8 May 2025
EMA/158781/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 13-15 May 2025

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

13 May 2025, 09:00 – 15 May 2025, 13:00 - Room 2C and virtual

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 13-15/05/2025.

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 (room 2C)	Mon 12 May 25	17.00-20.00 (TBC)

1. Maximum residue limits

1.1. Opinions

1.1.1. EMEA/V/MRL/003649/MODF/0004 – porcine

Action: For adoption

CVMP opinion including EPMAR

Action: For information

Summary of opinion

1.2. Oral explanations

No items

1.3. List of outstanding issues

1.3.1. EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues

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/006442/0000 – chickens, embryonated chicken eggs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006356 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/005987/0000 – 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

2.3.1. EMEA/V/C/006481/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.2. EMEA/V/C/006455/0000 – 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/006646/0000 – chickens

Action: For adoption

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

2.4.2. EMEA/V/C/006645/0000 – chickens

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/006595/0000 – rabbits

Action: For information

Letter of withdrawal of the marketing authorisation application

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. NexGard Combo – esafoxolaner / eprinomectin / praziquantel – EMEA/V/C/005094/VRA/0012/G – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one

Rapporteur: A. Golombiewski, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. Stronghold Plus – selamectin / sarolaner – EMA/VRA/0000243880 – cats

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: K. Boerkamp

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. Bluevac BTV – Bluetongue virus vaccine (inactivated) - EMA/VRA/0000255727 – sheep

Variation requiring assessment: to change the posology for sheep, to vaccinate with one single dose of the bivalent vaccine BTV-1+4.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, comments on the product information

Action: For endorsement

Summary of Opinion

3.1.4. Divence Penta – bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine - EMA/VRA/0000263803 – 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

3.2. Oral explanations

No items

3.3. List of outstanding issues

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

Variation requiring assessment: to implement the following changes: addition of indications and addition of associated non-mixed use

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

Action: For adoption

Comments on the product information, list of outstanding issues

3.4. List of questions

No items

3.5. Re-examinations of CVMP opinions on variations requiring assessment

No items

3.6. Other issues

No items

4. Referrals and related procedures

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

No items

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

No items

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

No items

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

No items

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

No items

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

No items

4.7. Other issues

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

No items

4.7.1. Referrals

No items

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

No items

5. Post-authorisation issues for marketing authorisations

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

5.1. Pharmacovigilance

5.1.1. Signal evaluation and recommendations

Action: For adoption

Outcome of the signal management process, list of finalised signals

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

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

EMA: V. Janiak

Action: For adoption

Outcome of the signal management process

5.1.3. Apoquel - oclacitinib maleate

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

Action: For adoption

Outcome of the signal management process

5.1.4. Divence Penta - Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine

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

Action: For adoption

Outcome of the signal management process (see also 3.1)

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

No items

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

No items

5.5. Others

No items

6. Working parties

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

6.1. Antimicrobials Working Party (AWP)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Election for chair of ERAWP

Action: For election

Nomination(s) received: J. Poot to Mark Montforts

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 5 May 2025

Action: For information

6.6.2. Appointment of the Vice-Chair of NTWP

Action: For decision

Nominations received:

From C. Muñoz Madero for Rosario Bullido; acceptance; CV

From A. Golombiewski for Anja Pfalzgraff; acceptance; CV

6.6.3. Appointment of NTWP Operational Expert Group (OEG) experts on RNA interference and RNA antisense therapies

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1 Verbal report on PhVWP-V meeting held on 23 April 2025

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (February – April 2025)

Action: For information

6.8.2. Updated questions and answers to align to Regulation (EU) 2019/6

Question and answer on 100% active substance VMPs question and answer on powders and granules in one marketing authorisation

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 12 May 2025

Action: For information

6.9.2. Election for chair of SAWP-V

Action: For election

Nomination(s) received: Paul McNeill

6.10. Safety Working Party (SWP-V)

6.10.1. Concept paper on the development of a guideline on consumer safety of active substances of immunological veterinary medicinal products acting against endogenous targets

Action: For adoption

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.

No items

7.7. Other issues

No items

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

No items

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.1.1. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for dogs

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for horses

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 for chair of CVMP

Action: For election

Nomination received: from J. Poot: Johan Schefferlie, nomination's acceptance, CV

10.3. Draft agenda CVMP Interested Parties meeting (14 May 2025)

Agenda CVMP Interested Parties meeting 14 May 2025

Action: For information

11. CMDv

11.1. Verbal report from Chair of CMDv on the CMDv plenary meetings held on 19-20 March and 15-16 April 2025

Action: For information

12. Legislation

12.1. Reflection Paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations

Action: For adoption

12.2. Scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with Article 114(1)

Action: For adoption

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

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

EMEA/V/C/006457/0000 – dogs

Action: For adoption

Request from the applicant for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Pexion – imepitoin - EMEA/V/C/002543/VRA/0019/G – dogs

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Melovem – meloxicam - EMA/VRA/0000244473 – cattle, horses, pigs

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

EMA/VRA/0000224998 (WS) – Profender, Procox, Felpreva - cats, dogs

Variation requiring assessment: quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Profender – praziquantel / emodepside - EMA/VRA/0000243831 - cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

DogStem – equine umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244394 – dogs

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

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

HorStem – equine allogeneic umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244486 – horses

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

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Oncept IL-2 – active Canarypox virus, strain vCP1338, expressing feline interleukin-2 gene, live - EMA/VRA/0000244261 – cats

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

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Mirataz – mirtazapine - EMA/VRA/0000243883 – cats

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

Rapporteur's assessment report, comments on the product information

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

Evicto – selamectin – EMA/VRA/0000257048 – dogs, cats

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

Evanovo / Gumbohatch – EMA/VRA/0000244052 – chickens

Variation requiring assessment: quality-related changes

Rapporteur: M. O'Grady

Action: For adoption

List of questions, comments on the product information Evanovo, comments on the product information Gumbohatch

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

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

List of questions

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

Variation requiring assessment: quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

Rapporteur's assessment report including list of questions

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

List of questions, product information

Action: For endorsement

Rapporteur’s assessment report

4. Referrals and related procedures

4.7. Other issues

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

6.5 3Rs Working Party (3RsWP)

Minutes of the 3RsWP meeting held on 4-5 February 2025

Action: For information

Minutes of the OEG - 3RsWP - Batch release testing meeting held on 28 January 2025

Action: For information

NC and NAMs ESEC nominations

Action: For information

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

List of nominations for the Quality Chemical ESEC

7. Other scientific matters

7.7. Other issues

Azole Resistance in *Aspergillus*: publication of two peer-reviewed articles which have been published as part of the 12-months EMA-funded study on *Aspergillus*

Action: For information

Azole resistance in *Aspergillus* isolates from animals or their direct environment (2013–2023): a systematic review (link);
Aspergillus spp., aspergillosis and azole usage in animal species in Europe: results from a multisectoral survey and review of recent literature (link)

8. Co-operation with other EU or International bodies

8.1. VICH

VICH status of guidelines

Action: For information

VICH status of guidelines (EMA/CVMP/28625/2005)

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.3. Regulatory matters

Invented names