7 October 2025
EMA/CVMP/324854/2025
Committee for Veterinary Medicinal Products (CVMP)

# Committee for Veterinary Medicinal Products

## Minutes of the 9-10 September 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 virtually.

### 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 9-10 September 2025

The attendance list was completed and competing interests were identified for the September 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 June and July 2025 meetings will be circulated for adoption as soon as possible.

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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

No items

# 2. Marketing authorisations

## 2.1. Opinions

### 2.1.1. Portela – relfovetmab - EMEA/V/C/005890/0000 – cats

Indication: alleviation of pain associated with osteoarthritis in cats.

**Action:** For adoption

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

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

A divergent position has been signed by K. Baptiste.

**Action:** For information

The Committee noted the summary of opinion and the comments received from two CVMP members and three peer reviewers.

## 2.2. Oral explanations

No items

## 2.3. List of outstanding issues

### 2.3.1. EMEA/V/C/006513/0000 – 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.

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

## 2.4. List of questions

### 2.4.1. EMEA/V/C/006703/0000 – cats

**Action**: For adoption

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

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

### 2.4.2. EMEA/V/C/006679/0000 – turkeys

**Action**: For adoption

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

The Committed noted two peer review reports.

### 2.4.3. EMEA/V/C/006680/0000 – horses

**Action**: For adoption

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

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

### 2.4.4. EMEA/V/C/006702/0000 – cats

**Action**: For adoption

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

The Committed noted a peer review report and comments from two 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. Divence Tetra – Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine - EMA/VRA/0000288649 – cattle

Variation requiring assessment: to implement the outcome of the MAH's signal management process to add new, uncommon adverse events in the product information: milk production decrease, reduced food intake and decreased activity. Information on allowing the vaccine to reach room temperature before use was also added to the product information.

Rapporteur: J. Poot

**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. 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: treatment of infections with *Angiostrongylus vasorum*. Additionally, the product information has been aligned with version 9.1 of the QRD template.

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

**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.

### 3.2. Oral explanations

No items

### 3.3. List of outstanding issues

No items

### 3.4. List of questions

#### 3.4.1. Credelio, Lotimax, Credelio Plus – lotilaner, lotilaner, lotilaner / milbemycin oxime - EMA/VRA/0000261365 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) in dogs - addition of a new therapeutic indication or modification of an approved one. Additionally, the product information for all three products is being aligned with version 9.1 of the QRD template.

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsar

**Action**: For adoption

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

#### 3.4.2. Frontpro – afoxolaner – EMA/VRA/0000282075 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one. Additionally, the product information is being aligned with version 9.1 of the QRD template.

Rapporteur: K. Boerkamp, Co-Rapporteur: P. McNeill

**Action**: For adoption

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

#### 3.4.3. Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMA/VRA/0000281791 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

**Action**: For adoption

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

### 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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

### 4.7. Other issues

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

No items

#### 4.7.1. Referrals

No items

#### 4.7.2. Referrals under Article 35 of Directive 2001/82/EC

No items

## 5. Post-authorisation issues for marketing authorisations

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

### 5.1. Pharmacovigilance

No items

### 5.2. Post-authorisation measures

No items

### 5.3. Inspections and controls

No items

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

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)

No items

### 6.4. Immunologicals Working Party (IWP)

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

**Action:** For adoption

The Committee adopted the revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus and the revised guideline on duration of immunity achieved by veterinary vaccines. Both revisions consist of administrative changes to align the guidelines with the definitions and terminology provided in Article 4 of Regulation (EU) 2019/6. The references to the legislation applicable and other scientific guidelines have also been updated. As no changes were made to the scientific content, no concept paper or public consultation was deemed necessary. The documents will come into effect on 1 April 2026.

### 6.5. 3Rs Working Party (3RsWP)

### 6.6. Novel Therapies & Technologies Working Party (NTWP)

#### 6.6.1. Appointment of CVMP NTWP Operational Expert Groups (OEG) experts on RNAi&antisense

**Action**: for decision

The Committee appointed R. Martin, R. Belmar, H. Mitdank, V. Devesa, F. Koban, C. Lorenzer as experts of the NTWP OEGs on RNAi&antisense that will work with the 4 coordinators from NTWP.

