2 December 2025
EMA/380332/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 4-6 November 2025 meeting

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 4-6 November 2025

The attendance list was completed and competing interests were identified for the November 2025 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the October 2025 meeting were adopted.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

1.2.1. Substance – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: Oral explanation held on 4 November 2025.

The Committee listened to an oral explanation from the applicant and noted the rapporteur's revised EPMAR and the presentation from the applicant.

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. Vaxxinact H5 – avian influenza vaccine (subunit recombinant) - EMEA/V/C/006717/0000 – chickens, ducks, turkeys

Indication: for the active immunisation to prevent mortality, clinical signs and to reduce viral excretion in chickens and mulard ducks; to reduce mortality, clinical signs and viral excretion in muscovy ducks and turkeys; to reduce viral excretion in pekin ducks; associated with highly pathogenic avian influenza (HPAI) serotype 5, including the circulating clade 2.3.4.4b.

Exceptional circumstances

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, two peer review reports and comments from three CVMP members.

2.1.2. Ecovaxxin MS – *Mycoplasma synoviae* vaccine (live) - EMEA/V/C/006604/0000 – chickens

Indication: for active immunisation of future layer and future breeder chickens from 4 weeks of age to reduce air sac lesions, foot pad lesions (synovitis), ovarian regressions and egg production losses caused by *Mycoplasma synoviae* infections.

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 a CVMP member.

2.2. Oral explanations

No items

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006655/0000 – dogs

Action: For adoption

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

The Committee noted two peer review reports.

2.4. List of questions

2.4.1. EMEA/V/C/006753/0000 – dogs

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 Committed noted a peer review report and comments from three CVMP members.

2.4.2. EMEA/V/C/006749/0000 – cats, dogs, horses

Action: For adoption

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

The Committed noted a peer review report and comments from two CVMP members.

2.4.3. EMEA/V/C/006821/0000 – sheep, cattle

Action: For adoption

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

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. Abantide BCN Peptides – abantide – EMEA/V/C/006535/0000 - dogs

Action: For information

The Committee noted the letter of withdrawal of the marketing authorisation application for Abantide BCN Peptides. A WEPAR will be published on EMA's website in due course.

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. 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: treatment of tick infestation with *Hyalomma marginatum*, reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days, and reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days. Additionally, the product information has been aligned with version 9.1 of the QRD template.

Rapporteur: K. Boerkamp, Co-Rapporteur: P. McNeill

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.

3.1.2. 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: 'for the treatment of sarcoptic mange (*Sarcoptes scabiei* var. *canis*)' and 'for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for one month. The effect is indirect due to the activity of the veterinary medicinal product against the vector'. Additionally, the product information for all three products has been aligned with version 9.1 of the QRD template.

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsar

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

Grouped variation requiring assessment: to introduce several quality-related changes and to update the product information to upgrade 'Elevated temperature' from a common to very common adverse event and revising the description of the adverse events.

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 information

The Committee noted the summary of opinion.

3.1.4. Librela – bedinvetmab - EMA/VRA/0000301123 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process to include 'Diarrhoea' and 'Emesis' as rare adverse events and 'Immune-mediated polyarthritis', 'Paresis', 'Paralysis' and 'Seizure' as very rare adverse events in the product information. In addition, warnings were introduced when treating dogs with pre-existing immune-mediated conditions and pre-existing seizure disorder. Furthermore, the shelf-life was extended from 2 to 3 years.

Rapporteur: F. Hasslung Wikström

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

Variation requiring assessment: efficacy-related change.

Rapporteur: E. Werner

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. 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 in sheep, 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 the list of questions and the comments on the product information.

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

No items

3.6. Other issues

No items

4. Referrals and related procedures

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

No items

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

No items

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

No items

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

4.4.1. Phenoxypen WSP, 325 mg/g powder for oral solution use in drinking water for pigs and chickens – phenoxymethylpenicillin – EMA/REF/0000302825

Scope: efficacy

Rapporteur: A. Golombiewski, Co-Rapporteur: K. Boerkamp

Action: For discussion

The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the procedure for Phenoxypen WSP, 325 mg/g powder for oral solution use in drinking water for pigs and chickens (EMA/REF/0000302825). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the December 2025 CVMP meeting.

The Committee noted two peer review reports and the comments made by CVMP members.

