7 December 2015
EMA/CVMP/823166/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

8 December 2015, 09:00 – 10 December 2015, 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 rapporteurs' meetings and breakout sessions

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/004268/FULL/0001 *All food producing species*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information:*** Summary of opinion
• **Substance** EU/10/173 *Ovine and caprine species* After provisional MRLs	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information:*** Summary of opinion

1.2 Oral explanations and list of outstanding issues

- No items

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

• **Zactran** EMEA/V/C/000129/X/0027 *Extension to add a new food producing species* *Cattle*	Rapp: C. Friis Co-rapp: J. G. Beechinor ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Bravecto** EMEA/V/C/002526/X/0005 *Extension to add a new pharmaceutical form for dogs and a new target species* *Dogs*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***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/000077/X/0029 *Extension to include a new target species to add to the solution for injection range* *Cattle, pigs*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For decision***: Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues, product information
• **Poulvac E. coli** EMEA/V/C/002007/X/0008 *Extension to include a new target species* *Chickens*	Rapp: E. Werner Co-rapp: A.-M. Brady ***For decision***: Need for oral explanation ***For adoption:*** Scientific overview and benefit-risk assessment and list of outstanding issues, product information
• **Product** EMEA/V/C/003685/0000 *Dogs New vaccine*	***For decision***: Need for oral explanation ***For adoption:*** Scientific overview and benefit-risk assessment and list of outstanding issues, product information
• **Product** EMEA/V/C/004013/0000 *New vaccine* *Chickens*	***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

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement:*** EPAR module 6 scientific discussion for **Simparica** (EMEA/V/C/003991/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **Inflacam** (EMEA/V/C/002497/X/0009)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Porcilis PCV M Hyo** EMEA/V/C/003796/II/0003 *Quality*	Rapp: E. Werner ***For adoption****:* CVMP opinion, CVMP assessment report, product information

• **Versican Plus DHPPi/L4, Versican Plus DHPPi/L4R, Versican Plus Pi/L4R, Versican Plus DHPPi, Versican Plus Pi, Versican Plus Pi/L4** EMEA/V/C/xxxxxx/WS/0754/G *Quality*	Rapp: E. Werner ***For adoption**:* CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Aivlosin** EMEA/V/C/000083/II/0064 *To change the withdrawal period*	Rapp: H. Jukes Co-rapp: E. Persson ***For adoption**:* CVMP list of questions
• **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 list of questions
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0005 *Quality*	Rapp: A.-M. Brady ***For adoption***: List of questions
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0006 *To change the vaccination schedule*	Rapp: A.-M. Brady ***For adoption***: List of questions
• **BTVPUR AlSap 1-8** EMEA/V/C/002231/II/0007/G *To replace or add an antigen*	Rapp: C. Muñoz Madero **For adoption:** List of questions
• **Bravecto** EMEA/V/C/002526/II/0007 *Quality*	Rapp: G. J. Schefferlie **For adoption:** List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Trifexis** EMEA/V/C/002635/II/0008 *To add a new indication*	Rapp: C. Ibrahim Co-rapp: T. Høy ***For discussion***: Request from Eli Lilly and Company for an extension to the clock-stop

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***: Request from Elanco Animal Health for a 3-month delay for the submission of responses to the list of questions

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 list of outstanding issues ***For discussion***: 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

- 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/REC/001 *Recommendation*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For adoption***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	Period
Acticam (EMEA/V/C/000138)	09/12/2014 – 08/12/2015
Broadline (EMEA/V/C/002700)	04/12/2014 – 03/12/2015
Contacera (EMEA/V/C/002612)	06/12/2014 – 05/12/2015
DRAXXIN (EMEA/V/C/000077)	11/11/2014 – 10/11/2015
Easotic (EMEA/V/C/000140)	20/11/2014 – 19/11/2015
Equip WNV (EMEA/V/C/000137)	21/11/2014 – 20/11/2015
Inflacam (EMEA/V/C/002497)	09/12/2014 – 08/12/2015
Masivet (EMEA/V/C/000128)	17/11/2014 – 16/11/2015
Meloxivet (EMEA/V/C/000124)	14/11/2014 – 13/11/2015
Meloxoral (EMEA/V/C/000151)	19/11/2014 – 18/11/2015
Oxyglobin (EMEA/V/C/000045)	29/11/2014 – 28/11/2015
Panacur AquaSol (EMEA/V/C/002008)	09/12/2014 – 08/12/2015
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2014 – 15/11/2015
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2014 – 06/11/2015
Quadrisol (EMEA/V/C/000032)	04/12/2014 – 03/12/2015
Stronghold (EMEA/V/C/000050)	25/11/2014 – 24/11/2015
Vectra 3D (EMEA/V/C/002555)	04/12/2014 – 03/12/2015

