16 June 2026
EMA/139011/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 19-21 May 2026 meeting

Vice-Chair: F. Hasslung Wikström, deputising for Chair Gerrit Johan Schefferlie

19 May 2026, 09:00 – 21 May 2026, 13:00 - Room 1C and virtual

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

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 19-21 May 2026

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

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No contacts have been declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the March 2026 meeting will be adopted by written procedure.

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

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

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

Action: For 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 two CVMP members.

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

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

Action: For 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 a CVMP member.

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

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

Action: For 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.

2.1.6. Marek's disease and Newcastle disease vaccine (live recombinant) - EMEA/V/C/006679/0000 – chickens

Indication: active immunisation of one-day-old chickens and 18- to 19-day-old embryonated chicken eggs against Marek's disease (MD) and Newcastle disease (ND).

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

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

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

Action: Oral explanation to be held on 19 May 2026 at 14.15

The Committee heard an oral explanation.

The Committee noted rapporteurs' assessment of responses to the list of outstanding issues, comments on the product information.

2.3. List of outstanding issues

2.3.1. *Salmonella* typhimurium vaccine (live) – EMEA/V/C/006645/0000 – chickens

Indication: active immunisation of chickens to reduce organ colonisation and faecal excretion due to *Salmonella typhimurium.*

Action: For adoption

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

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

2.4. List of questions

2.4.1. Avian influenza vaccine (RNA particle) - EMEA/V/C/006287/0000 – ducks

Indication: for active immunisation of mule ducks from 1 day of age, to reduce mortality, clinical signs and viral shedding caused by highly pathogenic avian influenza virus, H5 subtype strains of clade 2.3.4.4b.

Exceptional circumstances.

Action: For adoption

The Committee adopted the scientific overview and list of questions together with the comments on the product information. The Committee noted four peer review reports and comments from two CVMP members.

2.4.2. Buprenorphine hydrochloride - EMEA/V/C/006917/0000 – mice, rats, rabbits

Indication: for the control of post-procedural pain in mice, rats, and rabbits (non-food-producing).

Action: For adoption

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

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. Porcine circovirus vaccine (recombinant) and *Mycoplasma hyopneumoniae* vaccine (inactivated) - EMEA/V/C/006603/0000 – pigs

Action: For endorsement

The Committee endorsed the request from the applicant for an extension of the clock stop.

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

Action: For endorsement

The Committee endorsed the request from the applicant for an extension of the clock stop.

2.6.3. Nobivac NXT HCPChFeLV – feline calicivirosis, feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia), feline chlamydiosis (live) and feline leukaemia (RNA particle) vaccine - EMEA/V/C/006520/0000 – cats

Action: For information

The Committee noted the letter from Intervet International b.v. to EC.

3. Variations to marketing authorisations

3.1. Opinions

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

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, 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. Librela – bedinvetmab - EMA/VRA/0000340267 - dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process to update the product information by adding "Joint swelling, Joint pain, Bone and Joint disorder and Arthritis" as very rare adverse events. Other related changes were made within the product information, including advice to consider performing additional diagnostics and discontinue treatment on a case-by-case basis where a dog presents with new or increased joint swelling and/or joint pain following Librela treatment.

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.

3.1.3. 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 from Annex II of the product information.

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

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion, the CVMP assessment report and the product information. The annex II was updated with deletion of SOB (specific obligation).

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

3.1.4. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMA/VRA/0000340561 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process to update the product information by adding "Hypersensitivity reactions (e.g. facial oedema, urticaria and anaphylaxis)" as very rare adverse events.

Rapporteur: C. Muñoz Madero

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

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

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

Action: For adoption

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.

3.1.6. 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 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 comments from the CVMP members.

3.1.7. Hepizovac – epizootic haemorrhagic disease vaccine (inactivated) - VRA/0000337091 – cattle

Variation requiring assessment: to fulfil the specific obligation regarding the stability of the antigen at 18 months of storage.

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

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.

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. Prevomax – maropitant - EMA/VRA/0000337350 – dogs, cats

Variation requiring assessment: to update the frequency for the adverse event 'Injection site pain' and to propose some editorial changes to further align the product information with QRD template version 9.1.

Rapporteur: S. Louet

Action: For adoption

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

3.4.2. Felpreva – tigolaner / emodepside / praziquantel - EMA/VRA/0000333761 – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: treatment of tick infestations with *Ixodes hexagonus*, *Rhipicephalus sanguineus*, *Haemaphysalis longicornis*.

Rapporteur: A. Golombiewski, Co-Rapporteur: E. Dewaele

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. Vectra 3D – dinotefuran / pyriproxyfen / permethrin - EMA/VRA/0000334831 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: reduction of the risk of infection with *Leishmania infantum* via transmission by *Phlebotomus* spp. for 1 month.

Rapporteur: A. Golombiewski, Co-Rapporteur: H. Bremer

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 adoption

The Committee adopted the withdrawal EPAR which 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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

4.7. Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

No items

5. Post-authorisation issues for marketing authorisations

Information relating to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections.