### 6.7. Pharmacovigilance Working Party (PhVWP-V)

No items

### 6.8. Quality Working Party (QWP)

#### 6.8.1. Guideline on in-use stability testing of VMPs

**Action**: For adoption

The Committee adopted the guideline on in-use stability testing of VMPs. The document will come into effect immediately after publication.

#### 6.8.2. Question and answer on histamine limits for gentamicin-containing VMPs

**Action**: For adoption

The Committee adopted the question and answer on histamine limits for gentamicin-containing VMPs (parenteral solutions indicated for horses).

### 6.9. Scientific Advice Working Party (SAWP-V)

#### 6.9.1. Verbal report on SAWP-V meeting held on 5 September 2025

**Action**: For information

The Committee received a verbal report on SAWP-V meeting held on 5 September 2025 and noted its agenda together with the final minutes of the SAWP-V meeting held on 11 July 2025.

### 6.10. Safety Working Party (SWP-V)

### 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

#### 7.1.2 Request for inclusion of polyethylenimine (PEI) in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

**Action**: For adoption

The Committee agreed to include polyethylenimine as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009, under the heading of 'Excipients'. This decision followed the Committee's review of a request that had been submitted by an applicant, in accordance with the relevant CVMP guidance.

### 7.2. Environmental risk assessment

No items

## 7.3. Antimicrobial resistance

### 7.3.1. Adjustment of the AMEG categorisation to align with the Commission Implementation Regulation 2022/1255

**Action**: For information

The Committee noted the adjustment of the AMEG categorisation to align with the Commission Implementation Regulation 2022/1255: Categorisation of antibiotics in the European Union AMEG infographic link.

## 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.*

### 7.5.1. EMEA/V/VAMF/0011

Rapporteur: E. Werner, Co-Rapporteur: F. Hasslung Wikström

**Action:** For adoption

The Committee adopted the VAMF evaluation report.

**Action:** For endorsement

The Committee endorsed the VAMF certificate.

## 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

#### 9.1.1. Request for classification

**Action**: For classification

The Committee discussed the veterinary medicinal product for dogs and classified it as intended for a limited market and eligible for authorisation according to Article 23.

#### 9.1.2. Request for classification

**Action**: For classification

The Committee discussed the veterinary medicinal product for pigs and classified it as non-intended for a limited market and not eligible for authorisation according to Article 23.

#### 9.1.3. Request for classification

**Action**: For classification

The Committee discussed the veterinary medicinal product for horses and classified it as intended for a limited market and eligible for authorisation according to Article 23.

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

#### 9.2.1. Summary of eligibility and table of offers from rapporteurs

**Action**: For decision

The Committee noted the eligibility requests and updates concerning intended applications and the rapporteurs' appointment offers for responsibilities at CVMP.

### 9.2.8. Updated procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer

**Action:** For adoption

The Committee adopted the updated procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer. This document has been updated (rev.4) to provide more clarity with regard to (co-)rapporteurship appointments taking into account case law and a European Ombudsman recommendation. The key elements of this revision are the requirement to consider the prior role of the (co-)rapporteur as coordinator for scientific advice for initial MA applications and any changes in rapporteurship. This document is also revised to reflect minor amendments with regards to referral and related procedures.

### 9.3. Regulatory matters

No items

# 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 endorsed the agenda of CVMP/CMDv Presidency meeting under the Danish EU Presidency, Copenhagen, 25-26 September 2025 (CVMP and joint CVMP-CMDv sessions).

### 10.2 Appointment of co-opted members at the October 2025 CVMP meeting

**Action**: For discussion

The Committee discussed the identification of expertise necessary for CVMP to complement its expertise and agreed to launch 2 calls for nominations for a co-opted member on quality (chemicals) and another on general clinical veterinary practice. The appointment will take place at the October CVMP meeting.

