



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 December 2025
EMA/34873/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 2-4 December 2025 meeting

Note on access to documents

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

The meeting was held 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 2-4 December 2025

The attendance list was completed and competing interests were identified for the December 2025 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters discussed (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see [Annex I](#)).

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

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

No contacts have been declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the October 2025 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

1.1.1. Substance (lidocaine) – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: For adoption

The Committee adopted, by consensus, the revised CVMP opinion including EPMAR, following a request from the European Commission. The Committee recommended the modification of maximum residue limits for lidocaine in porcine, to allow for the injection into the scrotum, testicles and spermatic cord in piglets up to 7 days of age. Lidocaine is currently included in Table 1 (Allowed substances) of the Annex to Commission Regulation (EU) No 37/2010 with a 'No MRL required' classification for porcine, but only for cutaneous and epilesional use.

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. Firocoxib CP-Pharma – firocoxib – EMEA/V/C/006921/0000 – dogs

Indication: for the relief of pain and inflammation associated with osteoarthritis and for the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

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.

[2.1.2. Varenzin – molidustat sodium - EMEA/V/C/006513/0000 – cats](#)

Indication: for the management of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats, by increasing haematocrit/ packed cell volume.

Action: For adoption

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

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

Action: For information

The Committee noted the summary of opinion, two peer review reports and comments from a CVMP member.

[2.1.3. Epizootic haemorrhagic disease vaccine \(recombinant protein\) - Laboratorios Syva S.A. – epizootic haemorrhagic disease vaccine \(recombinant protein\) - EMEA/V/C/006804/0000 – cattle](#)

Indication: for active immunisation of cattle to reduce viraemia and fever caused by epizootic haemorrhagic disease virus serotype 8.

Action: For adoption

The Committee adopted, by consensus, under exceptional circumstances, 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. EMEA/V/C/006520/0000 – cats](#)

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 a peer review report and comments from CVMP members.

2.4. List of questions

2.4.1. EMEA/V/C/006777/0000 – pigs

Action: For adoption

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

Action: For information

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

2.4.2. EMEA/V/C/006603/0000 – pigs

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.

2.4.3. EMEA/V/C/006776/0000 – horses

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 comments from CVMP members.

2.4.4. EMEA/V/C/006713 – dogs, cats

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 three CVMP members.

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

Action: For decision

The Committee noted the letter of withdrawal of the marketing authorisation application from the applicant.

3. Variations to marketing authorisations

3.1. Opinions

[3.1.1. Dexdomitor – dexmedetomidine - EMA/VRA/0000257740 – dogs, cats](#)

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one for Dexdomitor 0.5 mg/ml solution for injection: to be administered intravenously as a constant rate infusion (CRI) in dogs and cats as part of a multimodal protocol during inhalation anaesthesia. Additionally, the product information has been aligned with version 9.1 of the QRD template.

Rapporteur: H. Bremer, Co-Rapporteur: M. Leppänen

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 Felpreva – meloxicam – VRA/0000294131 – cats](#)

Variation requiring assessment: to change the frequency of the adverse event “Application site reaction (e.g. scratching, erythema, hair loss, inflammation)” from very rare to rare.

Rapporteur: A. Golombiewski

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.

[3.1.3 DuOtic / Osumia \(WS\) – betamethasone acetate / terbinafine - terbinafine / florfenicol / betamethasone acetate - EMA/VRA/0000278006 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

The Committee adopted the CVMP opinion.

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1 Cirbloc M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) - EMA/VRA/0000288333 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Baptiste

Action: For adoption

The Committee adopted the list of outstanding issues.

3.4. List of questions

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

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one.

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

Action: For adoption

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

3.4.2. 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/Parvorovac to the SPC.

Rapporteur: N.C. Kyvsgaard

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

3.6.1 Bluevac BTV, Bluevac-3, Hepizovac – EMA/VRA/0000272405 – cattle, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For information

The Committee noted the letter of withdrawal of the variation application from the Marketing Authorisation Holder.

4. Referrals and related procedures

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

No items

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

No items

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

No items

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

4.4.1. Phenoxipen WSP, 325 mg/g powder for use in drinking water for chickens – phenoxymethylpenicillin – EMA/REF/0000302825

Scope: Efficacy

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

Action: For adoption

The Committee adopted, by majority, the CVMP opinion on clarifications to the European Commission and the CVMP assessment report for the procedure for **Phenoxipen WSP, 325 mg/g powder for use in drinking water for chickens** (EMA/REF/0000302825). Having considered the request by the EC and all available data, the CVMP concluded that the benefit-risk balance of Phenoxipen WSP for the proposed indication and target species is positive, provided the indication and dosage instructions are amended as outlined in the CVMP opinion.

