EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 April 2018
EMA/CVMP/207411/2018 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2018 meeting

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Committee for Medicinal Products for Veterinary Use (CVMP)

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Draft agenda of April 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

17 April 2018, 09:00 – 19 April 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).

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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 Apr 18	16:00-20:00

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• No items	

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/004667/0000 *New product* *Honey bees*	***For adoption**:* CVMP opinion, CVMP assessment report, CVMP product information ***For information**:* Summary of opinion
• **Credelio** EMEA/V/C/004485/X/0001 *To add a new strength for a new target species* *Dogs*	***For adoption**:* CVMP opinion, CVMP assessment report, CVMP product information ***For information**:* Summary of opinion
• **Product** EMEA/V/C/004265/0000 *New product* *Horses*	***For decision***: Need for further outstanding issues ***For adoption**:* CVMP opinion, CVMP assessment report, CVMP product information ***For information**:* Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004689/0000 *New anti-inflammatory product* *Dogs*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004222/0000 *New product* *Horses*	**ORAL EXPLANATION** ***For discussion**:* Presentation from applicant, rapporteurs' assessment report of responses to list of outstanding issues, draft product information

• **Product** EMEA/V/C/004727/0000 *New product* *Horses*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues; comments on product information
• **Inflacam** EMEA/V/C/002497/X/0015 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Rheumocam** EMEA/V/C/000121/X/0022 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/004902/0000 *New vaccine* *Chickens*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004733/0000 *New product* *Cats*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004794/0000 *New fixed combination product* *Pigs (piglets)*	***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

• **Product** EMEA/V/C/0002836/0000 *New antiparasitic product* *Honey bees*	***For information****:* Letter of withdrawal of the marketing authorisation application

- ***For adoption:*** EPAR module scientific discussion for **Clevor** (EMEA/V/C/004417/0000)
- ***For adoption:*** Revised EPAR module scientific discussion for **Suvaxyn Circo** (EMEA/V/C/004242/0000)
- ***For information*****:** Withdrawal letter from MERIAL for **CERTIFECT** (EMEA/V/C/002002)

- ***For information*:** Withdrawal letter from Eli Lilly and Company Limited for **Trifexis** (EMEA/V/C/002635)
- ***For information*:** Withdrawal letter from Eli Lilly and Company Limited for **Meloxivet** (EMEA/V/C/000124)
- ***For information*:** Withdrawal letter from MERIAL for **BTVPUR AlSap 1** (EMEA/V/C/000146)
- ***For information*:** Withdrawal letter from MERIAL for **BTVPUR AlSap 8** (EMEA/V/C/002230)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Vectormune ND** EMEA/V/C/003829/II/0009/G *Quality*	Rapp: F. Klein ***For adoption***: CVMP opinion ***For endorsement****:* Rapporteur's assessment report
• **Oncept IL-2, Parvoduk, ProteqFlu, Proteq West Nile, ProteqFlu Te, Purevax FeLV, Purevax Rabies, Purevax RC, Purevac RCP, Purevax RCP FeLV, Pu8revax RCPCh, Purevax RCPCh FeLV, Vaxxitek HVT+IBD** EMEA/V/C/xxxxxx/WS1366 *Quality*	Rapp: B. Urbain ***For adoption****:* CVMP opinion ***For endorsement****:* Rapporteur's assessment report
• **Porcilis ColiClos** EMEA/V/C/002011/II/0007 *Quality*	Rapp: N. Garcia del Blanco ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Pexion** EMEA/V/C/002543/II/0011/G *To add a new therapeutic indication*	Rapp: S. Louet Co-rapp: H. Jukes ***For adoption****:* List of outstanding issues

3.3 List of questions

• **NexGard, Nexgard Spectra** EMEA/V/C/002729/WS1338 *To add three new therapeutic indications*	Rapp: J. G. Beechinor Co-rapp: P. Hekman ***For adoption****:* List of questions
• **Galliprant** EMEA/V/C/004222/0000 *To add a manufacturing site* *Quality*	Rapp: K. Baptiste ***For adoption****:* List of questions

• **HALAGON** EMEA/V/C/004201/II/0002/G *To add new manufacturers* *Quality*	Rapp: C. Muñoz ***For adoption***: 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

• No items	

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

• No items	

4.6 Article 30(3) of Regulation 726/2004

• **Veterinary medicinal products containing gentamicin for parenteral administration to horses** EMEA/V/A/128 *Quality*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Request from the Executive Director of the European Medicines Agency for a scientific opinion of CVMP 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

