



London, 31 May 2008  
Doc. Ref. EMEA/281942/2008

## COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

### Monthly Report of Application Procedures, Guidelines and Related Documents

The CVMP Monthly Report includes statistical data for the current year and the previous two ones 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					
	95-05	2006	2007	2008	Total
Submitted	37	14	7	2	60

Initial Evaluation					
	95-05	2006	2007	2008	Total
Full <sup>1</sup>	78	5	14	9	106
Abridged/Generics	3	3	1	2	9
Withdrawals	11	0	0	0	11
Positive Opinions	56	13	9	4	82
Negative Opinions	0	1	0	1	2

Marketing Authorisations					
	95-05	2006	2007	2008	Total
Granted	56	10	9	3	78
Withdrawals	1	0	0	1	2
Not renewed	1	0	1	0	2

<sup>1</sup> Initial applications submitted and validated: 115 applications in total (full + abridged), comprising 59 immunologicals and 56 pharmaceuticals. Negative opinions: in case of appeals, the opinion will not be counted twice.

Extensions - Annex II Applications <sup>2</sup>					
	95-05	2006	2007	2008	Total
Submitted	47	0	9	1	57
Withdrawals	1	0	0	0	1
Positive Opinions	30	2	1	5	38
Negative Opinions	0	0	0	0	0

Variations – Applications submitted					
	95-05	2006	2007	2008	Total
Type IA	207	18	29	7	311
Type IB		13	24	13	
Type II	86	25	47	13	171
Transfers	6	1	2	0	9

<sup>2</sup> Extensions applications submitted and validated: 57 line extensions in total, comprising 11 immunologicals and 46 pharmaceuticals; one opinion can cover a number of extensions

Renewals					
	95-05	2006	2007	2008	Total
Submitted	27	2	14	3	46
Positive Opinions	24	5	11	5	45
Negative Opinions	0	0	0	0	0

Establishment of MRLs for new substances					
	95-05	2006	2007	2008	Total
Submitted	60	3	2	1	66
Withdrawals	5	0	0	0	5
Positive Opinions <sup>3</sup>	44	5	3	1	53
Negative Opinions <sup>4</sup>	6	0	0	0	6

Arbitrations and Community Referrals					
	95-05	2006	2007	2008	Total
Referrals Submitted	11	10	6	5	32
Opinions Reached	-	4	10	2	16

Extensions / Modifications/Extrapolations of MRLs					
	95-05	2006	2007	2008	Total
Submitted	92	3	1	1	97
Withdrawals	4	0	0	0	4
Positive Opinions <sup>3</sup>	101	6	4	2	113
Negative Opinions <sup>4</sup>	5	1	0	0	6
Extrapolations	40	5	0	5	50

<sup>3</sup> Including opinions recommending definitive MRLs for substances with previously provisional maximum residue limits

<sup>4</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 2008 on Medicinal Products for Veterinary Use

#### Positive Opinions

Product	Marketing authorisation holder	Therapeutic area	EMEA/CVMP	European Commission
<ul style="list-style-type: none"> <li>▪ Brand name</li> <li>▪ INN</li> </ul>		<ul style="list-style-type: none"> <li>▪ Target species</li> <li>▪ Summary of indication</li> </ul>	<ul style="list-style-type: none"> <li>▪ Validation</li> <li>▪ Opinion</li> <li>▪ Active time</li> <li>▪ Clock stop</li> </ul>	<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>▪ Reconcile</li> <li>▪ fluoxetine (as fluoxetine HCl)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Elanco</li> </ul>	<ul style="list-style-type: none"> <li>▪ Dogs</li> <li>▪ Behavioural problems</li> </ul>	<ul style="list-style-type: none"> <li>▪ 15/05/2007</li> <li>▪ 16/04/2008</li> <li>▪ 210</li> <li>▪ 127</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>
<ul style="list-style-type: none"> <li>▪ Posatex</li> <li>▪ orbifloxacin, mometasone furoate and posaconazole</li> </ul>	<ul style="list-style-type: none"> <li>▪ Schering Plough Animal Health</li> </ul>	<ul style="list-style-type: none"> <li>▪ Dogs</li> <li>▪ Treatment of acute and recurrent otitis externa</li> </ul>	<ul style="list-style-type: none"> <li>▪ 17/10/2006</li> <li>▪ 210</li> <li>▪ 334</li> <li>▪ 15/04/2008</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>
<ul style="list-style-type: none"> <li>▪ Equioxx</li> <li>▪ firocoxib</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mérial</li> </ul>	<ul style="list-style-type: none"> <li>▪ Horse</li> <li>▪ Alleviation of pain and inflammation</li> </ul>	<ul style="list-style-type: none"> <li>▪ 19/03/2008</li> <li>▪ 14/05/2008</li> <li>▪ 55</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>
<ul style="list-style-type: none"> <li>▪ Zactran</li> <li>▪ gamithromycin</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mérial</li> </ul>	<ul style="list-style-type: none"> <li>▪ Cattle</li> <li>▪ Respiratory disease</li> </ul>	<ul style="list-style-type: none"> <li>▪ 13/03/2007</li> <li>▪ 14/05/2008</li> <li>▪ 204</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>

