7 October 2025
EMA/CVMP/324851/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 10-12 June 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 10-12 June 2025

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

There were no contacts declared.

iv. Adoption of the minutes of the previous meeting

The Committee adopted, by consensus, the minutes of three previous meetings: November 2024, April 2025 and May 2025.

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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

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

Action: For discussion

The Committee discussed the request from the European Commission for reconsideration of the CVMP opinion.

1.6.2. Substance – EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For discussion

The Committee agreed to the request from the applicant for an oral explanation to take place at the July CVMP meeting.

2. Marketing authorisations

2.1. Opinions

2.1.1. Numelvi – atinvicitinib – EMEA/V/C/006480/0000 – dogs

Indication: treatment of pruritus associated with allergic dermatitis including atopic dermatitis in dogs and treatment of clinical manifestations of atopic dermatitis in dogs.

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

2.1.2. Bravecto CombiUNO – fluralaner / milbemycin oxime - EMEA/V/C/006358/0000 – dogs

Indication: treatment of tick and flea infestations in dogs.

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion and a peer review report.

2.1.3. Zenrelia – ilunocitinib - EMEA/V/C/006332/0000 – dogs

Indication: treatment of pruritus associated with allergic dermatitis in dogs and treatment of clinical manifestations of atopic dermatitis in dogs.

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion and comments from a CVMP member.

2.1.4. BioBhyo – Brachyspira hyodysenteriae, strain AqDysH57, inactivated - EMEA/V/C/006336/0000 – pigs

Indication: active immunisation of pigs against infections caused by *Brachyspira hyodysenteriae.*

Action: For adoption

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

Action: For information

The Committee noted the summary of opinion together with comments from three CVMP members.

2.2. Oral explanations

No items

2.3. List of outstanding issues

2.3.1. EMEA/V/C/005890/0000 – cats

Action: For decision

The Committee agreed that an oral explanation was not needed at this time.

Action: For adoption

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

Action: For information

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

2.3.2. EMEA/V/C/006535/0000 - dogs

Action: For decision

The Committee agreed that an oral explanation was needed. This OE will take place at the October CVMP meeting.

Action: For adoption

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

Action: For information

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

2.4. List of questions

2.4.1. EMEA/V/C/006610/0000 – horses

Action: For adoption

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

Action: For information

The Committee noted two peer review reports.

2.4.2. EMEA/V/C/006655/0000 – dogs

Action: For adoption

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

Action: For information

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

No items

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Daxocox – enflicoxib - EMA/VRA/0000246340 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: treatment of pain and inflammation associated with orthopaedic or soft tissue surgery and alignment of the product information with version 9.1 of the QRD template.

Rapporteur: R. Breathnach, 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 member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion and the comments from a CVMP member.

3.1.2. Bravecto – fluralaner - EMA/VRA/0000268124 – cats, dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process to add new adverse events (pruritus, diarrhoea, ataxia) to the product information.

Rapporteur: K. Boerkamp

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.1.3. Poulvac E. coli – avian colibacillosis vaccine (live) - EMA/VRA/0000243824 – chickens

Variation requiring assessment: to reflect in the product information that administration of the vaccine was shown to reduce the use of antibiotics used to treat colibacillosis in the vaccinated chicken flocks. The constraints in the legal framework regarding such claims were noted by the committee.

Rapporteur: E. Werner, Co-Rapporteur: E. Augustynowicz

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion and the product information and comments from a CVMP member.

3.1.4 Nobivac L4, Nobivac LoVo L4 - canine leptospirosis vaccine (inactivated) - WS/2673 – dogs

Variation requiring assessment: addition of a new therapeutic indication or modification of an approved one and addition of associated non-mixed use with Nobivac Rabies. The procedure included a proposed name update from L4 to L6.

Rapporteur: E. Dewaele, Co-Rapporteur: R. Breathnach

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

3.1.5. NexGard; NexGard Spectra – afoxolaner; afoxolaner / milbemycin oxime - EMA/VRA/0000245082 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days and for reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days. The product information for both products – NexGard and NexGard Spectra – has also been aligned with version 9.1 of the QRD template; in addition, information included in SPC section 3.9 concerning the treatment effect for demodicosis has been updated.