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

No items

4.6. Request for a scientific opinion/advice under Articles 141(1)(c), 141(1)(e) or 141(1)(i) of Regulation (EU) 2019/6

4.6.1. Veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications – EMA/REF/0000290626

Scope: antimicrobial resistance

Rapporteur: S. Louet, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee started the procedure under Article 141(1)(i) of Regulation (EU) 2019/6 for a scientific advice for veterinary medicinal products containing amoxicillin (as a single active substance) for use in drinking water or in feed in pigs, for respiratory indications. The Committee adopted the list of questions to MAHs, the list of questions to stakeholders and the timetable. The end of the public consultation with stakeholders is on 19 February 2026 and any relevant data should be submitted to vet.referrals@ema.europa.eu

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. Librela – bedinvetmab

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

Action: For information

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

No items

5.4. Re-examination of limited markets and exceptional circumstances authorisations

No items

5.5. Others

No items

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

6.1.1. AWP work plan 2026

Action: For discussion

The Committee discussed the draft AWP Work Plan 2026.

6.1.2. Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species

Action: For adoption

The Committee adopted the concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 15-16 October 2025

Action: For information

The Committee received a verbal report on the ERAWP meeting held on 15–16 October 2025 and noted its agenda, together with the minutes from the meeting held on 17–18 June 2025.

6.2.2. ERAWP work plan 2026

Action: For discussion

The Committee discussed the draft ERAWP work plan for 2026.

6.2.3. Election of the Vice-chair of the ERAWP

Action: For decision

The Committee elected, unanimously, Irene de la Casa as vice-chair of the ERAWP for a 3-year mandate, starting on 5 November 2025.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 14-15 October 2025

Action: For information

The Committee received a verbal report on the EWP-V meeting held on 14-15 October 2025 and noted its agenda together with the minutes of the meeting held on 21 May 2025.

6.3.2. EWP-V work plan 2026

Action: For discussion

The Committee discussed the draft EWP-V work plan for 2026.

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 21-22 October 2025

Action: For information

The Committee received a verbal report on the IWP meeting held on 21-22 October 2025 and noted its agenda, together with the minutes of the meeting held on 19-20 March 2025 and the draft agenda of the IWP Interested Parties meeting to be held on 13 November 2025.

6.4.2. IWP work plan for 2026

Action: For discussion

The Committee discussed the draft IWP work plan for 2026.

6.5. 3Rs Working Party (3RsWP)

6.5.1. 2023-2024 3RsWP Biennial Report

Action: For adoption

The Committee adopted the 2023-2024 Biennial Report.

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2026

Action: For discussion

The Committee discussed the NTWP work plan for 2026.

6.6.2. NTWP - OEG on RNAi&antisense

Action: For information

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 PhVWP-V October 2025 meeting and noted its agenda together with the draft summary record of that meeting.

6.7.2. PhVWP-V work plan 2026

Action: For discussion

The Committee discussed the draft PhVWP-V Work Plan for 2026.

6.8. Quality Working Party (QWP)

6.8.1. QWP 3-year work plan 2026-2028

Action: For discussion

The Committee discussed the draft QWP 3-year work plan 2026-2028.

6.8.2. Guideline on development and manufacture of synthetic peptides

Action: For discussion

The Committee discussed the draft guideline on synthetic peptides together with the overview of comments received during public consultation. The adoption is expected to take place at the December CVMP meeting.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 31 October 2025

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 31 October 2025 and noted its agenda together with the final minutes of the SAWP-V meeting held on 3 October 2025.

6.9.6. SAWP-V work plan for 2026

Action: For discussion

The Committee discussed the draft SAWP-V work plan for 2026.

6.10. Safety Working Party (SWP-V)

6.10.1. SWP-V work plan for 2026

Action: For discussion

The Committee discussed the draft SWP-V work plan 2026.

6.11. Other working party and scientific group issues

6.11.1. European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG) work plan for 2026

Action: For discussion

The Committee discussed the draft ESUAvet WG work plan 2026.

6.11.2. European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG)

Action: For information

The Committee noted the results from the European sales and use of antimicrobials for veterinary medicine - annual surveillance report for 2024. The final report version will be sent to CVMP following endorsement by the ESUAvet WG, and it is expected to be adopted by CVMP during the December plenary meeting.

6.11.3. European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG)

Action: For information

The Committee received a verbal report on the ESUAvet WG recent activities.

