15 June 2026
EMA/139010/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 14-16 April 2026 meeting

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

Note on access to documents

Some documents mentioned in the minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

The meeting was held virtually.

At the start of the meeting, the Committee observed a minute of silence for the passing of the former CVMP member for Poland, Dr Anna Wachnik-Święcicka.

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 14-16 April 2026

The attendance list was completed and competing interests were identified for the April 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 February meeting were adopted.

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

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

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

No items

1.3. List of outstanding issues

No items

1.4. List of questions

No items

1.5. Re-examination of CVMP opinions on maximum residue limits

No items

1.6. Other issues

No items

2. Marketing authorisations

2.1. Opinions

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

Indication: for the active immunisation of cats to reduce mortality, clinical signs and virus excretion caused by infection with feline herpesvirus type 1 (FHV); to reduce clinical signs and virus excretion caused by infection with feline calicivirus (FCV); to prevent mortality, clinical signs, leucopenia and virus excretion caused by infection with panleucopenia virus (FPL); to reduce the clinical signs and bacterial excretion caused by infection with *Chlamydia felis,* and to reduce persistent viraemia and clinical signs caused by feline leukaemia virus (FeLV).

Nobivac NXT HCPChFeLV is the first veterinary vaccine recommended for authorisation in the EU that contains self-amplifying RNA packaged in a replication-deficient replicon viral particle as an active substance.

Action: For adoption

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

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

Action: For information

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

2.2. Oral explanations

No items

2.3. List of outstanding issues

No items

2.4. List of questions

2.4.1. Newcastle disease and avian infectious bronchitis vaccine (live) - EMEA/V/C/006870/0000 – chickens

Indication: active immunisation of chickens to reduce the presence of virus in the trachea and the detrimental effect on the ciliary activity caused by infection with strains of the Massachusetts serotype of avian infectious bronchitis virus, which may be manifested in respiratory clinical signs.
Active immunisation of chickens to reduce clinical signs and mortality, together with viral shedding caused by infection with Newcastle disease virus.

Action: For adoption

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

Action: For information

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

2.4.2. Avian infectious bronchitis vaccine (live) - EMEA/V/C/006871/0000 – chickens

Indication: active immunisation of chickens to reduce the presence of virus in the trachea and the detrimental effect on the ciliary activity caused by infection with strains of the Massachusetts serotype of avian infectious bronchitis virus, which may be manifested in respiratory clinical signs.

Action: For adoption

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

Action: For information

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

2.4.3. Newcastle disease vaccine (live) - EMEA/V/C/006872/0000 – chickens

Indication: active immunisation of chickens to reduce clinical signs and mortality, together with viral shedding caused by infection with Newcastle disease virus.

Action: For adoption

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

Action: For information

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

2.4.4. *Salmonella* enteritidis vaccine (live) – EMEA/V/C/006875/0000 – chickens

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

Action: For adoption

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

Action: For information

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

2.4.5. Florfenicol / mometasone furoate / terbinafine – EMEA/V/C/006831/0000 – dogs

Indication: treatment of acute canine otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of susceptible strains of bacteria sensitive to florfenicol (*Staphylococcus pseudintermedius)* and fungi sensitive to terbinafine (*Malassezia pachydermatis*).

Action: For adoption

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

Action: For information

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

2.4.6. Canine distemper, canine adenovirus, canine parainfluenza virus vaccine (live), canine parvovirus vaccine (live, recombinant) and canine leptospirosis vaccine (inactivated) - EMEA/V/C/006876/0000 – dogs

Indication: active immunisation of dogs from 6 weeks of age onwards to prevent or reduce symptoms or lesions caused by CDV, CAV1, CAV2, CPV, CPi, *Leptospira interrogans* and *L. kirschneri.*

Action: For adoption

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

Action: For information

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. Omeprazole - EMEA/V/C/006776/000 – horses

Action: For endorsement

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

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

Action: For endorsement

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

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

Action: For endorsement

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

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Solensia – frunevetmab - EMA/VRA/0000334838 - cats

Variation requiring assessment: implementation of the outcome of the MAH's signal management process to update the product information by adding 'Ataxia', 'Polyuria' and 'Polydipsia' as very rare adverse events.

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.

3.1.2. Startvac – *Staphylococcus aureus* and coagulase-negative staphylococci and *Escherichia coli* J5 vaccine (inactivated) - EMA/VRA/0000288186 – cattle

Variation requiring assessment: to allow the current vaccination schedule to be administered independently of the parturition date and administration of booster doses every three months.

