



21 December 2012  
EMA/807890/2012  
Committee for Medicinal Products for Veterinary Use (CVMP)

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

December 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	28	155
Advice given	73	18	24	29	144

Initial evaluation					
	95-09	2010	2011	2012	Total
Full (Submitted)	124	16	8	12	160
Abridged/ generics (Submitted)	11	2	3	0	16
Withdrawals	12	1	0	1	14
Positive opinions	104	14	19	9	146
Negative opinions	1	0	0	0	1

Marketing authorisations					
	95-09	2010	2011	2012	Total
Granted	100	9	22	8	139
Withdrawals	2	4	1	4	11
Not renewed	2	0	0	0	2

Extensions					
	95-09	2010	2011	2012	Total
Submitted	72	3	7	8	90
Withdrawals	3	1	0	1	5
Positive opinions	47	8	4	10	69
Negative opinions	0	0	0	0	0



<b>Variations – applications submitted</b>					
	95-09	2010	2011	2012	Total
Type IA	412	76	120	104	972
Type IB		63	101	96	
Type II	250	26	45	52	373
Transfers	14	8	3	2	27

<b>Renewals</b>					
	95-09	2010	2011	2012	Total
Submitted	68	7	14	10	99
Positive opinions	65	8	12	10	95
Negative opinions	0	0	0	0	0

<b>Arbitrations and Community referrals</b>					
	95-09	2010	2011	2012	Total
Referrals submitted	47	12	12	12	83
Opinions reached <sup>1</sup>	35 (5)	11 (1)	10	11 (1)	66 (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	5	9	14
Agreed	10	6	16
Scientific advice recommended	0	0	0

<b>MUMS/ Limited market classification</b>			
	2011	2012	Total
Positive with financial incentives	8	16	24
Positive without financial incentives	12	5	17
Negative	1	1	2

<b>Establishment of MRLs for new substances</b>					
	95-09	2010	2011	2012	Total
Submitted	70	3	1	1	75
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	5	128
Withdrawals	4	0	2	0	6
Positive opinions <sup>2</sup>	116	3	12	8 (2)	139
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>Invented name</li> <li>INN</li> </ul>	<ul style="list-style-type: none"> <li>Marketing authorisation holder</li> </ul>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Date of decision</li> <li>Notification</li> <li>Official Journal</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> <li>20/06/2012</li> <li>27/07/2012</li> </ul>
<ul style="list-style-type: none"> <li>Porcilis ColiClos</li> </ul>	<ul style="list-style-type: none"> <li>Intervet International 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> <li>17/06/2012</li> <li>27/07/2012</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> <li>23/07/2012</li> <li>25/07/2012</li> <li>31/08/2012</li> </ul>
<ul style="list-style-type: none"> <li>Nobivac L4</li> </ul>	<ul style="list-style-type: none"> <li>Intervet International 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> <li>16/07/2012</li> <li>18/07/2012</li> <li>31/08/2012</li> </ul>

