6 July 2015
EMA/CVMP/452291/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of July 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

7 July 2015, 09:00 – 9 July 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 rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 2A)	Tue 7 July 2015	16.00–20.00

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/004047/FULL/0001 Caprine species, *Equidae*, finfish and rabbits	***For adoption****:* CVMP list of outstanding issues

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

• **Product** EMEA/V/C/002804/0000 *New cardiovascular product* *Dogs*	***For adoption***: CVMP opinion, CVMP assessment report, divergent position, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/003942/0000 *New viral vaccine* *Pigs*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Product** EMEA/V/C/003829/0000 *New live viral vaccine* *Chickens*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

• **Product** EMEA/V/C/003866/0000 *New anti-inflammatory product* *Horses*	***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/003991/0000 *New ectoparasiticide* *Dogs*	***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/003782/0000 *New corticosteroid product* *Dogs*	***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/003924/0000 *New viral and bacterial vaccine* *Pigs*	***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

• **Inflacam** EMEA/V/C/002497/X/0009 *Extension to add a new strength and a new pharmaceutical form* *Horses*	Rapp: M. Holzhauser-Alberti Co-rapp: E.-M. Vestergaard ***For adoption****:* Scientific overview and benefit-risk assessment and list of questions, comments on PI, assessment and LoQ of ASMF applicant's and restricted parts

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement*:** Refusal EPAR - scientific discussion for **Lodipressin** (EMEA/V/C/003786/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **Innovax ILT** (EMEA/V/C/003869/0000)
- ***For endorsement*:** EPAR module 6 scientific discussion for **UpCard** (EMEA/V/C/003836/0000)
- ***For endorsement*:** EPAR module 6 scientific discussion for **Canigen L4** (EMEA/V/C/004079/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Hiprabovis IBR Marker Live** EMEA/V/C/00158/II/0006 *Quality*	Rapp: A.-M. Brady Co-rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Advocate** EMEA/V/C/000076/II/0026/G *New indication for dogs*	Rapp: M. Nevalainen Co-rapp: M. Azevedo Mendes ***For adoption****:* CVMP opinion, CVMP assessment report, product information
• **Suvaxyn CSF Marker** EMEA/V/C/002757/II/0002 *Quality*	Rapp: M. Blixenkrone-Møller ***For adoption:*** CVMP opinion, CVMP assessment report
• **Purevax RCPCh and Purevax RCPCh FeLV** EMEA/V/C/XXXX/WS/0759 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report
• **Oxyglobin** EMEA/V/C/000045/II/0021 *Quality*	Rapp: R. Breathnach ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Ingelvac CircoFLEX** EMEA/V/C/000126/II/0019 *To update the product information*	Rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information

3.2 Oral explanations and list of outstanding issues

• **Aivlosin** EMEA/V/C/000083/II/0062/G *Quality*	Rapp: H. Jukes ***For adoption****:* CVMP list of outstanding issues

3.3 List of questions

• **Eurican Herpes 205** EMEA/V/C/000059/II/0017 *Quality*	Rapp: A.-M. Brady ***For adoption**:* CVMP list of questions
• **Hiprabovis IBR Marker Live** EMEA/V/C/000158/II/0005 *Quality*	Rapp: A.-M. Brady ***For adoption**:* CVMP list of questions
• **Vaxxitek HVT + IBD** EMEA/V/C/000065/II/0016 *Quality*	Rapp: B. Urbain ***For adoption:*** CVMP list of questions
• **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 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

- 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: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: Timetable, List of questions ***For discussion and decision***: Notification from France under Article 78 of Directive 2001/82/EC and assessment report Appointment of rapporteur, co-rapporteur and peer reviewers.

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 relating to certain referrals issues 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

