7 September 2015
EMA/CVMP/593362/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of September 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

8 September 2015, 09:00 – 10 September 2015, 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 held on 7-9 July 2015 and of the August 2015 CVMP meeting by written procedure

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

Scientific Advice Working Party (room 3E)	Tue 8 Sept 15	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

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/003669/EXPL/0002 *Extrapolation request under Art. 27*	***For discussion**:* Rapporteur's EPMAR
• **Substance** EMEA/V/MRL/002993/FULL/0002 *Use in bovine species*	***For discussion**:* Request to delay the submission of the responses to the list of outstanding issues

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/003782/0000 *New corticosteroid product* *Dogs*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/003991/0000 *New ectoparasiticide* *Dogs*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/003924/0000 *New viral and bacterial 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/002590/0000 *New hormonal product* *Cattle*	**ORAL EXPLANATION – Tuesday 8 September, 11.30** ***For discussion:*** Applicant's presentation, CVMP assessment report, product information

• **Product** EMEA/V/C/002763/0000 *New product for treatment of mastitis* *Cattle*	**ORAL EXPLANATION – Tuesday 8 September, 14.00** ***For discussion:*** Applicant's presentation, CVMP assessment report, product information
• **Bravecto** **EMEA/V/C/002526/X/0005** *Extension to add a new pharmaceutical form* *Dogs and cats*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and benefit-risk assessment and LoOI, product information combined for dogs and cats

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/002390 *New vaccine* *Atlantic salmon*	***For adoption***: List of participants for the AHEG meeting to be held on 21 and 22 September 2015, mandate

- ***For endorsement:*** EPAR module 6 scientific discussion for Porcilis PCV ID (EMEA/V/C/003942/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for Vectormune ND (EMEA/V/C/003829/0000)
- ***For endorsement*****:** EPAR module 6 scientific discussion for FORTEKOR PLUS (EMEA/V/C/002804/0000)
- ***For endorsement*****:** EPAR module 6 scientific discussion for Novaquin (EMEA/V/C/003866/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Circovac, Eurican Herpes 205, Ibraxion, Purevax RCPCh FeLV and Purevax RCPCh** EMEA/V/C/XXXXXX/WS/0774 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report
• **RESPIPORC FLU3** EMEA/V/C/000153/II/0010 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report

• **Gripovac 3** EMEA/V/C/000157/II/0008 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report
• **SevoFlo** EMEA/V/C/000072/II/0016 *Quality*	Rapp: J.G. Beechinor ***For adoption***: CVMP opinion, CVMP assessment report
• **Ingelvac CircoFLEX** EMEA/V/C/000126/II/0020 *Quality*	Rapp: M. Tollis ***For adoption****:* CVMP opinion, CVMP assessment report
• **Aivlosin** EMEA/V/C/000083/II/0062/G *Quality*	Rapp: H. Jukes ***For adoption****:* CVMP opinion, CVMP assessment report
• **NexGard, NexGard Spectra** EMEA/V/C/XXXXXX/WS/0756 *Quality*	Rapp: P. Hekman ***For adoption****:* CVMP opinion, CVMP assessment report
• **ZULVAC SBV** EMEA/V/C/002781/II/0002/G *To change the vaccination schedule in sheep, and to extend the DOI in cattle*	Rapp: A.-M. Brady ***For adoption****:* CVMP opinion, CVMP assessment report, product information
• **Versican Plus DHPPi/L4R, Versican Plus Pi/L4R, Versican Plus Pi/L4, Versican Plus DHPPi/L4, Versican Plus DHPPi, Versican Plus Pi** EMEA/V/C/XXXXXXX/WS/0753/G *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report
• **Eurican Herpes 205** EMEA/V/C/000059/II/0017 *Quality*	Rapp: A.-M. Brady ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **STARTVAC** EMEA/V/C/000130/II/0003/G *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information

3.2 Oral explanations and list of outstanding issues

• **DRAXXIN** EMEA/V/C/000077/II/0031 *Additional indication*	Rapp: C. Ibrahim Co-rapp: C. Munoz ***For adoption****:* List of outstanding issues

3.3 List of questions

• **Porcilis PCV M Hyo** EMEA/V/C/003796/II/0003 *Quality*	Rapp: E. Werner ***For adoption**:* CVMP list of questions
• **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/XXXXXXX/WS/0754/G *Quality*	Rapp: E. Werner ***For adoption:*** CVMP 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

• **Denagard 45% and associated names** EMEA/V/A/114 *Tiamulin hydrogen fumarate* *SPC harmonisation*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: List of questions, timetable ***For discussion and decision***: Notification from Germany under Article 34 of Directive 2001/82/EC and Annex to the notification Appointment of rapporteur, co-rapporteur and peer reviewers. ***For information***:List of products concerned

4.3 Article 35 of Directive 2001/82/EC

- No items

4.4 Article 78 of Directive 2001/82/EC

• **Closamectin pour-on solution and associated names** EMEA/V/A/113 *Animal safety*	Rapp: J.-C. Rouby Co-rapp: H. Jukes **ORAL EXPLANATION – 9 September 2015, 11.30** ***For discussion***: Presentation from Norbrook Laboratories Ltd, rapporteurs assessment report including co-rapporteur's comments, report from peer reviewer, report from peer reviewer