Action: To note

The Committee noted the divergent views not supporting the aforementioned conclusion from A. Golombiewski, K. Baptiste, K. Zlatkov, L. Nepejchalová and N. Kyvsgaard.

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. Senvelgo – velagliflozin - EMA/VS/0000282395

Signal management process

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

Action: For endorsement

The Committee endorsed the draft Rapporteur's Assessment Report.

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

No items

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

No items

5.5. Others

No items

6. Working parties

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

6.1. Antimicrobials Working Party (AWP)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

6.3.1. Guideline for the evaluation of efficacy of ectoparasiticides - general requirements

Action: For discussion

The Committee discussed the revised guideline for the evaluation of efficacy of ectoparasiticides - general requirements.

6.3.2. Guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees

Action: For discussion

The Committee discussed the revised guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees.

6.3.3. Concept paper on the development of a guideline for using owner assessment as efficacy parameter

Action: For discussion

The Committee discussed the concept paper on the development of a guideline for using owner assessment as efficacy parameter.

6.3.4. Question and answer on the information contained within section 4.2 of the SPC on pharmacodynamic properties for pharmaceutical products

Action: For discussion

The Committee discussed the revised Q&A document on the information contained within section 4.2 of the SPC on pharmacodynamic properties for pharmaceutical products.

6.4. Immunologicals Working Party (IWP)

6.4.1. Revision of the Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs)

Action: For discussion

The Committee discussed the draft revised Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs).

6.4.2. Revision of IWP guidelines to align with Regulation (EU) 2019/6

Action: For discussion

The Committee discussed the:

- Draft revised Guideline on environmental risk assessment for immunological veterinary medicinal products ([EMA/CVMP/IWP/165768/2024](#)).
- Draft revised Guideline on user safety for immunological veterinary medicinal products ([EMA/CVMP/IWP/165764/2024](#)).
- Draft revised Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines.

6.4.3. Verbal report on the IWP interested parties meeting held on 13 November 2025

Action: For information

The Committee received a verbal report from the IWP interested parties meeting held on 13 November 2025 and noted its agenda.

6.5. 3Rs Working Party (3RsWP)

[6.5.1. 3RsWP work plan for 2026-2028](#)

Action: For adoption

The Committee adopted the 3RsWP work plan for 2026–2028.

6.6. Novel Therapies & Technologies Working Party (NTWP)

[6.6.1. Verbal report on NTWP meeting held on 19 November 2025](#)

Action: For information

The Committee received a verbal report on NTWP meeting held on 19 November 2025 and noted its agenda together with the final minutes of meeting held on 18 September 2025.

[6.6.2. NTWP work plan for 2026](#)

Action: For adoption

The Committee adopted the NTWP work plan for 2026.

[6.6.3. Appointment of expert for CVMP NTWP Operational Expert Group \(OEG\) on RNAi & antisense](#)

Action: For decision

The Committee appointed Carlos Ballesteros as CVMP NTWP Operational Expert Groups (OEG) expert on RNAi & antisense.

[6.6.4. Establishment of a novel therapies ESEC](#)

Action: For discussion

The Committee discussed the establishment of a novel therapies ESEC and noted its mandate.

6.7. Pharmacovigilance Working Party (PhVWP-V)

[6.7.1. Verbal report on PhVWP-V meeting held on 25-26 November 2025](#)

Action: For information

The Committee received a verbal report on PhVWP-V meeting held on 25-26 November 2025 and noted its final agenda together with the draft summary record of the November 2025 PhVWP-V meeting.

[6.7.2. PhVWP-V work plan 2026](#)

Action: For adoption

The Committee adopted the draft PhVWP-V Work Plan 2026.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held in October-November 2025 and interested parties meeting held in October 2025

Action: For information

The Committee received a verbal report on QWP meetings held in October-November 2025 and interested parties meeting held in October 2025 and noted the minutes of the QWP meeting held on 8-9 September 2025, the agenda and minutes of the QWP meeting held on 6-8 October 2025, the agenda of the QWP meeting held on 3-4 November 2025 together with interested parties meeting agenda.

6.8.2. QWP 3-year work plan 2026-2028

Action: For adoption

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

6.8.3. Guideline on development and manufacture of synthetic peptides

Action: For adoption

The Committee adopted the Guideline on development and manufacture of synthetic peptides.

