7 April 2015
EMA/CVMP/220258/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

8 April 2015, 09:00 – 10 April 2015, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of declarations of interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting.

Disclaimers

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

ii. CVMP delegates list of intended participation and identified conflicts of interests

iii. Declaration of contacts between members and companies with regard to points on the agenda

iv. Adoption of the minutes of the previous meeting

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 2A)	Wed 8 April 2015	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003923/FULL/0001 *Honey*	**ORAL EXPLANATION - Wednesday 8 April** ***For discussion***:Applicant's presentation; comments from EFSA

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

• **Substance** EMEA/V/MRL/003915/FULL/0001 *Bovine species*	**ORAL EXPLANATION - Thursday 9 April** ***For discussion***: Applicant's presentation; responses to questions raised to applicant

1.5 Other issues

• **Substance** EMEA/V/MRL/003135/MODF/0003 *Salmonidae* Review under Art.11	***For discussion****:* Rapporteur's assessment of responses to list of questions; rapporteur's EPMAR

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/003764/0000 *New product for psycholeptic use* Dogs **D210**	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Cerenia** EMEA/V/C/000106/X/023 *Extension to include* a new route of *administration* Cats and dogs **D180**	Rapp: C. Friis Co-rapp: E. Lander Persson ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/003836/0000 *New cardiovascular product* Dogs	***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information, rapporteurs' assessment of responses and LoOI ASMF applicant's part, and restricted part

2.3 List of questions

• **Product** EMEA/V/C/003991/0000 *New ectoparasiticide* Dogs	***For adoption****:* Scientific overview and benefit-risk assessment and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **Product** EMEA/V/C/003786/0000 *New cardiovascular product* Cats	**ORAL EXPLANATION - Thursday 9 April** ***For discussion:*** Verbal report from the Ad hoc expert group (AHEG) to CVMP; report from the AHEG meeting to be held on 7 April 2015 ***For discussion***: Applicant's presentation for oral explanation with CVMP; rapporteur's presentation; rapporteur's assessment report; co-rapporteur's critique

2.5 Other issues

• **Product** EMEA/V/C/002794/0000) *New haematological product* Dogs **Withdrawal of application**	***For information***: Draft WEPAR

- ***For endorsement*****:** EPAR module 6 scientific discussion for **Suvaxyn CSF Marker** (EMEA/V/C/002757/0000)
- ***For endorsement*****:** EPAR module 6 scientific discussion for **Metacam** (EMEA/V/C/000033/X/0107)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **RHINISENG** EMEA/V/C/000160/II/0004 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report

• **RESPIPORC FLU3** EMEA/V/C/000153/II/0009 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report
• **Gripovac 3** EMEA/V/C/000157/II/0007 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report
• **Suvaxyn PCV, Equip WNV, Poulvac E.coli** EMEA/V/C/XXXXXX/WS/0649/G *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Poulvac E. coli** EMEA/V/C/002007/II/0006 *To add a route of administration*	Rapp: E. Werner ***For adoption****:* List of outstanding issues

3.3 List of questions

• **Aivlosin** EMEA/V/C/000083/II/0062/G *Quality*	Rapp: H. Jukes ***For adoption****:* List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- No items

4 REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

• **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** *(zinc oxide)* EMEA/V/A/108 *ERA*	Rapp: P. Hekman Co-rapp: H. Jukes **ORAL EXPLANATION - Thursday 9 April** ***For discussion***: Presentation from Huvepharma NV, updated rapporteur's assessment report, updated co-rapporteur's assessment report

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

- No items

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

- No items

4.6 Article 30(3) of Regulation 726/2004

• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report

4.7 Other issues

- No items

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

Information on certain topics discussed under section 5.1 cannot be released at the present time as it is deemed to be confidential

5.2 Post-authorisation measures and annual reassessments

• **Improvac** EMEA/V/C/000136 REC 027	Rapp: E.-M. Vestergaard Co-rapp: A.-M. Brady ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Advocate (EMEA/V/C/000076)	02/04/2014 – 01/04/2015
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2014 – 16/03/2015
CaniLeish (EMEA/V/C/002232)	14/03/2014 – 13/03/2015
ClomicaIm (EMEA/V/C/000039)	01/04/2014 – 31/04/2015
ECOPORC SHIGA (EMEA/V/C/002588)	10/04/2014 – 09/04/2015
Eurican Herpes 205 (EMEA/V/C/000059)	26/03/2014 – 25/03/2015
Incurin (EMEA/V/C/000047)	24/03/2014 – 23/03/2015
Locatim (EMEA/V/C/000041)	29/03/2014 – 28/03/2015

Product	Period
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2014 – 05/04/2015
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14/03/2014 – 13/03/2015

5.4 Renewals

• **RHINISENG** EMEA/V/C/000160/R/0003	Rapp: E.-M. Vestergaard Co-rapp: J. G. Beechinor ***For adoption***: List of outstanding issues
• **Equilis Te** EMEA/V/C/000093/R/0006	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: CVMP opinion, CVMP assessment report
• **Bovilis BTV8** EMEA/V/C/000148/R/0007	Rapp: M. Tollis Co-rapp: A.-M. Brady ***For adoption:*** CVMP opinion, CVMP assessment report
• **COXEVAC** EMEA/V/C/000155/R/0009	Rapp: J.-C. Rouby Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report

5.5 Pharmacovigilance - PSURs and SARs

• **Activyl** EMEA/V/C/000163	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-31.08.14
• **Rabigen SAG2** EMEA/V/C/000043	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.11-31.10.14
• **APOQUEL** EMEA/V/C/002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14
• **BTVPUR Alsap 2-4** EMEA/V/C/000139	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14

• **Oncept IL-2** EMEA/V/C/002562	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14
• **Palladia** EMEA/V/C/000150	Rapp: E. Lander Persson ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-30.11.14
• **Panacur AquaSol** EMEA/V/C/002008	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14
• **Porcilis ColiClos** EMEA/V/C/002011	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **Posatex** EMEA/V/C/000122	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.14-31.12.14
• **PRILACTONE** EMEA/V/C/000105	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.12-31.12.14
• **Vectra Felis** EMEA/V/C/002746	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-31.12.14
• **Zuprevo** EMEA/V/C/002009	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14
• **Vectra 3D** EMEA/V/C/0002255	Rapp: C. Ibrahim ***For endorsement***: Surveillance analysis findings

- ***For information:*** Nobivac Myxo-RHD final study report for the post-authorisation safety study, cover letter and timetable
- ***For endorsement:*** List of products and calendar for signal detection analysis

5.6 Supervision and sanctions

Information relating to GMP and Pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- No items

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

Information on certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be confidential

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to be commercially confidential

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs

7.11 Other working party and scientific group issues

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential

- ***For adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009

8.2 Environmental risk assessment

Information on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential

8.3 Antimicrobial resistance

- No items

8.4 Pharmacovigilance

- No items

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information

- No items

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information:*** Agenda of the meeting to be held on 9-10 April 2015; minutes of the meeting held 12-13 March 2015; presentation from the Chair of CMDv

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: CVMP Interested Parties' meeting to be held on 6 May 2015, draft agenda

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP
April 2015	8-10							8	
May 2015	5-7	12-13		19-20		26-27	26–28	5	21-22
June 2015	2-4		16-17		17-18	30 Jun-1 Jul		2	
July 2015	7-9							7	
Sept 2015	8-10	23-24		15-16		22-23		8	24-25
Oct 2015	6-8				20-21			6	