9 October 2025
EMA/334046/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 15-17 July 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 15-17 July 2025

The attendance list was completed and competing interests were identified for the July 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 between members and companies declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the June meeting will be adopted at the September 2025 meeting of the Committee.

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

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

Action: Oral explanation to be held on Tuesday, 15 July 2025, (14:30).

The Committee listened to an oral explanation from the applicant and noted the rapporteur's assessment of the responses to the list of outstanding issues together with the rapporteur's EPMAR. The adoption of the opinion is expected for the September meeting of the Committee.

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. Hemosyvet – etamsylate - EMEA/V/C/006461/0000 – cats, cattle, dogs, goats, horses, pigs and sheep

Indication: prevention and treatment of surgical, post traumatic, obstetric and gynaecological haemorrhages.

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. Cevac Reomune – avian reovirus vaccine (inactivated) - EMEA/V/C/006142/0000 – chickens

Indication: passive immunisation of broilers induced by active immunisation of broiler breeders to reduce clinical signs of tenosynovitis induced by avian reovirus infection.

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.

2.2. Oral explanations

No items

2.3. List of outstanding issues

No items

2.4. List of questions

2.4.1. EMEA/V/C/006681/0000 – cats

Action: For adoption

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

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

2.4.2. EMEA/V/C/006682/0000 – cats

Action: For adoption

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

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

2.4.3. EMEA/V/C/006683/0000 – cats

Action: For adoption

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

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

2.4.4. EMEA/V/C/006604/0000 – chickens

Action: For adoption

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

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

2.4.5. EMEA/V/C/006638/0000 – dogs

Action: For adoption

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

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1 EMEA/V/C/006300/0000 – cats

The Committee agreed to extend the clock-stop.

3. Variations to marketing authorisations

3.1. Opinions

3.1.1 Syvazul BTV 3 – Bluetongue virus vaccine (inactivated) - EMA/VRA/0000269481 – sheep

Variation requiring assessment: to add cattle as target species, and to increase the minimum specification for antigen content in the finished product.

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

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.

3.1.2. Eluracat – capromorelin tartrate – EMA/VRA/0000276253 – cats

Variation requiring assessment: to implement the outcome of the MAH's signal management process to add 'Anorexia' and 'Behavioural disorder' as rare, and 'Dyspnoea', 'Loss of consciousness, Sedation', 'Recumbency', 'Muscle weakness' and 'Hiding' as very rare adverse events in the product information.

Rapporteur: R. Carapeto Garcia

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. Divence IBR Marker Live – infectious bovine rhinotracheitis vaccine (live recombinant) - EMA/VRA/0000276264 – 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 member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

The Committee noted the comments from two CVMP members.

3.1.4. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMA/VRA/0000276349 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process to include 'Facial paralysis' as a very rare adverse event in the product information and to align it 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 member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.1.5 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 name update from L4 to L6.

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

Action: For adoption

The Committee adopted, by consensus, the revised CVMP opinion and revised product information. The proposed subsequent update of the name suffix from L4 to L6 (G.I.7.a) was not accepted.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the revised rapporteur's assessment report.

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) - EMA/VRA/0000269293 – pigs

Variation requiring assessment

Rapporteur: E. Werner

Action: For adoption

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

The Committee noted comments from a CVMP member.

3.4.2. Galliprant – grapiprant - EMA/VRA/0000272384 – dogs

Variation requiring assessment: to modify the approved therapeutic indication.

Rapporteur: K. Baptiste, Co-Rapporteur: E. Dewaele

Action: For adoption

There was no adoption of the list of questions and the comments on the product information. During the plenary, the Committee noted the withdrawal letter from the applicant on the variation. As this was done before adoption of the list of questions, no withdrawal EPAR will be published.

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

4.6.1. Quarter-based selective dry cow therapy – EMA/REF/0000285673

Antimicrobial resistance

Scope: Notification / letter

Action: For decision

The Committee noted the request from Germany for a scientific advice under Article 141(1)(i) of Regulation (EU) 2019/6 and appointed A. Golombiewski as rapporteur, M. Leppänen as co-rapporteur and four peer reviewers.

The Committee adopted the timetable together with the list of questions for stakeholders regarding submission of available data that may assist the CVMP in reaching its scientific advice. Relevant data should be submitted to vet.referrals@ema.europa.eu by 9 October 2025. Further information on this procedure is available on the relevant EMA website.