# 11. CMDv

No items

# 12. Legislation

No items

# 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 (Bupivacaine) – EMEA/V/MRL/005009/MODF/0003 – bovine

**Action**: For information

The Committee noted the letter of withdrawal of the application for a modification of the MRL status for Bupivacaine.

## 3. Variations to marketing authorisations

### 3.1. Opinions under Regulation (EU) 2019/6

BTVPUR – Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 4) - EMA/VRA/0000269417 – cattle, 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.

Cytopoint – lokivetmab - EMA/VRA/0000263599 – 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.

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

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 recommendation.

**Action:** For endorsement

The Committee endorsed the rapporteur's assessment report.

### Evicto – meloxicam – EMA/VRA/002283 – 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, 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.

### ProZinc – insulin human – EMA/VRA/0000247545 – cats, 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 recommendations.

**Action:** For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Variation requiring assessment: quality-related changes.

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

**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.

### Zulvac 1+8 Bovis - Bluetongue vaccine (inactivated) - EMA/VRA/0000263047- WS – cows

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, 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.

### Arthricox – firocoxib – EMA/VRA/0000265601 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

**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.

### Equioxx – firocoxib – EMA/VRA/0000247013 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

**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.

### 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, 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.

### Zulvac SBV – Schmallenberg virus vaccine (inactivated) – EMA/VRA/0000269443 – sheep, cattle

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

Rapporteur: G. Kulcsár

**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.

## Osurnia – terbinafine / florfenicol / betamethasone acetate - EMA/VRA/0000269514 – 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.

## Novaquin – meloxicam - EMA/VRA/0000261536 – 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, 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.

## Chanhold – selamectin - EMA/VRA/0000272326 – cats, 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.

## RenuTend - EMA/VRA/0000281948 - horses

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

**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.

## Felpreva - EMA/VRA/0000288311 - cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. C. Golombiewski

**Action:** For adoption

The Committee adopted, by consensus, the CVMP opinion.

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

**Action:** For endorsement

The Committee endorsed the rapporteur's assessment report.

## Draxxin - EMA/VRA/0000288472 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: A. C. 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.

## Credelio, Lotimax, AdTab, Credelio Plus - EMA/VRA/0000285644 – dogs, cats

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 recommendations.

**Action:** For endorsement

The Committee endorsed the rapporteur's assessment report.

## Semintra - EMA/VRA/0000288420 – cats

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.

## Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMA/VRA/0000282419 – horses

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.

## Emevet – maropitant – EMA/VRA/0000285688 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: M. Leppänen

**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.

## Simparica Trio – sarolaner / moxidectin / pyrantel embonate – EMA/VRA/0000288112 – 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.

## Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate – EMA/VRA/0000290816 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

**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.

Semintra - EMA/VRA/0000287663 - cats

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.

Senvelgo - EMA/VRA/0000286769 - cats

Variation requiring assessment: quality-related changes.

Rapporteur: K. Baptiste

**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.

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, 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.

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

Kriptazen – halofuginone – EMA/VRA/000282647 – cattle

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

Rapporteur: E. Augustynowicz

**Action**: For adoption

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

## DuOtic/Osurnia (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 list of questions.

## Zuprevo – tildipirosin - EMA/VRA/0000281934 – cattle, pigs

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

**Action**: For adoption

The Committee adopted the list of questions.

## Zenalpha – medetomidine hydrochloride / vatinoxan hydrochloride - EMA/VRA/0000281977 – dogs

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

Rapporteur: R. Breathnach

**Action**: For adoption

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

## Vectormune HVT-AIV– avian influenza vaccine (live recombinant)- EMA/VRA/0000284472 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

**Action**: For adoption

The Committee adopted the list of questions.

## Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMA/VRA/0000281715– horses

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.

## Melosus – meloxicam – EMA/VRA/0000282328 – dogs

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

Rapporteur: N.C. Kyvsgaard

**Action**: For adoption

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

Enteroporc Coli AC – neonatal piglet colibacillosis (recombinant, inactivated) and Clostridium perfringens vaccine (inactivated) - EMA/VRA/0000281745 – pigs

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

Rapporteur: N.C. Kyvsgaard

**Action**: For adoption

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

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

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.