5.1. Pharmacovigilance

No items

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

No items

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

5.4.1. 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 opinion and the CVMP assessment report.

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)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Appointment of a new ERAWP member – recommendation from the Veterinary Domain

Action: For endorsement

The Committee endorsed the recommendation from the *ad hoc* Veterinary Domain meeting held on 30 April 2026 to appoint Mojca Durjava as new ERAWP member.

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 21-22 April 2026

Action: For information

The Committee received a verbal report on IWP meeting held on 21-22 April 2026 and noted its agenda together with the minutes of the IWP meeting held on 21-22 October 2025.

6.4.2. Concept paper for the revision of the Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances

Action: For discussion

The Committee discussed the concept paper for the revision of the Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances. The adoption of the document is expected for the June plenary of the Committee.

6.4.3. Concept paper for the revision of the Guideline on data requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs) by new MS of the same origin and integration with the Reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products

Action: For discussion

The Committee discussed the concept paper for the revision of the Guideline on data requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs) by new MS of the same origin and integration with the Reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products. The adoption of the document is expected for the June plenary of the Committee.

6.4.4. Call for nomination

Action: For information

The Committee noted the call for nominations for the chair of IWP. The election is expected to take place at the June plenary meeting.

6.5. 3Rs Working Party (3RsWP)

6.5.1. Resignation of the 3RsWP vice-chair

Action: For information

The Committee noted that the vice-chair of the 3RsWP is stepping down of the role and agreed with the need of an additional member to the 3RsWP.

6.5.2. Verbal feedback on 3RsWP Stakeholders meeting 31 March 2026

Action: For information

The Committee received a verbal report on 3RsWP Stakeholders meeting 31 March 2026.

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 22 April 2026

Action: For information

The Committee received a verbal report on PhVWP-V meeting held on 22 April 2026 and noted its summary records.

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 18 May 2026

Action: For information

The Committee received a verbal report on SAWP-V meeting held on 18 May 2026 and noted its agenda and the minutes of the SAWP-V meeting held on 10 April 2026.

6.10. Safety Working Party (SWP-V)

6.10.1. Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances

Action: For adoption

The Committee adopted the revised guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances (EMA/CVMP/SWP/591282/2021). The document comes into force with its publication.

6.11. Other working party and scientific group issues

6.11.1. WPs mandate (complementing procedures)

Action: For discussion

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

7.3.1. CVMP activities related to antimicrobials: status report on EMA/CVMP activities (2021–2025) and EMANS 2028 Strategic Overview (Theme 4)

Action: For discussion

The Committee discussed the status of the CVMP activities related to antimicrobials: report on EMA/CVMP activities (2021–2025) and EMANS 2028 Strategic Overview (Theme 4). The document is expected to be adopted during the June Committee meeting.

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

7.7.1. Notification of an ITF briefing meeting

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

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 discussed the veterinary medicinal product for dogs. The Committee agreed that the product is classified as limited market but not eligible for article 23.

9.1.2. Request for classification

Action: For classification

The Committee discussed the veterinary medicinal product for dogs and cats. The Committee agreed that the product is not a limited market and not eligible for article 23.

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 information

9.2.2. Eligibility request

Action: For decision

9.2.3. Eligibility request

Action: For decision

9.2.4. Eligibility request

Action: For decision

9.2.5. Eligibility request

Action: For decision

9.2.6. Eligibility request

Action: For decision

9.2.7. Eligibility request

Action: For decision

9.2.8. Appointment of rapporteurs - MRL application

Action: For decision

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

10. Organisational and strategic matters

10.1. CVMP Interested Parties meeting 2026

Action: For information

The Committee noted the draft agenda of the CVMP Interested Parties meeting 2026.

11. CMDv

No items

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

Elmaro – maropitant - EMA/VRA/0000336228 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

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.

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, 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.

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

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

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.

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

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

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.

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, 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.

Poulvac E. coli – Avian colibacillosis vaccine (live) – VRA/0000335058 – chickens and turkeys

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.

3.4. List of questions

Cepedex – dexmedetomidine - EMA/VRA/0000337599 – cats, dogs

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 list of questions and the comments on the product information.

Profender + non-CAPs – praziquantel / emodepside - EMA/VRA/0000323435 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of questions.

ProZinc – insulin human - EMA/VRA/0000336187 – cats and dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

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 and noted the list of finalised signals.

5.3 Inspections and controls

6. Working parties

6.5 3Rs Working Party (3RsWP)

6.5.1 Minutes of the 3RsWP plenary meeting held on 28-29 January 2026

Action: For information

The Committee noted the minutes of the 3RsWP plenary meeting held on 28-29 January 2026.

6.5.2 Agenda of the 3RsWP plenary and stakeholder meetings held on 31 March – 1 April 2026

Action: For information

The Committee noted the agenda of 3RsWP plenary and stakeholder meetings.

6.5.3 NC and NAMs ESEC nominations

Action: For information

The Committee noted the NC and NAMs ESEC nominations.

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

The Committee adopted the nominations for the Quality Chemical ESEC.

