10 March 2026
EMA/CVMP/32668/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 10-12 February 2026 meeting

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

Note on access to documents

Some documents mentioned in the 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).

The meeting was held virtually.

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

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 10-12 February 2026

The attendance list was completed and competing interests were identified for the February 2026 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters discussed (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took 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 the meeting (see Annex I).

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

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

No contacts have been declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the December 2025 and January 2026 meetings were adopted.

v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

Information relating to briefing meetings taking place with applicants/marketing authorisation holders cannot be released at the present time as it is deemed to be commercially confidential.

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, for vomiting induced by motion sickness, prevention and for treatment of vomiting in dogs. The product is to be used in conjunction with maropitant solution for injection and in combination with other supportive measures.

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion, the CVMP assessment report, and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion, a peer review report and comments from CVMP members.

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

Action: For decision

The Committee decided that there is no need for an oral explanation.

Action: For adoption

The Committee adopted the scientific overview, list of outstanding issues and the comments on the product information.

Action: For information

The Committee noted two peer review reports.

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

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

Action: For decision

The Committee decided that there is no need for an oral explanation.

Action: For adoption

The Committee adopted the scientific overview, list of outstanding issues and the comments on the product information.

Action: For information

The Committee noted two peer review reports.

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

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

Action: For decision

The Committee decided that there is no need for an oral explanation.

Action: For adoption

The Committee adopted the scientific overview, list of outstanding issues and the comments on the product information.

Action: For information

The Committee noted a peer review report.

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

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

Action: For decision

The Committee decided that there is no need for an oral explanation**.**

Action: For adoption

The Committee adopted the scientific overview, list of outstanding issues and the comments on the product information.

Action: For information

The Committee noted two peer review reports.

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

Action: For decision

The Committee decided that there is no need for an oral explanation.

Action: For adoption

The Committee adopted the scientific overview, list of outstanding issues and the comments on the product information.

Action: For information

The Committee noted two peer review reports.

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

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

Action: For decision

The Committee decided that there is no need for an oral explanation.

Action: For adoption

The Committee adopted the scientific overview, list of outstanding issues and the comments on the product information.

Action: For information

The Committee noted three peer review reports together with the comments from CVMP members.

2.4. List of questions

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

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

Action: For adoption

The Committee adopted the scientific overview and list of questions together with the comments on the product information.

Action: For information

The Committee noted two peer review reports and comments from CVMP members.

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. Velagliflozin - EMEA/V/C/006610/0000 – horses

Action: For endorsement

The Committee endorsed the request from the applicant to extend the clock stop.

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

Action: For endorsement

The Committee endorsed the request from the applicant for an extension of 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 to update the product information by adding "milk production decrease" as a rare adverse event in cattle and sheep, and as a common adverse event in goats.

Rapporteur: C. Miras

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the 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

The Committee adopted, by consensus, the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

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 the product (0.5 ml dose) via the intramuscular route in pigs for fattening.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Action: For information

The Committee noted the summary of opinion.

3.1.4. Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs – fluralaner - EMA/VRA/0000322275 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process to update the product information by adding "Pruritus", "Allergic oedema" and "Hypersensitivity reaction" as very rare adverse events. "Diarrhoea" and "Emesis" were also added as rare adverse events. The following sentence was also added: "If accidental skin exposure occurs, wash the skin immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with clean water."

Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the 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 to update the product information by adding "lethargy and lameness" as very rare adverse events.

Rapporteur: R. Carapeto García

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the 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 to update the product information by adding "injection site lump, injection site mass, injection site nodule" as rare adverse events.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the 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 to update the product information by adding "injection site lump, injection site mass, injection site nodule" as rare adverse events.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the 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 independent of the parturition date and administration of booster doses every three months.

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

Action: For decision

The Committee agreed that there was no need for oral explanation

Action: For adoption

The Committee adopted the list of outstanding issues and the 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: F. Klein

Action: For adoption

The Committee adopted the 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

The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique and agreed that no outstanding issues remained. The scientific advice for this procedure is foreseen to be adopted at the March 2026 CVMP meeting.

