9 March 2015
EMA/CVMP/159020/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of March 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

10 March 2015, 09:00 - 12 March 2015, 13:00 - Room 3A

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 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 3A)	Tue 10 March 2015	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

• **Substance** EMEA/V/MRL/003988/FULL/0001 *Bovine*	***For decision***: Need for oral explanation ***For discussion***: Joint rapporteurs' assessment of the responses to the list of questions, joint rapporteurs EPMAR after list of questions, peer reviewers' reports

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/003135/MODF/0003 *Salmonidae*	***For discussion****:* Rapporteur's assessment of responses to list of questions, rapporteur's EPMAR, peer reviewers' reports

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Rheumocam** EMEA/V/C/000121/X/0015 *Extension to include a new strength* *Horses*	Rapp: M. Holzhauser-Alberti 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/002590/0000 *New hormonal product* *Cattle*	***For decision:*** Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information

• **Product** *EMEA/V/C/003869/0000* *New viral vaccine* *Chickens*	**For decision:** Need for oral explanation **For adoption**: Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/004079/0000 *New bacterial vaccine* *Dogs*	***For adoption****:* Scientific overview and benefit-risk assessment and list of questions, comments on 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 adoption****:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/003685/0000 *New vaccine* *Dogs*	***For adoption****:* Scientific overview and benefit-risk assessment and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **Product** EMEA/V/C/003786/0000 *New cardiovascular product* *Cats*	Rapp: C. Ibrahim Co-rapp: H. Jukes ***For adoption****:* Draft list of questions to AHEG ***For endorsement****:* List of AHEG members, draft agenda for AHEG meeting, list of documents to be sent to AHEG members, draft re-examination timetable

2.5 Other issues

- ***For endorsement:*** EPAR module 6 scientific discussion for **Coliprotec F4** (EMEA/V/C/003797/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **COXEVAC** (EMEA/V/C/000155/S/0007)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **BROADLINE** EMEA/V/C/002700/II/0001 *To add new indications*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report ***For information:*** Summary of opinion
• **Nobilis IB4-91** EMEA/V/C/000036/WS/0607(0019) *To add a claim for the mixed-use*	Rapp: A.-M. Brady Co-rapp: J.-C. Rouby ***For adoption***: CVMP opinion, CVMP assessment report
• **Versican Plus DHPPi; Versican Plus DHPPi/L4R; Versican Plus DHPPi/L4** EMEA/V/C/XXXXXX/WS/0620 *To extend the duration of immunity*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report
• **DRAXXIN** EMEA/V/C/000077/II/0034 *To change the withdrawal periods*	Rapp: C. Ibrahim ***For adoption****:* CVMP opinion, CVMP assessment report ***For information:*** Summary of opinion

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **COXEVAC** EMEA/V/C/000155/II/0008/G *Quality*	Rapp: J.-C. Rouby ***For adoption****:* List of questions
• **BTVPUR AlSap range** EMEA/V/C/XXXXXX/WS/0669 *Quality*	Rapp: M. Tollis ***For adoption***: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **DRAXXIN** EMEA/V/C/0000077/II/0031 *To add a new indication*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For discussion**:* Revised request from Zoetis Belgium SA to extend the clock-stop period

4 REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

• **Coglapix vakcina A.U.V. suspension for injection for pigs** *(Actinobacillus pleuropneumoniae strains serotype 1 and 2)* EMEA/V/A/109 *Efficacy*	Rapp: M. Tollis Co-rapp: G. Kulcsár ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report, Co-rapporteur's assessment report

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

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

- No items

4.6 Article 30(3) of Regulation 726/2004

• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For discussion***: Draft CVMP assessment report

4.7 Other issues

- No items

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

5.1 General issues

Information on certain topics discussed under section 5.1 cannot be released at the present time as it is deemed to be confidential

5.2 Post-authorisation measures and annual reassessments

• **Equilis Te** EMEA/V/C/000093	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