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

7.1.1. Request for inclusion of sulfobutyl ether Beta-cyclodextrin sodium (SBECD) in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

Action: For adoption

The Committee agreed to include sulfobutyl ether Beta-cyclodextrin sodium (SBECD) in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009.

The Committee also adopted the CVMP assessment report and noted comments from a CVMP member.

7.1.2. Request for inclusion of polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer (PCL-PVAc-PE) in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

Action: For adoption

The Committee agreed to include polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer (PCL-PVAc-PE) in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009.

The Committee also adopted the CVMP assessment report and noted comments from a CVMP member.

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

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

Action: For decision

The Committee elected, unanimously, Damien Bouchard as the Chair of the ADRA temporary Working Party for a 3-year mandate.

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

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.1.1. Request for classification

Action: For classification

The Committee discussed the veterinary medicinal product for dogs. The Committee classified the product as not intended for a limited market according to Article 4(29).

9.1.2. Request for classification

Action: For classification

The Committee discussed the veterinary medicinal product for Atlantic salmon. The Committee classified the product as intended for a limited market according to Article 4(29) and not eligible for authorisation according to Article 23 (Applications for limited markets).

9.1.3. Request for classification

Action: For classification

The Committee discussed the veterinary medicinal product for Atlantic salmon. The Committee classified the product as intended for a limited market according to Article 4(29) and not eligible for authorisation according to Article 23 (Applications for limited markets).

9.1.4. Request for classification

Action: For classification

The Committee discussed the veterinary medicinal product for turkeys. The Committee classified the product as intended for a limited market according to Article 4(29) and eligible for authorisation according to Article 23 (Applications for limited markets).

9.1.5. Request for classification

Action: For classification

The Committee discussed the veterinary medicinal product for honeybees. The Committee classified the product as intended for a limited market according to Article 4(29) and not eligible for authorisation according to Article 23 (Applications for limited markets).

9.1.6. Draft questions and answers on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)

Action: For adoption

The Committee adopted the questions and answers on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets). This document supersedes the Reflection paper on classification of a product as intended for a limited market (EMA/CVMP/235292/2020).

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

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

10. Organisational and strategic matters

10.1. CVMP work plan 2026

Action: For discussion

The Committee further discussed the CVMP work plan 2026.

10.2. Danish Presidency meeting

Action: For information

The Committee received a verbal update on the Danish Presidency meeting and noted its minutes.

10.3. Update on IRIS roadmap and upcoming changes in pre-submission process

Action: For information

11. CMDv

No items

12. Legislation

No items

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

Nobilis Multriva IBm+ND+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm, Nobilis Multriva RT+IBm+ND+EDS, Nobilis Multriva IBm+ND, Nobilis Multriva IBm+ND+Gm+REOm+EDS – WS – EMA/VRA/0000285373 – chickens

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.

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

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.

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

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.

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, to update the administrative information concerning the holder's representative, and to make additional editorial changes.

Rapporteur: R. Breathnach

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.

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

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

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.

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

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.

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

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

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.

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

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.

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm, Nobilis Multriva RT+IBm+ND+EDS – WS – EMA/VRA/0000285303 – chickens

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 recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Profender – praziquantel / emodepside – WS – EMA/VRA/0000276433– dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

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.

Equisolon – prednisolone – EMA/VRA/0000278449 – horses

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.

3.4. List of questions

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 the list of questions.

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, Nobilis Multriva RT+IBm+ND+Gm+REOm, Nobilis Multriva Gm+REOm, Nobilis Multriva IBm+ND+Gm+REOm+EDS - Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated), Avian metapneumovirus, avian infectious bronchitis, Newcastle disease, avian infectious bursal disease and avian reovirus vaccine (inactivated), Avian infectious bursal disease and avian reovirus vaccine (inactivated), Avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated) - EMA/VRA/0000285378 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

The Committee adopted the rapporteur's assessment report including 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 (November 2025) and the list of finalised signals.

Union veterinary pharmacovigilance database best practice guide (BPG) and MAH signal assessment report template

Action: For information

The Committee noted the revised Veterinary Union Pharmacovigilance Database – Best Practice Guide together with the revised Veterinary Signal AR template.

5.2 Post-authorisation measures

Poulvac Procerta HVT-IBD-ND – EMA/PAM/0000295789

Post-authorisation recommendation: quality-related issues.

