12 January 2015
EMA/CVMP/21488/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

13 January 2015, 09:00 – 15 January, 13:00 - Room 2A

Declaration on conflict of interests

In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting are asked to declare any conflict of 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)	Tue 13 Jan 20115	16.00-20.00

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1 Opinions

• **Substance** EMEA/V/MRL/003915/FULL/0001 *Bovine species*	***For adoption***: CVMP opinion, CVMP assessment report ***For discussion***: Rapporteurs' assessment of the responses to the list of outstanding issues, revised rapporteur's assessment report, rapporteur's EPMAR, comments

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/003307/EXTN/0003 *Extension to poultry*	***For discussion***: Rapporteur's assessment report, rapporteur's EPMAR, peer reviewer's report, comments

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/003786/0000 *New cardiovascular product* *Cats*	***For adoption***: CVMP opinion, CVMP assessment report
• **Stronghold** EMEA/V/C/000050/X/051/G *Extension to include new strengths* *Cats and dogs*	Rapp: H. Jukes Co-rapp: I. Malemis ***For adoption***: CVMP opinion, CVMP assessment report, CVMP product information
• **Product** EMEA/V/C/003797/0000 *New live bacterial vaccine* *Pigs*	***For adoption***: CVMP opinion, CVMP assessment report, CVMP product information

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/003866/0000 *New anti-inflammatory product* *Horses*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/002763/0000 *New immunostimulating product* *Cattle*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, comments on draft product information
• **Zactran** EMEA/V/C/000129/X/0027 *Extension to include a new food producing species* *Cattle*	Rapp: C. Friis Co-rapp: J. G. Beechinor ***For adoption***: Scientific overview and benefit-risk assessment and list of questions, comments on draft product information
• **Cerenia** EMEA/V/C/000106/X/023 *Extension to include a new route of administration* *Cats and dogs*	Rapp: C. Friis Co-rapp: E. Lander Persson ***For adoption***: Scientific overview and benefit-risk assessment and list of questions, comments on draft product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/002390 *New vaccine* *Atlantic salmon*	Rapp: A.-M. Brady Co-Rapp: D. Murphy ***For information***: Letter requesting a clock extension

- ***For endorsement:*** EPAR module 6 scientific discussion for **NEXGARD SPECTRA** (EMEA/V/C/003842/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Purevax RCPCh; Purevax RCP; Purevax RC; Purevax RCPCh FeLV; Purevax RCP FeLV** EMEA/V/C/xxxxxx/WS/0606 *To extend the duration of immunity (DOI)*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report
• **Bluevac BTV8** EMEA/V/C/0000156/II/004/G *Quality*	Rapp: E. Werner ***For adoption*:** CVMP opinion, CVMP assessment report
• **ERYSENG PARVO** EMEA/V/C/xxxxxx/WS/0618 *To amend the product information*	Rapp: D. Murphy ***For adoption***: CVMP opinion, CVMP assessment report
• **Acticam** EMEA/V/C/000138/II/014 *Quality*	Rapp: D. Murphy ***For adoption***: CVMP opinion, CVMP assessment report
• **Metacam; Novem** EMEA/V/C/xxxxxx/WS/0661 *To add manufacturing sites*	Rapp: F. Hasslung Wikström ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **DRAXXIN** EMEA/V/C/0000077/II/0031 *New indication*	Rapp: C. Ibrahim Co-rapp: C. Munoz ***For adoption**:* List of questions
• **Poulvac E.coli, Suvaxyn PCV, Equip WNV** EMEA/V/C/xxxxxx/WS/0649/G *Quality*	Rapp: E. Werner ***For adoption**:* List of questions

• **Versican Plus DHPPi; Versican Plus DHPPi/L4R; Versican Plus DHPPi/L4** EMEA/V/C/xxxxxx/WS/0620 *To extend the duration of immunity*	Rapp: E. Werner ***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

- No items

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

• **All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** EMEA/V/A/095 *ERA*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti ***For decision****:* Request from the applicant/MAHs for a further extension of the clock stop

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 discussion***: Rapporteur's assessment report

4.7 Other issues

- No items

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

5.1 General issues

- No Items

5.2 Post-authorisation measures and annual reassessments

• **Purevax Rabies** EMEA/V/C/002003/REC001,002	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For endorsement***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2014 – 08.01.2015
BTVPUR AlSap 1 (EMEA/V/C/002230)	17.12.2013 – 16.12.2014
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	17.12.2013 – 16.12.2014
CORTAVANCE (EMEA/V/C/000110)	09.01.2014 – 08.01.2015
Gripovac 3 (EMEA/V/C/000157)	14.01.2014 – 13.01.2015
MELOXIDYL (EMEA/V/C/000115)	15.01.2014 – 14.01.2015
Metacam (EMEA/V/C/000033)	07.01.2014 – 06.01.2015
Onsior (EMEA/V/C/000127)	16.12.2013 – 15.12.2014
Porcilis PCV (EMEA/V/C/000135)	12.01.2014 – 11.01.2015
Prac-Tic (EMEA/V/C/000103)	18.12.2013 – 17.12.2014
ProMeris (EMEA/V/C/000107)	19.12.2013 – 18.12.2014
ProMeris Duo (EMEA/V/C/000108)	19.12.2013 – 18.12.2014
RESPIPORC FLU3 (EMEA/V/C/000153)	14.01.2014 – 13.01.2015
Rheumocam (EMEA/V/C/000121)	10.01.2014 – 09.01.2015
TruScient (EMEA/V/C/002000)	14.12.2013 – 13.12.2014
Ypozane (EMEA/V/C/000112)	11.01.2014 – 10.01.2015
ZULVAC 8 Bovis (EMEA/V/C/000145)	15.01.2014 – 14.01.2015
ZULVAC 8 Ovis (EMEA/V/C/000147)	15.01.2014 – 14.01.2015

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **Cimalgex** EMEA/V/C/000162	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-31.08.14
• **Pexion** EMEA/V/C/002543	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-31.08.14
• **Bovilis BTV8** EMEA/V/C/000148	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09.14
• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 11.02.14-31.08.14
• **Equisolon** EMEA/V/C/002382	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 12.03.14-12.09.14
• **Kexxtone** EMEA/V/C/002235	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14
• **RevitaCAM** EMEA/V/C/002379	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-31.08.14
• **Suvaxyn PCV** EMEA/V/C/000149	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14
• **ZULVAC 1 Bovis** EMEA/V/C/000145	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-31.08.14

• **ZULVAC 1 Ovis** EMEA/V/C/000147	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-31.08.14

- ***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

- ***For adoption:*** 2015 EMA GMP re-inspection programme

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For adoption***: EU comments on the revised draft VICH guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species - residue depletion in fish groups

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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

- No items

8.3 Antimicrobial resistance

- ***For information***: ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals

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 notifications of intent for new MRL applications and notifications 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 15-16 January 2015; minutes of the meeting held 11-12 December 2014

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement***: Review of the PIQ/QRD process - Product information review
- ***For discussion and adoption***: CVMP work plan
- ***For discussion***: Guidance on principles to prepare CVMP assessment reports; template scientific overview and benefit-risk assessment, including list of questions for veterinary pharmaceutical products
- ***For discussion***: CVMP implementation of multinational assessment teams: appointments and responsibilities of rapporteur and co-rapporteur for procedure regarding veterinary medicinal products; table to declare potential interest in participating in a multinational assessment team and the expertise available per National Competent Authority

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
Jan 2015	13-15	20-21	27-28			27-28		13	
Feb 2015	10-12			3-4			3–5	10	19-20
Mar. 2015	10-12				26-27	24-25		10	
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	