18 May 2026
EMA/113692/2026 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 19-21 May 2026

Chair: Johan Schefferlie deputising to F. Hasslung Wikström; Vice-chair: F. Hasslung Wikström

19 May 2026, 09:00 – 21 May 2026, 13:00 - Room 1C 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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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 19-21/05/2026. See 03/2026 and 04/2026 CVMP minutes (to be published post 05/2026 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 (room 0A)	Mon 18 May 25	17.00-20.00

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

No items

2. Marketing authorisations

2.1. Opinions

2.1.2. Feline calicivirosis and feline viral rhinotracheitis vaccine (live) - EMEA/V/C/006702/0000 – cats

Indication: for active immunisation of cats against feline calicivirus and feline herpesvirus type 1

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. Feline calicivirosis, feline viral rhinotracheitis and feline panleucopenia vaccine (live) – EMEA/V/C/006681/0000 – cats

Indication: for active immunisation of cats against feline herpesvirus type 1, feline calicivirus, feline panleucopenia virus

Action: For adoption

CVMP opinion , CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.5. Feline calicivirosis, feline herpesvirus viral rhinotracheitis, feline infectious enteritis (feline panleucopenia) and feline chlamydiosis (live) vaccine - EMEA/V/C/006703/0000 – cats

Indication: for active immunisation of cats against feline herpesvirus type 1 (FHV), feline calicivirus (FCV), feline panleucopenia virus (FPL) and *Chlamydia felis*.

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.6. Marek's disease and Newcastle disease vaccine (live recombinant) - EMEA/V/C/006679/0000 – chickens

Indication: active immunisation of one-day-old chickens and 18- to 19-day-old embryonated chicken eggs against Marek's disease (MD) and Newcastle disease (ND).

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.2. Oral explanations

2.2.1. Velagliflozin - EMEA/V/C/006610/0000 – horses

Indication: for the treatment of hyperinsulinaemia and associated clinical signs (e.g., laminitis) in insulin-dysregulated horses and ponies not responsive to changes in husbandry and exercise regimen.

Action: Oral explanation

Rapporteurs' assessment of responses to list of outstanding issues, comments on the product information

2.3. List of outstanding issues

2.3.1. *Salmonella typhimurium* vaccine (live) – EMEA/V/C/006645/0000 – chickens

Indication: active immunisation of chickens to reduce organ colonisation and faecal excretion due to *Salmonella typhimurium*

Action: For adoption

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

2.4. List of questions

2.4.1. Avian influenza vaccine (mRNA) - EMEA/V/C/006287/0000 – ducks

Indication: for active immunisation of mule ducks from 1 day of age, to reduce mortality, clinical signs and viral shedding caused by highly pathogenic avian influenza virus, H5 subtype strains of clade 2.3.4.4b.

Exceptional circumstances

Action: For adoption

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

2.4.2. Buprenorphine hydrochloride - EMEA/V/C/006917/0000 – mice, rats, rabbits

Indication: for the control of post-procedural pain in mice, rats, and rabbits (non-food-producing)

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. Porcine circovirus vaccine (recombinant) and Mycoplasma hyopneumoniae vaccine (inactivated) - EMEA/V/C/006603/0000 – pigs

Action: For endorsement

Request from the applicant for an extension of clock stop

2.6.2. Enteric necrotic disease vaccine (vector, live recombinant) - EMEA/V/C/006822/0000 – chickens

Action: For endorsement

Request from the applicant for an extension of clock stop

2.6.3. Feline calicivirosis, feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia), feline chlamydiosis (live) and feline leukaemia vaccine (RNA particle) vaccine - EMEA/V/C/006520/0000 – cats

Action: For discussion

Letter from EC on CVMP opinion for Nobivac NXT HCPChFeLV

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. BTVPUR – Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 4) - EMA/VRA/0000322270 – sheep, cattle

Variation requiring assessment: to update the product information by including a new vaccination practice against BTV8 in sheep.

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. Librela – bedinvetmab - EMA/VRA/0000340267 - dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process. The applicant has taken the opportunity to implement minor corrections in the SPC and package leaflet.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/VRA/0000321483 – chickens

Variation requiring assessment: to provide results of duration of immunity studies to clear the specific obligation from Annex II of the product information.

Rapporteur: C. Miras, Co-rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.4. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMA/VRA/0000340561 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process and to implement an editorial change.

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.5. Respivac aMPV – turkey rhinotracheitis virus, live - EMA/VRA/0000309778 – chickens

Variation requiring assessment: to add turkeys as a new target species and to establish a higher minimum composition per dose in chickens than the one currently authorised. Additionally, the product information is aligned with version 9.1 of the QRD template.

Rapporteur: E. Werner, Co-rapporteur: C. Miras

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.6. Enteroporc Coli AC – neonatal piglet colibacillosis (recombinant, inactivated) and Clostridium perfringens vaccine (inactivated) - VRA/0000284808 – pigs

Variation requiring assessment: to add the mixed, associated use of Enteroporc Coli AC and Parvoruvax / Parvoruvac to the SPC.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.7. Hepizovac – epizootic haemorrhagic disease vaccine (inactivated) - VRA/0000337091 – cattle

Variation requiring assessment: to fulfil the specific obligation regarding the stability of the antigen at 18 months of storage.

Rapporteur: J. Poot, Co-Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. Prevomax – maropitant - EMA/VRA/0000337350 – dogs, cats

Variation requiring assessment: to update the frequency for the adverse event 'Injection site pain' and to propose some editorial changes to further align the product information with QRD template version 9.1.