Rapporteur: E. Werner

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in responses to the Committee's recommendation which is now considered fulfilled.

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

The Committee adopted the ERA ESEC Expert nominations.

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

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

The Committed noted the draft agenda of the November CMDv meeting to be held on 12-14 November 2025 together with the agenda of the CMDv meeting held on 15-16 October 2025.

ANNEX I

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 4-6 November 2025 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	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Toomas Tiirats	Member	Estonia	No restrictions applicable to this meeting	
Minna Leppänen	Member	Finland	No interests declared	
Kristina Lehmann	Alternate	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	
Andrea Christina Golombiewski	Member	Germany	No restrictions applicable to this meeting	
Esther Werner	Alternate	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No participation in discussion, final deliberations and voting on:	EMA/VRA/0000282075 EMEA/V/C/006717/0000
Paul McNeill	Member	Ireland	No interests declared	
Alice Blennerhassett	Alternate	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Zanda Auce	Member	Latvia	No interests declared	
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	
Urska Peunik	Alternate	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
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	
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
Mariette Salery	Expert	France	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Aranzazu González-Canga	Expert	Spain	No interests declared	
Luis Agote Casado	Expert	Spain	No interests declared	
Gavin Ryan	Expert	Ireland	No interests declared	
Francisca Moya	Expert	Spain	No interests declared	
Rocio Fernandez Granda	Expert	Spain	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Alberto de Prado Lopez	Expert	Spain	No interests declared	
Raul Belmar Liberato	Expert	Spain	No restrictions applicable to this meeting	
Jesus Alberto Sanchez Rodriguez	Expert	Spain	No interests declared	
Florence PILLET	Expert	France	No restrictions applicable to this meeting	
Anne-Marie JACQUES	Expert	France	No interests declared	
Nathalie BRIDOUX	Expert	France	No interests declared	
Thierry GODARD	Expert	France	No interests declared	
Tiphaine Moreac-Pesselier	Expert	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Pascale MACOURS	Expert	France	No interests declared	
Anne SAGNIER	Expert	France	No interests declared	
Walid OUMESSAD	Expert	France	No interests declared	
Mathilde HARVEY	Expert	France	No interests declared	
Delphine Urban	Expert	France	No interests declared	
Saila Antila	Expert	Finland	No interests declared	
Ulla Nevalainen	Expert	Finland	No interests declared	
Erik den Hertog	Expert	Netherlands	No restrictions applicable to this meeting	
Frida Martin	Expert	Sweden	No interests declared	
Jenny Larsson	Expert	Sweden	No interests declared	
Wiebke Weiher	Expert	Germany	No interests declared	
Sandra-Maria Wienhold	Expert		No restrictions applicable to this meeting	
Jens Barthel	Expert	Germany	No interests declared	
Nuria Doñamayor Alonso	Expert	Germany	No restrictions applicable to this meeting	
Sandra Bertulat	Expert	Germany	No interests declared	
Jan Brosda	Expert	Germany	No interests declared	
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Kerstin Cramer	Expert	Germany	No interests declared	
Roswitha Merkel	Expert	Germany	No interests declared	
Anke Finnah	Expert	Germany	No interests declared	
Babett Kobe	Expert	Germany	No interests declared	
Maike Goemmel	Expert	Germany	No interests declared	
Heike Gyra	Expert	Germany	No interests declared	
Jana Hundt	Expert	Germany	No interests declared	
Rolf Beckmann	Expert	Germany	No interests declared	
Ingun Lemke	Expert	Germany	No interests declared	
Daniela Loos	Expert	Germany	No interests declared	
Henriette Rau	Expert	Germany	No interests declared	
Yasemin Suzer	Expert	Germany	No interests declared	
Hannah Pratt	Expert	Ireland	No interests declared	
Susann Bradley	Expert	Ireland	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Tatyana Devine	Expert	Ireland	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Katariina Kivilahti-Mäntylä	Expert	Finland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Lucie Pokludova	Expert	Czech Republic	No interests declared	
Kathrin Schmidt	Expert	Germany	No interests declared	

CVMP working parties and CMDv	Chair
AWP	Damien Bouchard
IWP	Esther Werner
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)**
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
EWP	Cristina Muñoz Madero
3Rs	Sarah Adler-Flindt
ERAWP	Mark Montforts
PhVWP	James Mount
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.