18 April 2016
EMA/CVMP/273497/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2016 meeting

Chair: Anja Holm

Vice-chair: David Murphy

19 April 2016, 09:00 – 21 April 2016, 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)	Tue 19 April 2016	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/003200/EXTN/0003 *Extension to bovine tissues and milk*	**ORAL EXPLANATION – Tuesday 19 April, 14:30** ***For discussion***: Applicant's presentation, responses to the list of outstanding issues

1.3 List of questions

- No items

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/002390/0000 *New vaccine* *Atlantic salmon*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004199/0000 *New anaesthetic product* *Dogs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Draxxin** EMEA/V/C/0077/X/029 *Extension for new target species*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For discussion****:* Rapporteurs' AR of the remaining LoOI, draft product information
• **Product** EMEA/V/C/004202/0000 *New product for psycholeptic use* *Dogs and cats*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues, product information

2.3 List of questions

• **Product** EMEA/V/C/004099/0000 *New antibacterial and anti-inflammatory product* *Cattle*	***For adoption**:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement*:** EPAR module scientific discussion for **Poulvac E. coli** (EMEA/V/C/002007/X/0008)
- ***For endorsement:*** EPAR module scientific discussion for **Evalon** (EMEA/V/C/004013/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Aivlosin** EMEA/V/C/000083/II/0064 *To change the withdrawal period for eggs*	Rapp: H. Jukes Co-rapp: E. Lander Persson ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Versican Plus Pi/L4R and Versican Plus DHPPi/L4R** EMEA/V/C/xxxxxx/WS/0785 *To extend the duration of immunity*	Rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report, product information of Versican Plus Pi/L4R and Versican Plus DHPPi/L4R
• **Metacam** EMEA/V/C/000033/II/0118/G *Quality*	Rapp: F. Hasslung Wikström ***For adoption***: CVMP opinion, CVMP assessment report
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0005 *Quality*	Rapp: A.-M. Brady ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0002 *Quality*	Rapp: B. Urbain ***For adoption**:* List of questions

• **Comfortis and Trifexis** EMEA/V/C/xxxxxx/WS/0906/G *Quality*	Rapp: C. Ibrahim ***For adoption***: List of questions
• **Vectormune ND** EMEA/V/C/003829/II/0004 *Quality*	Rapp: F. Klein ***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 *Environmental risk assessment*	Rapp: C. Ibrahim Co-rapp: S. Louet **ORAL EXPLANATION – Wednesday 20 April, 11:30** ***For discussion***: Presentation from MAHs, revised rapporteur's assessment report including co-rapporteur's critique
• **All veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally** EMEA/V/A/111 *Antimicrobial resistance*	Rapp: K. Baptiste Co-rapp: S. Louet ***For adoption***: CVMP opinion, CVMP assessment report
• **All veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** EMEA/V/A/110 *Indications, dosage and withdrawal periods*	Rapp: B. Urbain Co-rapp: K. Baptiste ***For decision***: Need for oral explanation ***For discussion***: Rapporteur's assessment with co-rapporteur's critique following list of outstanding issues and revised rapporteur's assessment report

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

- No items

4.7 Other issues

- ***For information***: Questions and answers document on Closamectin pour-on solution and associated names, notification of Commission Decision

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

5.1 General issues

- No Items

5.2 Post-authorisation measures and annual reassessments

• **Fevaxyn Pentofel** EMEA/V/C/000030/REC/027	Rapp: E.-M. Vestergaard Co-rapp: J. G. Beechinor ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Advocate (EMEA/V/C/000076)	02/04/2015 – 01/04/2016
BLUEVAC BTV8 (EMEA/V/C/000156)	14/04/2015 – 13/04/2016
Clomicalm (EMEA/V/C/000039)	01/04/2015 – 31/03/2016
ECOPORC SHIGA (EMEA/V/C/002588)	10/04/2015 – 09/04/2016
Eurican Herpes 205 (EMEA/V/C/000059)	26/03/2015 – 25/03/2016
Incurin (EMEA/V/C/000047)	24/03/2015 – 23/03/2016
Locatim (EMEA/V/C/000041)	29/03/2015 – 28/03/2016
Neocolipor (EMEA/V/C/000035)	14/04/2015 – 13/03/2016
Parvoduk (EMEA/V/C/002740)	11/04/2015 – 10/04/2016
Procox (EMEA/V/C/002006)	20/04/2015 – 19/04/2016
Purevax FeLV (EMEA/V/C/000056)	13/04/2015 – 12/04/2016
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2015 – 05/04/2016

