14 April 2026
EMA/127395/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 10-12 March 2026 meeting

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

10 March 2026, 09:00 – 12 March 2026, 13:00 - Room 1C and virtual

Health & Safety Information

In accordance with **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 in-person.

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 March 2026

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

iv. Adoption of the minutes of the previous meeting

The adoption of minutes of the February 2026 meeting was postponed to April 2026.

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

1.4.1. Substance – EMEA/V/MRL/006954/FULL/0001 – bovine

Action: For adoption

The Committee adopted the scientific overview and list of questions.

Action: For information

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

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

Indication: for active immunisation of healthy chickens to reduce faecal excretion and colonisation of internal organs with *Salmonella infantis*.

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 and a peer review report.

2.1.2. Bluetongue virus vaccine (inactivated) - EMEA/V/C/006821/0000 – sheep

Indication: for active immunisation of sheep to reduce viraemia and pyrexia caused by the serotype 3 of the bluetongue virus. Accelerated assessment.

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 and comments from CVMP members.

2.2. Oral explanations

No items

2.3. List of outstanding issues

2.3.1. Equine interleukin-5 vaccine (recombinant protein, conjugate) - EMEA/V/C/006180/0000 – horses

Indication: for the active immunisation of horses affected by a hyper-eosinophilic condition to normalise the level of eosinophil immune cells in blood and reduce clinical signs by induction of antibodies against equine interleukin-5.

Action: For decision

The Committee agreed that an oral explanation was needed.

Action: For adoption

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

Action: For information

The Committee noted three peer review reports.

2.4. List of questions

2.4.1. Porcine circovirus type 2d, ORF2 capsid protein – EMEA/V/C/006873/000 – pigs

Indication: for the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and loss in body weight gain.

Action: For adoption

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

Action: For information

The Committee noted a peer review report and comments from a CVMP member.

2.4.2. Double-stranded RNA with nucleotide sequence complementary to the calmodulin mRNA of *Varroa destructor* - EMEA/V/C/006823/0000 – honey bees

Indication: for reduction of varroa mite (*Varroa destructor*) infestation to prevent varroosis in honey bees during the productive season or in the autumn going into overwintering.

Action: For adoption

The Committee adopted the scientific overview, the list of questions and the comments on the product information as well as the new active substance report.

Action: For information

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

No items

3. Variations to marketing authorisations

3.1. Opinions

No items

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1. Respivac aMPV – turkey rhinotracheitis virus, live - EMA/VRA/0000309778 – chickens

Variation requiring assessment: to add turkeys as a new target species; 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 decision

The Committee agreed that no oral explanation was needed.

Action: For adoption

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

3.3.2. Enteroporc Coli AC – neonatal piglet colibacillosis (recombinant, inactivated) and *Clostridium perfringens* vaccine (inactivated) - VRA/0000284808 – pigs

Variation requiring assessment: to add the mixed, associated use of Enteroporc Coli AC and Parvoruvax / Parvoruvac to the SPC.

Rapporteur: N.C. Kyvsgaard

Action: For decision

The Committee agreed that no oral explanation was needed.

Action: For adoption

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

Action: For information

The Committee noted comments from CVMP members.

3.4. List of questions

3.4.1. BTVPUR – bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 4) - EMA/VRA/0000322270 – cattle, sheep

Variation requiring assessment: to update the product information by including a new vaccination practice against BTV8 in sheep.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the list of questions and the comments on the product information

Action: For information

The Committee noted the comments from a CVMP member.

3.4.2. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000321340 – chickens

Variation requiring assessment: to add turkey as a new target species and to add a new strength.

Rapporteur: C. Miras, Co-Rapporteur: L. Nepejchalová

Action: For adoption

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

Action: For information

The Committee noted the comments from CVMP members.

3.4.3. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000321483 – chickens

Variation requiring assessment: to provide results of duration of immunity studies to fulfil the specific obligation.

Rapporteur: C. Miras, Co-Rapporteur: L. Nepejchalová

Action: For adoption

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

Action: For information

The Committee noted the comments from a CVMP member.

3.4.4. Clevor – ropinirole - EMA/VRA/0000321228 – dogs

Variation requiring assessment: change in the pack size of the finished product; to update the product information to include home use following the addition of a pack size.

