6 June 2025
EMA/196317/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 10-12 June 2025

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

10 June 2025, 09:00 – 12 June 2025, 13:00 – virtual and room 2C

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

Disclaimer

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CVMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CVMP members and the work the Committee undertakes.

Declaration of interests

In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take 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 meeting.

Note on access to documents

Some documents mentioned in the agenda/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).

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Introduction

i. Adoption of the agenda.

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 to be held 10-12.06.2025. See 05.2025 CVMP minutes (to be published post 06.2025 CVMP meeting).

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

iv. Adoption of the minutes of the previous meetings: November 2024, April 2025, May 2025.

v. Topics and experts' participation in discussions, rapporteur's meetings and breakout sessions held in advance or in the margins of the present CVMP meeting.

Scientific Advice Working Party (virtual)	Fri 6 Jun 25	10.00-13.00

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

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

Request from the applicant for an oral explanation

2. Marketing authorisations

2.1. Opinions

2.1.1. EMEA/V/C/006480/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006358/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006332/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.4. EMEA/V/C/006336/0000 – pigs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.2. Oral explanations

No items

2.3. List of outstanding issues

2.3.1. EMEA/V/C/005890/0000 – cats

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

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

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.4. List of questions

2.4.1. EMEA/V/C/006610/0000 – horses

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4.2. EMEA/V/C/006655/0000 – dogs

Action: For adoption

Scientific overview and list of questions, comments on the product information

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 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

Variation requiring assessment: to implement the outcome of the MAH's signal management process

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: to add new information to the product information

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

Action: For adoption

CVMP opinion, CVMP assessment report

Action: For information

Summary of opinion, product information

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

Variation requiring assessment: to implement the following changes: addition of new therapeutic indications or modification of an approved one and addition of associated non-mixed use

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

Action: For adoption

CVMP opinion, CVMP assessment report

Action: For information

Summary of opinion

3.2. Oral explanations

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

Variation requiring assessment: to implement the following changes: addition of new therapeutic indications or modification of an approved one; and addition of associated non-mixed use

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

Action: For action

Oral explanation

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

List of questions, 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

List of questions, comments on the product information

3.4.3. 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.

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

Action: For adoption

List of questions, 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, anti-parasitic resistance

Scope: Notification

Action: For decision

Notification from Germany under Article 82 of Regulation (EU) 2019/6; Appointment of rapporteur, co-rapporteur and peer reviewers

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

Outcome of the signal management process, list of finalised signals

5.1.2. Senvelgo – velagliflozin

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

Action: For adoption

Outcome of the signal management process

5.1.3. Solensia – frunevetmab

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

Action: For adoption

Outcome of the signal management process

5.1.4. Librela - bedinvetmab

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

Action: For adoption

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

CVMP opinion, CVMP Re-examination report

5.5. Others

No items

6. Working parties

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

6.1. Antimicrobials Working Party (AWP)

6.1.1. Verbal report on AWP meeting held on 27th and 28th May 2025

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

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

Action: For information

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

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

Action: For information

6.7.3. Revised VeDDRA documents

Action: For discussion

6.8. Quality Working Party (QWP)

6.8.1. 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

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

6.9.2. Election for Vice-chair of SAWP-V

Action: For election

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

7.4. 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

Assessment report and list of questions

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

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

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

Action: For decision

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

14. Annex

2. Marketing authorisations

2.6. Other issues

EMEA/V/C/006180/0000 – horses

Action: For endorsement

Request from the applicant for an extension of clock stop

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

CVMP opinion.

Action: For endorsement

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report.

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

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

List of outstanding issues, assessment report

Equioxx – firocoxib – EMA/VRA/0000247013 – horses

Variation requiring assessment: quality-related changes

Rapporteur: J.G. Beechinor

Action: For endorsement

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

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

List of questions, 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

List of questions, 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

List of questions, 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

List of questions

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

Variation requiring assessment: quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

List of questions

Cytopoint – lokivetmab - EMA/VRA/0000263599 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

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

List of questions, 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

List of questions, 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

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's assessment report

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

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

Action: For information

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

Action: For information

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

Action: For information

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH status of guidelines

Action: For information

9.3. Regulatory matters

Invented names

11. CMDv

Reports from CMDv

Action: To note

Report for release February-March 2025 (link)