13 January 2023
EMA/22156/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 17 – 19 January 2023

Chair: G. J. Schefferlie – Vice-chair: F. Hasslung Wikström

17 January 2023, 09:00 – 19 January 2023, 13:00 - Room 1C and virtual

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

Disclaimer

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CVMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CVMP members and the work the Committee undertakes.

Declaration of interests

In accordance with the Agency's 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.

Note on access to documents

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/729522/2016).

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Introduction

i. Adoption of the agenda

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session to be held 17-19 January 2023. See January 2023 CVMP minutes (to be published post February 2023 CVMP meeting)

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. Topics and experts' participation in discussions, rapporteur's meetings and breakout sessions held in advance or in the margins of the present CVMP meeting

Scientific Advice Working Party (virtual)	Mon 16 Jan 2023	10.00-13.00

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

No items

1.3. List of outstanding issues

No items

1.4. List of questions

No items

1.5. Re-examination of CVMP opinions on maximum residue limits

No items

1.6. Other issues

No items

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

No items

2.1. Opinions under Regulation (EC) No 726/2004

No items

2.2. Oral explanations under Regulation (EU) 2019/6

No items

2.2. Oral explanations under Regulation (EC) No 726/2004

No items

2.3. List of outstanding issues under Regulation (EU) 2019/6

No items

2.3. List of outstanding issues under Regulation (EC) No 726/2004

No items

2.4. List of questions under Regulation (EU) 2019/6

2.4.1. EMEA/V/C/006103/0000 – dogs, cattle, cats

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4. List of questions under Regulation (EC) No 726/2004

No items

2.5. Re-examinations of CVMP opinions under Regulation (EU) 2019/6

No items

2.5. Re-examinations of CVMP opinions under Regulation (EC) No 726/2004

No items

2.6. Other issues under Regulation (EU) 2019/6

2.6. Other issues under Regulation (EC) No 726/2004

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Purevax RC – EMEA/V/C/000091/VRA/0030 - cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1. Opinions under Commission Regulation (EC) No 1234/2008

No items

3.2. Oral explanations under Regulation (EU) 2019/6

No items

3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

No items

3.3. List of outstanding issues under Regulation (EU) 2019/6

No items

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

No items

3.4. List of questions under Regulation (EU) 2019/6

3.4.1. Porcilis PCV M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMEA/V/C/003796/VRA/0017 – pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

3.4.2. Stronghold – selamectin - EMEA/V/C/000050/VRA/0059 – cats, dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: J.G. Beechinor

Action: For adoption

List of questions, comments on the product information

3.4.3. Bravecto – fluralaner - EMEA/V/C/002526/VRA/0058 – dogs, cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

3.4.4. Purevax Rabies – rabies vaccine (live recombinant) - EMEA/V/C/002003/VRA/0017 – cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: B. Urbain

Action: For adoption

List of questions, comments on the product information

3.4.5. Poulvac E. coli – avian colibacillosis vaccine (live) - EMEA/V/C/002007/VRA/0020 – chicken, turkeys

Variation requiring assessment: to align the product information with version 9.0 of the QRD template. Additionally, the MAH is taking the opportunity to correct the name of the MAH in the product information.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

3.4. List of questions, comments on the product information 3.4. List of questions under Commission Regulation (EC) No 1234/2008

No items

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

No items

3.5. Re-examinations of CVMP opinions on variations under Commission Regulation (EU) No 726/2004

No items

3.6. Other issues under Regulation (EU) 2019/6

No items

3.6. Other issues under Commission Regulation (EC) No 1234/2008

No items

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

No items

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

No items

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

No items

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

No items

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

No items

4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6

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

4.7.1. Referrals under Regulation (EU) 2019/6

No items

4.7.2. Referrals under Article 33(4) of Directive 2001/82/EC

4.7.2.1. Catophos 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats – EMEA/V/A/147

Scope: Bioequivalence

Rapporteur: A. Golombiewski, Co-Rapporteur: L. Nepejchalová

Action: For discussion

Rapporteur's assessment report including co-rapporteur's critique

4.7.2.2. Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats – EMEA/V/A/148

Scope: Bioequivalence

Rapporteur: A. Golombiewski, Co-Rapporteur: L. Nepejchalová

Action: For discussion

Rapporteur's assessment report including co-rapporteur's critique

5. Post-authorisation issues for marketing authorisations

Information *relating* to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine *the purpose of such inspections*

5.1. Pharmacovigilance under Regulation (EU) 2019/6

5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

No items

5.1. Post-authorisation measures under Regulation (EU) 2019/6

No items

5.2. Post-authorisation measures under Regulation (EC) No 726/2004

No items

5.2. Inspections and controls under Regulation (EU) 2019/6

5.3. Supervision and sanctions under Regulation (EC) No 726/2004

No items

5.3. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

No items

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

6.5. Joint CHMP/CVMP 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

No items

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential

7.1. MRL issues

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

No items

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.7. Other issues

7.7.2. Draft procedural advice for vaccine platform technology master file (vPTMF) certification

Action: For adoption

Draft procedural advice for vaccine platform technology master file (vPTMF) certification (EMA/CVMP/184591/2022) and overview of comments received during public consultation

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.1.1. VICH GL35 (Pharmacovigilance: electronic standards for transfer of data) and GL42 (Pharmacovigilance: data elements for submission of adverse event reports)

Action: For endorsement

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. EMA Veterinary Medicines Info Day 2023

Action: For information

EMA Veterinary Info Day 2023 to be held on 16-17 February 2023 - draft programme

11. CMDv

11.1. Verbal report from CMDv Chair on the CMDv meetings held on 10-11 November 2022 and 8-9 December 2022

Action: For information

12. Legislation

12.1 Article 34 of Regulation (EU) 2019/6

Presenter: R. Carapeto

Action: For adoption

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Bovela - bovine viral diarrhoea vaccine (modified live) - EMEA/V/C/003703/WS2322/0024 - cattle

Variation requiring assessment: Quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2383 - Advocate - imidacloprid/moxidectin – dogs, cats, ferrets

Variation requiring assessment: Quality-related changes

Rapporteur: T. Muhonen

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Nobivac Myxo-RHD Plus – myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant) - EMEA/V/C/004989/VRA/0001 – rabbits

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Galliprant – grapiprant - EMEA/V/C/004222/VRA/0019 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Suvaxyn Circo+MH RTU – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMEA/V/C/003924/VRA/0019 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions under Regulation (EU) 2019/6

Prevomax – maropitant – EMEA/V/C/04331/VRA/0014 – dogs, cats

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

Masivet – masitinib – EMEA/V/C/00128/VRA/0022 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.2. Post-authorisation measures under Regulation (EC) No 726/2004

Circovac – EMEA/V/C/000114/REC/026-028

Rapporteur: P. Pasquali

Action: For endorsement

Rapporteur's assessment report

5.2. Inspections and controls under Regulation (EU) 2019/6

7. Other scientific matters

7.1 MRL issues

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9. Procedural and regulatory matters

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

Annex to 17-19 January 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Jan 2023	17-19						24-25		16		
Feb 2023	14-16			7-8		23	22		10		28
Mar 2023	21-23	14-15	29-30				28-29	6-8	20	30-31	1
April 2023	18-20						26		14		
May 2023	15-17								12		