Product	Period
Veraflox (EMEA/V/C/000159)	12/04/2015 – 11/04/2016

5.4 Renewals

• **Nobivac Myxo-RHD** EMEA/V/C/002004/R/0005	Rapp: E. Werner Co-rapp: M. Tollis **For adoption**: CVMP opinion, CVMP assessment report, product information
• **Emdocam** EMEA/V/C/002283/R/0007	Rapp: D. Murphy Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Nobilis Influenza H5N2** EMEA/V/C/000118/R/0012	Rapp: A.-M. Brady Co-rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- ***For endorsement:*** Rapporteur assessment report of the final study results on post-authorisation safety study (PASS) for **Trifexis** (EMEA/V/C/002635)

• **APOQUEL** EMEA/V/C/002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.15-30.11.15
• **Bovela** EMEA/V/C/003703	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **BTVPUR AlSap 1** EMEA/V/C/002230	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.15-31.12.15
• **BTVPUR AlSap 1-8** EMEA/V/C/002231	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.15-31.12.15
• **Equilis Prequenza** EMEA/V/C/000094	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15-31.01.16

• **Equilis Prequenza Te** EMEA/V/C/000095	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15-31.01.16
• **Oxyglobin** EMEA/V/C/000045	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 30.11.12-30.11.15
• **Panacur AquaSol** EMEA/V/C/002008	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.15-31.12.15
• **SevoFlo** EMEA/V/C/000072	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.12-30.11.15
• **Sileo** EMEA/V/C/003764	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 10.06.15-31.12.15
• **Upcard** EMEA/V/C/003836	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 31.07.15-31.01.16
• **Versican Plus DHPPi/L4** EMEA/V/C/003678	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.15-30.11.15
• **Zuprevo** EMEA/V/C/002009	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.14-30.11.15

- ***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

- ***For endorsement***: CVMP representation at the forthcoming VICH Steering Committee (June 2016)

- ***For endorsement***: Proposal on draft VICH guideline (A-1 vs 5) on the use of cell cultures for the detection of extraneous agents in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines; draft concept paper for two VICH guidelines: (1) general principles for detection of extraneous agents in veterinary vaccines and defining the testing of seeds and materials of animal origin, (2) a list of extraneous agents that need to be covered
- ***For discussion***: Concept paper on the need to elaborate on the next steps in the global approach to demonstrate Bioequivalence

6.2 Codex Alimentarius

Information on certain topics discussed under section 6.2 cannot be released at the present time as it is deemed to be confidential

6.3 Other EU bodies and international organisations

- ***For discussion***: Draft guidance document of the EFSA Panel on Plant protection products and their residues with regard to the establishment of the residue definition for dietary risk assessment

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information on certain topics discussed under section 7 cannot be released at the present time as it is deemed to be confidential

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

- No items

8.3 Antimicrobial resistance

- ***For information***: Verbal report on the Antimicrobial Advice ad hoc expert group (AMEG) meeting on colistin held on 5 April 2016
- ***For information***: Verbal report on the ESVAC network and stakeholders meeting held on 1-2 March 2016
- ***For information***: Invitation to provide comments on the draft ESVAC Vision and Strategy 2016-2020
- ***For endorsement***: Representation of CVMP at the 4th International Conference on Responsible Use of Antibiotics in Animals (The Hague, 26-28 September 2016)

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

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***: Draft agenda of the meeting to be held on 21-22 April 2016, draft minutes of the meeting held on 17 March 2016

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement:*** CVMP Interested parties meeting to be held on 20 April 2016, draft agenda
- ***For discussion:*** Draft agenda of CVMP/CMDv presidency meeting in the Netherlands
- ***For information:*** Presentation on the Veterinary Change programme
- ***For information:*** Feedback from the Scientific Co-ordination Board meeting held on 18 March 2016, 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	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
Apr 2016	19-21								19		
May 2016	17-19	19	25-26		31		24-25	31	17	26-27	
Jun 2016	14-16			21-22	1	29-30		1-2	14		
Jul 2016	12-14						5/6		12		
Sep 2016	6-8								6		