6 February 2026
EMA/31907/2026 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 10-12 February 2026

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

10 February 2026, 09:00 – 12 February 2026, 13:00 – virtual and room 1D

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 10-12/02/2026. See 02/2026 CVMP minutes (to be published post 03/2026 CVMP meeting).

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

iv. Adoption of the minutes of the December 2025 and January 2026 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 06 Jan 26	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. Maropitant – EMEA/V/C/006655/0000 – dogs

Indication: prevention of nausea induced by chemotherapy, prevention of vomiting induced by motion sickness, prevention and treatment of vomiting, in conjunction with maropitant solution for injection and in combination with other supportive measures in dogs.

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. Feline calicivirosis, feline viral rhinotracheitis and feline panleucopenia vaccine (live) – EMEA/V/C/006681/0000 – cats

Indication: for active immunisation of cats against feline herpesvirus type 1, feline calicivirus, feline panleucopenia virus.

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. Feline calicivirosis, feline rhinotracheitis, feline panleucopenialeukopenia (live) and feline leukemia (RNA particle) vaccine - EMEA/V/C/006682/0000 – cats

Indication: for active immunisation of cats against feline calicivirus, feline herpesvirus type 1, feline panleukopenia virus and feline leukemia virus.

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. Feline calicivirosis and feline viral rhinotracheitis vaccine (live) - EMEA/V/C/006702/0000 – cats

Indication: for active immunisation of cats against feline calicivirus and feline herpesvirus type 1.

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.4. Feline leukemia (RNA particle) vaccine - EMEA/V/C/006683/0000 – cats

Indication: for active immunisation of cats to prevent persistent viraemia and clinical signs caused by feline leukemia virus (FeLV).

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues and scientific overview, comments on the product information

2.3.5. Feline calicivirosis, feline herpesvirus viral rhinotracheitis, feline infectious enteritis (feline panleucopenia) and feline chlamydiosis (live) vaccine - EMEA/V/C/006703/0000 – cats

Indication: for active immunisation of cats against feline herpesvirus type 1 (FHV), feline calicivirus (FCV), feline panleucopenia virus (FPL) and *Chlamydia felis*.

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.6. Fuzapladib sodium – EMEA/V/C/006499/0000 – dogs

Indication: for the treatment of clinical signs associated with acute pancreatitis.

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. Enteric necrotic disease vaccine (vector, live recombinant) - EMEA/V/C/006822/0000 – chickens

Indication: for active immunisation of broiler chickens to reduce mortality, clinical symptoms and lesions due to necrotic enteritis caused by *Clostridium perfringens*.

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. Velagliflozine - EMEA/V/C/006610/0000 – horses

Action: For endorsement

Request to extend the clock stop

2.6.2. Equine adipose-derived mesenchymal stem cells - EMEA/V/C/006680/0000 – horses

Action: For endorsement

Request to extend the clock stop

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Coxevac – *Coxiella burnetii* vaccine (inactivated) - EMA/VRA/0000317028 – cattle, goats, sheep

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

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. 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

CVMP opinion, CVMP assessment report, product information

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

Variation requiring assessment: to introduce the possibility of using a needle-free device to administer Suvaxyn PRRS MLV via the intramuscular route

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

Rapporteur's assessment report

Action: For information

Summary of opinion

3.1.4. Bravecto – fluralaner - EMA/VRA/0000322275 – dogs

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

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.5. YURVAC RHD – Rabbit haemorrhagic disease and RHDV2 vaccine (recombinant) - EMA/VRA/0000322419 – rabbits

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

Rapporteur: R. Carapeto García

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.6. Versican Plus DHPPi/L4 – canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) - EMA/VRA/0000321328 – dogs

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

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.7. Versican Plus DHPPi/L4R – canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis and rabies vaccine (inactivated) - EMA/VRA/0000309942 – dogs

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

Rapporteur: E. Werner

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

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

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

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. Prevexxion RN / Prevexxion RN+HVT / Prevexxion RN+HVT+IBD / Vaxxitek HVT+IBD / non-CAP (WS) – EMA/VRA/0000304883 – chickens

Variation requiring assessment: to update the Marek's solvent label in the product information of the impacted vaccines.

