3 October 2025
EMA/322060/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 7-9 October 2025

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

7 October 2025, 09:00 – 9 October 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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Table of contents

Introduction **5**

i. Adoption of the agenda 5

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 7-9/10/2025. See 09/2025 CVMP minutes (to be published post 10/2025 CVMP meeting) 5

iii. Declaration of contacts between members and companies with regard to points on the agenda. 5

iv. Adoption of the minutes of the previous meetings: June, July and September. 5

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. 5

1. Maximum residue limits **5**

1.1. Opinions 5

1.2. Oral explanations 5

1.3. List of outstanding issues 5

1.4. List of questions 5

1.5. Re-examination of CVMP opinions on maximum residue limits 5

1.6. Other issues 5

2. Marketing authorisations **5**

2.1. Opinions 5

2.1.1. EMEA/V/C/006455/0000 – dogs 5

2.1.2. EMEA/V/C/006751/0000 – chickens, turkeys 6

2.2. Oral explanations 6

2.2.1. EMEA/V/C/006535/0000 - dogs 6

2.3. List of outstanding issues 6

2.4. List of questions 6

2.4.1. EMEA/V/C/006804/0000 – cattle 6

2.5. Re-examinations of CVMP opinions 6

2.6. Other issues 6

2.6.1. EMEA/V/C/006645/0000 – chickens 6

3. Variations to marketing authorisations **7**

3.1. Opinions 7

3.1.1. YURVAC RHD – rabbit haemorrhagic disease and RHDV2 vaccine (recombinant) - EMA/VRA/0000294120 – rabbits 7

3.1.2 Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000288171 – chickens 7

3.2. Oral explanations 7

3.3. List of outstanding issues 7

3.3.1. Dexdomitor – dexmedetomidine - EMA/VRA/0000257740 – dogs, cats 7

3.4. List of questions 8

3.4.1. Startvac – *Staphylococcus aureus* and coagulase-negative staphylococci and *Escherichia coli* J5 vaccine (inactivated) - EMA/VRA/0000288186 – cattle 8

3.5. Re-examinations of CVMP opinions on variations requiring assessment 8

3.6. Other issues 8

4. Referrals and related procedures **8**

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6 8

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6 8
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 8
4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure 8
4.4.1. Phenoxipen WSP, 325 mg/g powder for oral solution use in drinking water for pigs and chickens – phenoxymethylpenicillin – EMA/REF/0000302825 8
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 8
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 9
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 9
4.7. Other issues 9
5. Post-authorisation issues for marketing authorisations 9
5.1. Pharmacovigilance 9
5.1.1. Coxevac – *Coxiella burnetii* vaccine (inactivated) 9
5.2. Post-authorisation measures 9
5.3. Inspections and controls 9
5.4. Re-examination of limited markets and exceptional circumstances authorisations 9
5.5. Others 9
6. Working parties 10
6.1. Antimicrobials Working Party (AWP) 10
6.1.1. Verbal report on AWP meeting held on 23-24 September 2025 10
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 companion animal species 10
6.2. Environmental Risk Assessment Working Party (ERAWP) 10
6.3. Efficacy Working Party (EWP-V) 10
6.4. Immunologicals Working Party (IWP) 10
6.5. 3Rs Working Party (3RsWP) 10
6.5.1. Verbal report on 3RsWP meeting held on 18-19 September 2025 10
6.6. Novel Therapies & Technologies Working Party (NTWP) 10
6.6.1. Verbal report on NTWP meeting held on 18 September 2025 10
6.7. Pharmacovigilance Working Party (PhVWP-V) 10
6.7.1. Verbal report on PhVWP-V meeting held on 23-24 September 2025 10
6.7.2. Revised VeDDRA call for comments 10
6.8. Quality Working Party (QWP) 10
6.8.1. Verbal report on QWP meetings (July-September 2025) 10
6.8.2. Questions and answers on skip testing 11
6.9. Scientific Advice Working Party (SAWP-V) 11
6.9.1. Verbal report on SAWP-V meeting held on 3 October 2025 11
6.10. Safety Working Party (SWP-V) 11
6.10.1. Appointment of a new SWP-V member 11
6.11. Other working party and scientific group issues 11

7. Other scientific matters 11
7.1. MRL issues 11
7.2. Environmental risk assessment 11
7.3. Antimicrobial resistance 11
7.3.1. Appointment of temporary Working Party experts on Dosage Review and Adjustment of established Antibiotics (ADRA) 11
7.3.2. Work plan for the Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party 2025-2026 11
7.3.3. Appointment of temporary Working Party Chair on Dosage Review and Adjustment of established Antibiotics (ADRA) 11
7.4. Pharmacovigilance 11
7.5. Vaccine antigen master file (VAMF) certification 12
7.6. Platform technology master file (PTMF) certification 12
7.6.1 EMEA/V/VPTMF/0004 12
7.7. Other issues 12
8. Co-operation with other EU or International bodies 12
8.1. VICH 12
8.2. Codex Alimentarius 12
8.3. Other EU bodies and international organisations 12
9. Procedural and regulatory matters 12
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 12
9.1.1. Request for classification 12
9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers 12
9.3. Regulatory matters 12
10. Organisational and strategic matters 13
10.1. Appointment of co-opted members 13
10.2. Verbal report on Veterinary Domain meeting held on 16 September 2025 13
10.3. CVMP work plan 2026 13
10.4 Code of conduct of the European Medicines Agency – provisions for members and experts of scientific committees 13
11. CMDv 13
11.1. Verbal report from Chair of CMDv on the CMDv plenary meeting held on 17-18 September 2025 13
12. Legislation 13
13. Any other business 13
13.1. AOB 13
13.2. Meeting highlights 13
14. Annex 14

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 7-9/10/2025. See 09/2025 CVMP minutes (to be published post 10/2025 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 meetings: June, July and September.

