 210</li> <li>• 312</li> </ul>	<ul style="list-style-type: none"> <li>• 20/04/2012</li> </ul>
Eprinomectin	<ul style="list-style-type: none"> <li>• Ovine and caprine</li> </ul>	<ul style="list-style-type: none"> <li>• 18/05/2010</li> <li>• 13/04/2012</li> <li>• 183</li> <li>• 515</li> </ul>	<ul style="list-style-type: none"> <li>• 20/04/2012</li> </ul>
Monepantel	<ul style="list-style-type: none"> <li>• Ovine and caprine milk</li> </ul>	<ul style="list-style-type: none"> <li>• 13/09/2011</li> <li>• 16/05/2012</li> <li>• 210</li> <li>• 36</li> </ul>	<ul style="list-style-type: none"> <li>• 25/05/2012</li> </ul>

Manganese carbonate	<ul style="list-style-type: none"> <li>All food producing species</li> </ul>	<ul style="list-style-type: none"> <li>15/02/2012</li> <li>12/07/2012</li> <li>148</li> <li>0</li> </ul>	<ul style="list-style-type: none"> <li>25/07/2012</li> </ul>
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## Arbitrations and Community referrals in 2012

Type of referral	<ul style="list-style-type: none"> <li>Date of clock start</li> <li>CVMP opinion</li> </ul>	<ul style="list-style-type: none"> <li>Product name</li> <li>INN</li> </ul>
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>09/11/2010</li> <li>13/06/2012</li> </ul>	<ul style="list-style-type: none"> <li>Baytril 10% oral solution and associated names</li> <li>Enrofloxacin</li> </ul>
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>09/03/2011</li> <li>08/03/2012</li> <li>13/06/2012 (re-examination)</li> </ul>	<ul style="list-style-type: none"> <li>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</li> </ul>
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>04/05/2011</li> <li>08/02/2012</li> </ul>	<ul style="list-style-type: none"> <li>Prontax 5 mg/ml pour-on solution for cattle</li> <li>Doramectin</li> </ul>
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>04/05/2011</li> <li>08/02/2012</li> </ul>	<ul style="list-style-type: none"> <li>Prontax 10 mg/ml solution for injection for sheep, cattle and pigs</li> <li>Doramectin</li> </ul>
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>04/05/2011</li> <li>08/03/2012</li> </ul>	<ul style="list-style-type: none"> <li>All pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix</li> <li>Tilmicosin</li> </ul>
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>14/09/2011</li> <li>08/03/2012</li> </ul>	<ul style="list-style-type: none"> <li>Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names</li> <li>Praziquantel, pyrantel and febantel</li> </ul>
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>15/09/2011</li> </ul>	<ul style="list-style-type: none"> <li>All long acting formulations for injection containing barium selenate for all food producing species</li> <li>Barium selenate</li> </ul>
Procedure under Art. 30(3) of Regulation (EC) No 726/2004	<ul style="list-style-type: none"> <li>15/09/2011</li> <li>11/07/2012</li> </ul>	<ul style="list-style-type: none"> <li>N/a</li> <li>Dapsone</li> </ul>
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>12/10/2011</li> <li>13/06/2012</li> </ul>	<ul style="list-style-type: none"> <li>Nuflor 300 mg/ml solution for injection for cattle and sheep</li> </ul>

Type of referral	<ul style="list-style-type: none"> <li>Date of clock start</li> <li>CVMP opinion</li> </ul>	<ul style="list-style-type: none"> <li>Product name</li> <li>INN</li> </ul>
		<ul style="list-style-type: none"> <li>Florfenicol</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>12/10/2011</li> <li>13/04/2012</li> </ul>	<ul style="list-style-type: none"> <li>Hipralona Enro-S and its generics</li> <li>Enrofloxacin</li> </ul>
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>10/01/2012</li> <li>13/06/2012</li> </ul>	<ul style="list-style-type: none"> <li>Nuflor Swine Once 450 mg/ml solution for injection</li> <li>Florfenicol</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>12/04/2012</li> </ul>	<ul style="list-style-type: none"> <li>All injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian foodproducing species</li> <li>Doramectin</li> </ul>
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>15/05/2012</li> </ul>	<ul style="list-style-type: none"> <li>Micotil 300 Injectie and associated names</li> <li>Tilmicosin</li> </ul>
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>15/05/2012</li> </ul>	<ul style="list-style-type: none"> <li>Florgane 300 mg/ml suspension for injection for cattle and pigs</li> <li>Florfenicol</li> </ul>
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>11/07/2012</li> </ul>	<ul style="list-style-type: none"> <li>Melosolute 40 mg/ml solution for injection for cattle, pigs and horses</li> <li>Meloxicam</li> </ul>
Referral under Article 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>11/07/2012</li> </ul>	<ul style="list-style-type: none"> <li>Strenzen 500/125 mg/g powder for use in drinking water for pigs</li> <li>Amoxicillin/clavulanic acid</li> </ul>

## Guidelines and working documents in 2012

### CVMP Quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/277/02-Rev.3	Draft guideline on the Active Substance Master File Procedure	Adopted June 2012
EMA/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

Reference number	Document title	Status
		(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
EMA/CVMP/ERA/52740/2012	Draft guidance on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine	Adopted for consultation, July 2012  (End of consultation 01 September 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
EMA/CVMP/EWP/82829/2009-Rev.2	Revised Questions and Answers on: Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs	Adopted July 2012

Reference number	Document title	Status
	and cats	

### 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
EMA/CVMP/PhVWP/5507/2011	Concept paper for the revision of the CVMP guideline on harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products	Adopted for consultation, July 2012  (End of consultation 31



Reference number	Document title	Status
		October 2012)

### Application of 3Rs (Replacement, Refinement and Reduction) in testing

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/252137/2012	Recommendation to marketing authorisation holders, highlighting the need to ensure compliance with 3Rs methods described in the European Pharmacopoeia	Adopted July 2012
EMA/CHMP/CVMP/JEG-3Rs/169839/2011-Rev.1	Concept paper on the need for revision of the position on the replacement of animal studies by <i>in vitro</i> models	Adopted for consultation, July 2012  (End of consultation 31 October 2012)

### General

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