13 March 2016
EMA/CVMP/192750/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of March 2016 meeting

Chair: Anja Holm

Vice-chair: David Murphy

15 March 2016, 09:00 – 17 March 2016, 13:00 - Room 3E and 3A

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 3E)	Tue 15 March 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

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/003158/EXTN/0003 *Ovine species*	***For adoption***: Scientific overview and list of questions
• **Substance** EMEA/V/MRL/004333/FULL/0001 *Bovine species*	***For adoption***: Scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/002390 *New vaccine* *Atlantic salmon*	**ORAL EXPLANATION – Tuesday 15 March 2016, 14:30** ***For discussion:*** Report from the 2nd AHEG meeting, applicant's presentation, updated scientific overview and benefit-risk assessment, draft product information
• **Draxxin** EMEA/V/C/0077/X/029 *Extension for new target species*	Rapp: C. Ibrahim Co-rapp: C. Munoz **ORAL EXPLANATION – Wednesday 16 March 2016, 14:30** ***For discussion****:* Applicant's presentation, draft product information, rapporteur's and co-rapporteur's assessment report of LoOI

• **Product** EMEA/V/C/004199/0000 *New anaesthetic product* *Dogs*	***For decision***: Need for oral explanation ***For adoption:*** Scientific overview and benefit-risk assessment and list of outstanding issues, draft product information

2.3 List of questions

• **Metacam** EMEA/V/C/000033/X/119 *Extension to add a new route for the 40mg/ml solution for injection* *Cattle and horses*	Rapp: F. Hasslung Wikström Co-rapp: C. Friis ***For adoption:*** Scientific overview and benefit-risk assessment and list of questions, comments on draft product information

2.4 Re-examination of CVMP opinions

• **Bravecto** EMEA/V/C/002526/X/0005 *Extension to add a new pharmaceutical form (spot-on solution) for dogs and a new target species (cats) for this spot-on formulation* *Dogs*	**ORAL EXPLANATION – Tuesday 15 March 2016; 11:50** ***For adoption****:* CVMP assessment report for the re-examination of the CVMP opinion, final CVMP opinion, product information ***For discussion:*** Report from the AHEG meeting*;* applicant's presentation ***For information***: Summary of opinion

2.5 Other issues

- ***For endorsement:*** EPAR module scientific discussion for **ZACTRAN** (EMEA/V/C/000129/X/0027)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Profender** EMEA/V/C/000097/II/0032 *To add therapeutic indications for Profender spot-on solution for cats*	Rapp: R. Breathnach Co-rapp: M. Mendes ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0006 *To change the vaccination schedule*	Rapp: A.-M. Brady ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

3.2 Oral explanations and list of outstanding issues

• **Aivlosin** EMEA/V/C/000083/II/0064 *To change the withdrawal period for eggs*	Rapp: H. Jukes Co-rapp: E. Persson ***For adoption**:* CVMP list of outstanding issues
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0005 *Quality*	Rapp: A.-M. Brady ***For adoption**:* CVMP list of outstanding issues

3.3 List of questions

- No items

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

• **CattleMarker IBR Inactivated emulsion for injection for cattle** *(Infectious bovine rhinotracheitis (IBR) vaccine)* EMEA/V/A/115 *Animal safety*	Rapp: E. Werner Co-rapp: F. Klein ***For adoption***: CVMP opinion, CVMP assessment report

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 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 decision**:* Need for oral explanation ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

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

- 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

• **ZULVAC SBV** EMEA/V/C/002781/ANX/001, 002, 003	Rapp: A.-M. Brady Co-rapp: G. Kulcsar ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2015 – 16/03/2016
CaniLeish (EMEA/V/C/002232)	14/03/2015 – 13/03/2016
Coliprotec F4 (EMEA/V/C/003797)	16/03/2015 – 15/03/2016
Econor (EMEA/V/C/000042)	12/03/2015 – 11/03/2016
Equisolon (EMEA/V/C/002382)	12/03/2015 – 11/03/2016
Fungitraxx (EMEA/V/C/002722)	12/03/2015 – 11/03/2016
Ibraxion (EMEA/V/C/000051)	09/03/2015 – 08/03/2016
Melosus (EMEA/V/C/002001)	21/02/2015 – 20/02/2016
Novem (EMEA/V/C/000086)	02/03/2015 – 01/03/2016
Pexion (EMEA/V/C/002543)	25/02/2015 – 24/02/2016
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	28/02/2015 – 29/02/2016
ProteqFlu (EMEA/V/C/000073)	06/03/2015 – 05/03/2016
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2015 – 05/03/2016
Purevax RC (EMEA/V/C/000091)	23/02/2015 – 22/02/2016
Purevax RCP (EMEA/V/C/000090)	23/02/2015 – 22/02/2016
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2015 – 22/02/2016
Purevax RCPCh (EMEA/V/C/000088)	23/02/2015 – 22/02/2016
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2015 – 22/02/2016