• **Suprelorin** EMEA/V/C/000109/REC/015.1 *Recommendation*	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the recommendation
• **Fevaxyn Pentofel** EMEA/V/C/000030/REC/027.1 *Recommendation*	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the recommendation
• **ZULVAC SBV**	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Advocate (EMEA/V/C/000076)	02/04/2017 – 01/04/2018
BLUEVAC BTV8 (EMEA/V/C/000156)	14/04/2017 – 13/03/2018
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2017 – 16/03/2018
Clomicalm (EMEA/V/C/000039)	01/04/2017 – 31/03/2018
Coliprotec F4 (EMEA/V/C/003797)	16/03/2017 – 15/03/2018
Ecoporc SHIGA (EMEA/V/C/002588)	10/04/2017 – 09/04/2018
Eurican Herpes 205 (EMEA/V/C/000059)	26/03/2017 – 25/03/2018
Evalon (EMEA/V/C/004013)	18/04/2017 – 17/04/2018
Incurin (EMEA/V/C/000047)	24/03/2017 – 23/03/2018
Locatim (EMEA/V/C/000041)	29/03/2017 – 28/03/2018
Neocolipor (EMEA/V/C/000035)	14/04/2017 – 13/03/2018
Parvoduk (EMEA/V/C/002740)	11/04/2017 – 10/04/2018
Purevax FeLV (EMEA/V/C/000056)	13/04/2017 – 12/04/2018
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2017 – 05/04/2018
Veraflox (EMEA/V/C/000159)	12/04/2017 – 11/04/2018

5.4 Renewals

• **AFTOVAXPUR DOE** EMEA/V/C/002292/R/0009	Rapp: N. Garcia del Blanco Co-rapp: P. Pasquali ***For adoption***: CVMP opinion, CVMP assessment report, CVMP product information

5.5 Pharmacovigilance - PSURs and SARs

• **DRAXXIN** EMEA/V/C/000077	Rapp: G. Hahn ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.06.17 - 30.11.17
• **Pexion** EMEA/V/C/002543	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.16 - 31.08.17
• **Oncept IL-2** EMEA/V/C/002562	Rapp: J.-C. Rouby ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.12.16 - 30.11.17
• **Palladia** EMEA/V/C/000150	Rapp: E. Lander Persson ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.14 - 30.11.17
• **SevoFlo** EMEA/V/C/000072	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.15 - 30.11.17
• **Simparica** EMEA/V/C/003991	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.06.17 - 30.11.17
• **Zeleris** EMEA/V/C/004099	Rapp: W. Schlumbohm ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 15.05.17 - 30.11.17

- ***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***: Revised draft of VICH guideline 56 on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods following comments received from the VICH Expert Working Group
- ***For adoption***: Final draft annex to VICH GL3(R) guideline on stability studies for climatic zones III and IV
- ***For information***: Draft training materials for VICH guideline 52 on bioequivalence: blood level bioequivalence study - draft EU comments
- ***To note***: 36th VICH Steering Committee meeting to be held on 25-26 and 28 June 2018 in Bruges and 10th VICH Outreach Forum meeting to be held on 26-27 June 2018 in Bruges

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For discussion***: Rapporteur's report on the appropriateness of the existing 'No MRL required' classification of theophylline
- ***For information:*** ECHA recommendation to include N-methyl-pyrrolidone in the list of substances subject to authorisation

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

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 endorsement***: Participation of H. Jukes, as a EMA/CVMP representative, at the "TOPRA Annual Symposium 2018" – Antimicrobial resistance session; title of the lecture: "Update on the new AMEG mandate and CVMP's Guideline for risk assessment of antimicrobials"
- ***For information:*** Pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation (PPHOVA) - Minutes of Adobe Connect meeting held on 16 March 2018
- ***For information:*** Antimicrobial Advice Ad Hoc Expert Group (AMEG) - Minutes of Adobe Connect meeting held on 20 March 2018; Questionnaire for Stakeholders on Early Hazard Characterisation/Preliminary Risk Profile (PRP)

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***: Verbal report from the CMDv chair on the meetings held in February and March 2018, draft minutes of the meeting held on 15-16 March 2018; draft agenda of meeting to be held on 19 April 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement***: CVMP Interested Parties meeting – draft minutes of the meeting held on 6 September 2017
- ***For discussion***: EMA letter to CVMP Chair regarding Rules of Procedure of standing working parties
- ***For information***: Update on the EMA relocation

- ***For information***: Verbal update on the EMA working group on operational preparedness for veterinary medicines
- ***For information***: Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 18 April 2018, draft agenda; draft minutes from the SPG meeting held on 14 February 2018
- ***For information***: Agenda for EMA veterinary medicines innovation day to be held on 19 April 2018
- ***For information***: Agenda for the Stakeholders meeting on Brexit regulatory preparedness for veterinary medicinal products in the centralised procedure 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
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		
Sep 2018	11-13	13	18-19				25-26		11		