Rapporteur: E. Werner, Co-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 endorsement

The Committee endorsed the rapporteur's assessment report.

Action: For information

The Committee noted the summary of opinion.

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. Upcard – torasemide - EMA/VRA/0000326002 – dogs

Variation requiring assessment: to add a new pharmaceutical form: oral solution.

Rapporteur: C. Muñoz Madero, Co-Rapporteur: P. McNeill

Action: For adoption

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

3.4.2. Firocoxib CP-Pharma – firocoxib - EMA/VRA/0000326568 – dogs

Variation requiring assessment: to add horses as a new target species.

Rapporteur: K. Boerkamp, Co-Rapporteur: L. Nepejchalová

Action: For adoption

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

3.4.3. Mirataz – mirtazapine – EMA/VRA/0000326548 – cats

Variation requiring assessment: to update the product information on the basis of new target animal safety data.

Rapporteur: S. Louet, Co-Rapporteur: M. Glanda

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

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: Opinion

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the CVMP assessment report for the referral procedure for veterinary medicinal products containing albendazole as a single active substance presented as an oral suspension for sheep. The CVMP recommended changes to the dose and the inclusion of warnings on the effective use in the product information of the concerned veterinary medicinal products authorised at doses or lower dose limits of 3.75-5 mg albendazole per kg bodyweight and indicated against gastrointestinal nematodes in sheep.

The Committee concluded that the benefit-risk balance of veterinary medicinal products containing albendazole as a single active substance presented as an oral suspension for sheep remains favourable and that those marketing authorisations should be amended.

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

5.1.1. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate EMA/VS/0000320744

Outcome of the signal management process.

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the CVMP assessment report, recommending the update of the SPC to include 'Application site inflammation', placing the adverse event 'application site pain and pruritus' under close monitoring and the submission of an additional signal for 'Ataxia'.

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. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/S/0000321438

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-rapporteur: L. Nepejchalová

Action: For adoption

The Committee adopted the CVMP opinion and the CVMP rapporteur's 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)

6.1.1. Verbal report on AWP meeting held on 17-18 March 2026

Action: For information

The Committee received a verbal report on the AWP meeting held on 17-18 March 2026 and noted its agenda and the minutes of the meeting held on 9-10 December 2025.

6.1.2. 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 adoption

The Committee adopted 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 (EMA/CVMP/AWP/741087/2009) for release for a 4-month public consultation.

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

No items

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. Verbal report on NTWP meeting held on 9-10 April 2026

Action: For information

The Committee received a verbal report on the NTWP meeting held on 9-10 April 2026 and noted its agenda together with the minutes of the meeting held on 5 February 2026.

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 March 2026 meeting and noted its agenda and the draft summary record. An election of a new chair is envisaged for the June CVMP meeting.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings February and March 2026

Action: For information

The Committee received a verbal report on QWP meetings February and March 2026 and noted the minutes of the QWP meeting held on 19-20 January 2026, the agenda and minutes of the QWP meeting held on 16-17 February 2026 together with the agenda of the QWP meeting held on 16-18 March 2026.

6.8.2. Guideline on development and manufacture of synthetic peptides – overview of comments

Action: For adoption

The Committee adopted the overview of comments of Guideline on development and manufacture of synthetic peptides (EMA/66185/2026).

6.8.3. CVMP Annex to VICH GL18 on residual solvents

Action: For adoption

The Committee adopted the revision of the Annex to VICH GL18 on residual solvent (EMEA/CVMP/511/03) for a 1.5-month period of public consultation.

6.8.4. Update to Q&A on reduced testing

Action: For adoption

The Committee adopted an update to the question and answer on reduced testing, which will be published on the Agency's website under 'Quality of medicines: questions and answers – Part 2'.

6.8.5. Revised Guideline on declaration of herbal substances and herbal preparations in herbal medicinal product

Action: For information

The Committee noted the revised guideline on declaration of herbal substances and herbal preparations in herbal medicinal product for public consultation.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 10 April 2026

Action: For information

The Committee received a verbal report on SAWP-V meeting held on 10 April 2026 and noted its agenda and the minutes of the SAWP-V meeting held on 6 March 2026.

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 19-20 March 2026

Action: For information

The Committee received a verbal report on SWP-V meeting held on 19-20 March 2026 and noted its agenda together with the minutes of the SWP-V meeting held on 13-14 November 2025.