Action: For information

The Committee noted three peer review reports and comments received from CVMP members.

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

Outcome of the signal management process

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

Action: For adoption

The Committee adopted the CVMP assessment report.

5.1.2. Solensia – frunevetmab

Outcome of the signal management process

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

Action: For adoption

The Committee adopted the CVMP assessment reports.

5.1.3. Librela – bedinvetmab

Outcome of the signal management process

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

Action: For discussion

The Committee discussed the draft CVMP 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)

N/A

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

The Committee discussed the concept paper for the development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs (EMA/CVMP/ERA/499198/2024) and the overview of comments received on the concept paper during public consultation (EMA/CVMP/ERA/307722/2025), and gave the ERAWP the mandate to start with the work on the guideline.

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

The Committee discussed the concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product (EMA/CVMP/ERA/75412/2023) and the overview of comments received on the concept paper during public consultation (EMA/CVMP/ERA/369161/2025). The assignment for the ERAWP will be discussed at the March 2026 CVMP meeting.

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

The Committee adopted the revised Q&A document.

Action: For information

The Committee noted the comments from CVMP members.

6.4. Immunologicals Working Party (IWP)

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

Action: For adoption

The Committee adopted the draft guideline on quality aspects of mRNA vaccines for veterinary use (EMA/CVMP/IWP/128476/2025) for 6-month of public consultation.

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

The Committee received a verbal report on the NTWP meeting held on 5 February 2026 and noted its agenda together with the minutes of the meeting held on 19 November 2025.

6.6.2. Risk Management Plan (RMP) template for novel therapies

Presenter: J. Poot

Action: For discussion

The Committee was informed about the progress made on the Risk Management Plan (RMP) template for novel therapies. CVMP members were invited to provide comments on the document, which will be presented for adoption at the next CVMP meeting.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting

Action: For information

The Committee received a verbal report on the January PhVWP-V meeting and noted its agenda and draft summary record.

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

Action: For adoption

The Committee adopted the concept paper for the revision of the Guideline on veterinary good pharmacovigilance practices (VGVP) Module: signal management for 1-month of public consultation.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held on 1-2 December 2025 and 19-20 January 2026

Action: For information

The Committee received a verbal report on the QWP meetings held on 1-2 December 2025 and 19-20 January 2026 and noted the minutes of the QWP meeting held on 3-4 November 2025, the agenda and minutes of the QWP meeting held on 1-2 December 2025 and the agenda of the QWP meeting held on 19-20 January 2026.

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

Action: For adoption

The Committee adopted the guideline on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/426245/2023) and implementation of submission of risk assessments to control elemental impurities required by the European Pharmacopeia in immunological veterinary medicinal products (EMA/CVMP/366323/2025).

The Committee adopted the overview of comments received during the public consultation (EMA/CVMP/426245/2023).

Action: For endorsement

The Committee endorsed the 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

The Committee adopted the revised Q&A on complex manufacturing processes.

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

The Committee received a verbal report on SAWP-V meeting held on 6 February 2026 and noted its agenda together with the final minutes of the SAWP-V meeting held on 9 January 2026.

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

Indication: vaccines intended for chickens, based on the live herpesvirus of turkeys (rHVT), genetically modified to express one or more genes of interest

Action: For adoption

The Committee adopted the CVMP evaluation report.

Action: For endorsement

The Committee endorsed the 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. Development of a VICH GL on between strength biowaivers for veterinary immediate release solid oral dose forms – EU comments

Action: For adoption

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

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 discussion

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

The Committee classified the veterinary medicinal product for Atlantic salmon as limited market and eligible for Article 23.

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

The Committee adopted the mandate, objectives and rules of procedure for the Veterinary Domain.

11. CMDv

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

Action: For information

The Committee received a verbal report on the CMDv meetings held on 10-11 December 2025 and 21-22 January 2026 and noted their agendas.

12. Legislation

No items

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights (link)

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

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Variation requiring assessment: quality-related changes.