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

5.1.1. Senvelgo – velagliflozin - EMA/VS/0000231544

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

Action: For adoption

The Committee adopted the outcome of the signal management process (link).

5.1.2. Divence IBR Marker Live - Infectious bovine rhinotracheitis vaccine (live recombinant) – EMA/VS/0000268510

Rapporteur: J. Poot, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the outcome of the signal management process (link).

5.1.3. Librela – bedinvetmab - dogs

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

Action: For information

The Committee received an update on the communication of suspected adverse events that have been reported for Librela, which are not currently listed in the EU product information. The CVMP has therefore requested the MAH, Zoetis, to carry out an in-depth analysis of all available information on suspected musculoskeletal disorders reported since the medicine's authorisation. Results of this analysis are expected to be submitted by the MAH by end of September 2025. The CVMP will review the information provided by the MAH, as well as all available evidence, to assess the potential risk of musculoskeletal disorders in dogs treated with Librela and determine whether any change, for example an update of the product information, will be needed. EMA will communicate further once the review has concluded towards the end of 2025, or sooner if new important information arises.

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

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)

6.2.1. Verbal report on ERAWP meeting held on 17-18 June 2025

Action: For information

The Committee received a verbal report on the ERAWP meeting held on 17–18 June 2025 and noted the meeting's agenda, the minutes from the meeting held on 20–21 February 2025 and the agenda of the ERA ESEC workshop on aquaculture.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances

Action: For adoption

The Committee adopted the guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances, together with the overview of comments received on the guideline.

6.3.2. Appointment of a new EWP-V member

Action: For endorsement

The Committee noted the selection committee proposal to CVMP and endorsed the appointment of Kirsten Brolin Thomsen as new EWP-V member.

6.4. Immunologicals Working Party (IWP)

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP meeting held on 20-21 May 2025

Action: For information

The Committee received a verbal report on 3RsWP meeting held on 20-21 May 2025 and noted its agenda.

6.5.2 Election for Chair and Vice-chair of the 3RsWP

Action: For election

The Committee re-elected, unanimously, Sonja Beken as a Chair and Sarah Adler-Flindt, by majority, as a Vice-chair of the 3RsWP for another 3-year mandate.

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 7 July 2025

Action: For information

The Committee received a verbal report on NTWP meeting held on 7 July 2025 and noted its agenda together with final minutes of the meeting held on 5 May 2025.

6.7. Pharmacovigilance Working Party (PhVWP)

6.7.1. Verbal report on PhVWP-V meeting held on 8 July 2025

Action: For information

The Committee noted the verbal report on PhVWP-V meeting held on 8 July 2025 and its agenda together with the draft summary record of the meeting.

6.7.2. Endorsement of new PhVWP-V member (replacement of previous member)

Action: For endorsement

The Committee endorsed the nomination of Kira Rosenkilde to replace a previous member of the PhVWP.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (May-June 2025)

Action: For information

The Committee received a verbal report on QWP meetings (May-June 2025) and noted the agendas of both QWP meetings together with the minutes of the QWP meetings held on 14-15 April 2025 and on 12-13 May 2025.

6.8.2. Selection of two QWP members

Action: For endorsement

The Committee endorsed the quality domain governance recommendation for two new QWP members: Cynthia Huttner and Luka Kosec.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 11 July 2025

Action: For information

The Committee received the verbal report on SAWP-V meeting held on 11 July 2025 and noted its agenda together with the final minutes of the SAWP-V meeting held on 6 June 2025.

Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 17-18 June 2025

Action: For information

The Committee received a verbal report on SWP-V meeting held on 17-18 June 2025 and noted its agenda together with the minutes of the SWP-V meeting held on 20-21 March 2025.

6.10. Other working party and scientific group issues

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

7.1.1. Request for inclusion of sunflower oil 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 adopted the inclusion of sunflower oil 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, which was updated to its revision 61.

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

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

Action: For information

The Committee noted the adjustment of AMEG categorisation to align with the Commission Implementation Regulation 2022/1255: Categorisation of antibiotics in the European Union - Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals.

7.3.2. Mandate for Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party

Action: For adoption

The Committee adopted the ADRA temporary working party mandate, objectives and rules of procedure.

7.3.3. Appointment of temporary Working Party experts on Dosage Review and Adjustment of established Antibiotics (ADRA)

Action: For information

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/00012

Action: For adoption

The Committee adopted the VAMF evaluation report.

Action: endorsement

The Committee endorsed the VAMF certificate.