6.8.4. Questions and answers on co-processed excipients

Action: For discussion

The Committee discussed the Q&A on co-processed excipients.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 28 November 2025

Action: For information

The Committee received a verbal report on SAWP-V meeting held on 28 November 2025 and noted its agenda together with the final minutes of the SAWP-V meeting held on 31 October 2025.

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 13-14 November 2025

Action: For information

The Committee received a verbal report on SWP-V meeting held on 13-14 November 2025 and noted its agenda and the minutes of the meeting held on 17-18 June 2025.

6.10.2. Overview of Comments on Concept paper for development of a guideline on consumer safety of active substances of IVMPs acting against endogenous targets

Action: For information

The Committee noted the Overview of Comments on Concept paper for development of a guideline on consumer safety of active substances of IVMPs acting against endogenous targets.

6.11. Other working party and scientific group issues

6.11.1. ASMF working group

Action: For adoption

The Committee adopted the updated guideline on ASMF worksharing procedure.

6.11.2. European sales and use of antimicrobials for veterinary medicine (ESUAvet) working group

Action: For adoption

The Committee adopted the 'European sales and use of antimicrobials for veterinary medicine - Annual surveillance report for 2024'.

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

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

8.1.3. Feedback from VICH Steering Committee and Forum meetings of 10-13 November 2025

Action: For information

The Committee received a verbal report from Steering Committee and Forum meetings and noted its agendas.

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 horses as limited market and eligible for authorisation under article 23 of Regulation (EU) 2019/6.

9.1.2. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for horses as 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

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. CVMP / CMDv Informal meeting under the Danish EU Presidency, Copenhagen, 25-26 September 2025

Action: For adoption

The Committee adopted the minutes of the CVMP and the joint CVMP-CMDv sessions.

11. CMDv

11.1. Verbal report on the CMDv meetings held on 15-16 October 2025 and 12-13 November 2025

Action: For information

The Committee received a verbal report on the CMDv meetings held on 15-16 October 2025 and 12-13 November 2025 and noted the agenda of the CMDv meeting held on 12-13 November 2025.

12. Legislation

12.1 Scientific advice relating to the amendment of Regulation (EU) 2024/1973

Action: For information

The Committee noted the external notification of the postponement of EMA/CVMP scientific advice relating to the amendment of Regulation (EU) 2024/1973 to extend its scope to animals of the equine species and set out conditions for the use of certain antimicrobials in these animals in accordance with Articles 112 and 113 of Regulation (EU) 2019/6.

12.2 European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6

Action: For discussion

The Committee discussed the European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6. The Commission asked CVMP to provide responses, by 30 April 2026, to a set of questions on both clinical and safety aspects for five substances (midazolam, rifampicin, griseofulvin, ketoconazole, sevoflurane), none of which are included in Commission Implementing Regulation (EU) 2025/901 (the "new" horse list). The work will occur from December 2025 until mid-February 2026. Discussion at CVMP is expected to happen in March and adoption of the CVMP opinion at the April 2026 plenary meeting.

12.3 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 a European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6. The 2024 scientific advice under Article 107(6) and the 2025 scientific advice under Article 114(3) were based on different sets of criteria established in Regulation (EU) 2019/6. In order to ensure coherence between the related implementing acts, the Commission asked the Committee to respond to some questions on nine antimicrobial substances by 30 April 2026. The Committee agreed that the work would be led by rapporteur(s) with input from relevant experts covering both the AMR side and the availability side, and that one or two virtual meetings would take place in January/February 2026. The appointment of rapporteurs was deferred.

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights ([link](#))

13.2. SNE / Veterinary Pharmacovigilance Specialist

Action: For information

The Committee noted the available position for SNE/Veterinary Pharmacovigilance Specialist at EMA.

14. Annex

2. Marketing authorisations and extensions

2.6. Other issues

[EMA/V/C/006638/0000 – dogs](#)

Action: For decision

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

3. Variations to marketing authorisations

3.1. Opinions

[ProteqFlu - Te Equine influenza \(live recombinant\) and tetanus vaccine - EMA/VRA/0000301140 – horses](#)

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.

Action: For information

The Committee noted the comments of a CVMP member.

[Eluracat – capromorelin tartrate - EMA/VRA/0000288081 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Carapeto

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.

[Zuprevo – tildipirosin - EMA/VRA/0000281934 – cattle, pigs](#)

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.

[Mirataz – mirtazapine - EMA/VRA/0000288548 – cats](#)

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

Rapporteur: S. Louet

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.

[Dexdomitor – dexmedetomidine - EMA/VRA/0000296146 – cats, dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

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.

