17 May 2019
EMA/CVMP/277755/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 21-22 May 2019 meeting

Chair: D. Murphy

Vice-chair: H. Jukes

Tuesday, 21 May 2019, 09:00 – Wednesday, 22 May 2019, 18:30:00 - Room 1C

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 1C)	Tue 21 May 2019	16:30-19:00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- 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/004973/0000 *New antiparasitic product* *Cats and dogs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/004897/0000 *New vaccine* *Cattle*	***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/004846/0000 *New antiparasitic product* *Dogs*	***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/005073/0000 *New product* *Cattle, pigs, sheep*	***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/004733/0000 *New product* *Cats*	***For information:*** Request from applicant to postpone the oral explanation

- ***For adoption:*** EPAR module scientific discussion for **Baycox Iron** (EMEA/V/C/004794/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Bravecto Plus** EMEA/V/C/004440/II/0003 *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Ingelvac CircoFLEX** EMEA/V/C/000126/II/0030/G *Quality*	Rapp: P. Pasquali ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Clomicalm** EMEA/V/C/000039/II/0027 *Quality*	Rapp: G. Hahn ***For adoption****:* CVMP opinion ***For endorsement****:* Rapporteur's assessment report
• **MiPet Easecto**, **Stronghold Plus** and **Simparica** EMEA/V/C/xxxxxx/WS1611 *Quality*	Rapp: J. G. Beechinor ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Fevaxyn Pentofel** EMEA/V/C/000030/WS1569/0047/G *Quality*	Rapp: M. Blixenkrone-Møller ***For adoption:*** CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report
• **Melovem** EMEA/V/C/000152/II/0011/G *Quality*	Rapp: R. Breathnach ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **CYTOPOINT** EMEA/V/C/003939/II/0005 *Quality*	Rapp: R. Breathnach ***For adoption:*** CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report
• **CLYNAV** EMEA/V/C/002390/II/0007 *Quality*	Rapp: J. G. Beechinor ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report

• **Porcilis PCV M Hyo** EMEA/V/C/003796/II/0011/G *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Coliprotec F4/F18** EMEA/V/C/004225/II/0005 *To add a new therapeutic indication*	Rapp: R. Cooney Co-Rapp: E. Augustynowicz **ORAL EXPLANATION – Tuesday 21 May 2019** ***For discussion:*** Presentation from the MAH

3.3 List of questions

• **Quadrisol** EMEA/V/C/000032/II/0038 *To introduce a new pharmacovigilance system*	Rapp: R. Breathnach ***For adoption:*** List of questions
• **Panacur AquaSol** EMEA/V/C/002008/II/0017 *Quality*	Rapp: G. J. Schefferlie ***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

• **Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep** EMEA/V/A/130 *Withdrawal periods*	Rapp: G. J. Schefferlie Co-rapp: S. Louet ***For discussion***: Revised rapporteur's assessment report including co-rapporteur's critique following responses to the list of outstanding issues

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

- No items

4.7 Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

• **Versican Plus DHPPi/L4** EMEA/V/C/003678/REC/001-002 *Recommendation*	Rapp: E. Werner Co-rapp: G. Kulcsár ***For endorsement***: Rapporteur's assessment report
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759/REC/001-002 *Recommendation*	Rapp: E. Werner Co-rapp: G. Kulcsár ***For endorsement***: Rapporteur's assessment report
• **Versican Plus DHPPi/L4** EMEA/V/C/003678/REC/015 *Recommendation*	Rapp: E. Werner Co-rapp: G. Kulcsár ***For endorsement***: Rapporteur's assessment report
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759/REC/012.2 *Recommendation*	Rapp: E. Werner Co-rapp: G. Kulcsár ***For endorsement***: Rapporteur's assessment report
• **Vaxxitek HVT+IBD** EMEA/V/C/000065/REC/026.1 *Recommendation*	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the recommendation
• **ZOLVIX** EMEA/V/C/000154/REC/006 *Recommendation*	Rapp: N. C. Kyvsgaard ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Bravecto Plus (EMEA/V/C/004440)	08.05.2018 – 07.05.2019
Credelio (EMEA/V/C/004247)	25.04.2018 – 24.04.2019