Product	Period
RevitaCAM (EMEA/V/C/002379)	23/02/2015 – 22/02/2016
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08/03/2015 – 07/03/2016
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14/03/2015 – 13/03/2016

5.4 Renewals

• **Proteq West Nile** **EMEA/V/C/002005/R/0007**	Rapp: J-C. Rouby Co-rapp: F. Hasslung Wikstrom ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **MS-H Vaccine** **EMEA/V/C/000161/R/0009**	Rapp: B. Urbain Co-rapp: G. Kulcsar ***For adoption:*** CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **CERTIFECT** EMEA/V/C/002002	Rapp: S. Louet ***For adoption***: CVMP assessment report on the addendum PSUR for the period 01.06.15-31.10.15
• **Dicural** EMEA/V/C/000031	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.15-28.10.15
• **Pexion** EMEA/V/C/002543	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-31.08.15
• **BTVPUR Alsap 2-4** EMEA/V/C/000139	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.15-30.11.15
• **EQUIP WNV** EMEA/V/C/000137	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.15-30.11.15
• **Meloxidolor** EMEA/V/C/002590	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 23.04.15-22.11.15
• **Oncept IL-2** EMEA/V/C/002562	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.15-30.11.15

• **Parvoduk** EMEA/V/C/002740	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 31.05.15-31.10.15
• **Porcilis ColiClos** EMEA/V/C/002011	Rapp: A-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.15-31.12.15
• **Porcilis PCV M Hyo** EMEA/V/C/003796	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.15-31.12.15
• **Procox** EMEA/V/C/002006	Rapp: E. Lander Persson ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.15-31.10.15
• **ProteqFlu** EMEA/V/C/000073	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-30.09.15
• **ProteqFlu-Te** EMEA/V/C/000074	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-30.09.15
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.05615-30.11.15
• **VIRBAGEN OMEGA** EMEA/V/C/000061	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15-30.11.15

- ***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

- ***For adoption***: Criteria for classification of critical medicinal products; template for criticality assessment report

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement***: Draft VICH guideline on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for circulation to the VICH Expert Working Group
- ***For discussion***: Proposal on draft VICH guideline 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

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For discussion***: Draft EFSA opinion on reference points for action for malachite green
- ***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

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 discussion***: Feedback on the 1st meeting of EFSA BIOCONTAM – BIOHAZ Working Group concerning the request for a scientific opinion on the risk for the development of antimicrobial resistance due to feeding of calves with milk held on 22 February 2016; Questions on data available from EMA/CVMP
- ***For discussion***: Proposal for future collaboration between the EMA and VetCAST
- ***For information***: Update on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety.
- ***For information***: Verbal report on the Antimicrobial Advice ad hoc expert group (AMEG) meeting held on 26 February 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

- ***For endorsement:*** 6th Annual Report Veterinary MUMS Limited market
- ***For adoption:*** Terms of Reference for the CVMP ad hoc group on veterinary vaccine availability

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 17-18 March 2016, draft minutes of the meeting held on 18-19 February 2016; chair's presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion and decision:*** CVMP Interested parties meeting to be held on 20 April 2016, draft agenda
- ***For discussion and endorsement:*** Request from International Veterinary Regenerative Medicine Society (IVRMS) to become a CVMP interested party
- ***For information***: EMA/IFAH-Europe Info Day to be held on 17-18 March 2016: programme, presentation by A. Holm
- ***For information***: Verbal report from the Strategic Planning Group (SPG) to be held on 16 March; draft agenda, draft minutes from the meeting held on 9 December 2015
- ***For information****:* Verbal report from the HMA/EMA TF on adherence to timetables and forthcoming meeting with industry on 21 April 2016
- ***For information***: Announcement regarding the mandatory use of the eSubmissions Gateway/Web Client for centralised veterinary applications to the European Medicines Agency from 1 January 2017

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
Mar 2016	15-17						22-23	1-3	15	3-4	22
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		