Rapporteur: J. G. Beechinor, Co-Rapporteur: K. Boerkamp

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion and the comments from a CVMP member.

3.2. Oral explanations

3.2.1 Nobivac L4, Nobivac LoVo L4 - canine leptospirosis vaccine (inactivated) - WS/2673 – dogs

Rapporteur: E. Dewaele, Co-Rapporteur: R. Breathnach

Action: For action

The Committee heard the oral explanation from the applicant. For more information please see agenda point 3.1.4.

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. 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.

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

Action: For adoption

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

3.4.2. Bravecto TriUNO – fluralaner / moxidectin / pyrantel - EMA/VRA/0000263135 – dogs

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

Rapporteur: R. Breathnach, Co-Rapporteur: A. Golombiewski

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/000027181

Efficacy, antiparasitic resistance

Scope: Notification

Action: For decision

The Committee noted the notification from Germany under Article 82 of Regulation (EU) 2019/6 due to concerns that doses or lower dose limits of 3.75 – 5.0 mg/kg bodyweight may no longer be appropriate to ensure the effective use of veterinary medicinal products (VMPs) containing albendazole as a single active substance, presented as oral suspension and indicated against gastrointestinal nematodes in sheep, which could also contribute to the further development of antiparasitic resistance. Following consideration, the Committee started a procedure for these VMPs. The CVMP appointed A. Golombieskwi as rapporteur, C. Muñoz Madero as co-rapporteur, and two peer reviewers.
The CVMP invited all stakeholders (e.g. veterinary healthcare professionals, farmers, academia) to

submit data relevant to this procedure (link). The committee noted the draft list of products concerned. Further information on this referral procedure is available on the relevant EMA website.

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. Signal evaluation and recommendations

Action: For adoption

The Committee adopted the monthly outcomes of the signal management process, the list of finalised signals.

5.1.2. Senvelgo – velagliflozin

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

Action: For adoption

The Committee postponed the adoption of the outcome of the signal management process.

5.1.3. Solensia – frunevetmab

Rapporteur: R. Breathnach, Co-Rapporteur: J. Poot

Action: For adoption

The Committee adopted the outcome of the signal management process.

5.1.4. Librela - bedinvetmab

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

Action: For adoption

The Committee adopted the outcome of the signal management process.

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 Innovax-ND-H5 – Avian influenza vaccine (live recombinant) - EMA/S/0000246877

Re-examination of the marketing authorisation for Innovax-ND-H5 in line with Article 27(3) of Regulation (EU) 2019/6

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion and the CVMP re-examination report. The Committee confirmed that the benefit risk of Innovax-ND-H5 remains positive.

Action: For information

The Committee noted the comments from a CVMP member.

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 27th and 28th May 2025

Action: For information

The Committee noted the verbal report on AWP meeting held on 27th and 28th May 2025 together with its agenda and the minutes of the March AWP meeting.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Concept paper for the development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs

Action: For adoption

The Committee adopted the draft concept paper for the development of a guideline on the methodology of environmental risk assessment for parasiticidal VMPs for cats and dogs (EMA/CVMP/ERA/499198/2024) for 4-months release for public consultation.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 21 May 2025

Action: For information

The Committee received a verbal report on EWP-V meeting held on 21 May 2025 and noted its agenda together with the minutes of the meeting held on 25 February 2025.

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V 20-21 May 2025 meeting

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 20-21 May 2025 and noted the agenda together with the draft summary record of this meeting. The Committee also noted the summary record of the meeting held on 23 April 2025.

6.7.2. Verbal report on PhVWP-V-PhV IWG Interested Parties meeting held on 21 May 2025

Action: For information

The Committee received a verbal report on the PhVWP-V-PhV IWG meeting held on 21 May 2025 and noted its agenda. The Committee noted the draft PhVWP-V-PhV IWG Interested Parties' summary record together with the summary of feedback from that meeting.

6.7.3. Revised VeDDRA documents

Action: For adoption

The Committee adopted the revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products; list of changes to VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products for 2025; non-current VeDDRA low level terms (LLT) and codes; guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans, and call for comments.