Rapporteur: L. Nepejchalová

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

The Norwegian CVMP member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the 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

The Committee adopted, by consensus, the CVMP opinion.

The Norwegian CVMP member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

The Norwegian CVMP member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the 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

The Committee adopted, by consensus, the CVMP opinion and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.4. List of questions

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

The Committee adopted the list of questions

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Background information: background note; comments from a CVMP member

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

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the 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

The Committee adopted the monthly outcomes of the signal management process.

Action: For information

The Committee noted the list of finalised signals.

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

6. Working parties

6.1. Antimicrobial Working Party (AWP)

6.1.1 Presentation on the December AWP meeting

Action: For information

The Committee noted the presentation on the December AWP meeting 2025.

6.5 3Rs Working Party (3RsWP)

6.5.2. NC and NAMs ESEC nominations

Action: For information

The Committee adopted the ERA ESEC Expert 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

The Committee adopted the 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

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

Action: For adoption

The Committee adopted the VICH GL 34(R1) on *Mycoplasma*: Test for the detection of *Mycoplasma* contamination (EMA/CVMP/VICH/463/2002). This version reflects the implementation of VICH GL34 in the EU. The revised guideline will be released for implementation by April 2026, coinciding with the date on which the revised Ph. Eur. chapter becomes applicable.

Status of VICH 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

ANNEX I

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 10-12 February 2026 CVMP meeting, which was held remotely.

An asterisk (*) after the name, in the first column, signals that the participant attended in-person.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
G. Johan Schefferlie*	**Chair**	**CHAIR**	**No interests declared**	
Petra Falb	Member	Austria	No restrictions applicable to this meeting	
Manuela Leitner	Alternate	Austria	No interests declared	
Els Dewaele	Member	Belgium	No interests declared	
Frederic Klein	Alternate	Belgium	No restrictions applicable to this meeting	
Tsvetanka Valova	Alternate	Bulgaria	No interests declared	
Irena Žarković	Member	Croatia	No restrictions applicable to this meeting	
Irena Caleta	Alternate	Croatia	No restrictions applicable to this meeting	
Leona Nepejchalová	Member	Czechia	No interests declared	
Niels Christian Kyvsgaard	Member	Denmark	No interests declared	
Merete Blixenkrone-Møller	Alternate	Denmark	No interests declared	
Minna Leppänen	Member	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	
Andrea Christina Golombiewski	Alternate	Germany	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Esther Werner	Member	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Amalia Papadaki	Alternate	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No participation in discussion, final deliberations and voting on:	EMEA/V/C/006610/0000 EMA/VRA/0000304883 EMA/VS/0000282395
Paul McNeill	Member	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Zanda Auce	Member	Latvia	No interests declared	
Renate Kuske	Alternate	Latvia	No restrictions applicable to this meeting	
Vaida Kurapkiene	Alternate	Lithuania	No restrictions applicable to this meeting	
Despoina Iatridou	Alternate	Luxembourg	No interests declared	
Caroline Coner	Member	Luxembourg	No interests declared	
Jacqueline Poot	Member	Netherlands	No interests declared	
Kim Boerkamp	Alternate	Netherlands	No restrictions applicable to this meeting	
Hanne Bergendahl	Member	Norway	No interests declared	
Knud Sveen Torjesen	Alternate	Norway	No interests declared	
Ewa Augustynowicz	Alternate	Poland	No interests declared	
Marcin Glanda	Alternate	Poland	No interests declared	
João Pedro Duarte Da Silva	Member	Portugal	No interests declared	
Gabriela Tuchila	Member	Romania	No interests declared	
Eva Chobotová	Member	Slovakia	No interests declared	
Katarina Massányiová	Alternate	Slovakia	No interests declared	
Mojca Ogriz	Alternate	Slovenia	No interests declared	
Urska Peunik	Member	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Frida Hasslung Wikström	Member (Vice-Chair)	Sweden	No interests declared	
Hanna Bremer	Alternate	Sweden	No interests declared	
Keith Baptiste	Co-opted member	Denmark	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Ricardo Carapeto García	Co-opted member	Spain	No interests declared	
Rory Breathnach	Co-opted member	Ireland	No restrictions applicable to this meeting	
Mary O'Grady	Co-opted member	Ireland	No interests declared	
Carina Bergman	Co-opted member	Sweden	No interests declared	