## Negative Opinions

<b>Product</b>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b>	<b>EMEA/CVMP</b>	<b>European Commission</b>
<ul style="list-style-type: none"> <li>▪ Brand name</li> <li>▪ INN</li> </ul>		<ul style="list-style-type: none"> <li>▪ Target species</li> <li>▪ Summary of indication</li> </ul>	<ul style="list-style-type: none"> <li>▪ Validation</li> <li>▪ Opinion</li> <li>▪ Active time</li> <li>▪ Clock stop</li> </ul>	<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>▪ Masivet</li> <li>▪ masitinib</li> </ul>	<ul style="list-style-type: none"> <li>▪ AB Science</li> </ul>	<ul style="list-style-type: none"> <li>▪ Dogs</li> <li>▪ Mast cell tumours</li> </ul>	<ul style="list-style-type: none"> <li>▪ 13/03/2007</li> <li>▪ 15/05/2008</li> <li>▪ 182</li> <li>▪ 246</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>

## Withdrawals prior to opinion

<b>Product</b>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b>	<b>EMEA/CVMP</b>	<b>European Commission</b>
<ul style="list-style-type: none"> <li>▪ Brand name</li> <li>▪ INN</li> </ul>		<ul style="list-style-type: none"> <li>▪ Target species</li> <li>▪ Summary of indication</li> </ul>	<ul style="list-style-type: none"> <li>▪ Validation</li> <li>▪ Opinion</li> <li>▪ Active time</li> <li>▪ Clock stop</li> </ul>	<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>▪</li> </ul>		<ul style="list-style-type: none"> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>

## CVMP Opinions in 2008 on establishment of MRLs for new substances

### Positive Opinions

<b>Substance INN</b>	<b>Therapeutic area</b>	<b>EMEA/CVMP</b>	<b>European Commission</b>
	<ul style="list-style-type: none"> <li>▪ Target species</li> </ul>	<ul style="list-style-type: none"> <li>▪ Validation</li> <li>▪ Opinion</li> <li>▪ Active time</li> <li>▪ Clock stop</li> </ul>	<ul style="list-style-type: none"> <li>▪ Opinion received</li> <li>▪ Date of regulation</li> <li>▪ Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>▪ Lectin</li> </ul>	<ul style="list-style-type: none"> <li>▪ Porcine</li> </ul>	<ul style="list-style-type: none"> <li>▪ 18.10.2007</li> <li>▪ 16.01.2008</li> <li>▪ 90 days</li> <li>▪ 0 days</li> </ul>	<ul style="list-style-type: none"> <li>▪</li> </ul>

## Arbitrations and Community Referrals in 2008

<b>Type of referral</b>	<b>Date of clock start / CVMP opinion</b>	<ul style="list-style-type: none"> <li>▪ <b>Product name</b></li> <li>▪ <b>INN</b></li> </ul>
Referral under Art. 35 of Directive 2001/82/EC	16/01/2008 (clock start)	<ul style="list-style-type: none"> <li>▪ Injectable veterinary medicinal products containing ivermectin indicated for use in cattle</li> <li>▪ Ivermectin</li> </ul>
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/02/2008	<ul style="list-style-type: none"> <li>▪ Compagel gel for horses</li> <li>▪ Heparin sodium, levomenthol, hydroxyethyl salicylate</li> </ul>
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/02/2008	<ul style="list-style-type: none"> <li>▪ Solacyl</li> <li>▪ Sodium salicylate</li> </ul>
Referral under Art.	15/04/2008 (clock re-start)	<ul style="list-style-type: none"> <li>▪ Suramox 15% and Stabox 15%</li> </ul>

