4 April 2025
EMA/122052/2025– draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 8-10 April 2025

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

8 April 2025, 09:00 – 10 April 2025, 13:00 – virtual and Room 1D

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 8-10/04/2025. See 03/2025 CVMP minutes (to be published post 04/2025 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 meeting.

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 04 Apr 25	10.00-13.00 (TBC)

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. EMEA/V/C/006589/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006614/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006439/0000 – dogs

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/006480/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues and scientific overview, comments on the product information

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

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/006593/0000 – horses

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/006230/0000 – cats

Action: For information

Letter of withdrawal of the marketing authorisation application

3. Variations to marketing authorisations

3.1. Opinions

No items

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

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

Rapporteur: R. Breathnach, Co-Rapporteur: C. Muñoz Madero

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

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

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

Outcome of the signal management process; list of finalised signals

Action: For adoption

5.1.2. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate

Outcome of the signal management process

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

5.1.3. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate

Outcome of the signal management process

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leppänen

Action: For adoption

5.1.4. Zenalpha – medetomidine hydrochloride / vatinoxan hydrochloride

Outcome of the signal management process

Rapporteur: R. Breathnach, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

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

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leitner

Action: For adoption

List of questions

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 the AWP meeting held on 18-19 March 2025

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Election for chair of ERAWP

Action: For election

6.2.2. Concept paper for the development of a reflection paper on the environmental risk assessment of antimicrobial resistance in the environment

Action: For adoption

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 25 February 2025

Action: For information

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 19-20 March 2025

Action: For information

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Appointment of a new member

Action: For decision

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 25-26 March 2025

Action: For information

6.8. Quality Working Party (QWP)

No items

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 4 April 2025

Action: For information

6.9.2. Election for new member of SAWP

Action: For decision

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 20-21 March 2025

Action: For information

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

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Dosage review and adjustment of selected antibiotic veterinary medicines (ADRA)

Action: For information

Information session for veterinary pharmaceutical industry (online on 22 May 2025) – EMA event page

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.

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

No items

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

10. Organisational and strategic matters

10.6. Veterinary Medicine Safety Day campaign

Action: For information

11. CMDv

No items

12. Legislation

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

2.6. Other issues

EMEA/V/C/006513/0000 – cats

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

Clevor – ropinirole – EMA/VRA/0000257048 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Newflend ND H9 – Newcastle disease and avian influenza vaccine (live, recombinant) - EMEA/V/C/005860/VRA/0003 - chickens

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

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

ReproCyc ParvoFLEX – porcine parvovirosis vaccine (inactivated) - EMA/VRA/0000247569 – pigs

Variation requiring assessment: quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Zycortal – desoxycortone pivalate - EMA/VRA/0000240475 – dogs

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

Rapporteur: H. Bergendahl

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0019 – 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

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

Equioxx – firocoxib – EMA/VRA/0000247013 – horses

Variation requiring assessment: quality-related changes

Rapporteur: J.G. Beechinor

Action: For adoption

List of questions

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

Variation requiring assessment: quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

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

List of questions, comments on the product information

Coxatab – firocoxib - EMA/VRA/0000247285 – dogs

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

Rapporteur: L. Nepejchalová

Action: For adoption

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

Syvazul BTV – Bluetongue virus vaccine (inactivated) - EMA/VRA/0000255137 – sheep, cattle

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions

Posatex – posaconazole / mometasone furoate / orbifloxacin - EMA/VRA/0000255315 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

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

Innovax-ILT-IBD - EMA/PAM/0000252918

Post-authorisation recommendation

Rapporteur: J. Poot

Action: For endorsement

Rapporteur's assessment report

Neoleish - EMA/PAM/0000253312

Post-authorisation recommendation

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's assessment report

5. Post-authorisation issues for marketing authorisations

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

ERA ESEC Expert nominations

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

List of nominations for the Quality Chemical ESEC

6.11. European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group

Publication of the first ESUAvet report; 2023 data

Action: For information

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

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

9.2.1. Transfer of (co-)rapporteurships responsibilities

Action: For decision

Transfer of (co-)rapporteurships responsibilities from:

Anna Wachnik-Święcicka to Marcin Glanda

Boris Kolar to Urska Peunik

9.3. Regulatory matters

Invented names

11. CMDv

Report from the Chair of CMDv

Action: To note

Report for release December 2024-January 2025 (link)