13 March 2018
EMA/CVMP/125055/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of March 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

13 March 2018, 09:00 – 15 March 2018, 13:00 - Room 3A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of competing 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 CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP 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. Intended participation and competing 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, 13 March 2018	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003647/EXTN/0002 *Porcine*	***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

• **Substance** EMEA/V/MRL/003135/MODF/0003 *Salmonidae*	***For adoption**:* CVMP opinion including EPMAR, CVMP assessment report ***For information***: Summary of opinion

1.5 Other issues

• **Substance** EMEA/V/MRL/004543/FULL/0001 *Equidae*	***For information**:* Letter of withdrawal of the application

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004440/0000 *New antiparasitic product* *Cats*	**ORAL EXPLANATION – Tuesday 13 March 2018** ***For discussion**:* Rapporteur's assessment report of responses to list of outstanding issues, presentation from applicant ***For adoption**:* Draft CVMP opinion, draft CVMP assessment report, draft product information ***For information**:* Summary of opinion
• **Product** EMEA/V/C/002436/X/0008 *To add a new strength* *Cats*	***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/0002836/0000 *New antiparasitic product* *Honey bees*	**ORAL EXPLANATION – Wednesday 14 March 2018** ***For discussion**:* Presentation from applicant, rapporteurs' assessment of responses to list of outstanding issues; draft product information
• **Product** EMEA/V/C/004265/0000 *New product for musculo-skeletal disorder* *Horses*	**ORAL EXPLANATION – Wednesday 14 March 2018** ***For discussion**:* Presentation from applicant, rapporteurs' assessment report of responses to list of outstanding issues, draft product information
• **Product** EMEA/V/C/004595/0000 *New vaccine* *Cows and heifers*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues; comments on product information

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For information:*** Revised EPAR module scientific discussion for **Oxybee** (EMEA/V/C/004296/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Onsior** EMEA/V/C/000127/II/0018/G *To add a new therapeutic indication and to make changes in the PI*	Rapp: G. J. Schefferlie Co-rapp: E.-M. Vestergaard ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Activyl Tick Plus** EMEA/V/C/002234/II/0011 *To change conditions regarding supply and use*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

• **Zolvix** EMEA/V/C/000154/II/0023/G *Quality*	Rapp: E.-M. Vestergaard ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Naxcel and NAPs** EMEA/V/C/WS1241 *Quality*	Rapp: S. Louet ***For adoption***: CVMP opinion **For endorsement**: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **LEUCOGEN, LEUCOFELIGEN FeLV/RCP, Nobivac LeuFel** EMEA/V/C/xxxxxx/WS1282 *Changes in the PI*	Rapp: E. Werner ***For adoption***: List of questions ***For information***: product information for LEUCOGEN, product information for LEUCOFELIGEN FeLV/RCP, product information for Nobivac LeuFel

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

- No items

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

- No items

4.6 Article 30(3) of Regulation 726/2004

• **Diethanolamine** EMEA/V/A/127 *To consider the potential risk for the consumer resulting from the use of diethanolamine as an excipient in VMPs for food producing species*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Request from Belgium for a scientific opinion of CVMP; discussion document Appointment of rapporteur, co-rapporteur and peer reviewers

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

• **Onsior** EMEA/V/C/000127/REC/006-007 *Recommendation*	Rapp: G.-J. Schefferlie ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Activyl (EMEA/V/C/000163)	18/02/2017 – 17/02/2018
Bovalto Ibraxion (EMEA/V/C/000051)	09/03/2017 – 08/03/2018
CaniLeish (EMEA/V/C/002232)	14/03/2017 – 13/03/2018
Cimalgex (EMEA/V/C/000162)	18/02/2017 – 17/02/2018
Econor (EMEA/V/C/000042)	12/03/2017 – 11/03/2018
Equisolon (EMEA/V/C/002382)	12/03/2017 – 11/03/2018
Fungitraxx (EMEA/V/C/002722)	12/03/2017 – 11/03/2018
Melosus (EMEA/V/C/002001)	21/02/2017 – 20/02/2018
Novem (EMEA/V/C/000086)	02/03/2017 – 01/03/2018
Pexion (EMEA/V/C/002543)	25/02/2017 – 24/02/2018
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	29/02/2017 – 28/02/2018
ProteqFlu (EMEA/V/C/000073)	06/03/2017 – 05/03/2018
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2017 – 05/03/2018