Type of referral	Date of clock start / CVMP opinion	<ul style="list-style-type: none"> <li>▪ Product name</li> <li>▪ INN</li> </ul>
35 of Directive 2001/82/EC		<ul style="list-style-type: none"> <li>▪ Amoxicillin</li> </ul>
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008	<ul style="list-style-type: none"> <li>▪ ENRO-K 10% oral solution</li> <li>▪ Enrofloxacin</li> </ul>
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008	<ul style="list-style-type: none"> <li>▪ Unisol (avifox) 10% oral solution</li> <li>▪ Enrofloxacin</li> </ul>
Referral for arbitration – Art. 33(4) of Directive 2001/82/EC	13/05/2008	<ul style="list-style-type: none"> <li>▪ Pharnasin 100% w/w water soluble granules</li> <li>▪ Tylosine tartrate</li> </ul>

### Guidelines and Working Documents in 2008

#### CVMP Efficacy

Reference number	Document title	Status

#### CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status

#### CVMP Immunologicals

Reference number	Document title	Status
EMEA/CVMP/IWP/205351/2006	Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus	Adopted, March 2008  (This guideline has been updated following comments received from IFAH Europe)
EMEA/CVMP/IWP/105504/2007-CONSULTATION	Guideline on the requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs)	Adopted for consultation, March 2008  (End of consultation: September 2008)
EMEA/CVMP/IWP/37267/2008-CONSULTATION	Concept paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue	Adopted for consultation, March 2008  (End of consultation: May 2008)

### CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/ CVMP/ PhVWP/ 72829/ 2007	EMA public bulletin 2007 on veterinary pharmacovigilance	Adopted, February 2008
EMA/ CVMP/ VICH/ 547/ 00	VICH guideline (GL24) on Management of Adverse Event Reports	Adopted, March 2008

### Joint CHMP/ CVMP Quality

Reference number	Document title	Status
EMA/ CHMP/ CVMP/ QWP/ 28271/ 2008 – CONSULTATION	Reflection paper on the acceptability of water for injections prepared by reverse osmosis	Adopted for consultation, February 2008
EMA/ CVMP/ VICH/ 581467/ 2007 -CONSULTATION	VICH guideline (GL45) on Quality: Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products	Adopted for consultation, February 2008 (End of consultaion: August 2008)
EMA/ HMPC/ CHMP/ CVMP/ 214 869/ 2006	Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products	Adopted, March 2008

### CVMP Safety

Reference number	Document title	Status
EMA/ CVMP/ 27466/ 2008	Report of the Focus group meeting on user safety guideline	Adopted , March 2008
EMA/ CVMP/ SWP/ 173804/ 2008-CONSULTATION	Concept paper for the revision of the Guideline on User Safety	Adopted for consultation, April 2008. (end of consultation: May 2008)

### CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/ CVMP/ SAGAM/ 428938/ 2007-CONSULTATION	Reflection paper on antimicrobials resistance surveillance as post-marketing authorisation commitment	Adopted for consultation, January 2008. (End of consultation: April 2008)

EMEA/CVMP/SAGAM/81730/2006-CONSULTATION	Reflection paper on the use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, February 2008. (End of consultation: August 2008)
---	---	--

### CVMP General

Reference number	Document title	Status
EMEA/CVMP/28510/2008-CONSULTATION	Guideline on Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats	Adopted for consultation, January 2008. (End of consultation: July 2008)
EMEA/328/98-Rev.3	Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure	Adopted, January 2008
EMEA/410/01-Rev.4	Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Adopted, February 2008
EMEA/CVMP/182112/2006	CVMP Reflection Paper regarding the assessment of environmental risks of veterinary medicinal products	Adopted for consultation, March 2008 (end of consultation: June 2008))
	Reflection paper on Criteria for requiring one additional five-year renewal on pharmacovigilance grounds	Adopted, May 2008 (to become part of Volume 9B, which will be published published for consultation shortly)