9 January 2026
EMA/CVMP/5317/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 13-15 January 2026

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

13 January 2026, 09:00 – 15 January 2026, 13:00 - Room 1C 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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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 13-15/01/2026. See 12/2025 CVMP minutes (to be published post 02/2026 CVMP meeting).

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

iv. Adoption of the minutes of the 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 09 Jan 26	10.00-13.00

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. Lotilaner / milbemycin oxime - EMEA/V/C/006911/0000 – dogs

Indication: for use in dogs with, or at risk from, mixed infestations/infections by ticks, fleas, mites, gastrointestinal nematodes, heartworm and/or lungworm. This veterinary medicinal product is only indicated for use when treatment against ticks/fleas/mites and gastrointestinal nematodes or the treatment against ticks/fleas/mites and prevention of heartworm disease/angiostrongylosis is indicated at the same time.

Action: For adoption

CVMP opinion, CVMP assessment report, comments on the product information

Action: For information

Summary of opinion

2.2. Oral explanations

No items

2.3. List of outstanding issues

2.3.1. *Salmonella Infantis* vaccine (live) – EMEA/V/C/006646/0000 – chickens

Indication: for active immunisation of chickens to reduce organ colonization and faecal excretion due to *Salmonella Infantis.*
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. Bluetongue virus vaccine (inactivated) - EMEA/V/C/006821/0000 – sheep, cattle

Indication: for active immunisation of sheep to reduce viraemia, preventing mortality and to reduce clinical signs caused by the serotype 3 of the bluetongue virus. For active immunisation of cattle against the serotype 3 of the bluetongue 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. Velagliflozin - EMEA/V/C/006610/0000 – horses

Indication: for the treatment of hyperinsulinaemia and associated clinical signs (e.g., laminitis) in insulin-dysregulated horses and ponies not responsive to changes in husbandry and exercise regimen.

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

No items

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. Canine adipose-derived mesenchymal stem cells - EMEA/V/C/006457/0000 – dogs

Action: For endorsement

Request from the applicant for an extension of clock stop

2.6.2. Verdinexor - EMEA/V/C/005902 – dogs

Action: For endorsement

Request from the applicant for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions

No items

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. RESPIVAC aMPV – turkey rhinotracheitis virus, live - EMA/VRA/0000309778 – chickens

Variation requiring assessment: I.III.1.a – to add turkeys as a new target species; G.I.4 – to establish a higher minimum composition per dose in chickens than the one currently authorised. Additionally, the product information is aligned with version 9.1 of the QRD template.

Rapporteur: E. Werner, Co-Rapporteur: C. Miras

Action: For adoption

List of questions and scientific overview, 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

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

5.4.1. Syvazul BTV 3 – Bluetongue virus vaccine (inactivated) - EMA/S/0000309717

Re-examination of the marketing authorisation for Syvazul BTV 3 in line with Article 27(3) of Regulation (EU) 2019/6.

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

Action: For adoption

List of questions

5.4.2. Bluevac-3 – Bluetongue virus vaccine (inactivated) - EMA/S/0000310022

Re-examination of the marketing authorisation for Bluevac-3 in line with Article 27(3) of Regulation (EU) 2019/6.

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

Action: For adoption

Opinion, CVMP assessment report, product information

5.5. Other issues

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 9-10 December 2025

Action: For information

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 discussion

Concept paper for the development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs; overview of comments received on the concept paper during public consultation

6.3. Efficacy Working Party (EWP-V)

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

Action: For adoption

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

Action: For adoption

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

Action: For adoption

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 adoption

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

Action: For adoption

- Draft revised Guideline on environmental risk assessment for immunological veterinary medicinal products (EMA/CVMP/IWP/165768/2024)
- Draft revised Guideline on user safety for immunological veterinary medicinal products (EMA/CVMP/IWP/165764/2024)
- Draft revised Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines (EMA/CVMP/IWP/165762/2024)

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP meeting held on 19-20 November 2025

Action: For information

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Mandate of Novel therapies ESEC

Action: For adoption

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Concept paper for the revision of the Guideline on veterinary good pharmacovigilance practices (VGVP) Module: signal management

Action: For discussion

6.8. Quality Working Party (QWP)

6.8.1. Revised Question and answer on titanium dioxide

Action: For adoption

6.8.2. Questions and answers on co-processed excipients

Action: For adoption

6.8.3. Revised Question and answer on 'How to use a CEP'

Action: For adoption

6.8.4. Revised Quality of medicines questions and answers

Action: For adoption

6.8.5. Revised Question and answer on complex manufacturing processes

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 9 January 2026

Action: For information

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

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

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. Concept paper for revision of VICH GL47 on Comparative Metabolism Studies in Laboratory Animals

Action: For discussion

8.1.2. Revision of VICH GL8 on Stability Testing for Medicated Premixes

Action: For agreement

8.2. Draft status report including EU comments 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

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

No items

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 15 December 2025

Action: For information

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

Action: For discussion

11. CMDv

No items

12. Legislation

12.2. The Biotech Act

Action: For information

13. Any other business

13.2. Meeting highlights

Action: For comments

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

Vectormune ND/Vectormune HVT-AIV/Newflend ND H9/Ultifend ND IBD (WS) – EMA/VRA/0000292249 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Versican Plus DHPPi/L4R/Versican Plus DHPPi/L4/Versican Plus DHPPi /Versican Plus Pi /Versican Plus Pi/L4R/Versican Plus Pi/L4 (WS) – EMA/VRA/0000290574 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMA/VRA/0000309871 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Arti-Cell Forte – alisvetcel - EMA/VRA/0000310983 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Librela / Equip WNV / Suvaxyn CSF Marker / Suvaxyn Circo+MH RTU / Cytopoint / Suvaxyn Circo / Suvaxyn PRRS MLV / CircoMax / CircoMax Myco/Solensia and NAPs (WS) - EMA/VRA/0000295122 – dogs, horses, pigs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Improvac and NAPs (WS) - EMA/VRA/0000295128 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Purevax RCPCh FeLV, Purevax RCPCh – feline calicivirosis vaccine (inactivated), feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia), feline chlamydiosis vaccine (live) and feline leukaemia vaccine (live recombinant) - EMA/VRA/0000293649 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: E. Dewaele

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

Coxevac – *Coxiella burnetii* vaccine (inactivated) - EMA/VRA/0000308623 – cattle, goats, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

List of questions

Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4, Versican Plus Pi/L4R (WS) - EMA/VRA/0000293810 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information Versican Plus DHPPi/L4R, comments on the product information Versican Plus DHPPi/L4, comments on the product information Versican Plus L4, comments on the product information Versican Plus Pi/L4, comments on the product information Versican Plus Pi/L4R

Bluevac BTV - Bluetongue virus vaccine (inactivated) - EMA/VRA/0000309935 – cattle and sheep

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Vectormune ND/Vectormune FP ILT + AE/Vectormune HVT-AIV/Newflend ND H9/Ultifend ND IBD/ Vectormune FP ILT (WS) – EMA/VRA/0000290574 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

List of questions

Zenrelia – ilunocitinib - EMA/VRA/0000309679 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

List of questions

Halagon – halofuginone - EMA/VRA/0000309721 – cattle

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

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions, comments on the product information

Cimalgex and NAPs (WS) – EMA/VRA/0000295102 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

Opinion

3.6. Other issues

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

Rapporteur: K. Baptiste, Co-Rapporteur: S. Louet

Action: For endorsement

Request from the applicant for an extension of clock stop.

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.3. Inspections and controls under Regulation (EU) 2019

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

VICH status of guidelines

Action: For information

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