6.8. Quality Working Party (QWP)

6.8.1. Draft concept paper on the need for Revision of Note for Guidance on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water

Action: For adoption

The Committee adopted the draft concept paper on the need for Revision of Note for Guidance on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water (EMA/CVMP/QWP/85848/2025) for a 4-month period of public consultation.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 6 June 2025

Action: For information

The Committee received a verbal report on SAWP-V meeting held on 6 June 2025 and noted its agenda together with the final minutes of the SAWP-V meeting held on 12 May 2025.

6.9.2. Election for Vice-chair of SAWP-V

Action: For election

The Committee elected, by majority, Hanna Bremer as a Vice-chair of SAWP-V for a 3-year mandate.

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

No items

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 strategy on antimicrobials 2026-2030

Presenter: Z. Kunsagi

Action: For discussion

The Committee agreed that the publication of a dedicated CVMP strategy on antimicrobials will be discontinued, as the proposed actions in this field are already covered in other documents, including the European Medicines Agencies Network Strategy 2028 (EMANS).

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.

7.6.1 EMEA/V/VPTMF/0004

Action: For adoption

The Committee adopted the assessment report and list of questions.

Action: For information

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

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

8.1.1. EU expert in Pharmacovigilance Expert Working Group

Action: For decision

8.1.2. VICH guideline on target animal safety of veterinary monoclonal antibody products (VMAPs)

Action: For endorsement

The Committee endorsed the draft GL on target animal safety of veterinary monoclonal antibody products.

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

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.1. Election of Vice-Chair CVMP

Action: For election

The Committee re-elected, unanimously, Frida Hasslung Wikström as Vice-Chair of the CVMP for a further 3-year mandate.

10.3. Identification of expertise for the upcoming appointment of co-opted member

Action: For decision

The Committee agreed to keep the Toxicology and Residues area for one co-opted member, following review of the current expertise of the Committee. A call for nominations will be circulated after the meeting.

10.4. Veterinary Domain verbal report meeting held on 23 May 2025

Action: For information

The Committee received verbal report on the Veterinary Domain meeting held on 23 May 2025 and noted its agenda together with the minutes of the 21 January 2025 meeting.

10.5. F2F Oral Explanations

Action: For information

The Committee was informed of the pilot to reconvene F2F oral explanations (OEs) when CVMP is held in-person. For these meetings, OEs can still take place remotely. The pilot will be of one year (July 2025-June 2026). It was noted that the Agency will not accept requests for changes to timetable of procedures to accommodate in-person OEs.

11. CMDv

No items

12. Legislation

No items

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

2. Marketing authorisations

2.6. Other issues

EMEA/V/C/006180/0000 – horses

Action: For endorsement

The Committee endorsed the request from the applicant for a clock-stop extension.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Nobilis IB Primo QX / Nobilis IB 4-91 - EMA/VRA/0000245796 - chickens

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Ecoporc Shiga – genetically modified STx2e antigen vaccine - EMA/VRA/0000247420 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

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

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

The Committee noted the comments from a CVMP member.

Reconcile – fluoxetine - EMA/VRA/0000263755 – dogs

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.

The Committee noted comments from a CVMP member.

Meloxidyl – meloxicam - EMA/VRA/0000246351 – cats, dogs, horses, cattle, pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: H. Bremer

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.

The Committee noted comments from CVMP members.

Mometamax Ultra – gentamicin / posaconazole / mometasone furoate - EMA/VRA/0000247986 – dogs

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

Rapporteur: K. Baptiste

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.

The Committee noted comments from a CVMP member.

Imoxat – imidacloprid / moxidectin - EMA/VRA/0000247407 – cats, dogs, ferrets

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

Rapporteur: J.G. Beechinor

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.

3.3. List of outstanding issues under Regulation (EU) 2019/6

ProZinc – insulin human – EMA/VRA/0000247545 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of outstanding issues and the assessment report.

