19 June 2018
EMA/CVMP/365941/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Agenda of June 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

19 June 2018, 09:00 – 21 June 2018, 13:00 - Room 2A

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 2A)	Tue 17 June 18	16:00-20:00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMA/V/MRL/004856/FULL/0001 *Chicken*	***For decision**:* Need for oral explanation

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/004689/0000 *New anti-inflammatory product* *Dogs*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion
• **Product** EMEA/V/C/004727/0000 *New product* *Horses*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Product** EMEA/V/C/004222/0000 *New product* *Horses*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Product** EMEA/V/C/004291/0000 *New antiparasitic product* *Cattle*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

• **Product** EMEA/V/C/004868/0000 *New antiprotozoal product* *Calves*	***For adoption**:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004897/0000 *New vaccine* *Cattle*	***For adoption**:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Inflacam** EMEA/V/C/002497/X/0015 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet ***For information**:* Request from applicant to extend clock-stop for 2 months
• **Rheumocam** EMEA/V/C/000121/X/0022 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet ***For information**:* Request from applicant to extend clock-stop for 2 months

- ***For adoption:*** EPAR module scientific discussion for **Credelio** (EMEA/V/C/004247/X/0001)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **BTVPUR** EMEA/V/C/002231/II/0010 *To add a new serotype for sheep and cattle*	Rapp: C. Muñoz Co-rapp: P. Pasquali ***For adoption**:* CVMP opinion, CVMP assessment report, product information
• **Circovac and EQUIOXX** EMEA/V/C/xxxxxx/WS1382 *Quality*	Rapp: J. G. Beechinor ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **LEUCOFELIGEN FeLV/RCP, Nobivac LeuFel and LEUCOGEN** EMEA/V/C/000143/WS1282/0007 EMEA/V/C/004778/WS1282/0001 EMEA/V/C/000144/WS1282/0006 *To modify the duration of immunity*	Rapp: E. Werner ***For adoption**:* CVMP list of outstanding issues

3.3 List of questions

• **Velactis** EMEA/V/C/003739/II/0004 *To fulfil the conditions for lifting the suspension of the marketing authorisation*	Rapp: W. Schlumbohm Co-rapp: F. Wikström ***For adoption**:* CVMP list of questions ***For decision:*** Request from applicant to extend clock-stop for 6 months
• **Econor** EMEA/V/C/000042/II/0052 *New preclinical data*	Rapp: H. Jukes ***For adoption**:* CVMP list of questions
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0009 *To change the onset of immunity for cattle and sheep*	Rapp: N. Garcia del Blanco Co-Rapp: P. Pasquali ***For adoption**:* CVMP list of questions
• **ClomicaIm** EMEA/V/C/000039/II/0027 *Quality*	Rapp: G. Hahn ***For adoption**:* CVMP list of questions
• **OSURNIA** EMEA/V/C/003753/II/0008 *Quality*	Rapp: S. Louet ***For adoption**:* CVMP list of questions
• **Porcilis PCV M Hyo** EMEA/V/C/003753/II/0008 *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

• **Veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep** EMEA/V/A/126 *Withdrawal periods*	Rapp: S. Louet Co-rapp: G. J. Schefferlie ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

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 risk for the consumer resulting from the use of diethanolamine as an excipient in VMPs for food producing species*	Rapp: B. Urbain Co-rapp: G. Hahn ***For discussion:*** Rapporteurs' assessment report with co-rapporteur's critique

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

• **CYTOPOINT** EMEA/V/C/003939/ANX/001 *Condition*	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the recommendation
• **Fevaxyn Pentofel** EMEA/V/C/000030/REC/028 *Recommendation*	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the recommendation
• **Onsior** EMEA/V/C/000127/REC/006.1 *Recommendation*	Rapp: G.-J. Schefferlie ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	Period
Circovac (EMEA/V/C/000114)	21.06.2017 – 20.06.2018
Convenia (EMEA/V/C/000098)	19.06.2017 – 18.06.2018
Equilis West Nile (EMEA/V/C/002241)	06.06.2017 – 05.06.2018
LEUCOGEN (EMEA/V/C/000144)	17.06.2017 – 16.06.2018
MS-H Vaccine (EMEA/V/C/000161)	14.06.2017 – 13.06.2018
Nobilis IB 4-91 (EMEA/V/C/000036)	09.06.2017 – 08.06.2018
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2017 – 13.06.2018
Porcilis Pesti (EMEA/V/C/000046)	09.06.2017 – 08.06.2018
Poulvac E. coli (EMEA/V/C/002007)	15.06.2017 – 14.06.2018
Prevomax (EMEA/V/C/004331)	19.06.2017 – 18.06.2018
Sevohale (EMEA/V/C/004199)	21.06.2017 – 20.06.2018
Sileo (EMEA/V/C/003764)	10.06.2017 – 09.06.2018
Spironolactone Ceva (EMEA/V/C/000105)	20.06.2017 – 19.06.2018
Vectra Fellis (EMEA/V/C/002746)	06.06.2017 – 05.06.2018

