4 October 2019
EMA/545556/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 8-10 October 2019 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

8 October 2019, 09:00 – 10 October, 13:00 - 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)	Tuesday, 8 October 2019	16:30-20:00

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003131/MODF/0003 *Sheep*	***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

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004735/0000 *New product* *Dogs*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Product** EMEA/V/C/004733/0000 *New product* *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/005018/0000 *New product* *Dogs*	**Oral explanation** – Tuesday 8 October 2019, 15:00 ***For discussion****:* Rapporteurs' assessment of responses to list of outstanding issues; draft product information
• **Product** EMEA/V/C/004991/0000 *New product* *Horses*	**Oral explanation** – Wednesday 9 October 2019, 11:00 ***For discussion****:* Rapporteurs' assessment of responses to list of outstanding issues; draft product information

2.3 List of questions

• **Product** EMEA/V/C/005094/0000 *New product* *Cats*	***For adoption**:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/005219/0000 *New product* *Pigs*	***For adoption**:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/005148/0000 *New vaccine* *Pigs*	***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

- No items

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Meloxidolor, Novaquin, Sedadex** and **Prevomax** EMEA/V/C/XXXXX/WS1666 *To introduce a new phamacovigilance system*	Rapp: C. Muñoz Madero Co-rapp: M. Turk ***For adoption***: CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Suvaxyn Circo** and **Suvaxyn Circo+MH RTU** EMEA/V/C/XXXXX/WS1668 *Quality-related changes*	Rapp: F. Klein ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **Exzolt** EMEA/V/C/004344/II/0006 *Quality-related changes*	Rapp: P. Hekman ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Panacur AquaSol** EMEA/V/C/002008/II/0017 *Quality-related changes*	Rapp: G. J. Schefferlie ***For decision:*** Need for oral explanation ***For adoption:*** List of outstanding issues

3.3 List of questions

- No items

3.4 Re-examination of CVMP opinions

• **Velactis** EMEA/V/C/003739/II/0004 *Update of product information and submission of new data to demonstrate the safe use of the product*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion***: Request for re-examination from the applicant ***For decision***: Appointment of rapporteur, co-rapporteur and peer reviewers

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

• **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof** EMEA/V/A/138 *Harmonisation of withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from Germany under Article 35 of Directive 2001/82/EC; Appointment of rapporteur, co-rapporteur and peer reviewers

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

- 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

• **HorStem** EMEA/V/C/004265/ANX/001 *Condition of the Marketing Authorisation*	Rapp: W. Schlumbohm Co-Rapp: C. Muñoz Madero ***For adoption:*** Rapporteur's assessment report
• **ZULVAC BTV** EMEA/V/C/004185/ANX/001 *Condition of the Marketing Authorisation*	Rapp: F. Klein ***For endorsement***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Cerenia (EMEA/V/C/000106)	29.09.2018 – 28.09.2019
COXEVAC (EMEA/V/C/000155)	30.09.2018 – 29.09.2019
ERAVAC (EMEA/V/C/004239)	22.09.2018 – 21.09.2019
Palladia (EMEA/V/C/000150)	23.09.2018 – 22.09.2019
Previcox (EMEA/V/C/000082)	13.09.2018 – 12.09.2019
Recocam (EMEA/V/C/002247)	13.09.2018 – 12.09.2019
RHINISENG (EMEA/V/C/000160)	16.09.2018 – 15.09.2019

5.4 Renewals

• **Coliprotec F4** EMEA/V/C/003797/R/0005	Rapp: E. Augustynowicz Co-rapp: C. Muñoz Madero ***For adoption***: List of outstanding issues
• **ZULVAC SBV** EMEA/V/C/002781/R/0007	Rapp: G. Kulcsár Co-rapp: M. Blixenkrone-Møller ***For adoption***: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Easotic** EMEA/V/C/000140	Rapp: N. C. Kyvsgaard ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.2016-31.05.2019
• **EQUIP WNV** EMEA/V/C/000137	Rapp: J.-C. Rouby ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.2018-31.05.2019
• **Halocur** EMEA/V/C/000040	Rapp: S. Louet ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.05.2016-30.04.2019

• **LETIFEND** EMEA/V/C/003865	Rapp: C. Muñoz Madero ***For endorsement***: Rapporteur evaluation on the PSUR for the period 01.11.2018-30.04.2019
• **MS-H vaccine** EMEA/V/C/000161	Rapp: B. Urbain ***For endorsement***: Rapporteur assessment report on the PSUR for the period 15.06.2016-14.06.2019
• **Naxcel** EMEA/V/C/000079	Rapp: S. Louet ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.2016-31.05.2019
• **Nobivac Myxo RHD** EMEA/V/C/002004	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.05.2016-30.04.2019
• **Porcilis PCV M Hyo** EMEA/V/C/003796	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.2018-31.05.2019
• **Zeleris** EMEA/V/C/004099	Rapp: W. Schlumbohm ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.12.2018-31.05.2019

- ***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 information***: Draft agenda for VICH Steering Committee meeting scheduled to take place on 18–21 November 2019 in Tokyo, Japan

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 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:*** List of substances considered as not falling within the scope of Regulation (EC) No. 470/2009

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 adoption:*** CVMP draft reflection paper on 'Promoting the authorisation of alternatives to antimicrobials in the EU' – *see also agenda point 9*

8.4 Pharmacovigilance

Information on certain topics discussed under section 8.4 cannot be released at the present time as it is deemed to be confidential

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

- ***For adoption:*** CVMP draft reflection paper on 'Promoting the authorisation of alternatives to antimicrobials in the EU' – *see also agenda point 8.3*

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 update from the CMDv chair on the meetings held on 18-19 July and 12-13 September 2019; minutes of the September meeting; draft agenda of the meeting to be held on 10-11 October 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) on the meeting to be held on 9 October 2019; draft agenda of the meeting; draft minutes of the SPG meeting held on 11 September 2019
- ***For information***: Informal presidency CVMP/CMDv meeting held during the Finnish presidency on 25-27 September 2019 in Porvoo, Finland; report on conclusions of the meeting
- ***For information:*** Upcoming informal presidency CVMP/CMDv meeting (to be held during the Croatian presidency) to be held on 4-5 June 2020 in Maisons–Alfort, France

13. LEGISLATION

- ***For adoption:*** Draft report on the criteria to designate antimicrobials for human use
- ***For information:*** Verbal update on work progress of the expert groups concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6 on signal detection and adverse events and pharmacovigilance inspections and pharmacovigilance system master file and on pharmacovigilance communication

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
Oct 2019	8-10								8		
Nov 2019	5-7						10-20	21-22	5		
Dec 2019	3-5								3		
Jan 2020	21-23								21		