5.4 Renewals

• **BLUEVAC BTV8** EMEA/V/C/000156/R/0006	Rapp: E. Werner Co-rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Zuprevo** EMEA/V/C/002009/R/0010	Rapp: C. Ibrahim Co-rapp: E. Lander Persson ***For adoption***: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Advocate** EMEA/V/C/000076	Rapp: M. Nevalainen ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.04 - 30.06.15 (second targeted PSUR)

• **Vectra 3D** EMEA/V/C/002555	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for period 01.01.15 - 30.06.15
• **Cimalgex** EMEA/V/C/000162	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14 – 31.08.15
• **ECOPORC SHIGA** EMEA/V/C/002588	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15 – 31.07.15
• **NEXGARD SPECTRA** EMEA/V/C/003842	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 15.01.15 – 31.07.15
• **ProZinc** EMEA/V/C/002634	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15 – 31.07.15
• **Reconcile** EMEA/V/C/000133	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14 – 31.07.015
• **Rheumocam** EMEA/V/C/000121	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14 – 31.07.015
• **Suvaxyn PCV** EMEA/V/C/000149	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15 – 31.07.015
• **Versican Plus L4** EMEA/V/C/003680	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15 – 31.07.015

- ***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 adoption***: Revised VICH GL50 on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use, for sign-off for publication at step 3

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For discussion***: EFSA mandate on the risk for the development of AMR from raw milk due to feeding of calves with milk containing residues of antibiotics - *See also 8.3*
- ***For information***: EFSA request for CVMP expert in the Working Group on *Echinococcus multilocularis* - scientific opinion

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

8.3 Antimicrobial resistance

- ***For discussion***: EFSA mandate on the risk for the development of AMR from raw milk due to feeding of calves with milk containing residues of antibiotics - *See also 6.3*
- ***For discussion***: AWP comments on Emergence of plasmid-mediated colistin resistance mechanism MCR-1 in animals and humans beings in China: a microbiological and molecular biology study; Colistin resistance: a major breach in our last line of defence
- ***For information***: Report of the EC workshop: the impact on public health and animal health of the use of antibiotics in animals, analysis of the EMA scientific advice; agenda of the workshop: (http://ec.europa.eu/dgs/health_food-safety/docs/amr-20151126-workshop-agenda_en.pdf)

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

- ***For information***: Verbal update on the first meeting of the ad hoc expert group on RD114 held on 2-3 December 2015; agenda of the meeting

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 10-11 December 2015; draft minutes of the meeting held on 5-6 November 2015

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: Guideline on the principles for preparing assessment reports for veterinary medicinal products, and template guidance for scientific overview and list of questions
- ***For adoption***: Presidency CVMP and Joint CVMP/CMDv meetings, held on 21-22 September in Luxembourg; draft minutes of CVMP presidency meeting; draft minutes of joint CVMP/CMDv presidency meeting

- ***For adoption***: CVMP planning tool for on-going and future activities
- ***For decision****:* Appointment of CVMP co-opted members - Nominations received:

  - Environmental risk assessment

  - Antimicrobials and antimicrobials resistance
- ***For discussion****:* Draft public CVMP work plan for 2016
- ***For information***: Verbal report from the Strategic Planning Group (SPG) to be held on 9 December, draft agenda; draft minutes from the meeting held on 8 October 2015
- ***For information***: EMA/IFAH Infoday to be held on 17-18 March 2016, draft programme
- ***To note****:* Table of actions following the November 2015 CVMP meeting

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
Dec 2015	8-10	10	10	2-3	1-2			1-3	8	3-4
Jan 2016	19-21						26-27		19	
Feb 2016	16-18	18	23-24	2-3	23-24	11-12		3-5	16	
Mar 2016	15-17						22-23		15	3-4
Apr 2016	19-21								19	