Rapporteur: C. Muñoz Madero

Action: For adoption

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

Action: For information

The Committee noted the comments from a CVMP member.

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

No items

3.6. Other issues

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

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

Action: For information

The Committee noted the letter of withdrawal of the application. A withdrawal EPAR will be published on the EMA website.

4. Referrals and related procedures

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

4.1.1. Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep - EMA/REF/0000271819

Efficacy, anti-parasitic resistance

Rapporteur: A. Golombiewski, Co-Rapporteur: C. Muñoz Madero

Scope: List of outstanding issues

Action: For discussion

The Committee discussed the rapporteur’s assessment report including the co-rapporteur's critique. The adoption of the opinion is expected for the April 2026 CVMP meeting.

Action: For information

The Committee noted the comments from CVMP members.

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 antibiotic dry cow therapy – EMA/REF/0000285673

Antimicrobial resistance

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

Scope: Scientific advice

Action: For adoption

The Committee adopted the CVMP scientific advice (EMA/CVMP/44250/2026) and the CVMP assessment report (EMA/CVMP/44249/2026). Both documents will be published on the EMA website. The CVMP considered quarter-based selective antibiotic dry cow therapy to be consistent with the latest scientific knowledge aimed at reducing antibiotic use, without compromising animal health. The Committee deliberated on how this approach could be reflected in the product information (summary of product characteristics, labelling and package leaflet) of the relevant intramammary dry cow antibiotic veterinary medicines. Such information may assist veterinarians and farmers in determining whether cow based or quarter based selective antibiotic dry cow therapy is more appropriate under specific herd conditions.

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 - EMA/VS/0000302562

Outcome of the signal management process (signal for arthritis).

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

Action: For adoption

The Committee adopted the CVMP assessment report.

5.1.2. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMA/VS/0000318981

Outcome of the signal management process (signal for allergic oedema, anaphylaxis, hypersensitivity reaction and urticaria).

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leppänen

Action: For adoption

The Committee adopted the CVMP assessment report.

5.1.3. Mometamax Ultra – gentamicin / posaconazole / mometasone furoate – EMA/VS/0000319678

Outcome of the signal management process (signal for application site erythema, application site pruritus).

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

Action: For adoption

The Committee adopted the CVMP assessment report.

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

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

The Committee adopted, by consensus, the CVMP opinion. The Committee recommended the extension for one year of the validity of the marketing authorisation in exceptional circumstances.

Action: For information

The Committee noted the comments from a CVMP member.

5.4.2. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000314905

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

Rapporteur: C. Miras Co-Rapp: L. Nepejchalová

Action: For adoption

The Committee adopted the list of questions.

5.4.3. Hepizovac – epizootic haemorrhagic disease vaccine (inactivated) - EMA/S/0000322659

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

Rapporteur: J. Poot, Co-Rapporteur: L. Nepejchalová

Action: For adoption

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

Action: For information

The Committee noted the comments from CVMP members.

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 Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in animals in the European Union: development of resistance and impact on public and animal health

Action: For discussion

The Committee discussed the revised draft of the reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in animals in the European Union: development of resistance and impact on public and animal health. Adoption of the document is expected at the April 2026 CVMP meeting.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 24-25 February 2026

Action: For information

The Committee received a verbal report on ERAWP meeting held on 24–25 February 2026 and noted its agenda together with the minutes of the meeting held 15–16 October 2025.

6.2.2. Appointment of a new ERAWP member – call for nominations

Action: For endorsement

The Committee endorsed the call for nominations for one expert for the Environmental Risk Assessment Working Party, the selection procedure and the draft timetable.

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

Action: For decision

The Committee agreed that the ERAWP should prepare 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 and noted the overview of comments received on the concept paper (EMA/CVMP/ERA/75412/2023) during public consultation (EMA/CVMP/ERA/369161/2025).

6.2.4. Updated guideline on the plant testing strategy for veterinary medicinal products

Action: For adoption

The Committee adopted the guideline on the plant testing strategy for veterinary medicinal products.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 17 February 2026

Action: For information

The Committee received a verbal report on EWP-V meeting held on 17 February 2026 and noted its agenda together with the minutes of the meeting held on 14-15 October 2025.