An asterisk (*) after the role, in the first column, signals that the participant attended in person.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Lorena Touriño González	Expert	Spain	No interests declared	
Jaime Garcia Sanchez	Expert	Spain	No restrictions applicable to this meeting	
Cristina Ballesteros Tercero	Expert	Spain	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Sonia Gil Morales	Expert	Spain	No interests declared	
Ulla Nevalainen	Expert	Finland	No interests declared	
Stella Attia	Expert	Finland	No interests declared	
Katariina Kivilahti-Mäntylä	Expert	Finland	No interests declared	
Jenny Larsson	Expert	Sweden	No interests declared	
Frida Martin	Expert	Sweden	No interests declared	
Ulrika Falkenö	Expert	Sweden	No interests declared	
Karl Ljungvall	Expert	Sweden	No participation in discussion, final deliberations and voting on:	EMA/VS/0000282395
Michelle Mulchrone	Expert	Ireland	No interests declared	
Kira Rosenkilde Underbjerg	Expert	Denmark	No interests declared	
Kathrin Schirmann	Expert	Germany	No interests declared	
Philippe Berny	Expert	France	No restrictions applicable to this meeting	
Mark Montforts	Expert	Ireland	No interests declared	
Haru Kroneis	Expert	Austria	No interests declared	
Rene van Herwijnen	Expert	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Ana Isabel Olias Molero	Expert	Spain	No interests declared	
Mariette Salery	Expert	France	No interests declared	
Nathalie Bridoux	Expert	France	No interests declared	
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Sandra Bertulat	Expert	Germany	No interests declared	
Andrea Springer	Expert	Germany	No interests declared	
Uta Herbst	Expert	Germany	No interests declared	
Maren Osmers	Expert	Germany	No interests declared	
Gunther Speichert	Expert	Germany	No interests declared	
Jens Schönfeld	Expert	Germany	No interests declared	
Katja Kaulich	Expert	Germany	No interests declared	
Kathrin Schmidt	Expert	Germany	No interests declared	
Christina Bredtmann	Expert	Germany	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Kirsten Thomsen	Expert	Denmark	No interests declared	
Anne Malene Nissen	Expert	Denmark	No interests declared	
Sarah Hanley	Expert	Ireland	No interests declared	
Jana Hundt	Expert	Germany	No interests declared	
Maike Goemmel	Expert	Germany	No interests declared	
Dagmar Sommer	Expert	Germany	No interests declared	
Yasemin Suzer	Expert	Germany	No interests declared	
Babett Kobe	Expert	Germany	No interests declared	
Karen Rösner-Friese	Expert	Germany	No interests declared	
Regina Wolf	Expert	Germany	No interests declared	
Lucie Pokludova	Expert	Czech Republic	No interests declared	
Anne Sagnier	Expert	France	No interests declared	
Mathilde Harvey	Expert	France	No interests declared	
Thierry Godard	Expert	France	No interests declared	
Mahrez Zerrouki	Expert	France	No interests declared	
Pascale Macours	Expert	France	No interests declared	
Anne-Marie Jacques	Expert	France	No interests declared	
Anita Bottger	Expert	Netherlands	No interests declared	
Aranzazu González-Canga	Expert	Spain	No interests declared	

CVMP working parties and CMDv	Chair
AWP	Damien Bouchard

CVMP working parties and CMDv	Chair
IWP	Esther Werner
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)**
SAWP-V	Paul McNeill
SWP-V	Carina Bergman
EWP	Cristina Muñoz Madero
ERAWP	Mark Montforts
PhVWP	James Mount
NTWP	Jacqueline Poot
A representative from the European Commission attended the meeting.	
Observers from SwissMedic (Switzerland) attended the meeting.	
Meeting run with support from the relevant EMA staff.	

Experts' declared interests were evaluated against the agenda topics or activities they participated in.