The following 23 items are for silent endorsement

Product	**Period**
Activyl (EMEA/V/C/000163)	18/02/2014 – 17/02/2015
Cimalgex (EMEA/V/C/000162)	18/02/2014 – 17/02/2015
Econor (EMEA/V/C/000042)	12/03/2014 – 11/03/2015
Equisolon (EMEA/V/C)/002382	12/03/2014 – 11/03/2015
Fungitraxx (EMEA/V/C/002722)	12/03/2014 – 11/03/2015
Ibraxion (EMEA/V/C/000051	09/03/2014 – 08/03/2015
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2014 – 12/02/2015
Melosus (EMEA/V/C/002001)	21/02/2014 – 20/02/2015
Novem (EMEA/V/C/000086)	02/03/2014 – 01/03/2015
Pexion (EMEA/V/C/002543)	25/02/2014 – 24/02/2015
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	28/02/2014 – 27/02/2015
ProteqFlu (EMEA/V/C/000073)	06/03/2014 – 05/03/2015
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2014 – 05/03/2015
Purevax Rabies (EMEA/V/C/002003)	18/02/2014 – 17/02/2015
Purevax RC (EMEA/V/C/000091)	23/02/2014 – 22/02/2015
Purevax RCCh (EMEA/V/C/000092)	23/02/2014 – 22/02/2015
Purevax RCP (EMEA/V/C/000090)	23/02/2014 – 22/02/2015
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2014 – 22/02/2015
Purevax RCPCh (EMEA/V/C/000088)	23/02/2014 – 22/02/2015
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2014 – 22/02/2015

Product	Period
RevitaCAM (EMEA/V/C/002379)	23/02/2014 – 22/02/2015
Semintra (EMEA/V/C/002436)	13/02/2014 – 12/02/2015
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08/03/2014 – 07/03/2015

5.4 Renewals

• **Equilis Te** EMEA/V/C/000093/R/0006	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Cimalgex** EMEA/V/C/000162/PSU/008	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-31.08.14
• **Eurican Herpes 205** EMEA/V/C/000059/PSU/018	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.11-30.09.14
• **NexGard** EMEA/V/C/002729/PSU/002	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.08.14
• **Procox** EMEA/V/C/002006/PSU/007	Rapp: E. Lander Persson ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.13-31.10.14
• **Recuvyra** EMEA/V/C/002239/PSU/011	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.14.31.10.14
• **Veraflox** EMEA/V/C/000159/PSU/013	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.13-30.10.14

- ***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***: Revised draft guideline by EU topic leader on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for circulation to MRK EWG
- ***For adoption***: VICH guideline 54: Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish an acute reference dose (ARfD); for formal adoption for consultation at step 4 in the EU
- ***For adoption:*** VICH guideline 53 on electronic exchange of documents: electronic file formats for formal adoption following sign off by the VICH Steering Committee at step 6, for implementation in the EU at step 7

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information:*** EFSA's public consultation on conclusions and recommendations of the EFSA/WHO expert working group on threshold of toxicological concern approach http://www.efsa.europa.eu/en/consultations/call/150212.htm

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 from the ESVAC annual network meeting to be held on 3-4 March 2015
- ***For information***: Principles on assignment of defined daily dose for animals (DDDA) and defined course dose for animals (DCDA)

8.4 Pharmacovigilance

- No items

8.5 Other issues

- 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

- ***For decision*:** Timing for appointment of rapporteurs

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information***: Agenda of the meeting to be held on 12-13 March 2015; minutes of the meeting held 12-13 February 2015

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Report from break-out session on CVMP implementation of multinational assessment teams
- ***For information***: Verbal report from the chair of the Strategic Planning Group meeting to be held on 11 March; draft agenda, draft minutes
- ***For information***: CVMP Interested Parties' meeting to be held on 6 May 2015: first announcement/invitation, and draft minutes of previous meeting held on 7 May 2014
- ***To note****:* Table of actions following the February 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	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP
Mar. 2015	10-12				26-27	24-25		10	
April 2015	8-10							8	
May 2015	5-7	12-13		19-20		26-27	26–28	5	21-22
June 2015	2-4		16-17		17-18	30 Jun-1 Jul		2	
July 2015	7-9							7	
Sept 2015	8-10					22-23		8	