7 March 2025
EMA/87728/2025 – draft 3- cor.1
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 11-13 March 2025

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

11 March 2025, 09:00 – 13 March 2025, 13:00 - Room 2C 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 11-13/03/2025. See 02/2025 CVMP minutes (to be published post 03/2025 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)	Fri 07 Mar 25	10.00-13.00 (TBC)

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

2.1. Opinions

2.1.1 EMEA/V/C/006522/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

Summary of opinion

2.1.2. EMEA/V/C/006235/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006247/0000 – sea bream

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.4. EMEA/V/C/006592/0000 – cattle

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.2. Oral explanations

2.2.1. EMEA/V/C/006230/0000 – cats

Action: Oral explanation to be held on 11 March 2025 at 14:30

Rapporteurs' assessment of responses to list of outstanding issues, comments on the product information, presentation from the applicant

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006332/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.3.2. EMEA/V/C/006336/0000 – pigs

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.3.3. EMEA/V/C/006358/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.4. List of questions

2.4.1. EMEA/V/C/006520/0000 – cats

Action: For adoption

List of questions, comments on the product information

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

No items

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Rheumocam – meloxicam - EMEA/V/C/000121/VRA/0038 – cats

Variation requiring assessment: to add a new strength

Rapporteur: S. Louet, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. NexGard Combo – esafoxolaner / eprinomectin / praziquantel – EMEA/V/C/005094/VRA/0012/G – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one

Rapporteur: A. Golombiewski, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. Veraflox – pradofloxacin - EMA/VRA/0000236570 – dogs and cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and the EMA Guideline on the SPC for antimicrobial medicinal products (EMA/CVMP/383441/2005-Rev.1 Corr) and to update the MIC data available in the SPC

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.4. Osurnia – terbinafine / florfenicol / betamethasone acetate- EMA/VRA/0000247996 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, comments on the product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1. Nobivac L4, Nobivac LoVo L4 - canine leptospirosis vaccine (inactivated) - WS/2673 – dogs

Variation requiring assessment: to implement the following changes: G.I.7 – addition of indications G.I.4 – addition of associated non-mixed use. A consequential name update from L4 to L6 is also proposed

Rapporteur: E. Dewaele, Co-Rapporteur: R. Breathnach

Action: For adoption

Product information Nobivac L4, product information Nobivac LoVo L4, Rapporteurs' assessment report and List of outstanding issues

3.4. List of questions

3.4.1. Poulvac E. coli – avian colibacillosis vaccine (live) - EMA/VRA/0000243824 – chickens

Variation requiring assessment: to add new information to the product information

Rapporteur: E. Werner, Co-Rapporteur: E. Augustynowicz

Action: For adoption

List of questions, comments on the product information

3.4.2. Stronghold Plus – selamectin / sarolaner – EMA/VRA/0000243880 – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one

Rapporteur: R. Breathnach, Co-Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

3.5. Re-examinations of CVMP opinions on variations requiring assessment

No items

3.6. Other issues

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/advice under Articles 141(1)(c), 141(1)(e) or 141(1)(i) 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

No items

4.7.1. Referrals

No items

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

5.1.1. Signal evaluation and recommendations

Outcome of the signal management process

Action: for adoption

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

No items

5.4. Re-examination of limited markets and exceptional circumstances authorisations

No items

5.5. Others

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)

6.2.1. Election for chair of ERAWP

Presenter: J. Schefferlie

Action: For election

Nomination(s) received:

6.2.2. Verbal report on ERAWP meeting held on 20-21 February 2025

Action: For information

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 26 February 2025

Action: For information

6.7.2. Revised PhVWP-V mandate

Action: For adoption

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 7 March 2025

Action: For information

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

6.11.1. European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group

Action: For adoption

First ESUAvet report: 2023 data

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.

7.5.1. EMEA/V/VAMF/0011

Action: For adoption

Assessment report and list of questions

7.5.2. EMEA/V/VAMF/00012

Action: For adoption

VAMF evaluation report and list of questions

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.

7.6.1. EMEA/V/PTMF/0003

Action: For adoption

vPTMF Assessment report

Action: For endorsement

vPTMF certificate

7.7. Other issues

No items

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

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

No items

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

9.1.1. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for cats

9.1.2. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for European seabass

9.1.3. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for common carp

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

9.3. Regulatory matters

10. Organisational and strategic matters

11. CMDv

11.1. Verbal report from Chair of CMDv on the CMDv plenary meetings held on 23-24 January and 19-20 February 2025

Action: For information

12. Legislation

12.1. Verbal report on the work progress of the expert group for the scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with Article 114(1)

Action: For information

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Quadrisol – vedaprofen - EMEA/V/C/000032/VRA/0040 – horses

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Sevohale – sevoflurane - EMA/VRA/0000236258 – dogs, cats

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

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Bravecto – fluralaner - EMA/VRA/0000248764 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2760 – Forceris, Gleptosil – pigs

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Sevohale – sevoflurane - EMA/VRA/0000247321 – dogs, cats

Variation requiring assessment: quality-related changes

Rapporteur: J.G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2768 – Porcilis ColiClos, Porcilis Porcoli Diluvac Forte, Porcilis AR-T DF – pigs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

Mirataz – mirtazapine - EMA/VRA/0000243883 – cats

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

Rapporteur's assessment report including List of questions, comments on the product information

Melovem – meloxicam - EMA/VRA/0000244473– cattle, horses, pigs

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

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

Profender – praziquantel / emodepside - EMA/VRA/0000243831– cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

Oncept IL-2 – active Canarypox virus, strain vCP1338, expressing feline interleukin-2 gene, live - EMA/VRA/0000244261 – cats

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

Rapporteur: C. Miras

Action: For adoption

List of questions, comments on product information

Action: For endorsement

Assessment report

Dogstem – equine umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244394 – dogs

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

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions, comments on product information

Action: For endorsement

Assessment report

HorStem – equine allogeneic umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244486 – horses

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

Rapporteur: A. Golombiewski

Action: For adoption

List of Questions, comments on product information

Action: For endorsement

Assessment report

EMA/VRA/0000225508 (WS) - Tulaven (Tulapro) – tulathromycin – cattle, pigs, sheep

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

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

6.5 3Rs Working Party (3RsWP)

Minutes of the OEG - 3RsWP - Batch release testing meeting held on 18 October 2024

Action: For information

Agenda of the OEG - 3RsWP - Batch release testing meeting held on 28 January 2025

Action: For information

NC and NAMs ESEC nominations

Action: For information

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

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

9.3. Regulatory matters

Invented names

10. Regulatory matters