7.5.2. EMEA/V/VAMF/00010

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

8.1.1. EU expert in Pharmacovigilance Expert Working Group

Action: For endorsement

The Committee endorsed Anita Bottger as the new EU expert in the VICH Pharmacovigilance Expert Working Group.

8.1.2. VICH GL 61 on Pharmaceutical Development

Action: For endorsement

8.1.3. Concept paper for the revision of VICH GL6 - Environmental impact assessments (EIAs) for veterinary medicinal product (VMPs) Phase 1

Action: For discussion

8.1.4. Concept paper for the revision of VICH GL27 - Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance

Action: For discussion

8.1.5. Concept paper for the revision of GL34 - Test for the detection of Mycoplasma contamination

Action: For discussion

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 Atlantic salmon. The Committee classified the product as intended for a 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

9.2.1. Summary of eligibility and table of offers from rapporteurs

Action: For decision

The Committee agreed on the eligibility requests and updates concerning intended applications; rapporteur's appointment offers for responsibilities at CVMP.

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Election of co-opted member on Toxicology and Residues

Action: For decision

The Committee re-elected, unanimously, Carina Bergman as a CVMP co-opted member on Toxicology and Residues.

10.2. CVMP/CMDv Informal meeting under the Polish EU Presidency, Warsaw, 8-9 May 2025

Action: For adoption

The Committee adopted the minutes of the CVMP session and the joint CVMP-CMDv session under the Polish EU Presidency, Warsaw, 8-9 May 2025.

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

Action: For discussion

The Committee discussed the agenda of the CVMP/CMDv Informal meeting under the Danish EU Presidency, Copenhagen, 25-26 September 2025.

10.5. F2F Committee Meeting Schedule 2026

Action: For information

The Committee noted the F2F committee meeting schedule for 2026.

11. CMDv

11.1. Verbal report from Chair of CMDv on the CMDv plenary meeting held on 18-19 June 2025

Action: For information

The Committee received a verbal report from the CMDv chair on the June CMDv meeting and noted its agenda together with the agenda of the CMDv meeting to be held on 23-24 July 2025 and minutes from the April 2025 CMDv meeting

12. Legislation

12.1 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

Action: For information

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

2. Marketing authorisations and extensions

2.6. Other issues under Regulation (EU) 2019/6

EMEA/V/C/006481/0000 – dogs

Action: For decision

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

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, 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.

Recocam – meloxicam - EMA/VRA/0000255256 – cattle, horses, pigs

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

Bovela – bovine viral diarrhoea vaccine (modified live)- EMA/VRA/0000256950 – cattle

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

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.

Clynav – salmon pancreas disease vaccine (recombinant DNA plasmid) - EMA/VRA/0000269302 – Atlantic salmon

Variation requiring assessment: quality-related changes.

Rapporteur: G. Beechinor

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.

Zulvac 8 Ovis – Bluetongue vaccine (inactivated) - EMA/VRA/0000256429 – 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.

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, 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.

Evanovo / Gumbohatch - EMA/VRA/0000244052 (WS)– chickens

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

Action: For adoption

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

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

Action: For endorsement

The Committee endorsed the Rapporteur's assessment report.

Suprelorin – deslorelin acetate - EMA/VRA/0000263609 – dogs, cats, ferrets

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.

Prevexxion RN/Prevexxion RN+HVT+IBD /Prevexxion RN+HVT /Vaxxitek HVT+IBD - EMA/VRA/0000258455 (WS) – chicken

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

The Committee adopted, by consensus, the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Arthricox – firocoxib – EMA/VRA/0000265601 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

Action: For adoption

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

Emdocam – meloxicam – EMA/VRA/0000269297 – horses

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

Rapporteur: P. McNeil

Action: For adoption

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

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 the list of questions.

Respiporc FLUpan H1N1, Respiporc Flu 3– Porcine influenza vaccine (inactivated) – EMA/VRA/0000258482 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

The Committee adopted the list of questions.

Porcilis Porcoli Diluvac Forte – E. coli vaccine (inactivated) – EMA/VRA/0000269151– pigs

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.

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 the list of questions and the comments on the product information.

Chanhold – selamectin - EMA/VRA/0000272326 – cats and 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 the list of questions and the comments on the product information.

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 the list of questions and the comments on the product information.