Equioxx – firocoxib – EMA/VRA/0000247013 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: J.G. Beechinor

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Tulaven (Tulapro) – tulathromycin - EMA/VRA/0000225508 (WS) – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of outstanding issues.

3.4. List of questions under Regulation (EU) 2019/6

Meloxidolor – meloxicam – EMA/VRA/0000263855 – dogs, cats, cattle (calves) and pigs

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.

Novaquin – meloxicam - EMA/VRA/0000261536 – horses

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

Rapporteur: J.G. Beechinor

Action: For adoption

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

Zulvac 1+8 Bovis– Bluetongue vaccine (inactivated) - EMA/VRA/0000263047 – cats, dogs

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

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

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

Equilis Te – tetanus vaccine for horses, equine influenza (inactivated) and tetanus vaccine - EMA/VRA/0000238879 – horses

Variation requiring assessment: quality-related changes

Rapporteur: E.Werner, Co-Rapporteur: M. Blixenkrone- Møller

Action: For adoption

The Committee adopted the list of questions.

Tulinovet – tulathromycin - EMA/VRA/0000263760 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: L. Nepejchalová

Action: For adoption

The Committee adopted the list of questions.

Cytopoint – lokivetmab - EMA/VRA/0000263599 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of questions.

Zulvac 1+8 Ovis – Bluetongue vaccine (inactivated) - EMA/VRA/0000263033 – sheep

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

Rapporteur: F. Marsilio

Action: For adoption

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

Prevexxion RN+HVT+IBD – Infectious bursal disease and Marek's disease vaccine (live recombinant) – EMA/VRA/0000263785 – chickens

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: F. Klein

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

5.2 Post-authorisation measures under Regulation (EU) 2019/6

Rabitec – EMA/PAM/0000263291

Quality-related measures.

Rapporteur: E. Werner

Action: For endorsement

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

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

The Committee adopted the ERA ESEC Expert nominations.

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

The Committee noted the NC and NAMs ESEC nominations.

Minutes of the 3RsWP meeting held on 2-3 April 2025

Action: For information

The Committee noted the minutes of the 3RsWP meeting held on 2-3 April 2025.

Agenda of the 3RsWP meeting held on 20-21 May 2025

Action: For information

The Committee noted the agenda of the 3RsWP meeting held on 20-21 May 2025.

Minutes of the OEG - 3RsWP - Batch release testing meeting held on 6 March 2025

Action: For information

The Committee noted the minutes of the OEG - 3RsWP - Batch release testing meeting.

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.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9.3. Regulatory matters

Invented names

11. CMDv

Report from CMDv

Action: To note

The Committee noted the draft agenda of the CMDv meeting to be held on 18-19 June 2025 , the final agenda of the CMDv meeting held on 21-22 May 2025 together with the report for release February-March 2025 (link).

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the June 2025 meeting, which was held in person.

An asterisk (*) after the role, in the first column, signals that the participant attended virtually.
Additional experts participated in (part of) the meeting, remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
G. Johan Schefferlie	**Chair**	**CHAIR**	**No interests declared**	
Petra Falb*	Member	Austria	No interests declared	
Manuela Leitner	Alternate	Austria	No interests declared	
Els Dewaele	Member	Belgium	No interests declared	
Frederic Klein*	Alternate	Belgium	No restrictions applicable to this meeting	
Frane Božić	Member	Croatia	No interests declared	
Leona Nepejchalová*	Member	Czechia	No interests declared	
Jiří Bureš	Alternate	Czechia	No interests declared	
Niels Christian Kyvsgaard	Member	Denmark	No interests declared	
Merete Blixenkrone-Møller*	Alternate	Denmark	No interests declared	
Toomas Tiirats*	Member	Estonia	No interests declared	
Minna Leppänen	Member	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras*	Alternate	France	No interests declared	
Andrea Christina Golombiewski	Member	Germany	No restrictions applicable to this meeting	
Esther Werner	Alternate	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No participation in discussions, final deliberations and voting on	EMEA/V/C/006610/0000
Paul McNeill	Member	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Zanda Auce	Member	Latvia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Renate Kuske*	Alternate	Latvia	No interests declared	
Vaida Kurapkiene*	Alternate	Lithuania	No interests declared	
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	
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	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	
Ricardo Carapeto García	Co-opted member	Spain	No interests declared	
Mary O'Grady	Co-opted member	Ireland	No interests declared	
Carina Bergman	Co-opted member	Sweden	No interests declared	