Rapporteur: S. Louet

Action: For adoption

List of questions, comments on the product information

3.4.2. Felpreva – tigolaner / emodepside / praziquantel - EMA/VRA/0000333761 – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: treatment of tick infestations with *Ixodes hexagonus*, *Rhipicephalus sanguineus*, *Haemaphysalis longicornis*.

Rapporteur: A. Golombiewski, Co-Rapporteur: E. Dewaele

Action: For adoption

List of questions, comments on the product information

3.4.3. Vectra 3D – dinotefuran / pyriproxyfen / permethrin - EMA/VRA/0000334831 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: reduction of the risk of infection with *Leishmania infantum* via transmission by *Phlebotomus* spp. for 1 month.

Rapporteur: A. Golombiewski, Co-Rapporteur: H. Bremer

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

3.6.1 Mometamax Ultra - gentamicin / posaconazole / mometasone furoate - EMA/VRA/0000300844 – dogs

Rapporteur: K. Baptiste, Co-Rapporteur: S. Louet

Action: For adoption

Withdrawal EPAR

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

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

No items

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. Hepizovac – epizootic haemorrhagic disease vaccine (inactivated) - EMA/S/0000322659

Re-examination of the marketing authorisation for Hepizovac in line with Article 27(3) of Regulation (EU) 2019/6.

Rapporteur: J. Poot, Co-Rapporteur: L. Nepejchalová

Action: For adoption

Opinion; CVMP assessment 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)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Appointment of a new ERAWP member – recommendation from the Veterinary Domain

Action: For endorsement

Minutes and recommendation following the ad hoc Veterinary Domain meeting held on 30 April 2026

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 21-22 April 2026

Action: For information

6.4.2. Concept paper for the revision of the Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances

Action: For discussion

6.4.3. Concept paper for the revision of the Guideline on data requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs) by new MS of the same origin and integration with the Reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products

Action: For discussion

6.5. 3Rs Working Party (3RsWP)

6.5.1. Resignation of the 3RsWP vice-chair

Action: For information

6.5.2. Verbal feedback on 3RsWP Stakeholders meeting 31 March 2026

Action: For information

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 meeting

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 18 May 2026

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances

Action: For adoption

6.11. Other working party and scientific group issues

6.11.1. WPs mandate (complementing procedures)

Action: For discussion

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

7.3.1. CVMP activities related to antimicrobials: status report on EMA/CVMP activities (2021–2025) and EMANS 2028 Strategic Overview (Theme 4)

Action: For discussion

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

7.7.1. Notification of an ITF briefing meeting

Action: For information

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 dogs and cats

9.2. CVMP recommendation for veterinary medicinal product for dogs and cats 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

9.2.2. Eligibility request

Action: For decision

9.2.3. Eligibility request

Action: For decision

9.2.4. Eligibility request

Action: For decision

9.2.5. Eligibility request

Action: For decision

9.2.6. Eligibility request

Action: For decision

9.2.7. Eligibility request

Action: For decision

9.2.8. Appointment of rapporteurs - MRL application

Action: For decision

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

10. Organisational and strategic matters

10.1. CVMP Interested Parties meeting 2026

Action: For information

Draft agenda CVMP Interested Parties meeting 2026

11. CMDv

No items

12. Legislation

No items

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

Elmaro – maropitant - EMA/VRA/0000336228 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's Assessment Report

Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMA/VRA/0000322477 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP Opinion and product information

Action: For endorsement

Rapporteur's assessment report

Veraflox – pradofloxacin – EMA/VRA/0000301203 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Draxxin – tulathromycin - EMA/VRA/0000314905 – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Locatim – bovine concentrated lactoserum containing specific immunoglobulins G against *E. coli* F5 (K99) adhesin ≥2.8 log10/ml – EMA/VRA/0000322515 – cattle

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

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Poulvac E. coli – Avian colibacillosis vaccine (live) – VRA/0000335058 – chickens and turkeys

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

Cepedex – dexmedetomidine - EMA/VRA/0000337599 – cats, dogs

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

Profender + non-CAPs – praziquantel / emodepside - EMA/VRA/0000323435 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

List of questions

ProZinc – insulin human - EMA/VRA/0000336187 – cats and dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance

Signal evaluation and recommendations

Action: For adoption

Outcome of the signal management process, list of finalised signals

5.3 Inspections and controls

6. Working parties

6.5 3Rs Working Party (3RsWP)

Minutes of the 3RsWP plenary meeting held on 28-29 January 2026

Action: For information

Agenda of the 3RsWP plenary meeting held on 31 March – 1 April 2026

Action: For information

NC and NAMs ESEC nominations

Action: For information

NC and NAMs ESEC nominations

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

6.10 Safety Working Party (SWP-V)

Deadline for development of a harmonised tool for calculating human dietary exposure (REDEX)

Action: For information

6.11. Other working party and scientific group issues

Minutes of the Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party meetings held in March and April 2026

Action: For information

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL61 on Pharmaceutical Development

Action: For adoption

VICH GL61 on Pharmaceutical Development

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

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

Transfer of (co-)rapporteurships responsibilities

Action: For decision

Transfer of (co-)rapporteurships responsibilities from: A. Blennerhassett to P. McNeill

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

Vet Assessors Day 2026

Action: For information

Draft agenda

11. CMDv

Reports from CMDv

Action: To note

Final agenda of the CMDv meeting held on 22-23 April 2026