4. Referrals and related procedures

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

Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep - EMA/REF/000027181

Efficacy, anti-parasitic resistance

Rapporteur: A. Golombiewski, Co-Rapporteur: C. Muñoz Madero

Action: For decision

The Committee agreed to the request for an extension of the clock-stop.

Action: For adoption

The Committee adopted the revised timetable.

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 noted the monthly outcomes of the signal management process together with the list of finalised signals.

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

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.

6.7 Pharmacovigilance Working Party (PhVWP)

Final versions of the 2025 VeDDRA documents

Action: For information

The Committee noted 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)

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

VICH GL22 on reproduction toxicity

Action: For endorsement

The Committee endorsed the draft GL 22 on reproduction toxicity for sign-off by the VICH Steering Committee.

VICH GL23 (R) on genotoxicity testing

Action: For endorsement

The Committee endorsed the draft GL 23 on genotoxicity testing for sign-off by the VICH Steering Committee.

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

Action: For adoption

The Committee adopted the draft GL on target animal safety of veterinary monoclonal antibody products - version 10 for sign-off by the VICH Steering Committee.

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

ANNEX I

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

An asterisk (*) after the role, in the first column, signals that the participant attended in person.
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	
Tsvetanka Valova	Alternate	Bulgaria	No interests declared	
Irena Žarković	Member	Croatia	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	
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	EMA/VS/0000231544 WS/2673
Paul McNeill	Member	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Fulvio MARSILIO	Member	Italy	No interests declared	
Zanda Auce	Member	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 interests declared	
Hanne Bergendahl	Member	Norway	No restrictions applicable to this meeting	
Knud Sveen Torjesen	Alternate	Norway	No interests declared	
Ewa Augustynowicz	Alternate	Poland	No interests declared	
Marcin Glanda	Alternate	Poland	No interests declared	
Ines Dias	Alternate	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	
Consuelo Rubio Montejano	Alternate	Spain	No interests declared	
Frida Hasslung Wikström	Member (Vice-Chair)	Sweden	No interests declared	
Hanna Bremer	Alternate	Sweden	No interests declared	
Keith Baptiste	Co-opted member	Denmark	No interests declared	
Ricardo Carapeto García	Co-opted member	Spain	No interests declared	
Rory Breathnach	Co-opted member	Ireland	No 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
Mariette Salery	Expert	France	No interests declared	
Caroline Guittre	Expert	France	No interests declared	
Jenny Larsson	Expert	Sweden	No interests declared	
Mark Montforts	Expert	Ireland	No interests declared	
Christopher Janich	Expert	Belgium	No interests declared	
Tita-Maria Muhonen	Expert	Finland	No interests declared	
Aranzazu González-Canga	Expert	Spain	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Kirsten Thomsen	Expert	Denmark	No interests declared	
Malene Nissen	Expert	Denmark	No interests declared	
Anja Silke Christensen	Expert	Denmark	No interests declared	
Kira Rosenkilde Underbjerg	Expert	Denmark	No interests declared	
Elena Lucas Roldan	Expert	Spain	No interests declared	
Marta Camacho Artacho	Expert	Spain	No interests declared	
Lorena Touriño González	Expert	Spain	No interests declared	
Cristina Ballesteros	Expert	Spain	No interests declared	
Nuria Sanchez Ranchel	Expert	Spain	No interests declared	
Ana Isabel Olías Molero	Expert	Spain	No interests declared	
Miriam Schrader	Expert	Germany	No interests declared	
Andrea Orthmann	Expert	Germany	No interests declared	
Daniel Benesh	Expert	Germany	No interests declared	
Roswitha Merkel	Expert	Germany	No interests declared	
Sandra-Maria Wienhold	Expert	Germany	No restrictions applicable to this meeting	
Maren Osmers	Expert	Germany	No interests declared	
Paul Siller	Expert	Germany	No interests declared	
Christine Schwarz	Expert	Germany	No interests declared	
Jana Pantzke	Expert	Germany	No interests declared	
Uta Herbst	Expert	Germany	No interests declared	
Christina Bredtmann	Expert	Germany	No interests declared	
Laura Kulisch	Expert	Germany	No interests declared	
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Nadine Matzmohr	Expert	Germany	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	
Yasemin Suzer	Expert	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Eva Pomezna	Expert	Czech Republic	No interests declared	
Jaroslav Maxa	Expert	Czech Republic	No interests declared	
Anita Bottger	Expert	Netherlands	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Pascale Macours	Expert	France	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
CMDv	Laetitia Le Letty
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.