<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>• Contacera</li> <li>• Meloxicam</li> </ul>	<ul style="list-style-type: none"> <li>• Pfizer Limited</li> </ul>	<ul style="list-style-type: none"> <li>• Cattle, pigs and horses.</li> <li>• Anti-inflammatory and anti-rheumatic</li> </ul>	<ul style="list-style-type: none"> <li>• 12/10/2011</li> <li>• 11/10/2012</li> <li>• 210</li> <li>• 156</li> </ul>	<ul style="list-style-type: none"> <li>• 11/10/2012</li> <li>• 06/12/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Kexxtone</li> <li>• Monensin</li> </ul>	<ul style="list-style-type: none"> <li>• Eli Lilly and Company Limited</li> </ul>	<ul style="list-style-type: none"> <li>• Cattle</li> <li>• Reduction of the incidence of ketosis in the periparturient dairy cow/heifer</li> </ul>	<ul style="list-style-type: none"> <li>• 12/10/2011</li> <li>• 08/11/2012</li> <li>• 210</li> <li>• 185</li> </ul>	<ul style="list-style-type: none"> <li>• 08/11/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Semintra</li> <li>• Telmisartan</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Cats</li> <li>• Chronic kidney disease</li> </ul>	<ul style="list-style-type: none"> <li>• 15/02/2012</li> <li>• 13/12/2012</li> <li>• 210</li> <li>• 92</li> </ul>	<ul style="list-style-type: none"> <li>• 13/12/2012</li> </ul>
<ul style="list-style-type: none"> <li>• Pexion</li> <li>• Imepitoin</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• Control of epilepsy</li> </ul>	<ul style="list-style-type: none"> <li>• 12/10/2011</li> <li>• 13/12/2012</li> <li>• 208</li> <li>• 183</li> </ul>	<ul style="list-style-type: none"> <li>• 13/12/2012</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> <li>• 12/10/2012</li> <li>• 13/10/2012</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> <li>08/11/2012</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>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>12/09/2012</li> </ul>	<ul style="list-style-type: none"> <li>Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications</li> <li>Spiramycin</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>12/09/2012</li> </ul>	<ul style="list-style-type: none"> <li>Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications</li> <li>Dexamethasone</li> </ul>
Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>10/10/2012</li> </ul>	<ul style="list-style-type: none"> <li>Linco-Spectin 100 and its associated names</li> <li>Lincomycin, spectinomycin</li> </ul>
Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>07/11/2012</li> </ul>	<ul style="list-style-type: none"> <li>Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names</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>Enrofloxacin</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>07/11/2012</li> </ul>	<ul style="list-style-type: none"> <li>All veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys</li> <li>Enrofloxacin</li> </ul>
Referral under Article 13 of Regulation (EC) No. 1234/2008	<ul style="list-style-type: none"> <li>07/11/2012</li> </ul>	<ul style="list-style-type: none"> <li>Soludox 500 mg/g powder for use in drinking water for pigs and chickens</li> <li>Doxycycline hyclate</li> </ul>

## Guidelines and working documents in 2012

### CVMP Quality

Reference number	Document title	Status
EMA/CVMP/134/02-Rev.3/CHMP/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  (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	Guideline on the approach to establish a pharmacological ADI.	Adopted November 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)

Reference number	Document title	Status
EMA/CHMP/CVMP/SWP/169430/2 012-CONSULTATION	Draft guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities	November 2012  (End of consultation 31 May 2013)

#### 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)
EMA/CVMP/ERA/172074/2008 – Rev.4	Q&A document on the implementation of the CVMP Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted 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 and cats	Adopted July 2012
EMA/CVMP/EWP/206024/2011-CONSULTATION	Draft guideline on demonstration of palatability of veterinary medicinal products	Adopted for consultation, November 2012  (End of consultation 31 May 2013)
EMA/CVMP/EWP/1061/2011-CONSULTATION	Draft revised guideline on conduct of efficacy studies for non-steroidal anti-inflammatory drugs (NSAID)	Adopted for consultation, November 2012  (End of consultation 31 May 2013)

Reference number	Document title	Status
		2013)

### CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/810769/2011 replacing EMA/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
EMA/CVMP/IWP/594618/2010-CONSULTATION	Draft guideline on the requirements for combined vaccines and association of immunological veterinary medicinal products	Adopted for consultation, November 2012  (End of consultation 31 Jan 2013)
EMA/CVMP/IWP/105112/2011-CONSULTATION	Draft table of extraneous agents to be tested for in relation to the Guideline on Requirements for the Production and Control of Immunological Veterinary Medicinal Products	Adopted for consultation, November 2012  (End of consultation 31 May 2013)

### 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	Adopted June 2012

Reference number	Document title	Status
	animals and humans to veterinary medicinal products	
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 October 2012)

### Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/119489/2012-CONSULTATION	Draft reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, December 2012  (End of consultation 30 Juny 2013)
EMA/286416/2012-CONSULTATION	Draft reflection paper from the Agency project for European Surveillance of Veterinary Antimicrobial Consumption on collecting data on consumption of antimicrobial agents per animal species, on technical units of measurement and indicators for reporting consumption of antimicrobial agents in animals	Adopted for consultation, December 2012  (End of consultation 31 March 2013)

### 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
EMA/SOP/V/4003	Incident management for medicines for veterinary	Endorsed September 2012