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

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

Action: For adoption

The Committee adopted the Risk Management Plan (RMP) template for novel therapies.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held in February 2026

Action: For information

The Committee received a verbal report on PhVWP-V meeting held in February 2026 and noted its agenda together with the draft summary record of the February 2026 PhVWP-V meeting.

6.8. Quality Working Party (QWP)

No items

6.9. Scientific Advice Working Party (SAWP-V)

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

Action: For information

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

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

6.11.1. Concept paper on the development for guidance on demonstration of biosimilarity of biological veterinary medicinal products

Action: For discussion

The Committee discussed the concept paper on the development for guidance on demonstration of biosimilarity of biological veterinary medicinal products. The adoption of the draft concept paper is expected for the April meeting of the Committee.

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential

7.1. MRL issues

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

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 proposing development of a VICH GL to parallel ICH Q9

Action: For discussion

The topic will be further discussed in April.

8.1.2. Concept paper proposing a revision of VICH GL 57: marker residue depletion studies to establish product withdrawal periods in aquatic species

Action: For discussion

The topic will be further discussed in April.

8.1.3. VICH GL 61 on Pharmaceutical Development

Action: For endorsement

The Committee endorsed the updated VICH GL 61 on Pharmaceutical Development prior to sign-off at EWG level.

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

No items

9. Procedural and regulatory matters

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

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

9.1.1. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for dogs as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

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

9.2.1. Summary of eligibility and table of offers from rapporteurs

Action: For decision

9.2.2. Eligibility request

Action: For decision

The applicant requested an application under exceptional circumstances.

9.2.3. Eligibility request

Action: For decision

The applicant requested an application under exceptional circumstances.

9.2.7. Decision on the accelerated assessment request and application under exceptional circumstances

Action: For decision

The Committee agreed that the dossier can be submitted in line with the requirements for submissions under Article 25 of Regulation (EU) 2019/6 - Applications in exceptional circumstances and that the procedure can run under an accelerated assessment timetable.

9.2. 9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 25 February 2026

Action: For information

The Committee received a verbal report on the Veterinary Domain meeting held on 25 February 2026 and noted its agenda together with the minutes of the 15 December 2025 meeting.

10.2. CVMP/CMDv Informal meeting under the Cyprus EU Presidency, Vienna, 28-29 April 2026

Action: For adoption

The Committee adopted the CVMP session agenda and the CVMP-CMDv session agenda.

10.3. Veterinary Medicines Safety Day campaign, 8 April 2026

Action: For information

The Committee received an update on the Veterinary Medicines Safety Day campaign to be held on 8 April 2026.

10.4. EMA veterinary assessor day

Action: For information

The Committee received an update on the upcoming EMA veterinary assessor day.

11. CMDv

No items

12. Legislation

12.1 European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6: guidance concerning five substances not included in Commission Implementing Regulation (EU) 2025/901

Action: For discussion

The Committee discussed the draft report to the European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6: guidance concerning five substances not included in Commission Implementing Regulation (EU) 2025/901. The report is foreseen for adoption at the April meeting.

12.2. European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6: guidance on scientific issues in relation to Articles 107(6) and 114(3)

Action: For discussion

The Committee discussed the draft guidance on scientific issues in relation to Articles 107(6) and 114(3). Adoption of the document is expected for the April 2026 meeting of CVMP.

13. Any other business

13.1. EMT - reminder to delegates / experts for the annual update of their EMA DoI

Action: For information

The Committee noted the EMT reminder to delegates/experts for the annual update of their EMA DoI.

13.2. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

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

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

The Committee adopted 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 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

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

The Committee adopted 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.

Stelfonta – tigilanol tiglate - EMA/VRA/0000301147 – dogs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template and make additional minor editorial changes.

Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted 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.

3.3. List of outstanding issues

Veraflox – pradofloxacin – EMA/VRA/0000301203 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of outstanding issues.

3.4. List of questions

Credelio Plus – lotilaner / milbemycin oxime – EMA/VRA/0000322260 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of questions.

Locatim – bovine concentrated lactoserum containing specific immunoglobulins G against *E. coli* F5 (K99) adhesin ≥2.8 log10/ml – EMA/VRA/0000322515 – cattle

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

Rapporteur: F. Klein

Action: For adoption

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

Action: For information

The Committee noted the comments from CVMP members.