Vectormune FP ILT + AE – fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live) - EMA/VRA/0000282411 – chickens

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

Rapporteur: J. Poot

**Action**: For adoption

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

Evalon – coccidiosis vaccine (live) - EMA/VRA/0000282001 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

**Action**: For adoption

The Committee adopted the list of questions.

## 4. Referrals and related procedures

### 4.7. Other issues

## 5. Post-authorisation issues for marketing authorisations

### 5.1 Pharmacovigilance under Regulation (EU) 2019/6

Signal evaluation and recommendations

**Action:** For adoption

The Committee adopted the monthly outcomes of the signal management process (August 2025) and the list of finalised signals.

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

CircoMax – EMA/PAM/0000287641

Quality-related measures.

Rapporteur: N.C. Kyvsgaard

**Action:** For endorsement

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

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

## 6. Working parties

### 6.5 3Rs Working Party (3RsWP)

Minutes of the Batch release testing OEG meeting held on 16 May 2025

**Action:** For information

The Committee noted the minutes of the Batch release testing OEG meeting held on 16 May 2025.

NC and NAMs ESEC nominations

**Action**: For information

The Committee noted the NC and NAMs ESEC nominations.

### 6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

**Action**: For adoption

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

### 6.11. Other working party and scientific group issues

Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains

**Action**: For endorsement

The Committee endorsed the final mandate following its discussion at the July meeting. This document does not impact the SAWP-V neither SAWP-H.

## 7. Other scientific matters

### 7.7. Other issues

## 8. Co-operation with other EU or International bodies

### 8.1. VICH

VICH GL62 on target animal safety of veterinary monoclonal antibody products (VMAPs)

**Action**: For adoption

The Committee adopted the draft guideline on target animal safety of veterinary monoclonal antibody products for public consultation, following sign-off of the guideline by the VICH Steering Committee.

### VICH GL22(R) on studies to evaluate the safety of residues of veterinary drug in human food: reproduction studies

**Action**: For adoption

The Committee adopted the guideline on reproduction studies, following sign-off of the guideline by the VICH Steering Committee. The revised guideline will be implemented by August 2026.

### VICH GL23(R2) on studies to evaluate the safety of residues of veterinary drug in human food: genotoxicity studies

**Action**: For adoption

The Committee adopted the guideline on genotoxicity studies, following sign-off of the guideline by the VICH Steering Committee. The revised guideline will be implemented by August 2026.

## 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

## 11. CMDv

### Reports from CMDv

**Action**: To note

The Committee noted the final agenda of the CMDv meeting held on 23-24 July 2025.

# ANNEX I

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 9-10 September 2025 CVMP meeting, which was held remotely.

*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 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 restrictions applicable to this meeting | |
| Leona Nepejchalová | Member | Czechia | No interests declared | |
| Niels Christian | Member | Denmark | No interests declared | |
| Merete Blixenkrone-Møller | Alternate | Denmark | No interests declared | |
| Toomas Tiirats | Member | Estonia | No restrictions applicable to this meeting | |
| Minna Leppänen | Member | Finland | No interests declared | |
| Kristina | 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/0000282075<br>EMA/VRA/0000247545<br>EMA/VRA/0000269417<br>EMA/VRA/0000288420<br>EMA/VRA/0000286769<br>EMA/VRA/0000287663<br>EMA/VRA/0000278525 |
| Paul McNeill | Member | Ireland | No interests declared | |
| Alice Blennerhassett | Alternate | Ireland | No interests declared | |
| Fulvio MARSILIO | Member | Italy | 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 | |
| Caroline Coner | Member | 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 | |
| Gabriela Tuchila | Member | Romania | No interests declared | |
| Eva Chobotová | Member | Slovakia | No interests declared | |
| Urska Peunik | Alternate | Slovenia | No interests declared | |
| Cristina | 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 | Co-opted member | Spain | 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 | |

