4 November 2016
EMA/CVMP/706204/2016 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of November 2016 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

8 November 2016, 09:00 – 10 November 2016, 13:00 - Room 3E

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 8 Nov. 2016	16.00-18.00

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

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/004333/FULL/0001 *Bovine species*	***For adoption***: List of outstanding issues

1.3 List of questions

• **Substance** EMEA/V/MRL/004479/FULL/0001 *Porcine species*	***For adoption***: Scientific overview and list of questions
• **Substance** EMEA/V/MRL/004543/FULL/0001 *Equidae*	***For adoption****:* Scientific overview and list of questions
• **Substance** EMEA/V/MRL/003517/EXTN/0003 *Chicken*	***For adoption****:* Scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/003596/FULL/0002 *Honey*	***For information****:* Proposed date for the submission of responses to the list of questions
• **Substance** EMEA/V/MRL/004321/FULL/0001 *All food producing species*	***For decision****:* Request to further extend the deadline for submission of responses to list of questions

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004225/0000 *New vaccine* *Pigs*	***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/0003993/0000 *New vaccine* *Pigs*	**ORAL EXPLANATION – Tuesday 8 November, 14:45-15:30** ***For discussion***: Applicant's presentation, draft CVMP assessment report, draft product information, rapporteurs' assessment report of responses to LoOI
• **Product** EMEA/V/C/004194/0000 *New antiparasitic product* *Cats*	***For adoption*:** List of remaining outstanding issues ***For discussion****:* Rapporteurs' assessment report of the LoOI, draft CVMP assessment report, draft product information

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement*:** EPAR module scientific discussion for **DRAXXIN** (EMEA/V/C/000077/X/0029)
- ***For endorsement*:** EPAR module scientific discussion for **HALAGON** (EMEA/V/C/004201/0000)
- ***For endorsement*:** EPAR module scientific discussion for **Cepedex** (EMEA/V/C/004376/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Trifexis** EMEA/V/C/002635/II/0008 *To add a new therapeutic indication*	Rapp: C. Ibrahim Co-rapp: T. Høy ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Purevax RCPCh FeLV, Purevax RCP, Purevax RC, Purevax RCP FeLV and Purevax RCPCh** EMEA/V/C/xxxxxx/WS1013 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report
• **Cortavance and Easotic** EMEA/V/C/xxxxxx/WS0925 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report

• **Metacam** EMEA/V/C/000033/II/0123/G *Quality*	Rapp: F. Hasslung Wikström ***For adoption***: CVMP opinion, CVMP assessment report
• **Versican Plus DHPPi/L4, Versican Plus DHPPi, Versican Plus DHPPi/L4R** EMEA/V/C/xxxxxx/WS/0936 *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report, Versican Plus DHPPi product information, Versican Plus DHPPi/L4 product information, Versican Plus DHPPi/L4R product information
• **COXEVAC** EMEA/V/C/000155/II/0011 *Quality*	Rapp: J.-C. Rouby ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Stronghold** EMEA/V/C/000050/II/0055/G *Quality*	Rapp: H. Jukes ***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

- No items

4.2 Article 34 of Directive 2001/82/EC

• **Denagard 45% and associated names** EMEA/V/A/114 *Tiamulin hydrogen fumarate* *SPC harmonisation*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For decision:*** Need for further outstanding issues ***For discussion***: Rapporteur's revised assessment report including co-rapporteur's critique, draft product information

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** EMEA/V/A/117 *Withdrawal periods*	Rapp: B. Urbain Co-rapp: H. Jukes ***For adoption:*** CVMP opinion, CVMP assessment report
• **Veterinary medicinal products containing zinc oxide to be administered orally to food producing species** EMEA/V/A/118 *ERA and antimicrobial resistance*	Rapp: G. J. Schefferlie Co-rapp: J. Weeks ***For discussion:*** Written explanations from aniMedica GmbH
• **Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle** EMEA/V/A/119 *Withdrawal periods*	Rapp: C. Ibrahim Co-rapp: S. Louet ***For decision:*** Need for outstanding issues ***For discussion:*** Rapporteur's assessment report including co-rapporteur's critique
• **Veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp.** EMEA/V/A/121 *Efficacy*	Rapp: M. Nevalainen Co-rapp: A. Wachnik-Święcicka ***For decision:*** Need for outstanding issues ***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

