11 July 2025
EMA/231168/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 15-17 July 2025

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

15 July 2025, 09:00 – 17 July 2025, 13:00 – virtual and room 2C

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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Table of contents

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 15-17/07/2025. See 06/2025 CVMP minutes (to be published post 07/2025 CVMP meeting) Declaration of contacts between members and companies with regard to points on the agenda.

iii. Adoption of the minutes of the previous meeting - *postponed to September*.

iv. 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 11 July 25	10.00-13.00

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

Rapporteurs' assessment of responses to list of outstanding issues, rapporteur's EPMAR; presentation from the applicant

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

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006142/0000 – chickens

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

No items

2.4. List of questions

2.4.1. EMEA/V/C/006681/0000 – cats

Action: For adoption

List of questions and scientific overview, comments on the product information

2.4.2. EMEA/V/C/006682/0000 – cats

Action: For adoption

List of questions and scientific overview, comments on the product information

2.4.3. EMEA/V/C/006683/0000 – cats

Action: For adoption

List of questions and scientific overview, comments on the product information

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

Action: For adoption

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

2.4.5. EMEA/V/C/006638/0000 – 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

2.6.1. EMEA/V/C/006300/0000 – cats

Action: For decision

Request from the applicant for a further extension of 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 target species.

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

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

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 and to align the product information with the version 9.1. of the QRD template.

Rapporteur: R. Carapeto Garcia

Action: For adoption

CVMP opinion; product information

Action: For endorsement

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 and to clarify the temperature of use in section 3.9 of the SPC and section 9 of the PL to ensure the correct handling of the veterinary medicinal product.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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, and to align the product information with version 9.1 of the QRD template.

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

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: efficacy-related change.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

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

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

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

Rapporteur: tbc, Co-Rapporteur: tbc

Scope: Notification / letter

Action: For decision

Request from Germany for a scientific advice under Article 141(1)(i) of Regulation (EU) 2019/6, appointment of a rapporteur, a co-rapporteur and peer reviewers

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

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

Action: For adoption

Outcome of the signal management process

5.1.2. Divence IBR Marker Live - Infectious bovine rhinotracheitis vaccine (live recombinant)

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

Action: For adoption

Outcome of the signal management process

5.1.3. Librela – bedinvetmab

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

Action: For information

Update on communication

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 and ERA ESEC Workshop — Discussion on approaches proposed for use in the draft guideline on the 'ERA for VMPs for use in aquaculture' held on 26 June 2025

Action: For information

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

- Revised guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances
- Overview of comments received on the guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016) – Revision 1 (first version)
- Overview of comments received on the guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016) – Revision 1 (second version)

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

6.6. Novel Therapies & Technologies Working Party (NTWP)

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

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP)

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

Action: For information

6.8. Quality Working Party (QWP)

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

Action: For information

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

6.10. Safety Working Party (SWP-V)

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

Action: For information

6.11. 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

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

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

Action: For adoption

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

VAMF evaluation report

Action: endorsement

VAMF certificate

7.5.2. EMEA/V/VAMF/00010

Action: For adoption

VAMF evaluation report

Action: For endorsement

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

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

CVMP recommendation for veterinary medicinal product for Atlantic salmon

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

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

10. Organisational and strategic matters

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

Action: For decision

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

Action: For adoption

Minutes (CVMP session); Minutes (joint CVMP-CMDv session)

11. CMDv

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

Action: For information

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

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

Request from the applicant for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

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

Variation requiring assessment: Quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

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: P. McNeill

Action: For adoption

CVMP opinion, product information

Action: For endorsement

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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: Quality-related changes

Rapporteur: P. McNeill

Action: For adoption

CVMP opinion

Action: For endorsement

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

CVMP Opinion, product information

Action: For endorsement

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: Quality-related changes

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion, product information Evanovo, product information Gumbohatch

Action: For endorsement

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

Variation requiring assessment: Quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

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

CVMP opinion

Action: For endorsement

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

List of questions, 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. McNeill

Action: For adoption

List of questions, 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

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

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

List of questions, 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

List of questions, 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

List of questions, 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

List of questions, 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

Request for an extension of the clock-stop

Action: For adoption

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

Outcome of the signal management process, 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

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

6.7 Pharmacovigilance Working Party (PhVWP)

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 GL22 on reproduction toxicity

Action: For endorsement

VICH GL23 (R) on genotoxicity testing

Action: For endorsement

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

Action: For adoption

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

EMA tracking table of the requests for Limited markets classification (Article 4(29)) and confirmation of eligibility (Article 23)

Action: For information