[Sileo – dexmedetomidine hydrochloride - EMA/VRA/0000300547 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

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.

[Meloxidyl – meloxicam – VRA/0000300632 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

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.

[Nexgard / Nexgard Spectra / Frontpro – afoxolaner – VRA/0000303673 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

[AdTab – lotilaner – VRA/0000307496 – dogs, cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.4. List of questions

[Equioxx – firocoxib – VRA/0000297139 – horses](#)

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

Rapporteur: P. McNeill

Action: For adoption

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

[Veraflox – pradofloxacin - VRA/0000301203 – dogs, cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: A. C. Golombiewski

Action: For adoption

The Committee adopted the list of questions.

[Stelfonta – tigilanol tiglate - EMA/VRA/0000301147 – dogs](#)

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

Rapporteur: K. Boerkamp

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 and the list of finalised signals.

6. Working parties

6.1 Antimicrobials Working Party (AWP)

[AWP work plan 2026](#)

Action: For adoption

The Committee adopted the AWP work plan 2026.

6.2 Environmental Risk Assessment Working Party (ERAWP)

[ERAWP work plan 2026](#)

Action: For adoption

The Committee adopted the ERAWP work plan 2026.

6.3 Efficacy Working Party (EWP-V)

[EWP-V work plan 2026](#)

Action: For adoption

The Committee adopted the EWP-V work plan 2026.

6.4 Immunological Working Party (IWP-V)

[IWP-V work plan for 2026](#)

Action: For adoption

The Committee adopted the IWP-V work plan for 2026.

6.5. 3Rs Working Party (3RsWP)

[Agenda of the 3RsWP plenary meeting held on 19–20 November 2025](#)

Action: For information

The Committee noted the agenda of the 19–20 November 2025 3RsWP plenary meeting.

[Minutes of the 3RsWP plenary meeting held on 18–19 September 2025](#)

Action: For information

The Committee noted the minutes of the 18–19 November 2025 3RsWP plenary meeting.

6.7 Pharmacovigilance Working Party (PhVWP-V)

[Endorsement of new PhVWP-V member \(replacement of previous member\)](#)

Action: For endorsement

The Committee endorsed the nomination for Kinga Csécsei from Gábor Kulcsár.

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.

6.9. Scientific Advice Working Party (SAWP-V)

[SAWP-V work plan 2026](#)

Action: For adoption

The Committee adopted the SAWP-V work plan 2026.

6.10. Safety Working Party (SWP-V)

[SWP-V work plan for 2026](#)

Action: For adoption

The Committee adopted the SWP-V work plan 2026.

6.11. Other working party and scientific group issues

[ESUAvet Working Group work plan for 2026](#)

Action: For adoption

The Committee adopted the ESUAvet WG work plan 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

[CVMP work plan 2026](#)

Action: For adoption

The Committee adopted the CVMP work plan 2026.