Rapporteur: E. Dewaele

Action: For adoption

Rapporteur's assessment report with the list of questions

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

4.6.1. Quarter-based selective dry cow therapy – EMA/REF/0000285673

Antimicrobial resistance

Rapporteur: A. Golombiewski, Co-Rapporteur: M. Leppänen

Scope: List of outstanding issues

Action: For discussion

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

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

Outcome of the signal management process

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

Action: For adoption

CVMP assessment report

5.1.2. Solensia – frunevetmab

Outcome of the signal management process

Rapporteur: R. Breathnach, Co-Rapporteur: J. Poot

Action: For adoption

CVMP assessment report

5.1.3. Librela – bedinvetmab

Outcome of the signal management process

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

Action: For discussion

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)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Concept paper for the development of a guideline on the methodology of environmental risk assessment for ectoparasiticidal VMPs for cats and dogs

Action: For decision

6.2.2. Concept paper for the development of a reflection paper on the environmental risk assessment of antimicrobial resistance in the environment

Action: For discussion

6.3. Efficacy Working Party (EWP-V)

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

Action: For adoption

6.4. Immunologicals Working Party (IWP)

6.4.1. Guideline on quality aspects of mRNA vaccines for veterinary use

Action: For adoption

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 5 February 2026

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 27-28 January 2026

Action: For information

6.7.2. Concept paper for the revision of the Guideline on veterinary good pharmacovigilance practices (VGVP) Module: signal management - EMA/522332/2021

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held in December 2025 - January 2026

Action: For information

6.8.2. Guideline on risk management requirements for elemental impurities in veterinary medicinal products

Action: For adoption

Guideline on risk management requirements for elemental impurities in veterinary medicinal products; Implementation of submission of risk assessments to control elemental impurities required by the European Pharmacopeia in immunological veterinary medicinal products; overview of comments

Action: For endorsement

Deletion of Q&As published on the EMA website in relation to the control of elemental impurities

6.8.3. Revised Question and answer on complex manufacturing processes

Action: For adoption

6.8.4. Annex I to VICH GL18 on residual solvents: 'Specifications for class 1 and class 2 residual solvents in active substances' (EMEA/CVMP/511/03 -Rev.1)

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 6 February 2026

Action: For information

6.10. Safety Working Party (SWP-V)

No items

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

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.

7.6.1 EMEA/V/VPTMF/0004

Action: For adoption

CVMP evaluation 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

8.1.1. EU comments on VICH GL on between strength biowaivers for veterinary immediate release solid oral dose forms

Action: For adoption

8.1.2. Concept paper proposing development of a VICH GL to parallel ICH Q9

Action: For discussion

8.1.3. EU comments - VICH GL on principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals

Action: For endorsement

8.1.4. EU representative - VICH GL62 on target animal safety of veterinary monoclonal antibody products (VMAPs)

Action: For endorsement

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

8.3.1 Invitation to participate in development of guidance on the use of biomarkers of effect in risk assessment (joint mandate EFSA-EMA-ECHA)

Action: For decision

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 Atlantic salmon

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. Revision of the Mandate, objectives and rules of procedure for the Veterinary Domain

Action: For adoption

11. CMDv

11.1. Verbal report on the CMDv meetings held on 10-11 December 2025 and 21-22 January 2026

Action: For information

12. Legislation

No items

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Tulinovet - tulathromycin – EMA/VRA/0000304919 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Panacur Aquasol – fenbendazole - EMA/VRA/0000312772 – pigs, chicken

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Suvaxyn PPRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) – EMA/VRA/0000314858 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Innovax-ND-IBD-ILT – avian infectious laryngotracheitis, infectious bursal disease, Marek's disease and Newcastle disease vaccine (live recombinant) – EMA/VRA/0000315595 – chickens

Variation requiring assessment: quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

Tulissin – tulathromycin - EMA/VRA/0000316055 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

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

5.3. Inspections and controls under Regulation (EU) 2019

6. Working parties

6.1. Antimicrobial Working Party (AWP)

6.1.1 Presentation on the December AWP meeting

Action: For information

6.5 3Rs Working Party (3RsWP)

6.5.2. NC and NAMs ESEC nominations

Action: For information

NC and NAMs ESEC nominations

6.5.3. Minutes of the 3RsWP plenary meeting held on 19–20 November 2025

Action: For information

6.5.4. Agenda of the 3RsWP plenary meeting held on 28–29 January 2026

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

VICH GL34(R1) on Mycoplasma: Test for the detection of Mycoplasma contamination

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