Draxxin – tulathromycin - EMA/VRA/0000314905 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of questions.

Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMA/VRA/0000322477 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

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

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.

5.2 Post-authorisation measures

Cevac Reomune - EMA/PAM/0000324337

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

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

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

List of veterinary products to be tested in the Sampling and Testing Programme 2027

Action: For adoption

The Committee adopted the list of veterinary products to be tested in the Sampling and Testing Programme 2027.

6. Working parties

6.7 Pharmacovigilance Working Party (PhVWP-V)

Endorsement of new Swedish PhVWP-V member (replacement of previous member)

Action: For endorsement

The Committee endorsed the nomination for Ulrika Falkenö from Frida Hasslung Wikström.

Endorsement of new Spanish PhVWP-V member (replacement of previous member)

Action: For endorsement

The Committee endorsed the nomination for Marta Martin Juárez from Cristina Muñoz Madero.

Endorsement of new Romanian PhVWP-V member (replacement of previous member)

Action: For endorsement

The Committee endorsed the nomination for Diana Laura Stan from Gabriela Tuchilă.

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

The Committee adopted the nominations for the Quality Chemical ESEC.

Questions & Answers on the Implementation of 3DP Technology

Action: For adoption

The Committee adopted the Questions & Answers on the Implementation of 3DP Technology (Additive Manufacturing Technology) for Solid Oral Dosage Forms.

6.10 Other working party and scientific group issues

Dosage Review and Adjustment of established Antibiotics (ADRA) tWP: meeting minutes – 16.01.2026

Action: For information

The Committee noted the minutes of the ADRA tWP meeting held on 16 January 2026.

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

10. Organisational and strategic matters

Transfer of rapporteurship (ES)

Action: For adoption

The Committee adopted the transfer of rapporteurships from C. Rubio Montejano to S. Gil Morales.

11. CMDv

Reports from CMDv

Action: To note

The Committee noted the CMDv minutes of the September 2025, October 2025, November 2025 and December 2025 meetings, the final agenda of the CMDv meeting held on 21-22 January 2026, the CMDv Report for release September-December 2025 (link) together with the final agenda of the CMDv meeting held on 18-19 February 2026.

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 March 2026 CVMP meeting, which was held in person.

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

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	
Krasimir Zlatkov	Member	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	
Birgit Aasmäe	Alternate	Estonia	No restrictions applicable to this meeting	
Minna Leppänen	Member	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Andrea Christina Golombiewski	Alternate	Germany	No restrictions applicable to this meeting	
Esther Werner	Member	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No participation in discussion, final deliberations and voting on:	EMEA/V/MRL/006954/FULL/0001 EMA/VRA/0000322270
Paul McNeill	Member	Ireland	No interests declared	
Alice Blennerhassett*	Alternate	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No restrictions applicable to this meeting	
Renate Kuske*	Alternate	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	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Mojca Ogriz*	Alternate	Slovenia	No interests declared	
Urska Peunik	Member	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Sonia Gil Morales	Alternate	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	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Anita Bottger	Expert	Netherlands	No interests declared	
Mark Montforts	Expert	Netherlands	No interests declared	
Rene van Herwijnen	Expert	Netherlands	No interests declared	
Benoit Courty	Expert	France	No interests declared	
Anja Pfalzgraff*	Expert	Germany	No interests declared	
Christopher Janich	Expert	Germany	No interests declared	
Daniel Benesh	Expert	Germany	No interests declared	
Nathalie Bridoux	Expert	France	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Andrea Springer	Expert	Germany	No interests declared	
Dorothea Neubert	Expert	Germany	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	