*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 |
|---|---|---|---|---|
| Mariette Salery | Expert | France | No interests declared | |
| Renata Kovacova | Expert | Slovakia | No interests declared | |
| Trijntje van der Velde-Koerts | Expert | Netherlands | No restrictions applicable to this meeting | |
| Daniel Benesh | Expert | Germany | No interests declared | |
| Florence PILLET | Expert | France | No restrictions applicable to this meeting | |
| Walid OUMESSAD | Expert | France | No interests declared | |
| Nathalie BRIDOUX | Expert | France | No interests declared | |
| Anne SAGNIER | Expert | France | No interests declared | |
| Kathrin Dietze | Expert | Germany | No interests declared | |
| Hanna Kankkonen | Expert | Finland | No interests declared | |
| Svenja Rieke | Expert | Germany | No interests declared | |
| John Aspegren | Expert | Finland | No restrictions applicable to this meeting | |
| Jana Pantzke | Expert | Germany | No interests declared | |
| Paulin Dettmann | Expert | Germany | No restrictions applicable to this meeting | |
| Wiebke Weiher | Expert | Germany | No interests declared | |
| Christina Bredtmann | Expert | Germany | No interests declared | |
| Laura Kulisch | Expert | Germany | No interests declared | |
| Uta Herbst | Expert | Germany | | |
| Nuria Doñamayor Alonso | Expert | Germany | No restrictions applicable to this meeting | |
| Britta Selzsam | Expert | Germany | No interests declared | |
| Anja Pfalzgraff | Expert | Germany | No interests declared | |
| Sabine Klee | Expert | Germany | No interests declared | |
| Anne Hasle Buur | Expert | Denmark | No interests declared | |

| Name | Role | Member state or affiliation | Outcome restriction following evaluation of DoI | Topics on agenda for which restrictions apply |
|---|---|---|---|---|
| Violeta Georgieva Tsonkova | Expert | Denmark | No restrictions applicable to this meeting | |
| Ea Rebekka Vinten | Expert | Denmark | No restrictions applicable to this meeting | |
| Kathrine Just Andersen | Expert | Denmark | No interests declared | |
| Kirsten Thomsen | Expert | Denmark | No interests declared | |
| Anja Silke Christensen | Expert | Denmark | No interests declared | |
| Anne Malene Nissen | Expert | Denmark | No interests declared | |
| Trine Sidonia Jensen | Expert | Denmark | No restrictions applicable to this meeting | |
| Anita Bottger | Expert | Netherlands | No interests declared | |
| Maria Esperanza Herreros Avila | Expert | Spain | No interests declared | |
| Carlos Ballesteros | Expert | Spain | No interests declared | |
| Veronica Devesa | Expert | Spain | No interests declared | |
| Sonia Gil Morales | Expert | Spain | No interests declared | |
| Leyre Sánchez de Rojas | Expert | Spain | No interests declared | |
| Luis Agote Casado | Expert | Spain | No interests declared | |
| Sarah Buckley | Expert | Ireland | No interests declared | |
| Emily Hams | Expert | Ireland | No interests declared | |
| Hannah Pratt | Expert | Ireland | No interests declared | |
| Tatyana Devine | Expert | Ireland | No interests declared | |
| Cristina Ballesteros | Expert | Spain | No interests declared | |
| Maria Jose Ferrer | Expert | Spain | No interests declared | |
| Ana Isabel Olías Molero | Expert | Spain | No interests declared | |
| Mercedes Ureña | Expert | Spain | No interests declared | |
| Beatriz Corcho | Expert | Spain | No interests declared | |

| CVMP working parties and CMDv | Chair |
|---|---|
| AWP | Damien Bouchard |
| IWP | Esther Werner |
| QWP | Marie-Hélène Sabinotto *(veterinary vice chair)* |
| SAWP-V | Frida Hasslung Wikström |
| SWP-V | Carina Bergman |
| EWP | Cristina Muñoz Madero |
| NTWP | Anja Pfaltzgraff |
| A representative from the European Commission attended the meeting. | |
| Three 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.