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

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Philippe Berny	Expert	France	No restrictions applicable to this meeting	
Mark Montforts	Expert	Netherlands	No interests declared	
Charlotte Smith Bonde	Expert	Denmark	No restrictions applicable to this meeting	
Erik den Hertog	Expert	Netherlands	No restrictions applicable to this meeting	
Haru Kroneis	Expert	Austria	No interests declared	
Nathalie Bridoux	Expert	France	No interests declared	
Anita Bottger	Expert	Netherlands	No interests declared	
Florence Pillet	Expert	France	No restrictions applicable to this meeting	
Anne Sagnier	Expert	France	No interests declared	
Walid Oumessad	Expert	France	No restrictions applicable to this meeting	
Fabien Alleman	Expert	France	No restrictions applicable to this meeting	
Pascale Macours	Expert	France	No interests declared	
Mathilde Harvey	Expert	France	No interests declared	
Saila Antila	Expert	Finland	No interests declared	
Stella Attia	Expert	Finland	No interests declared	
Maike Goemmel	Expert	Germany	No interests declared	
Jana Hundt	Expert	Germany	No interests declared	
Heike Gyra	Expert	Germany	No interests declared	
Frida Martin	Expert	Sweden	No interests declared	
Fredrik Hulten	Expert	Sweden	No interests declared	
Eva Vernerova	Expert	Czech Republic	No interests declared	
Nadine Matzmohr	Expert	Germany	No interests declared	
Wiebke Weiher	Expert	Germany	No interests declared	
Paulin Dettmann	Expert	Germany	No restrictions applicable to this meeting	
Christina Bredtmann*	Expert	Germany	No interests declared	
Alina Roessner	Expert	Germany	No interests declared	
Jana Pantzke	Expert	Germany	No interests declared	
Maren Osmers	Expert	Germany	No interests declared	
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Andrea Springer	Expert	Germany	No interests declared	
Nuria Doñamayor Alonso	Expert	Germany	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Miriam Schrader	Expert	Germany	No interests declared	
Christopher Janich	Expert	Germany	No interests declared	
Svenja Rieke	Expert	Germany	No interests declared	
Caroline Bitterlich	Expert	Germany	No interests declared	
Christian Kühne	Expert	Germany	No interests declared	
Katja Boxberger	Expert	Germany	No interests declared	
Kathrin Schmidt	Expert	Germany	No interests declared	
Kathrin Schirmann	Expert	Germany	No interests declared	
Gerd Maack	Expert	Germany	No interests declared	
Raul Belmar Liberato	Expert	Spain	No restrictions applicable to this meeting	
Rocio Fernandez Granda	Expert	Spain	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Maria Ferrer	Expert	Spain	No interests declared	
Ana Isabel Olías	Expert	Spain	No interests declared	
Jaime García Sanchez	Expert	Spain	No restrictions applicable to this meeting	
Alberto de Prado Lopez	Expert	Spain	No interests declared	
Sonia Gil Morales	Expert	Spain	No interests declared	
Luis Agote Casado	Expert	Spain	No interests declared	
Aranzazu González-Canga	Expert	Spain	No interests declared	
Gavin Ryan	Expert	Ireland	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Mette Toftegaard Madsen	Expert	Denmark	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Helene Godiksen	Expert	Denmark	No restrictions applicable to this meeting	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Rhona McHugh	Expert	Ireland	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	
Alice Blennerhassett	Expert	Ireland	No interests declared	
Hannah Pratt	Expert	Ireland	No interests declared	
Uta Herbst	Expert	Germany	No interests declared	

CVMP working parties and CMDv	Chair
AWP	Damien Bouchard*
ERAWP	Mark Montforts*
PhVWP-V	James Mount*
IWP	Esther Werner
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
EWP	Cristina Muñoz Madero
A representative from the European Commission attended the meeting.	
Two 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.