28 November 2025
EMA/CVMP/366230/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 2-4 December 2025

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

2 December 2025, 09:00 – 4 December 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).

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
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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 28 Nov 25	10.00-13.00 (TBC)

1. Maximum residue limits

1.1. Opinions

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

Action: For adoption

Revised CVMP opinion including EPMAR

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/006921/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006513/0000 – cats

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006804/0000 – cattle

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/006520/0000 – cats

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/006777/0000 – pigs

Action: For adoption

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

2.4.2. EMEA/V/C/006603/0000 – pigs

Action: For adoption

Scientific overview and list of questions, comments on product information

2.4.3. EMEA/V/C/006776/0000 – horses

Action: For adoption

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

2.4.4. EMEA/V/C/006713/0000 – dogs, cats

Action: For adoption

Scientific overview and 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/006481/0000 – dogs

Action: For decision

Request from the applicant for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Dexdomitor – dexmedetomidine - EMA/VRA/0000257740 – dogs, cats

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

Rapporteur: H. Bremer, Co-Rapporteur: M. Leppänen

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2 Felpreva – meloxicam – EMA/VRA/0000294131 – cats

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

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1 Cirbloc M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) - EMA/VRA/0000288333 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Baptiste

Action: For adoption

List of outstanding issues, product information

3.4. List of questions

3.4.1. Mometamax Ultra - gentamicin / posaconazole / mometasone furoate - EMA/VRA/0000300844 – dogs

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

Action: For adoption

List of questions, comments on the product information

3.4.2. Enteroporc Coli AC – neonatal piglet colibacillosis (recombinant, inactivated) and *Clostridium perfringens* vaccine (inactivated) - VRA/0000284808 – pigs

Variation requiring assessment: to add the mixed, associated use of Enteroporc Coli AC and other national authorised products to the SPC.

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

3.6.1 Bluevac BTV, Bluevac-3, Hepizovac – EMA/VRA/0000272405 – cattle, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For information

Letter of withdrawal from the MAH

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 use in drinking water for chickens – phenoxymethylpenicillin – EMA/REF/0000302825

Scope: Efficacy

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

Action: For adoption

CVMP opinion on clarifications to the European Commission, CVMP assessment report

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

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. Senvelgo – velagliflozin - EMA/VS/0000282395

Signal management process

Rapporteur: K. Baptiste, Co-Rapporteur: M. O'Grady

Action: For endorsement

Draft Rapporteur's Assessment Report

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)

No items

6.3. Efficacy Working Party (EWP-V)

6.3.1. Guideline for the evaluation of efficacy of ectoparasiticides - general requirements

Action: For discussion

6.3.2. Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees

Action: For discussion

6.3.3. Concept paper on the development of a guideline for using owner assessment as efficacy parameter

Action: For discussion

6.3.4. Question and answer on the information contained within section 4.2 of the SPC on pharmacodynamic properties for pharmaceutical products

Action: For discussion

6.4. Immunologicals Working Party (IWP)

6.4.1. Revision of the Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs)

Action: For discussion

6.4.2. Revision of IWP guidelines to align with Regulation (EU) 2019/6

Action: For discussion

Draft revised Guideline on environmental risk assessment for immunological veterinary medicinal products.
Draft revised Guideline on user safety for immunological veterinary medicinal products.
Draft revised Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines.

6.4.3. Verbal report on the IWP interested parties meeting held on 13 November 2025

Action: For information

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 19 November 2025

Action: For information

6.6.2. NTWP work plan for 2026

Action: For adoption

6.6.3. Appointment of CVMP NTWP Operational Expert Groups (OEG) expert on RNAi&antisense

Action: For decision

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 25-26 November 2025

Action: For information

6.7.2. PhVWP-V work plan 2026

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held in October-November 2025 and interested parties meeting held in October 2025

Action: For information

6.8.2. QWP 3-year work plan 2026-2028

Action: For adoption

6.8.3. Guideline on development and manufacture of synthetic peptides

Action: For adoption

6.8.4. Questions and answers on co-processed excipients

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 28 November 2025

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 13-14 November 2025

Action: For information

6.11. Other working party and scientific group issues

6.11.1. ASMF working group

Action: For adoption

Updated guideline on ASMF worksharing procedure

6.11.2. European sales and use of antimicrobials for veterinary medicine (ESUAvet) working group

Action: For adoption

European sales and use of antimicrobials for veterinary medicine - annual surveillance report for 2024