Product	Period
Purevax Rabies (EMEA/V/C/002003)	18/02/2017 – 17/02/2018
Purevax RC (EMEA/V/C/000091)	23/02/2017 – 22/02/2018
Purevax RCP (EMEA/V/C/000090)	23/02/2017 – 22/02/2018
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2017 – 22/02/2018
Purevax RCPCh (EMEA/V/C/000088)	23/02/2017 – 22/02/2018
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2017 – 22/02/2018
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08/03/2017 – 07/03/2018
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14/03/2017 – 13/03/2018

5.4 Renewals

• **Meloxidolor** EMEA/V/C/002590/R/0007	Rapp: C. Muñoz Co-rapp: M. Turk ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For adoption***: Draft CVMP assessment report on the PSUR for the period 01.03.17-31.08.17
• **CYTOPOINT** EMEA/V/C/003939	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 25.04.17 - 31.10.17
• **Evalon** EMEA/V/C/004013	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.05.17 - 31.10.17
• **LETIFEND** EMEA/V/C/003865	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.05.17 - 31.10.17
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.09.16 - 31.08.17
• **Rabigen SAG2** EMEA/V/C/000043	Rapp: B. Urbain ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.11.14 - 31.10.17

• **Vectormune ND** EMEA/V/C/003829	Rapp: F. Klein ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.04.17 - 30.09.17

- ***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***: Revision of VICH GL18(R) on residual solvents in new veterinary medicinal products, active substances and excipients: first draft revised guideline
- ***For endorsement***: Revision of VICH anthelmintic guidelines, presentation:
  Draft EU comments on Group 3 Helminth numbers,
  Draft EU comments on Field studies for swine - GL16 proposal,
  Draft EU comments on Field studies for poultry - GL21 proposal

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-V 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 Working Group on the application of the 3Rs (J3RsWG)

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:*** Corrigendum to the MRL summary report for isoflurane in Equidae (EMEA/MRL/222/97-FINAL)

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

- No items

8.3 Antimicrobial resistance

- ***For information:*** Verbal report on the first meeting of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) held on 22 February 2018, agenda and draft minutes

8.4 Pharmacovigilance

- ***For information:*** Joint EMA/VMD response to “Alfie’s petition” regarding Lepto 4 vaccines, “Alfie’s petition”

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 be commercially confidential

- 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

- ***For decision:*** Eligibility requests based on Article 3(2)a or Article 3(2)b of Regulation 726/2004 for new fixed-dose combination products

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 adoption***: Dossier requirements for submission of MA and MRL applications to the EMA and to members of the CVMP - *see also 12*

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

- ***For information***: Draft minutes of the meeting held on 15-16 February 2018; draft agenda of meeting to be held on 15-16 March 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: Dossier requirements for submission of MA and MRL applications to the EMA and to members of the CVMP - *see also 10.2*
- ***For information***: Draft agenda of the Veterinary Innovation Day to be held on 19 April 2018; draft agenda update on Brexit regulatory preparedness activities for veterinary companies, to be held on 20 April 2018

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

NEXT MEETINGS OF THE CVMP AND ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Mar 2018	13-15					1	20-21	1	13		
Apr 2018	17-19								17		24
May 2018	23-25*		29-30		29-30		29-30		23	17-18	
Jun 2018	19-21	21		5-6		6-7		5-7	19		
Jul 2018	17-19								17		