2 September 2016
EMA/CVMP/566936/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of September 2016 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

6 September 2016, 09:00 – 8 September 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 July 2016 meeting and the August 2016 meeting by written procedure

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

Scientific Advice Working Party (room 2A)	Tue 6 Sep 2016	16.00-20.00 (TBC)

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/004380/FULL/0001 *Chickens*	***For decision***: Need for oral explanation; draft EPMAR

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

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004225/0000 *New vaccine* *Pigs*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004194/0000 *New antiparasitic product* *Cats*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/002723/0000 *New antiparasitic product* *Bees*	**ORAL EXPLANATION – Wednesday 7 September, 11:20-12:20** ***For discussion****:* Applicant's presentation, draft product information, rapporteur's assessment report of responses to LoOI, draft CVMP assessment report

2.3 List of questions

• **Product** EMEA/V/C/004331/0000 *New antiemetic product* *Dogs, cats*	***For adoption****:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **DRAXXIN** EMEA/V/C/000077/X/0029 *Extension to add a new target species* *Cattle, pigs*	Rapp: C. Friis Co-rapp: J.G. Beechinor **ORAL EXPLANATION – Tuesday 6 September, 14:00-15:00** ***For adoption:*** Final CVMP opinion, final CVMP assessment report, final product information ***For discussion***: Applicant's presentation, report from the AHEG meeting held on 1 September 2016 ***For information***: Summary of opinion

2.5 Other issues

- ***For endorsement*:** EPAR module scientific discussion for Metacam (EMEA/V/C/000033/X/0119)
- ***For endorsement*:** EPAR module scientific discussion for Sedadex (EMEA/V/C/004202/0000)
- ***For endorsement*:** EPAR module scientific discussion for ERAVAC (EMEA/V/C/004239/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Inflacam and Rheumocam** EMEA/V/C/xxxxxx/WS/0933/G *Quality*	Rapp: S. Louet ***For adoption***: CVMP opinion, CVMP assessment report, product information Inflacam, product information Rheumocam
• **DRAXXIN** EMEA/V/C/000077/II/0035 *To add wording to the SPC*	Rapp: C. Ibrahim ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Versican Plus DHPPi and Versican Plus Pi** EMEA/V/C/xxxxxx/WS/0958 *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information Versican Plus DHPPi, product information Versican Plus Pi
• **Versican Plus Pi/L4, Versican Plus DHPPi/L4 and Versican Plus L4** EMEA/V/C/xxxxxx/WS/0959 *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information Versican Plus DHPPi/L4, product information Versican Plus L4, product information Versican Plus Pi/L4
• **Bovela** EMEA/V/C/003703/II/0005/G *Quality*	Rapp: F. Klein ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **CORTAVANCE and Easotic** EMEA/V/C/xxxxxx/WS/0925 *Quality*	Rapp: C. Friis ***For adoption**:* CVMP list of outstanding issues

3.3 List of questions

• **Versican Plus DHPPi/L4, Versican Plus DHPPi, Versican Plus DHPPi/L4R** EMEA/V/C/xxxxxx/WS/0936 *Quality*	Rapp: E. Werner ***For adoption**:* List of questions
• **Broadline** EMEA/V/C/002700/II/0011 *Quality*	Rapp: B. Urbain ***For adoption***: List of questions
• **Aivlosin** EMEA/V/C/000083/II/0067/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

- No items

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

• **Zanil and associated names, and generic products thereof** EMEA/V/A/124 *Oxyclozanide* *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from France under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

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

• **OSURNIA** EMEA/V/C/003752/REC/010	Rapp: S. Louet Co-rapp: E. Lander Persson ***For adoption***: Rapporteurs' assessment report
• **Simparica** EMEA/V/C/003991/REC/008-010	Rapp: J. G. Beechinor Co-rapp: P. Hekman ***For adoption***: Rapporteurs' assessment report
• **ZOLVIX** EMEA/V/C/000154/REC/001-010	Rapp: C. Friis Co-rapp: J. G. Schefferlie ***For adoption***: Rapporteurs' assessment report

5.3 Product anniversary list

Product	**Period**
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2015 – 14/07/2016
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2015 – 05/09/2016
Cardalis (EMEA/V/C/002524)	23/07/2015 – 22/07/2016
Dexdomitor (EMEA/V/C/000070)	30/08/2015 – 29/08/2016
Emdocam (EMEA/V/C/002283)	18/08/2015 – 17/08/2016
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2015 – 07/09/2016
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2015 – 03/09/2016