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

Action: For discussion

The Committee discussed the revised guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances.

6.10.3. Guideline on user safety for pharmaceutical veterinary medicinal products

Action: For discussion

The Committee discussed the revised guideline on user safety for pharmaceutical veterinary medicinal products.

6.10.4. Guideline on user safety of topically administered veterinary medicinal products

Action: For discussion

The Committee discussed the revised guideline on user safety of topically administered veterinary medicinal products.

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 adoption

The Committee adopted the concept paper on the development for guidance on demonstration of biosimilarity of biological veterinary medicinal products.

6.11.2 Quality innovation group - Questions & Answers on the Implementation of 3DP Technology

Action: For information

The Committee noted the Questions & Answers on the Implementation of 3DP Technology (Additive Manufacturing Technology) for Solid Oral Dosage Forms (EMA/CHMP/CVMP/QIG/GMP/QWP/55150/2026).

6.11.3. Pharmacovigilance inspectors working group - VGVP Module on Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files – Rev. 1

Action: For discussion

The Committee discussed the first revision of the VGVP Module on Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files following considerations from the Pharmacovigilance inspectors working group based on their experience gained since Regulation (EU) 2019/6 came into force.

7. Other scientific matters

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

7.1. MRL issues

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

No items

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.7. Other issues

No items

8. Co-operation with other EU or International bodies

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

8.1. VICH

8.2. 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

No items

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

9.2.6. Decision on the application under exceptional circumstances

The Committee agreed that the application can be submitted in line with the requirements for submissions under exceptional circumstances.

9.2.7. Decision on the application under exceptional circumstances

The Committee decided that the application can be submitted in line with the requirements for submissions under exceptional circumstances.

9.2.8. Decision on the accelerated assessment request

The Committee decided that the accelerated assessment request is not sufficiently justified. The current epidemiological situation in the EU is not in an emergency status, and insufficient evidence has been provided to substantiate that the risk of the epidemiological situation with regard to human and/or animal health is considered to outweigh the benefit of a normal assessment timetable.

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.1. Outcome of VSFG survey on NCA capacity

Action: For information

The Committee noted the report on the outcome of VSFG survey on NCA capacity.

10.2. Workbook for veterinary assessors: "Best practices: practical considerations for the assessment of applications under Exceptional Circumstances (ECs)"

Action: For information

The Committee noted the Workbook for veterinary assessors: "Best practices: practical considerations for the assessment of applications under Exceptional Circumstances (ECs)".

11. CMDv

11.1. Verbal report from the CMDv chair on the CMDv meeting held on 18-19 March 2026

Action: For information

The Committee received a verbal report from the CMDv chair on the CMDv meeting held on 18-19 March 2026 and noted its agenda.

12. Legislation

12.1. 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 adoption

The Committee adopted the guidance on scientific issues in relation to Articles 107(6) and 114(3) of Regulation (EU) 2019/6.

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

Action: For adoption

The Committee adopted the guidance on scientific issues in relation to five substances (midazolam, rifampicin, griseofulvin, ketoconazole, sevoflurane) not included in Commission Implementing Regulation (EU) 2025/901.

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

1. Maximum Residue Limits

1.6. Other issues

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

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted, by consensus, an editorial correction to the CVMP opinion including EPMAR.

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

3. Variations to marketing authorisations

3.1. Opinions

EMA/VRA/0000320723 – Nobilis IB 4-91, Porcilis AR-T DF, Nobivac Bb, Porcilis ColiClos, Nobilis IB Primo QX, Nobivac Myxo-RHD Plus, Nobivac DP Plus, Bovilis Nasalgen-C - pigs

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 recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

BTVPUR – Bluetongue virus vaccine (inactivated) - EMA/VRA/0000326031 – sheep and cattle

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

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.

Action: For information

The Committee noted the comments from a CVMP member.

Zenrelia – ilunocitinib - EMA/VRA/0000309679 – 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.

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

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

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.

Rhiniseng – porcine progressive atrophic rhinitis vaccine (inactivated) - EMA/VRA/0000322270 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

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.

Action: For information

The Committee noted the comments from CVMP members.

EMA/VRA/0000304883 – Prevexxion RN / Prevexxion RN+HVT / Prevexxion RN+HVT+IBD / Vaxxitek HVT+IBD / non-CAPs – chickens

Variation requiring assessment: to update the Marek's solvent label in the product information of the impacted vaccines.