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

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

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

5.1 General issues

- No Items

5.2 Post-authorisation measures and annual reassessments

• **Equip WNV** EMEA/V/C/000137/REC/022	Rapp: J.-C. Rouby Co-rapp: M. Tollis ***For adoption***: Rapporteur's assessment report
• **Nobilis IB Primo QX** EMEA/V/C/002802/ANX/001	Rapp: A.-M. Brady Co-rapp: J.-C. Rouby ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2014 – 14/07/2015
Aivlosin (EMEA/V/C/000083)	09/09/2014 – 08/09/2015
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2014 – 05/09/2015
Cardalis (EMEA/V/C/002524)	23/07/2014 – 22/07/2015
Dexdomitor (EMEA/V/C/000070)	30/08/2014 – 29/08/2015
Emdocam (EMEA/V/C/002283)	18/08/2014 – 17/08/2015
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2014 – 03/09/2015

Product	Period
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2014 – 31/08/2015
Nobivac Bb for cats (EMEA/V/C/000068)	10/09/2014 – 09/09/2015
Nobivac L4 (EMEA/V/C/002010)	16/07/2014 – 15/07/2015
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2014 – 08/09/2015
OSURNIA (EMEA/V/C/003753)	31/07/2014 – 30/07/2015
Profender (EMEA/V/C/000097)	27/07/2014 – 26/07/2015
Proteq West Nile (EMEA/V/C/002005)	05/08/2014 – 04/08/2015
ProZinc (EMEA/V/C/002634)	12/07/2014 – 11/07/2015
Suprelorin (EMEA/V/C/000109)	10/07/2014 – 09/07/2015
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2014 – 06/08/2015
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2014 – 23/07/2015
Trocoxil (EMEA/V/C/000132)	09/09/2014 – 08/09/2015
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2014 – 08/08/2015
Versican Plus L4 (EMEA/V/C/003680)	31/07/2014 – 30/07/2015
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2014 – 30/07/2015
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2014 – 30/07/2015
ZACTRAN (EMEA/V/C/000129)	24/07/2014 – 23/07/2015
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2014 – 04/08/2015
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2014 – 04/08/2015

5.4 Renewals

• **Cimalgex** EMEA/V/C/000162/R/0002	Rapp: F. Hasslung Wikström Co-rapp: B. Urbain ***For adoption***: List of outstanding issues
• **Hiprabovis IBR Marker Live** EMEA/V/C/000158/R/0007	Rapp: A.-M. Brady Co-rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- ***For adoption***: Parvoduk CVMP assessment report on post authorization safety study
- ***For decision:*** Nobivac L4 (EMEA/V/C/002010) PSUR For the period 01.08.14-31.01.15 MAH request to reconsider the recommendation of the PSUR outcome; CVMP assessment report

• **Fungitraxx** EMEA/V/C/002722	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.14 – 31.03.15
• **Meloxidolor** EMEA/V/C/002590	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 22.10.14 – 22.04.15

• **Meloxoral** EMEA/V/C/000151	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 19.05.14 – 19.05.15
• **Nobilis IB 4-91** EMEA/V/C/000036	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13 – 31.03.15
• **Parvoduk** EMEA/V/C/002740	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.14 – 30.04.15
• **Porcilis AR-T DF** EMEA/V/C/000055	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14 – 31.05.15
• **Porcilis PCV M Hyo** EMEA/V/C/003796	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 07.11.14 – 31.05.15
• **Recuvyra** EMEA/V/C/002239	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.14 – 30.04.15
• **Versican Plus DHPPi/L4** EMEA/V/C/003678	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.14 – 31.05.15
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.14 – 31.05.15

- ***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 adoption***: VICH GL52 Bioequivalence: blood level bioequivalence study

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

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

Information on certain antimicrobial resistance related issues cannot be released at the present time as it is deemed to be confidential

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***: Agenda of the meeting to be held on 10-11 September 2015; minutes of the meeting held 9-10 July 2015*;* presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion and adoption***: Presidency CVMP and Joint CVMP/CMDv meetings, to be held on 21-22 September in Luxembourg; draft agenda CVMP presidency meeting, draft agenda joint CVMP/CMDv presidency meeting
- ***For discussion***: Guideline on the principles for preparing assessment reports for veterinary medicinal products; guidance template
- ***For information:*** Verbal report from the CVMP chair on the CVMP questionnaire on the functioning of the Committee
- ***For information:*** Verbal report from the CVMP chair on the Scientific Coordination Board on 29 June 2015, agenda of the meeting
- ***For information:*** Update on recent confidentiality arrangements with third country regulators and organisations
- ***For information:*** EMA 20th Anniversary programme

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
Sept 2015	8-10	10	23-24		15-16		22-23	30 Sept-2 Oct	8	24-25
Oct 2015	6-8			13-14		20-21			6	
Nov 2015	4-6						24-25		4	
Dec 2015	8-10		2-3		1-2			1-3	8	3-4
Jan 2016	TBC								TBC	