Product	Period
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2015 – 31/08/2016
Nobivac L4 (EMEA/V/C/002010)	16/07/2015 – 15/07/2016
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2015 – 06/09/2016
Novaquin (EMEA/V/C/003866)	08/09/2015 – 07/09/2016
OSURNIA (EMEA/V/C/003753)	31/07/2015 – 30/07/2016
Porcilis PCV ID (EMEA/V/C/003942)	28/08/2015 – 27/08/2016
Profender (EMEA/V/C/000097)	27/07/2015 – 26/07/2016
Proteq West Nile (EMEA/V/C/002005)	05/08/2015 – 04/08/2016
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2015 – 06/08/2016
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2015 – 23/07/2016
UpCard (EMEA/V/C/003836)	31/07/2015 – 30/07/2016
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2015 – 08/08/2016
Vectormune ND (EMEA/V/C/003829)	08/09/2015 – 07/09/2016
Versican Plus L4 (EMEA/V/C/003680)	31/07/2015 – 30/07/2016
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2015 – 30/07/2016
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2015 – 30/07/2016
ZACTRAN (EMEA/V/C/000129)	24/07/2015 – 23/07/2016
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2015 – 04/08/2016
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2015 – 04/08/2016

5.4 Renewals

• **Inflacam** EMEA/V/C/002497/R/0011	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Activyl Tick Plus** EMEA/V/c/002234/R/0009	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: List of questions

5.5 Pharmacovigilance - PSURs and SARs

• **Velactis** EMEA/V/C/003739	Rapp: W. Schlumbohm ***For adoption***: CVMP assessment report on the PSUR for the period 09.12.15-30.06.16

• **Parvoduk** EMEA/V/C/002740	Rapp: F. Klein ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.11.15-30.04.16
• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.15-29.02.16
• **HALOCUR** EMEA/V/C/000040	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 30.04.13-29.04.16
• **Meloxidolor** EMEA/V/C/002590	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 23.10.15-22.04.16
• **Recuvyra** EMEA/V/C/002239	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.15-30.04.16

- ***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 discussion and endorsement***: VICH GL54 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 5
- ***For information:*** Report from 33rd VICH Steering Committee meeting and 7th Outreach Forum meeting, presentation

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

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 endorsement:*** Presentation on the CVMP strategy on Antimicrobials 2016 – 2020 to be given by the AWP chair at the 4th International Conference on Responsible Use of Antibiotics in Animals, to be held in the Hague on 26-28 September
- ***For discussion:*** Draft response to the comments received on the CVMP strategy on antimicrobials 2016-2020, following the close of the public consultation
- ***For discussion:*** CVMP/MAHs Pilot project on harmonization of old veterinary antibiotics - draft terms of reference (PPHOVA)
- ***For information:*** Feedback on the 2nd web meeting of EFSA BIOCONTAM – BIOHAZ Working Group held on 23 August 2016 concerning the request for a scientific opinion on the risk for the development of antimicrobial resistance due to feeding of calves with milk

- ***For information:*** Verbal report on the 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) teleconferences held on 14 June, 28 June, 11 July and 2 September 2016; presentation
- ***For information:*** Verbal report on the Reduction of the Need for Antimicrobials in Food Producing Animals (RONAFA) teleconference held on 22 June

8.4 Pharmacovigilance

Information on certain topics discussed under section 8.4 cannot be released at the present time as it is deemed to be confidential

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 CMDv meeting to be held on 8-9 September 2016, draft minutes of the meeting held on 14-15 July 2016

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision:*** Appointment of CVMP co-opted members at the October 2016 meeting; identification of expertise necessary for CVMP to accomplish the mandate and appointment of co-opted members, CVMP list of expertise - 2016
- ***For decision:*** Verbal report on the survey results concerning appointment of rapporteurs for CVMP procedures; summary report, individual responses; next steps; presentation

13. LEGISLATION

- ***For discussion***: Update on development of CVMP recommendations for Methodological principles for the risk assessment and risk management recommendations (*"Volume 8"*)

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
Sep 2016	6-8		22-23		13-14			19-21	6	22-23	
Oct 2016	4-6	6		11-12		20-21			4		18-19
Nov 2016	8-10				29-30			29-30	8	24-25	
Dec 2016	6-8		14-15					1	6		
Jan 2017	17-19			31			24	31	17		