31 October 2025
EMA/348754/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 4-6 November 2025

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

4 November 2025, 09:00 – 6 November 2025, 13:00 – virtual and Rooms 2C and 2D

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 4-6/11/2025. See 10/2025 CVMP minutes (to be published post 11/2025 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)	31 Oct 25	10.00-13.00 (TBC)

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

1.2.1. Substance – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: Oral explanation to be held on 4 November 2025

Rapporteur's revised EPMAR; presentation from the applicant

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/006717/0000 – chickens, ducks, turkeys

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006604/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.2. Oral explanations

No items

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006655/0000 – dogs

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/006753 – dogs

Action: For adoption

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

2.4.2. EMEA/V/C/006749 – cats, dogs, horses

Action: For adoption

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

2.4.3. EMEA/V/C/006821/0000 – sheep, cattle

Action: For adoption

List of questions, comments on the product information

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. EMEA/V/C/006535/0000 - dogs

Action: For information

Letter of withdrawal of the marketing authorisation application

3. Variations to marketing authorisations

3.1. Opinions

3.1.1 Frontpro – afoxolaner – EMA/VRA/0000282075 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one. Additionally, the product information is being aligned with version 9.1 of the QRD template.

Rapporteur: K. Boerkamp, Co-Rapporteur: P. McNeill

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. Credelio, Lotimax, Credelio Plus – lotilaner, lotilaner, lotilaner / milbemycin oxime - EMA/VRA/0000261365 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) in dogs - addition of a new therapeutic indication or modification of an approved one. Additionally, the product information for all three products is being aligned with version 9.1 of the QRD template.

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsar

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMA/VRA/0000281791 – pigs

Variation requiring assessment: quality and safety related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.4. Librela – bedinvetmab - EMA/VRA/0000301123 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process. In addition, the applicant is extending the shelf-life and made minor editorial changes in the SPC and PL.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1. Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) - EMA/VRA/0000269293 – pigs

Variation requiring assessment: efficacy-related change.

Rapporteur: E. Werner

Action: For adoption

List of outstanding issues, comments on the product information

3.4. List of questions

3.4.1. Bluevac BTV – Bluetongue virus vaccine (inactivated) - EMA/VRA/0000293372 – sheep

Variation requiring assessment: to allow up to three different inactivated bluetongue virus serotypes to be included in the final vaccine, and to align the product information with version 9.1 of the QRD template.

Rapporteur: E. Werner, Co-Rapporteur: F. Marsilio

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

4.4.1. Phenoxipen WSP, 325 mg/g powder for oral solution use in drinking water for pigs and chickens – phenoxymethylpenicillin – EMA/REF/0000302825

Scope: efficacy

Rapporteur: A. Golombiewski, Co-Rapporteur: K. Boerkamp

Action: For discussion

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

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

4.6.1. Veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications – EMA/REF/0000290626

Scope: Antimicrobial resistance

Rapporteur: S. Louet, Co-Rapporteur: C. Muñoz Madero

Action: For discussion

List of questions to MAHs; list of questions to stakeholders; timetable

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

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. Librela – bedinvetmab

Signal management submission

Rapporteur: F. Hasslung Wikström, Co-Rapporteur: J. Poot

Action: For information

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)

6.1.1. AWP work plan 2026

Action: For discussion

6.1.2. Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species

Action: For adoption

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 15-16 October 2025

Action: For information

6.2.2. ERAWP work plan 2026

Action: For discussion

6.2.3. Election of the Vice-chair of the ERAWP

Action: For decision

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 14-15 October 2025

Action: For information

6.3.2. EWP-V work plan 2026

Action: For discussion

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 21-22 October 2025

Action: For information

6.4.2. IWP-V work plan for 2026

Action: For discussion

6.5. 3Rs Working Party (3RsWP)

6.5.1. 2023-2024 3RsWP Biennial Report

Action: For adoption

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2026

Action: For discussion

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting

Action: For information

6.7.2. PhVWP-V work plan 2026

Action: For discussion

6.8. Quality Working Party (QWP)

6.8.2. QWP 3-year work plan 2026-2028

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 31 October 2025

Action: For information

6.9.6. SAWP-V work plan for 2026

Action: For adoption

6.10. Safety Working Party (SWP-V)

6.10.1. SWP-V work plan for 2026

Action: For discussion

6.11. Other working party and scientific group issues

6.11.1. European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG) work plan for 2026

Action: For discussion

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

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Appointment of Chair for the temporary Working Party on Dosage Review and Adjustment of established Antibiotics (ADRA)

Action: For decision

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

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

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 veterinary medicinal product for dogs

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for Atlantic salmon

9.1.3. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for Atlantic salmon

9.1.4. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for turkeys

9.1.5. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for honeybees

9.1.6. Draft questions and answers on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)

Action: For adoption

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

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

10. Organisational and strategic matters

10.1. CVMP work plan 2026

Action: For discussion

CVMP work plan 2026

10.2. CVMP/CMDv Informal meeting under the Danish EU Presidency, Copenhagen, 25-26 September 2025

Action: For adoption

Minutes of the CVMP and the joint CVMP-CMDv sessions

10.3. Update on IRIS roadmap and upcoming changes in pre-submission process

Action: For information

11. CMDv

No item

12. Legislation

No items

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

Nobilis Multriva IBm+ND+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm, Nobilis Multriva RT+IBm+ND+EDS, Nobilis Multriva IBm+ND, Nobilis Multriva IBm+ND+Gm+REOm+EDS – WS – EMA/VRA/0000285373 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Kriptazen – halofuginone – EMA/VRA/000282647 – cattle

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: E. Augustynowicz

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Melosus – meloxicam – EMA/VRA/0000282328 – dogs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Zenalpha – medetomidine hydrochloride / vatinoxan hydrochloride - EMA/VRA/0000281977 – dogs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template, to update the administrative information concerning the holder's representative.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, Product information

Action: For endorsement

Rapporteur's assessment report

Evalon – coccidiosis vaccine (live) - EMA/VRA/0000282001 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Vectormune FP ILT + AE – fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live) - EMA/VRA/0000282411 – chickens

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000284472 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, rapporteur's assessment report

Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMA/VRA/0000281715 – horses

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion, product information, assessment report

Enteroporc Coli AC – neonatal piglet colibacillosis (recombinant, inactivated) and Clostridium perfringens vaccine (inactivated) - EMA/VRA/0000281745 – pigs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm, Nobilis Multriva RT+IBm+ND+EDS – WS – EMA/VRA/0000285303 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Profender – praziquantel / emodepside – WS – EMA/VRA/0000276433 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Equisolon – prednisolone – EMA/VRA/0000278449 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

Enteroporc Coli AC – neonatal piglet colibacillosis (recombinant, inactivated) and *Clostridium perfringens* vaccine (inactivated) - EMA/VRA/0000294024 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm, Nobilis Multriva Gm+REOm, Nobilis Multriva IBm+ND+Gm+REOm+EDS - Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated), Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease and avian reovirus vaccine (inactivated), Avian infectious bursal disease and avian reovirus vaccine (inactivated), Avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated) - EMA/VRA/0000285378 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance

Signal evaluation and recommendations

Action: For adoption

Outcome of the signal management process, list of finalised signals

Veterinary Union pharmacovigilance database best practice guide (BPG) and MAH signal assessment report template

Action: For information

5.2 Post-authorisation measures

Poulvac Procerta HVT-IBD-ND – EMA/PAM/0000295789

Post-authorisation recommendation, quality-related

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's assessment report

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

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

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

11. CMDv

Reports from CMDv

Action: To note