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 03 Oct 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/006455/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006751/0000 – chickens, turkeys

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/006535/0000 - dogs

Action: Oral explanation to be held on 7 October 2025 (14:10)

Rapporteurs' assessment of responses, presentation from the applicant

2.3. List of outstanding issues

No items

2.4. List of questions

2.4.1. EMEA/V/C/006804/0000 – cattle

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/006645/0000 – chickens

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. YURVAC RHD – rabbit haemorrhagic disease and RHDV2 vaccine (recombinant) - EMA/VRA/0000294120 – rabbits

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

Rapporteur: R. Carapeto García

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2 Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000288171 – chickens

Variation requiring assessment: to submit additional in-use stability data to solve the first of three specific obligations identified during the initial marketing authorisation and stated in Annex II of the PI.

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1. 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 decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.4. List of questions

3.4.1. Startvac – *Staphylococcus aureus* and coagulase-negative staphylococci and *Escherichia coli* J5 vaccine (inactivated) - EMA/VRA/0000288186 – cattle

Variation requiring assessment: G.I.9 to allow the current vaccination schedule to be administered independent of the parturition date and administration of booster doses every three months.

Rapporteur: E. Werner, Co-Rapporteur: C. Muñoz Madero

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

Field: Efficacy

Rapporteur: *to be appointed*, Co-Rapporteur: *to be appointed*

Action: For discussion

Request from the European Commission under Article 54(8) of Regulation (EU) 2019/6; Appointment of rapporteur, co-rapporteur and peer reviewers

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

Field: Antimicrobial resistance

Rapporteur: *to be appointed*, Co-Rapporteur: *to be appointed*

Scope: Start of procedure

Action: For decision

CVMP self-mandate under Article 141(1)(i) of Regulation (EU) 2019/6; Appointment of rapporteur, co-rapporteur and peer reviewers

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. Coxevac – *Coxiella burnetii* vaccine (inactivated)

Rapporteur: C. Miras, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

Outcome of the signal management process

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. Verbal report on AWP meeting held on 23-24 September 2025

Action: For information

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 companion animal species

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP meeting held on 18-19 September 2025

Action: For information

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 18 September 2025

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 23-24 September 2025

Action: For information

6.7.2. Revised VeDDRA call for comments

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (July-September 2025)

Action: For information

6.8.2. Questions and answers on skip testing

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 3 October 2025

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Appointment of a new SWP-V member

Action: For decision

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

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

Action: For decision

7.3.2. Work plan for the Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party 2025-2026

Action: For adoption

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

Action: For information

Call for nominations for the Chair of the CVMP temporary Working Party (tWP) on ADRA project, selection procedure and draft timetable

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.

7.6.1 EMEA/V/VPTMF/0004

Action: For adoption

vPTMF assessment report incl. LoOI

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 honeybees

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. Appointment of co-opted members

Action: For election

Nomination(s) received:

- Quality (Chemicals)
- General Clinical Veterinary Practice

10.2. Verbal report on Veterinary Domain meeting held on 16 September 2025

Action: For information

Agenda of the 16 September 2025 meeting and minutes of the 23 May 2025 meeting

10.3. CVMP work plan 2026

Action: For discussion

10.4 Code of conduct of the European Medicines Agency – provisions for members and experts of scientific committees

Action: For information

Code of conduct of the European Medicines Agency (link)

11. CMDv

11.1. Verbal report from Chair of CMDv on the CMDv plenary meeting held on 17-18 September 2025

Action: For information

12. Legislation

No items

13. Any other business

13.1. AOB

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

2. Marketing authorisations and extensions

2.6. Other issues

EMEA/V/C/006593 – horses

Action: For information

Letter of withdrawal of the marketing authorisation application

3. Variations to marketing authorisations

3.1. Opinions

Porcilis Porcoli Diluvac Forte – *E. coli* vaccine (inactivated) – EMA/VRA/0000269151 – pigs

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

Respiporc FLUpan H1N1, Respiporc Flu 3 – Porcine influenza vaccine (inactivated) – EMA/VRA/0000258482 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Emdocam – meloxicam – EMA/VRA/0000269297 – horses

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

Rapporteur: P. McNeill

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur’s assessment report

Posatex / Mometamax Ultra - EMA/VRA/0000285701 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

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 questions

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

Variation requiring assessment: quality-related changes.

Rapporteur: R. Carapeto

Action: For adoption

List of questions

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

List of questions, comments on the product information

Senvelgo – velagliflozin – EMA/VRA/0000293237 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: K. Baptiste

Action: For adoption

Rapporteur's assessment report

Nobivac L4, Canigen L4, Nobivac LoVo L4 – EMA/VRA/0000284846 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Dewaele

Action: For adoption

Rapporteur's assessment report

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

5.2 Post-authorisation measures

Purevax RCPCh FeLV – EMA/PAM/0000287615

Quality-related measures.

Rapporteur: E. Dewaele

Action: For endorsement

Rapporteur's assessment report

DuOtic – EMA/PAM/0000287416

Quality-related measures.

Rapporteur: P. McNeill

Action: For endorsement

Rapporteur's assessment report

5.3 Inspections and controls under Regulation (EU) 2019/6

6. Working parties

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

List of nominations for the Quality Chemical ESEC

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

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

9.2.1. Transfer of (co-)rapporteurships responsibilities

Action: For decision

Transfer of (co-)rapporteurships responsibilities from:

G. Beechinor to P. McNeill and A. Blennerhassett

9.3. Regulatory matters

Invented names