Rapporteur: E. Dewaele

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.

EMA/VRA/0000322708 – Clynav – Atlantic salmon

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

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

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

EMA/VRA/0000334631 – Zenrelia – 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.

EMA/VRA/0000321357 – Zenalpha – 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.

Coxatab – firocoxib - EMA/VRA/000326232 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: L. Nepejchalová

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.3. List of outstanding issues

MA/VRA/0000293810 - Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4R, Versican Plus Pi/L4 – canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis and rabies vaccine (inactivated), canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and

canine leptospirosis vaccine (inactivated), canine leptospirosis vaccine (inactivated), canine parainfluenza virus vaccine (live) and canine leptospirosis and rabies vaccine (inactivated), canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For decision

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

Action: For adoption

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

3.4. List of questions

NexGard Combo /Broadline – fipronil / (S)-methoprene / eprinomectin / praziquantel/ esafoxolaner / eprinomectin / praziquantel – VRA/0000291062 – cats

Variation requiring assessment: quality related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of questions.

Rabitec – rabies vaccine (live, oral) - EMA/VRA/0000326391– foxes and raccoon dogs

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.

Portela – relfovetmab – EMA/VRA/0000334629 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: M. Leitner

Action: For adoption

The Committee adopted the rapporteur's assessment report with the list of questions.

EMA/VRA/0000322711 – Reconcile – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the rapporteur's assessment report with 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.

5.2. Post-authorisation measures

Rabitec – rabies vaccine (live, oral) - EMA/PAM/0000326224 – dogs, foxes, raccoon dogs

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

6. Working parties

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

The Committee noted the NC and NAMs ESEC nominations.

Publication on past and future 3Rs activities at EMA

Action: For information

The Committee noted the Publication on past and future 3Rs activities at EMA https://doi.org/10.1016/j.namjnl.2026.100086.

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

The Committee adopted the list of nominations for the Quality Chemical ESEC.

6.11. Other working party and scientific group issues

Minutes of the Dosage Review and Adjustment of established Antibiotics (ADRA) meetings held in February 2026

Action: For information

The Committee noted the minutes of the ADRA meetings held on 16 and 27 February 2026.

7. Other scientific matters

7.1 MRL issues

Request on whether a full MRL evaluation is required in accordance with Commission regulation (EU) 2018/782 for reCG (recombinant equine Chorionic Gonadotropin) - cattle, sheep and pigs

Action: For adoption

The Committee adopted a report recommending inclusion of recombinant equine chorionic gonadotropin in Table 1 of the Annex to Commission Regulation (EU) 37/2010 with a "No MRL required" classification, pursuant to Section I.7 of Annex I of Commission Regulation (EU) 2018/782.

Action: For information

The Committee noted the CVMP assessment report.

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL 61 on Pharmaceutical Development

Action: For endorsement

The Committee endorsed the VICH GL61 on Pharmaceutical Development prior to sign-off at the VICH Steering Committee level.

9.3. Regulatory matters

Invented names

ANNEX I

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 14-16 April 2026 CVMP meeting, which was held remotely.

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

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
G. Johan Schefferlie*	Chair	CHAIR	No interests declared	
Petra Falb	Member	Austria	No restrictions applicable to this meeting	
Manuela Leitner	Alternate	Austria	No interests declared	
Els Dewaele	Member	Belgium	No interests declared	
Frederic Klein	Alternate	Belgium	No restrictions applicable to this meeting	
Tsvetanka Valova	Alternate	Bulgaria	No interests declared	
Irena Žarković	Member	Croatia	No restrictions applicable to this meeting	
Irena Caleta	Alternate	Croatia	No participation in discussion, final deliberations and voting on:	
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	
Esther Werner	Member	Germany	No interests declared	
Gábor Kulcsár	Member	Hungary	No participation in discussion, final	VRA/0000291062 EMA/VRA/0000326031