- No items

5.3 Product anniversary list

Product	**Period**
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	05/11/2015 – 04/11/2016
Halocur (EMEA/V/C/000040)	29/10/2015 – 28/10/2016
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2015 – 06/11/2016
Simparica (EMEA/V/C/003991)	06/11/2015 – 05/11/2016
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06/11/2015 – 05/11/2016
Virbagen Omega (EMEA/V/C/000061)	06/11/2015 – 05/11/2016
ZOLVIX (EMEA/V/C/000154)	04/11/2015 – 03/11/2016
Zycortal (EMEA/V/C/003782)	06/11/2015 – 05/11/2016

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For discussion and decision***: Revised timetable for the assessment of the PSUR for the period 01.03.16-31.08.15
• **Metacam and Novem** EMEA/V/C/000033 EMEA/V/C/000086	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13 – 30.04.16
• **Porcilis PCV** EMEA/V/C/000135	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 13.07.13 - 12.07.16
• **Bovela** EMEAV/C/003703	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16 - 30.06.16

• **Inflacam** EMEA/V/C/002497	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15 - 30.06.16
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16 - 30.06.16
• **Prac-tic** EMEA/V/C/000103	Rapp: C. Munoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15 - 30.06.16
• **Sileo** EMEA/V/C/003764	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16 - 30.06.16
• **Vectra 3D** EMEA/V/C/002555	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16 - 30.06.16
• **Vectra Felis** EMEA/V/C/002746	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16 - 30.06.16
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15 - 31.05.16

- ***For endorsement***: List of products and calendar for signal detection

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 adoption***: VICH GL 54 Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for sign off at step 6

6.2 Codex Alimentarius

- ***For information***: Feedback from the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) meeting held on 17-21 October 2016 in Houston, USA; report of the meeting

6.3 Other EU bodies and international organisations

- No items

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

- No items

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

- ***For discussion:*** EMA and EFSA joint 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 (RONAFA)
- ***For information:*** Verbal report on the 6th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 29 European countries in 2014; 6th ESVAC report: Sales of veterinary antimicrobial agents in 29 European countries in 2014. Trends from 2011 to 2014, press release link

- ***For information:*** Presentation of AMEG updated advice on the use of colistin products in animals within the European Union, at the European Antibiotic Awareness Day launch event to be held on 18 November 2016 in Brussels
- ***For information:*** 2nd International Symposium Alternatives to Antibiotics (ATA), Challenges and Solutions in Animal Production organized by the World Organization for Animal Health (OIE), to be held on 13-15 December 2016 in Paris

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***: Draft agenda of meeting to be held on 10-11 November 2016, minutes of the meeting held on 8-9 September 2016, draft minutes of meeting held on 6-7 October 2016; presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement and decision****:* Ad Hoc CVMP-CMDv Task Force on SPC harmonisation – mandate, objectives and rules of procedure; appointment of members of the Task Force
- ***For discussion****:* Draft public CVMP work plan for 2017
- ***For discussion:*** HMA/EMA Task Force on timetables
- ***For information:*** Extension of Common Repository to all EMA veterinary submissions

- ***For information:*** Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company
- ***For information:*** Update on multi-national assessment teams for post-authorisation procedures
- ***For information:*** Revision of dossier submission requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Medicinal Products for Veterinary use (CVMP); revised document in TC
- ***For information:*** EMA Veterinary Medicines Info Day to be held on 16-17 March 2017

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting
- ***To note***: CVMP Christmas party – 7 December 2016

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
Nov 2016	8-10				29-30		22-23	29–1	8	24-25	
Dec 2016	6-8		14-15						6		
Jan 2017	17-19			31-1			24-25	31–2	17		
Feb 2017	14-16	16	28-1		21-22	1-2			14	2-3	
Mar 2017	14-16						21-22		14		