6.10 Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

Minutes of the Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party meetings held in March and April 2026

Action: For information

The Committee noted the minutes of the ADRA tWP meeting held on 27 March 2026 together with the minutes of the ADRA tWP – Pharmacokinetics Subgroup meeting held on 17 April 2026.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL61 on Pharmaceutical Development

Action: For adoption

The Committee adopted the revised VICH GL61 on Pharmaceutical Development. The Guideline is for implementation by April 2027.

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

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

9.2.1. Transfer of (co-)rapporteurships responsibilities

Action: For decision

The Committee adopted the transfer of (co-)rapporteurship responsibilities from: A. Blennerhassett to P. McNeill.

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

10.1. Vet Assessors Day 2026

Action: For information

The Committee noted the draft agenda of Vet Assessors Day 2026.

11. CMDv

Reports from CMDv

Action: To note

The Committee noted the final agenda of the CMDv meeting held on 22-23 April 2026.

13. Any other business

ANNEX I

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 19-21 May 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
Frida Hasslung Wikström	**Vice-chair**	**Sweden**	**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 restrictions applicable to this meeting	
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	
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	
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	
Gábor Kulcsár	Member	Hungary	No interests declared	
Paul McNeill	Member	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No restrictions applicable to this meeting	
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	
Knud Sveen Torjesen	Member	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	
Urska Peunik	Member	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Sonia Gil Morales	Alternate	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
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
Ana Chilaika	Expert	Sweden	No restrictions applicable to this meeting	
Catarina Eriksson	Expert	Sweden	No interests declared	
Alejandro Rodriguez	Expert	Sweden	No interests declared	
Frida Martin	Expert	Sweden	No interests declared	
Mariette Salery	Expert	France	No interests declared	
Lorena Tourino Gonzalez	Expert	Spain	No interests declared	
Anke Finnah	Expert	Germany	No interests declared	
Daniel Benesh	Expert	Germany	No interests declared	
Jean-Christophe Faucon	Expert	France	No interests declared	
Anne-Marie Jacques	Expert	France	No interests declared	
Pascale Macours	Expert	France	No interests declared	
Mahrez Zerrouki	Expert	France	No interests declared	
Anne Sagnier	Expert	France	No interests declared	
Mathilde Harvey	Expert	France	No interests declared	
Laura Kulisch	Expert	Germany	No interests declared	
Christina Bredtmann	Expert	Germany	No interests declared	
Katja Boxberger	Expert	Germany	No interests declared	
Wiebke Weiher	Expert	Germany	No interests declared	
Julia Stiles	Expert	Germany	No interests declared	
Andrea Springer	Expert	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Nuria Doñamayor Alonso	Expert	Germany	No restrictions applicable to this meeting	
Maren Osmers	Expert	Germany	No interests declared	
Paulin Dettmann	Expert	Germany	No restrictions applicable to this meeting	
Jana Hundt	Expert	Germany	No interests declared	
Monika Hofmann	Expert	Germany	No interests declared	
Dagmar Sommer	Expert	Germany	No interests declared	
Sandra Schack	Expert	Germany	No interests declared	
Heike Gyra	Expert	Germany	No interests declared	
Dagmar Sommer	Expert	Germany	No interests declared	
Daniela Loos	Expert	Germany	No interests declared	
Rolf Beckmann	Expert	Germany	No interests declared	
Koenraad Brusselmans	Expert	Belgium	No interests declared	
Denise O'Mahony	Expert	Ireland	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Anja Silke Christensen	Expert	Denmark	No interests declared	
Charlotte Smith Bonde	Expert	Denmark	No restrictions applicable to this meeting	
Anne Malene Nissen	Expert	Denmark	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Theis Moeslund Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Leyre Sanchez Sanchez Rojas	Expert	Spain	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Rodrigo Garcia Fernandez	Expert	Spain	No restrictions applicable to this meeting	
Alberto de Prado Lopez	Expert	Spain	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Mario Rodriguez Brasero	Expert	Spain	No interests declared	
Aranzazu Gonzalez-Canga	Expert	Spain	No interests declared	
Mercedes Ureña Montilla	Expert	Spain	No interests declared	
Maria Esperanza Herreros Avila	Expert	Spain	No interests declared	
Jana Fluksova	Expert	Czech Republic	No interests declared	
Radka Smitalova	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
Caroline Ormston	Expert	Czech Republic	No interests declared	
Eva Vernerova	Expert	Czech Republic	No interests declared	
Lucie Pokludova	Expert	Czech Republic	No interests declared	
Sandra Bertulat*	Expert	Germany	No interests declared	
Kathrin Dietze*	Expert	Germany	No interests declared	

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

CVMP working parties and CMDv	Chair
IWP	Esther Werner*
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström*
SWP-V	Carina Bergman*
EWP	Cristina Muñoz Madero*
NTWP	Jacqueline Poot*
SAW-P	Paul McNeill*
PhVWP-V	James Mount
3Rs	Sarah Adler-Flindt
Observers from SwissMedic (Switzerland) attended the meeting.	
A representative 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.