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
			deliberations and voting on:	EMA/VRA/0000304883
Paul McNeill	Member	Ireland	No interests declared	
Alice Blennerhassett	Alternate	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No restrictions applicable to this meeting	
Zanda Auce	Member	Latvia	No interests declared	
Renate Kuske	Alternate	Latvia	No interests declared	
Vaida Kurapkiene	Alternate	Lithuania	No restrictions applicable to this meeting	
Despoina Iatridou	Alternate	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	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
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
Kira Rosenkilde Underbjerg	Expert	Denmark	No interests declared	
Anke Finnah	Expert	Germany	No interests declared	
Gavin Ryan	Expert	Ireland	No interests declared	
Sandra ten Voorde	Expert	Netherlands	No interests declared	
Trijntje van der Velde-Koerts	Expert	Netherlands	No restrictions applicable to this meeting	
Daniel Benesh	Expert	Germany	No interests declared	
Anja Pfalzgraff	Expert	Germany	No interests declared	
Christopher Janich	Expert	Germany	No interests declared	
Pascale Macours	Expert	France	No interests declared	
Dusan Palic	Expert	Germany	No restrictions applicable to this meeting	
Mariette Salery	Expert	France	No interests declared	
Maria Esperanza Herreros Avila	Expert	Spain	No interests declared	
Jaime García Sanchez	Expert	Spain	No restrictions applicable to this meeting	
Cristina Benito Sastre	Expert	Spain	No interests declared	
Rodrigo Garcia Fernandez	Expert	Spain	No restrictions applicable to this meeting	
Francisca Moya	Expert	Spain	No interests declared	
Patricia Vera Luque	Expert	Spain	No interests declared	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Raul Belmar Liberato	Expert	Spain	No restrictions applicable to this meeting	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Lorena Tourino Gonzalez	Expert	Spain	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
David Murphy	Expert	Ireland	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	
Dorothea Neubert	Expert	Germany	No interests declared	
Andrea Springer	Expert	Germany	No interests declared	
Karl Ljungvall	Expert	Sweden	No restrictions applicable to this meeting	
Sandra ten Voorde	Expert	Netherlands	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	
Conor Delaney	Expert	Ireland	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Tatyana Devine	Expert	Ireland	No interests declared	
Hannah Pratt	Expert	Ireland	No interests declared	
Denise O'Mahony	Expert	Ireland	No interests declared	
Anne Sagnier	Expert	France	No interests declared	
Anne-Marie Jacques	Expert	France	No interests declared	
Benoit Courty	Expert	France	No interests declared	
Khadija Selouaoui	Expert	France	No interests declared	
Mahrez Zerrouki	Expert	France	No interests declared	
Martine Redureau	Expert	France	No interests declared	
Lise Laborieux	Expert	France	No interests declared	
Jana Hundt	Expert	Germany	No interests declared	
Sandra Schack	Expert	Germany	No interests declared	
Daniela Kuelbs	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	
Laura Kulisch	Expert	Germany	No interests declared	
Christina Bredtmann	Expert	Germany	No interests declared	
Wiebke Weiher	Expert	Germany	No interests declared	
Paulin Dettmann	Expert	Germany	No restrictions applicable to this meeting	
Jan Brosda	Expert	Germany	No interests declared	
Julia Stiles	Expert	Germany	No interests declared	
Sandra-Maria Wienhold	Expert	Germany	No restrictions applicable to this meeting	
Gunther Speichert	Expert	Germany	No interests declared	
Bernhard Klaar	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	
Kathrin Schmidt	Expert	Germany	No interests declared	
Roswitha Merkel	Expert	Germany	No interests declared	
Martin Wolff	Expert	Germany	No restrictions applicable to this meeting	
Thea Neumann	Expert	Germany	No interests declared	
Uta Herbst	Expert	Germany	No interests declared	
Martina Kern	Expert	Germany	No interests declared	
Jens Schönfeld	Expert	Germany	No interests declared	
Dorothea Neubert	Expert	Germany	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Anne Malene Nissen	Expert	Denmark	No interests declared	
Anja Silke Christensen		Denmark	No interests declared	
Stine Gregers Hørsøe		Denmark	No interests declared	
Radka Smitalova		Czech Republic	No interests declared	
Jana Fluksova		Czech Republic	No interests declared	
Jitka Chumchalova		Czech Republic	No interests declared	
Zdenka Malanova		Czech Republic	No interests declared	
Vera Fichtelova		Czech Republic	No interests declared	
Dana Halova		Czech Republic	No interests declared	
Eva Pomezna		Czech Republic	No interests declared	
Lucie Bacova		Czech Republic	No interests declared	
Lucie Pokludova		Czech Republic	No interests declared	
Bryan Deane		Ireland	No interests declared	
Petra Kubova		Czech Republic	No interests declared	

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

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