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

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

8.1.3. Feedback from VICH Steering Committee and Forum meetings of 10-13 November 2025

Action: For information

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 veterinary medicinal product for horses

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for horses

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. 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

11. CMDv

11.1. Verbal report from on the CMDv meetings held on 15-16 October 2025 and 12-13 November 2025

Action: For information

12. Legislation

12.1 Scientific advice relating to the amendment of Regulation (EU) 2024/1973

Action: For information

Notification of the postponement of EMA/CVMP scientific advice relating to the amendment of Regulation (EU) 2024/1973 to extend its scope to animals of the equine species and set out conditions for the use of certain antimicrobials in these animals in accordance with Articles 112 and 113 of Regulation (EU) 2019/6

12.2 European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6

Action: For discussion

Request concerning five substances, none of which are included in Commission Implementing Regulation (EU) 2025/901, and for which the Commission is asking CVMP to provide responses to a set of questions by 30 April 2026.

13. Any other business

13.1. Meeting highlights

Action: For comments

13.2. SNE / Veterinary Pharmacovigilance Specialist

Action: For information

Position description: SNE/Veterinary Pharmacovigilance Specialist Job Details | EMA

14. Annex

2. Marketing authorisations and extensions

2.6. Other issues

EMEA/V/C/006638/0000 – dogs

Action: For decision

Request for an extension of clock stop.

3. Variations to marketing authorisations

3.1. Opinions

ProteqFlu - Te Equine influenza (live recombinant) and tetanus vaccine - EMA/VRA/0000301140 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Eluracat – capromorelin tartrate - EMA/VRA/0000288081 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Carapeto

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Zuprevo – tildipirosin - EMA/VRA/0000281934 – cattle, pigs

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Mirataz – mirtazapine - EMA/VRA/0000288548 – cats

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

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Dexdomitor – dexmedetomidine - EMA/VRA/0000296146 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Sileo – dexmedetomidine hydrochloride - EMA/VRA/0000300547 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Meloxidyl – meloxicam – VRA/0000300632 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion

Nexgard / Nexgard Spectra / Frontpro – afoxolaner – VRA/0000303673 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

AdTab – lotilaner – VRA/0000307496 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.3 List of outstanding issues

3.3.1. DuOtic / Osurnia (WS) – betamethasone acetate / terbinafine - terbinafine / florfenicol / betamethasone acetate - EMA/VRA/0000278006 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

List of outstanding issues

3.4. List of questions

Equioxx – firocoxib – VRA/0000297139 – horses

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

Rapporteur: P. McNeill

Action: For adoption

List of questions, comments on the product information

Veraflox – pradofloxacin - VRA/0000301203 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

Stelfonta – tigilanol tiglate - EMA/VRA/0000301147 – dogs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template and make additional minor editorial changes.

Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

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

6. Working parties

6.1 Antimicrobials Working Party (AWP)

6.1.1. AWP work plan 2026

Action: For adoption

6.2 Environmental Risk Assessment Working Party (ERAWP)

6.2.1. ERAWP work plan 2026

Action: For adoption

6.3 Efficacy Working Party (EWP-V)

6.3.1. EWP-V work plan 2026

Action: For adoption

6.4 Immunological Working Party (IWP-V)

6.4.1. IWP-V work plan for 2026

Action: For adoption

6.5. 3Rs Working Party (3RsWP)

6.5.1. Agenda of the 3RsWP plenary meeting held on 19–20 November 2025

Action: For information

6.5.2. Minutes of the 3RsWP plenary meeting held on 18–19 September 2025

Action: For information

6.7 Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Endorsement of new PhVWP-V member (replacement of previous member)

Action: For endorsement

Nomination for Kinga Csécsei from Gábor Kulcsár

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

SAWP-V work plan 2026

Action: For adoption

6.10. Safety Working Party (SWP-V)

SWP-V work plan for 2026

Action: For adoption

6.11. Other working party and scientific group issues

ESUAvet Working Group work plan for 2026

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

10. Organisational and strategic matters

CVMP work plan 2026

Action: For adoption