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	
Kira Rosenkilde Underbjerg	Expert	Denmark	No interests declared	
Florence PILLET	Expert	France	No restrictions applicable to this meeting	
Anne SAGNIER	Expert	France	No interests declared	
Anne-Marie JACQUES	Expert	France	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Ana Isabel Olias Molero	Expert	Spain	No interests declared	
Alberto de Prado Lopez	Expert	Spain	No interests declared	
Maria Esperanza Herreros Avila	Expert	Spain	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Raul Belmar Liberato	Expert	Spain	No restrictions applicable to this meeting	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Rodrigo Garcia Fernandez	Expert	Spain	No restrictions applicable to this meeting	
Cristina Ballesteros Tercero	Expert	Spain	No interests declared	
Leyre Sanchez Sanchez Rojas	Expert	Spain	No interests declared	
Aranzazu Gonzalez Canga	Expert	Spain	No interests declared	
Elena Lucas Roldan	Expert	Spain	No interests declared	
Irene de la Casa Resino	Expert	Spain	No interests declared	
Mercedes Ureña Montilla	Expert	Spain	No interests declared	
Stella Attia	Expert	Finland	No interests declared	
Tatyana Devine	Expert	Ireland	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Catarina Eriksson	Expert	Sweden	No interests declared	
Camilla Göktürk	Expert	Sweden	No interests declared	
Jenny Larsson	Expert	Sweden	No interests declared	
Frida Martin	Expert	Sweden	No interests declared	
Laura Kulisch	Expert	Germany	No interests declared	
Uta Herbst	Expert	Germany	No interests declared	
Svenja Rieke	Expert	Germany	No interests declared	
Anke Finnah	Expert	Germany	No interests declared	
Kerstin Cramer	Expert	Germany	No interests declared	
Sandra Bertulat	Expert	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Sandra-Maria Wienhold	Expert	Germany	No restrictions applicable to this meeting	
Martina Kern	Expert	Germany	No interests declared	
Wiebke Weiher	Expert	Germany	No interests declared	
Paulin Dettmann	Expert	Germany	No restrictions applicable to this meeting	
Christian Gerecke	Expert	Germany	No restrictions applicable to this meeting	
Catharina Husteden	Expert	Germany	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	
Andrea Springer	Expert	Germany	No interests declared	
Kathrin Schmidt	Expert	Germany	No interests declared	
Andrea Orthmann	Expert	Germany	No interests declared	
Miriam Schrader	Expert	Germany	No interests declared	
Bernhard Klaar	Expert	Germany	No interests declared	
Kathi Westphal-Settele	Expert	Germany	No restrictions applicable to this meeting	
Gunther Speichert	Expert	Germany	No interests declared	
Jens Schönfeld	Expert	Germany	No interests declared	
Christina Bredtmann	Expert	Germany	No interests declared	
Jan Brosda	Expert	Germany	No interests declared	
Inke Reimer	Expert	Germany	No interests declared	
Liselotte Withen	Expert	Denmark	No restrictions applicable to this meeting	
Anne Malene Nissen	Expert	Denmark	No interests declared	
Monika Hofmann	Expert	Germany	No interests declared	
Heike Gyra	Expert	Germany	No interests declared	
Ingun Lemke	Expert	Germany	No interests declared	
Henriette Rau	Expert	Germany	No interests declared	
Jana Hundt	Expert	Germany	No interests declared	
Yasemin Suzer	Expert	Germany	No interests declared	
Dagmar Sommer	Expert	Germany	No interests declared	
Babett Kobe	Expert	Germany	No interests declared	
Judith Romberg	Expert	Germany	No interests declared	
Karen Roesner-Friese	Expert	Germany	No interests declared	
Regina Wolf	Expert	Germany	No interests declared	
Koenraad Brusselmans	Expert	Belgium	No interests declared	
Eva Pomezna	Expert	Czech Republic	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Radka Smitalova	Expert	Czech Republic	No interests declared	
Jitka Chumchalova	Expert	Czech Republic	No interests declared	
Vilma Dosedlova	Expert	Czech Republic	No interests declared	
Jana Fluksova	Expert	Czech Republic	No interests declared	
Eva Vernerova	Expert	Czech Republic	No interests declared	
Caroline Ormston	Expert	Czech Republic	No interests declared	
Trine Sidonia Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Sabine Klee	Expert	Germany	No interests declared	
Tonje Hoy	Expert	Norway	No interests declared	
Laura Kulisch	Expert	Germany	No interests declared	

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

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*
ERAWP	Mark Montforts
NTWP	Jacqueline Poot*
SAW-P	Paul McNeill*
PhVWP-V	James Mount
Observers from SwissMedic (Switzerland) attended the meeting.	
Representatives from the European Commission attended the meeting.	
Meeting run with support from the relevant EMA staff.	

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

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