2 October 2015
EMA/CVMP/654741/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

6 October 2015, 09:00 – 8 October 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

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

Scientific Advice Working Party (room 3E)	Tue 6 October 2015	16.00-20.00 (TBC)

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003669/EXPL/0002 *Art. 27 extrapolation*	***For adoption***: CVMP opinion including EPMAR ***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

• **Product** EMEA/V/C/003739/0000 *New hormonal product* *Cattle*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/002763/0000 *New product for treatment of mastitis* *Cattle*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Inflacam** EMEA/V/C/002497/X/0009 *Extension to add a new strength and a new pharmaceutical form* *Horses*	Rapp: J.-C. Rouby Co-rapp: E.-M. Vestergaard ***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/002390 *New vaccine for Atlantic salmon*	***For discussion***: Verbal report from the Ad hoc expert group (AHEG) to CVMP ***For adoption***: Scientific overview and benefit-risk assessment and LoOI, product information

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- No items

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Hiprabovis IBR Marker Live** EMEA/V/C/000158/II/0005 *Quality*	Rapp: A.-M. Brady ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Ibraxion, Purevax RCPCh, Purevax RCPCh FeLV** EMEA/V/C/XXXXXXX/WS/0818 *Quality*	Rapp: B. Urbain ***For adoption:*** CVMP opinion, CVMP assessment report
• **Vaxxitek HVT+IBD** EMEA/V/C/000065/II/0016 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP Opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Nobilis IB4-91** EMEA/V/C/000036/II/0021/G *Quality*	Rapp: A.-M. Brady ***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

• **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys** *(Amoxicillin)* EMEA/V/A/112 *Bioequivalence and prudent use advice*	Rapp: E.-M. Vestergaard Co-rapp: H. Jukes ***For decision***: Need for outstanding issues ***For decision***: Applicant's request to provide an oral explanation ***For discussion***: Rapporteur's assessment report, co-rapporteur's assessment report
• **CattleMarker IBR Inactivated emulsion for injection for cattle** *(Infectious bovine rhinotracheitis (IBR) vaccine)* EMEA/V/A/115 *target animal safety*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision***: Notification from Belgium under Article 33(4) of Directive 2001/82/EC

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: J.-C. Rouby Co-rapp: H. Jukes ***For adoption***: CVMP opinion, CVMP assessment report

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

• **ZOLVIX** EMEA/V/C/000154/REC/027-028 *Recommendations - quality*	Rapp: C. Friis Co-rapp: G. J. Schefferlie ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
APOQUEL (EMEA/V/C/002688)	12/09/2014 – 11/09/2015
Cerenia (EMEA/V/C/000106)	29/09/2014 – 28/09/2015
COXEVAC (EMEA/V/C/000155)	30/09/2014 – 29/09/2015
Palladia (EMEA/V/C/000150)	23/09/2014 – 22/09/2015
Previcox (EMEA/V/C/000082)	13/09/2014 – 12/09/2015
Recocam (EMEA/V/C/002247)	13/09/2014 – 12/09/2015
Recuvyra (EMEA/V/C/002239)	06/10/2014 – 05/10/2015
RHINISENG (EMEA/V/C/000160)	16/09/2014 – 15/09/2015
Trifexis (EMEA/V/C/002635)	19/09/2013 – 18/09/2015

5.4 Renewals

• **Activyl** EMEA/V/C/000163/R/0008	Rapp: G.J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: List of outstanding issues
• **CaniLeish** EMEA/V/C/002233/R/0015	Rapp: J.-C. Rouby Co-rapp: M. Tollis ***For adoption***: List of outstanding issues
• **Cimalgex** EMEA/V/C/000162/R/0002	Rapp: F. Hasslung Wikström Co-rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Comfortis** EMEA/V/C/002233/R/0015	Rapp: C. Ibrahim Co-rapp: T. Høy ***For adoption***: CVMP opinion, CVMP assessment report, product information

• **Purevax Rabies** EMEA/V/C/002003/R/0004	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- ***For adoption***: Nobivac Myxo RHD CVMP assessment report on post authorisation safety study

• **Apoquel** EMEA/V/C/002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for period 01.12.14-31.05.15
• **Bovela** EMEA/V/C/003703	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for period 22.12.14-30.06.15
• **BTVPUR AlSap 2-4** EMEA/V/C/000139	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for period 01.12.14-31.05.15
• **Contacera** EMEA/V/C/002612	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for period 01.01.15-30.06.15
• **Equip WNV** EMEA/V/C/000137	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for period 22.11.14-31.05.15
• **Fevaxyn Pentofel** EMEA/V/C/000030	Rapp: E. M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for period 01.07.12-30.06.15
• **Meloxivet** EMEA/V/C/000124	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for period 01.06.12-31.05.15
• **MS-H vaccine** EMEA/V/C/000161	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for period 15.06.14-14.06.15
• **Oncept IL-2** EMEA/V/C/002562	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for period 01.12.14-31.05.15

• **Panacur AquaSol** EMEA/V/C/002008	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for period 01.01.15-30.06.15
• **Vectra Felis** EMEA/V/C/002746	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for period 01.01.15-30.06.15

- ***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 endorsement***: Updated draft VICH guideline on Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: residue studies in honey to be forwarded to the expert working group
- ***For information***: 32nd VICH Steering Committee meeting to be held on 25, 26 and 30 October 2015 in Tokyo, Japan.

6.2 Codex Alimentarius

- ***For discussion***: Codex Alimentarius work on antimicrobial resistance – request for information and comments

6.3 Other EU bodies and international organisations

- ***For information:*** Feedback on EFSA expert meeting on reference points for action for malachite green
- ***For information:*** Feedback on EFSA expert meeting on review of diflubenzuron
- ***For information:*** Feedback on EFSA expert meeting developing guidance on the establishment of the residue definition for dietary risk assessment; mandate for the EFSA work

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

- ***For information***: Verbal report on the ESVAC 5th annual report: sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2013
- ***For information***: Verbal report on the RONAFA (Joint EFSA/EMA 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) meeting held on 15 September 2015 in Parma

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 the meeting to be held on 8-9 October 2015; draft minutes of the meeting held 10-11 September 2015

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: 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 information***: Verbal report from the Strategic Planning Group (SPG) to be held on 8 October 2015, draft agenda; draft minutes from the meeting held on 3 June 2015
- ***For information:*** New booking policy for non-reimbursed delegates

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	19-21								TBC	