• **Activyl** EMEA/V/C/000163/REC/004-005-006	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: Rapporteur's assessment report
• **Zulvac SBV** EMEA/V/C/002781/ANX/004	Rapp: A.-M. Brady Co-rapp: G. Kulcsár ***For adoption***: Rapporteur's assessment report
• **Nobivac L4** EMEA/V/C/002010/REC/001	Rapp: B. Urbain Co-rapp: R. Breathnach ***For adoption***:Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
Circovac (EMEA/V/C/000114)	21/06/2014 - 20/06/2015
Convenia (EMEA/V/C/000098)	19/06/2014 - 18/06/2015
Equilis Prequenza (EMEA/V/C/000094)	08/07/2014 - 07/07/2015
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2014 - 07/07/2015
Equilis Te (EMEA/V/C/000093)	08/07/2014 - 07/07/2015
Equilis West Nile (EMEA/V/C/0)02241	06/06/2014 - 05/06/2015
EQUIOXX (EMEA/V/C/000142)	25/06/2014 - 24/06/2015
ERYSENG (EMEA/V/C/002761)	04/07/2014 - 03/07/2015
ERYSENG PARVO (EMEA/V/C/002762)	08/07/2014 - 07/07/2015
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25/06/2014 - 24/06/2015
LEUCOGEN (EMEA/V/C/000144)	17/06/2014 - 16/06/2015
Melovem (EMEA/V/C/000152)	07/07/2014 - 06/07/2015
MS-H vaccine (EMEA/V/C/000161)	14/06/2014 - 13/06/2015
Nobilis IB4-91 (EMEA/V/C/000036)	09/06/2014 - 08/06/2015
Porcilis ColiClos (EMEA/V/C/002011)	14/06/2014 - 13/06/2015
Porcilis Pesti (EMEA/V/C/000046)	09/06/2014 - 08/06/2015
Posatex (EMEA/V/C/000122)	23/06/2014 - 22/06/2015
Poulvac E. coli (EMEA/V/C/002007)	15/06/2014 - 14/06/2015
PRILACTONE (EMEA/V/C/000105)	20/06/2014 - 19/06/2015
Reconcile (EMEA/V/C/000133)	08/07/2014 - 07/07/2015
Vectra Felis (EMEA/V/C/002746)	06/06/2014 - 05/06/2015
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2014 - 03/07/2015
Versican Plus Pi (EMEA/V/C/003681)	04/07/2014 - 03/07/2015

5.4 Renewals

• **BTVPUR AlSap 1** EMEA/V/C/002230/R/0005	Rapp: C. Muñoz Madero Co-rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information

• **BTVPUR AlSap 1-8** EMEA/V/C/002231/R/0005	Rapp: C. Muñoz Madero Co-rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Meloxoral** EMEA/V/C/000151/R/0006	Rapp: H. Jukes Co-rapp: C. Ibrahim ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **COXEVAC** EMEA/V/C/000155	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-31.03.15
• **Nobivac L4** EMEA/V/C/002010	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **Pexion** EMEA/V/C/002543	Rapp: M. Holzhauser-Albert ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15
• **Purevax RC** EMEA/V/C/000091	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.12-28.02.15
• **Purevax RCP** EMEA/V/C/000090	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.12-28.02.15
• **Purevax RCP FeLV** EMEA/V/C/000089	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.12-28.02.15
• **Purevax RCPCh** EMEA/V/C/000088	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.12-28.02.15
• **Purevax RCPCh FeLV** EMEA/V/C/000085	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.12-28.02.15

• **BLUEVAC BTV8** EMEA/V/C/000156	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.14-31.10.14
• **Bovilis BTV8** EMEA/V/C/000148	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.14-31.03.15
• **Bravecto** EMEA/V/C/002526	Rapp: G.J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15
• **Proteq West Nile** EMEA/V/C/002005	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-28.02.15
• **Purevax Rabies** EMEA/V/C/002003	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-28.02.15
• **RevitaCAM** EMEA/V/C/002379	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15
• **RHINISENG** EMEA/V/C/000160	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-31.03.15
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15

- ***For adoption:*** Parvoduk CVMP assessment report on post authorization safety study
- ***For endorsement:*** Surveillance analysis findings for ZOLVIX
- ***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 endorsement***: Restart of the ESI EWG to ensure maintenance of GL30 Pharmacovigilance standard lists and review of IFAH document on impact of disharmonisation

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

- ***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 information:*** Verbal report from the meeting of the European Commission Working Group on Antimicrobial Resistance held on Brussels on 1 July 2015

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 9-10 July 2015; minutes of the meeting held 4-5 June 2015

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion and decision***: Presidency meeting to be held on 21-22 September 2015 in Luxembourg; draft CVMP presidency meeting agenda for the CVMP session and draft joint CVMP-CMDv informal meeting agenda
- ***For discussion***: Guideline on the principles for preparing assessment reports for veterinary medicinal products
- ***For endorsement:*** Information on revised CVMP meeting dates for 2016 onwards
- ***For information:*** Verbal report from the CVMP chair on the Scientific Coordination Board on 29 June 2015, agenda of the meeting

- ***For information:*** Draft minutes of the CVMP Interested Parties' Meeting held on 6 May 2015

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
July 2015	7-9								7	
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	