ANNEX I

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 2-4 December 2025 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	
Leona Nepejchalová	Member	Czechia	No interests declared	
Niels Christian Kyvsgaard	Member	Denmark	No interests declared	
Merete Blixenkrone-Møller	Alternate	Denmark	No interests declared	
Minna Leppänen	Member	Finland	No interests declared	
Kristina Lehmann*	Alternate	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	
Andrea Christina Golombiewski	Member	Germany	No restrictions applicable to this meeting	
Esther Werner	Alternate	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
Gábor Kulcsár	Member	Hungary	No participation in discussion, final deliberations and voting on:	EMA/VRA/0000301140 EMA/VS/0000282395 VRA/0000303673
Paul McNeill	Member	Ireland	No interests declared	
Alice Blennerhassett*	Alternate	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Zanda Auce	Member	Latvia	No interests declared	
Renate Kuske*	Alternate	Latvia	No restrictions applicable to this meeting	
Vaida Kurapkiene*	Alternate	Lithuania	No restrictions applicable to this meeting	
Despoina Iatridou*	Alternate	Luxembourg	No interests declared	
Kim Boerkamp	Alternate	Netherlands	No restrictions applicable to this meeting	
Ewa Augustynowicz	Alternate	Poland	No interests declared	
Marcin Glanda	Alternate	Poland	No interests declared	
João Pedro Duarte Da Silva*	Member	Portugal	No interests declared	
Diana Laura Stan	Alternate	Romania	No interests declared	
Eva Chobotová	Member	Slovakia	No interests declared	
Urska Peunik	Alternate	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Frida Hasslung Wikström	Member (Vice-Chair)	Sweden	No interests declared	
Hanna Bremer*	Alternate	Sweden	No interests declared	
Keith Baptiste	Co-opted member	Denmark	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics for which restriction apply
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	
Ricardo Carapeto Garcia	Co-opted member	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Stine Gregers Hørsøe*	Expert	Denmark	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Erik den Hertog	Expert	Netherlands	No restrictions applicable to this meeting	
Kira Rosenkilde Underbjerg	Expert	Denmark	No interests declared	
Nathalie Bridoux	Expert	France	No interests declared	
Luis Agote Casado	Expert	Spain	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	
Sonia Gil Morales	Expert	Spain	No interests declared	
Anke Finnah	Expert	Germany	No interests declared	
Catarina Eriksson	Expert	Sweden	No interests declared	
Daniel Benesh	Expert	Germany	No interests declared	
Nuria Doñamayor Alonso	Expert	Germany	No restrictions applicable to this meeting	
Svenja Rieke	Expert	Germany	No interests declared	
Jaana Palomäki	Expert	Finland	No restrictions applicable to this meeting	
John Aspegren	Expert	Finland	No restrictions applicable to this meeting	
Anne-Marie JACQUES	Expert	France	No interests declared	
Caroline Guittre	Expert	France	No interests declared	
Mariette Salery	Expert	France	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Carlos Ballesteros	Expert	Spain	No interests declared	
Beatriz Corcho	Expert	Spain	No interests declared	
Adrian Fandiño Lopez	Expert	Spain	No interests declared	
Maria Jose Ferrer Montesa	Expert	Spain	No interests declared	
Alberto de Prado Lopez	Expert	Spain	No interests declared	
Maria Esperanza Herreros Avila	Expert	Spain	No interests declared	
Jaime García Sanchez	Expert	Spain	No restrictions applicable to this meeting	
Cristina Ballesteros Tercero	Expert	Spain	No interests declared	
Sonia Gil Morales	Expert	Spain	No interests declared	
Raul Belmar Liberato	Expert	Spain	No restrictions applicable to this meeting	
Sandy Vermout	Expert	Belgium	No interests declared	
Maren Osmer	Expert	Germany	No interests declared	
Sandra-Maria Wienhold	Expert	Germany	No restrictions applicable to this meeting	
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Laura Kulisch	Expert	Germany	No interests declared	
Catharina Husteden	Expert	Germany	No interests declared	
Roswitha Merkel	Expert	Germany	No interests declared	
Jenny Larsson	Expert	Sweden	No interests declared	
Frida Martin	Expert	Sweden	No interests declared	
Kerstin Cramer	Expert	Germany	No interests declared	
Susanne Schust	Expert	Germany	No interests declared	
Kathrin Schmidt	Expert	Germany	No interests declared	
Kathrin Schirmann	Expert	Germany	No interests declared	
Kirsten Thomsen	Expert	Denmark	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Anne Malene Nissen	Expert	Denmark	No interests declared	
Anja Silke Christensen	Expert	Denmark	No interests declared	
Dagmar Sommer	Expert	Germany	No interests declared	
Jana Hundt	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	
Monika Hofmann	Expert	Germany	No interests declared	
Yasemin Suzer	Expert	Germany	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Hannah Pratt	Expert	Ireland	No interests declared	
Denise O'Mahony	Expert	Ireland	No interests declared	
Sarah Hanley	Expert	Ireland	No interests declared	
Anna Zadrozna	Expert	Poland	No interests declared	
Natalia Wąsowicz-Żendzian	Expert	Poland	No interests declared	
Mercedes Ureña Montilla	Expert	Spain	No interests declared	
Dana Halová	Expert	Czech Republic	No interests declared	
Jitka Chumchalova	Expert	Czech Republic	No interests declared	
Radka Smitalova	Expert	Czech Republic	No interests declared	
Vilma Dosedlová	Expert	Czech Republic	No interests declared	
Vera Fichtelova	Expert	Czech Republic	No interests declared	
Lucie Pokludova	Expert	Czech Republic	No interests declared	
Jens Barthel	Expert	Germany		
Jan Brosda	Expert	Germany	No interests declared	
Christina Bredtmann*	Expert	Germany	No interests declared	
Katja Boxberger*	Expert	Germany	No interests declared	
Anja Pfaltzgraff*	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 (<i>veterinary vice chair</i>)
SAWP-V	Frida Hasslung Wikström*
SWP-V	Carina Bergman*
EWP	Cristina Muñoz Madero*
PhVWP-V	James Mount
NTWP	Anja Pfaltzgraff*
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.