Product	Period
CYTOPOINT (EMEA/V/C/003939)	25.04.2018 – 24.04.2019
Equilis StrepE (EMEA/V/C/000078)	07.05.2018 – 06.05.2019
Evalon (EMEA/V/C/004013)	18.04.2018 – 17.04.2019
Improvac (EMEA/V/C/000136)	11.05.2018 – 10.05.2019
LETIFEND (EMEA/V/C/003865)	20.04.2018 – 19.04.2019
Meloxidolor (EMEA/V/C/002590)	22.04.2018 – 21.04.2019
Naxcel (EMEA/V/C/000079)	19.05.2018 – 18.05.2019
Oncept IL-2 (EMEA/V/C/002562)	03.05.2018 – 02.05.2019
Procox (EMEA/V/C/002006)	20.04.2018 – 19.04.2019
RESPIPORC FLUpan H1N1 (EMEA/V/C/003993)	17.05.2018 – 16.05.2019
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07.05.2018 – 06.05.2019
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07.05.2018 – 06.05.2019
Zeleris (EMEA/V/C/004099)	15.05.2018 – 14.05.2019
Zulvac BTV (EMEA/V/C/004185)	25.04.2018 – 24.04.2019
Zuprevo (EMEA/V/C/002009)	06.05.2018 – 05.05.2019

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **DRAXXIN** EMEA/V/C/000077	Rapp: G. Hahn ***For adoption:*** CVMP assessment report on the PSUR for the period 01.06.2018-20.11.2018
• **Canigen L4 & Nobivac L4** EMEA/V/C/004079	Rapp: B. Urbain ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 15.07.2012-31.12.2017
• **CLYNAV** EMEA/V/C/002390	Rapp: R. Breathnach ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.07.2018-31.12.2018

• **HALAGON** EMEA/V/C/004201	Rapp: C. Muñoz ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.07.2018-31.12.2018
• **Locatim** EMEA/V/C/000041	Rapp: B. Urbain ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.01.2016-31.12.2018
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.01.2018-31.12.2018
• **Sileo** EMEA/V/C/003764	Rapp: F. Hasslung Wikström ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.01.2018-31.12.2018
• **Vectra Felis** EMEA/V/C/002746	Rapp: G. Hahn ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.01.2017-31.12.2018
• **ZUPREVO** EMEA/V/C/002009	Rapp: W. Schlumbohm ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.12.2015-30.11.2018

- ***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

- No items

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement:*** EU comments on draft concept paper for a revision of GL22 on reproduction testing to include the extended one generation reproduction toxicity study
- ***For endorsement:*** EU comments on draft training slides on VICH pharmacovigilance guidelines
- ***For endorsement***: VICH Anthelmintics GLs revision - topic summary document and presentation; comments
- ***For discussion***: Nomination of an EU expert to the Bioequivalence Expert Working Group

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For decision:*** EFSA request to EMA to nominate an expert to contribute to the EC Mandate to assess the impact of the presence of low-level concentration in feed of the antimicrobial active

substances on animal health, human health and, where possible, on the environment - *see also 8.3*

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

8.3 Antimicrobial resistance

- ***For decision:*** EFSA request to EMA to nominate an expert to contribute to the EC Mandate to assess the impact of the presence of low-level concentration in feed of the antimicrobial active substances on animal health, human health and, where possible, on the environment - *see also 6.3*

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 16-17 April 2019; draft agenda of the meeting to be held on 23-24 May 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision***: Election of the chair of the Committee for Medicinal Products for Veterinary Use (CVMP) at the May 2019 CVMP meeting; nomination received for D. Murphy
- ***For information***: Informal presidency meeting held (during the Romanian presidency) on 6-8 May 2019 at Lake Balaton, Hungary; presentation on conclusions of the meeting
- ***For information***: Announcement of informal presidency CVMP/CMDv meeting (to be held during the Finnish presidency) on 25-27 September 2019 at Haikko Manor, Finland
- ***For information:*** Status of CVMP work plan for 2019

13. LEGISLATION

- ***For information:*** Verbal update on work progress of the expert groups concerning provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
May 2019	21-23						28-29		21		
Jun 2019	18-20	4							18		
Jul 2019	16-18						9-10		16		
Sep 2019	10-12						24-25		10		
Oct 2019	8-10								8		