5 September 2025
EMA/290141/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 9-11 September 2025

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

9 September 2025, 09:00 – 11 September 2025, 13:00 - Room 1D and virtual

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 9-11/09/2025. See 06/2025 and 07/2025 CVMP minutes (to be published post 09/2025 CVMP meeting).

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

iv. Adoption of the minutes of the June and July 2025 meetings.

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 05 Sep 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/005890/0000 – cats

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/006513/0000 – cats

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/006703/0000 – cats

Action: For adoption

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

2.4.2. EMEA/V/C/006679/0000 – turkeys

Action: For adoption

List of questions, comments on the product information

2.4.3. EMEA/V/C/006680/0000 – horses

Action: For adoption

List of questions, comments on the product information

2.4.4. EMEA/V/C/006702/0000 – 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. Divence Tetra – Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine - EMA/VRA/0000288649 – cattle

Variation requiring assessment: to implement the outcome of the MAH's signal management process, to clarify the temperature of use in section 3.9 of the SPC and section 9 of the package leaflet to ensure correct handling of the veterinary medicinal product.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. Bravecto TriUNO – fluralaner / moxidectin / pyrantel – EMA/VRA/0000263135 – 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 has been aligned with version 9.1 of the QRD template.

Rapporteur: R. Breathnach, Co-Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. 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

List of questions, comments on the product information

3.4.2. 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

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

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

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

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

No items

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)

No items

6.4. Immunologicals Working Party (IWP)

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

No items

6.8. Quality Working Party (QWP)

6.8.1. Guideline on in-use stability testing of VMPs

Action: For adoption

6.8.2. Question and answer on histamine limits for gentamicin-containing VMPs

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 5 September 2025

Action: For information

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

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

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

VAMF evaluation report

Action: For endorsement

VAMF certificate

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

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 veterinary medicinal product for dogs

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for pigs

9.1.3. 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

9.2.1. Summary of eligibility and table of offers from rapporteurs

Action: For decision

9.2.8. Updated procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer

Action: For adoption

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.2 Appointment of co-opted members at the October 2022 CVMP meeting

Action: For discussion

Identification of expertise necessary for CVMP to complement its expertise and appointment of co-opted members

11. CMDv

No items

12. Legislation

No items

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

1. Maximum Residue Limits

1.6. Other issues

Substance – EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For information

Letter of withdrawal

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

BTVPUR – Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 4) - EMA/VRA/0000269417 – cattle, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Cytopoint – lokivetmab - EMA/VRA/0000263599 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Tulinovet – tulathromycin - EMA/VRA/0000263760 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Evicto – meloxicam – EMA/VRA/002283 – 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

ProZinc – insulin human – EMA/VRA/0000247545 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Equilis Te, Equilis Prequenza Te – tetanus vaccine for horses, equine influenza (inactivated) and tetanus vaccine - EMA/VRA/0000238879 - WS – horses

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner, Co-Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Zulvac 1+8 Bovis - Bluetongue vaccine (inactivated) - EMA/VRA/0000263047- WS – cows

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

Action: For endorsement

Rapporteur's assessment report

Arthricox – firocoxib – EMA/VRA/0000265601 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Equioxx – firocoxib – EMA/VRA/0000247013 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Zulvac 1+8 Ovis – Bluetongue vaccine (inactivated) - EMA/VRA/0000263033 – sheep

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

Rapporteur: F. Marsilio

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Zulvac SBV – Schmallenberg virus vaccine (inactivated) – EMA/VRA/0000269443 – sheep, cattle

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

Rapporteur: G. Kulcsár

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Osurnia – terbinafine / florfenicol / betamethasone acetate - EMA/VRA/0000269514 – dogs

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

Novaquin – meloxicam - EMA/VRA/0000261536 – 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

Chanhold – selamectin - EMA/VRA/0000272326 – cats, dogs

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

RenuTend - EMA/VRA/0000281948 - horses

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Felpreva - EMA/VRA/0000288311 - cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. C. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Draxxin - EMA/VRA/0000288472 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: A. C. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Credelio, Lotimax, AdTab, Credelio Plus - EMA/VRA/0000285644 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Semintra - EMA/VRA/0000288420 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMA/VRA/0000282419 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP Opinion

Action: For endorsement

Rapporteur's assessment report

Emevet – maropitant – EMA/VRA/0000285688 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: M. Leppänen

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Simparica Trio – sarolaner / moxidectin / pyrantel embonate – EMA/VRA/0000288112 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate – EMA/VRA/0000290816 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Semintra - EMA/VRA/0000287663 - cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

Senvelgo - EMA/VRA/0000286769 - cats

Variation requiring assessment: quality-related changes.

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Meloxidolor – meloxicam – EMA/VRA/0000263855 – dogs, cats, cattle (calves) and pigs

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

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

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

List of questions, comments on the product information

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 questions

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

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

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.

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

List of questions

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

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

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

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 under Regulation (EU) 2019/6

Signal evaluation and recommendations

Action: For adoption

Outcome of the signal management process, list of finalised signals

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

CircoMax – EMA/PAM/0000287641

Rapporteur: N.C. Kyvsgaard

Action: For endorsement

Rapporteur's assessment report

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

6. Working parties

6.5 3Rs Working Party (3RsWP)

Minutes of the Batch release testing OEG meeting held on 16 May 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

6.11. Other working party and scientific group issues

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL62 on target animal safety of veterinary monoclonal antibody products (VMAPs)

Action: For adoption

VICH GL22(R) on studies to evaluate the safety of residues of veterinary drug in human food: reproduction studies

Action: For adoption

Guideline on reproduction studies

VICH GL23(R2) on studies to evaluate the safety of residues of veterinary drug in human food: genotoxicity studies

Action: For adoption

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