5.4 Renewals

• **Vectra 3D** EMEA/V/C/002555/R/0009	Rapp: G. Hahn Co-rapp: F. Hasslung Wikström ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Suvaxyn PRRS MLV** EMEA/V/C/000077	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 24.08.17-28.02.18
• **Credelio** EMEA/V/C/004247	Rapp: R. Breathnach ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.08.17-31.01.18
• **DRAXXIN** EMEA/V/C/000077	Rapp: G. Hahn ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.17-30.11.17

• **Exzolt** EMEA/V/C/004344	Rapp: P. Hekman ***For endorsement***: Rapporteur assessment report on the PSUR for the period 18.08.17 - 28.02.18
• **Innovax NB-IBD** EMEA/V/C/004422	Rapp: P. Hekman ***For endorsement***: Rapporteur assessment report on the PSUR for the period 22.08.17-28.02.18
• **Porcilis PCV ID** EMEA/V/C/003942	Rapp: P. Hekman ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.09.17-28.02.18
• **Sileo** EMEA/V/C/003764	Rapp: F. Hasslung Wikström ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.07.17-31.12.17
• **Stronghold** EMEA/V/C/000050	Rapp: H. Jukes ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.02.15-31.01.18
• **Trifexis** EMEA/V/C/002635	Rapp: G. Hahn ***For endorsement***: Rapporteur assessment report on the PSUR for the period 05.07.17-04.01.18
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: P. Pasquali ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.02.17-31.01.18
• **ZULVAC 8 Ovis** EMEA/V/C/000147	Rapp: P. Pasquali ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.02.17-31.01.18

- ***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 the VICH anthelmintic guidelines: draft EU comments on FDA questions regarding the use of geometric means topic and the scarcity of naturally infected dogs
- ***For endorsement:*** New VICH guideline on fixed combination products, draft EU comments on first draft of new guideline; draft EU comments on discussion document

- ***For endorsement:*** Sign-off of draft VICH GL58 for sign off by the VICH Steering Committee: stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV
- ***For endorsement:*** Sign-off of VICH GL56 for sign off by the VICH Steering Committee: study design recommendations for residues in honey for establishing MRLs and Withdrawal Periods
- ***For discussion:*** Proposal for formation of a VICH taskforce to consider the scope of a possible guideline on medicated premixes
- ***For discussion:*** JMAFF response to EU comments on their proposal for advancing the extraneous agents topic
- ***For discussion:*** JMAFF response to EU comments on the draft concept paper for development of a guideline on safety evaluation of biotechnology-derived/biological products
- ***For information***: 36th VICH Steering Committee meeting to be held on 25-26 and 28 June 2018 in Bruges (agenda draft 6) and 10th VICH Outreach Forum meeting to be held on 26-27 June 2018 in Bruges (agenda draft 4):
  - Quality Expert Working Group progress report
  - Electronic Standards Implementation Expert Working Group progress report
  - Biologicals Quality Monitoring Expert Working Group progress report
  - Metabolism and Residue Kinetics Expert Working Group progress report
  - Safety Expert Working Group progress report
  - Anthelmintics Expert Working Group progress report and progress on individual topics
  - Combination products Expert Working Group progress report

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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 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

- No items

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:*** Feedback on the development of the scientific advice prepared by the Antimicrobial Advice Ad Hoc Expert Group (AMEG)
- ***For information:*** AMR report of the Interagency Coordination Group to the UN Secretary-General

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 be commercially confidential

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 minutes of the meeting held on 24-25 May 2018; draft agenda of the meeting to be held on 21-22 June 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Roles and responsibilities at CVMP, outcome of discussion at the May 2018 CVMP meeting
- ***For discussion:*** CVMP work plan for 2019: general areas of activity
- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 20 June 2018 and draft agenda; draft minutes from the SPG meeting held on 18 April 2018
- ***For information:*** Agenda and draft minutes of the informal presidency meeting held on 7-8 May 2018 in Madrid, Spain

13. LEGISLATION

Information on certain topics discussed under section 13 cannot be released at the present time as it is deemed to be confidential

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
Jun 2018	19-21	21		5-6				5-7	19		
Jul 2018	17-19								17		
Sep 2018	11-13	13	18-19			20-21	25-26		11		
Oct 2018	9-11				23-24				9		
Nov 2018	6-8										