10 July 2026
EMA/161368/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 14-16 July 2026

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

14 July 2026, 09:00 – 16 July 2026, 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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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 14-16/07/2026. See 06/2026 CVMP minutes (to be published post 07/2026 CVMP meeting)

iii. Adoption of the minutes of the previous meeting – postponed to September

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

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 virtual)	Fri 10 July 26	10.00-13.00 CEST

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

1.4.1. EMEA/V/MRL/007033/FULL/0001

Action: For adoption

Scientific overview and list of questions

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. Bexagliflozin - EMEA/V/C/006300/0000 – cats

Indication: for the reduction of hyperglycaemia in cats with non-insulin dependent diabetes mellitus.

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. Buprenorphine hydrochloride - EMEA/V/C/006749/0000 – cats, dogs, horses

Indication: for post-operative analgesia and potentiation of sedative effects of centrally-acting agents.

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. Lotilaner / moxidectin / pyrantel / praziquantel – EMEA/V/C/006753/0000 – dogs

Indication: for the treatment of mixed external and internal parasitic infestations/infections by ectoparasites, cestodes and nematodes, when used against ectoparasites, cestodes and nematodes is indicated at the same time. Ectoparasites: For the treatment of tick (*Dermacentor reticulatus, Ixodes ricinus, I. hexagonus* and *Rhipicephalus sanguineus*) and flea (*Ctenocephalides felis* and C. canis) infestations in dogs. This veterinary medicinal product provides immediate and persistent killing activity for 1 month for ticks and fleas. The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD). For the treatment of demodicosis (caused by *Demodex canis*). Cestodes: Treatment of infections with tapeworms (*Echinococcus multilocularis, E. granulosus, Taenia spp., Dipylidium caninum*). Gastrointestinal nematodes: For the treatment of infections with roundworms (*Toxocara canis* immature adults (L5) and adults, and Toxascaris leonina adults) and hookworms (Ancylostoma caninum L4 larvae, immature adults (L5) and adults, and *Uncinaria stenocephala* adults). Other nematodes: For the prevention of heartworm disease (*Dirofilaria immitis*). For the treatment of angiostrongylosis (*Angiostrongylus vasorum*). For the prevention of angiostrongylosis by targeting immature adult (L5) and adult stages of *Angiostrongylus vasorum*.

Action: For adoption

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

2.3.3. Porcine circovirus type 2d, ORF2 capsid protein – EMEA/V/C/006873/0000 – pigs

Indication: for the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, the loss in body weight gain.

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.4. Canine adipose-derived mesenchymal stem cells - EMEA/V/C/006457/0000 – dogs

Indication: suspension for injection containing canine adipose-derived mesenchymal stem cells and it is intended for the control of pain, lameness and inflammation associated with degenerative joint disease in dogs.

Action: For adoption

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

2.4. List of questions

2.4.1. Porcine circovirus type 2d, ORF2 capsid protein – EMEA/V/C/006827/0000 – pigs

Indication: the proposed indication is for active immunisation of pigs from 3 weeks of age against porcine circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, faecal shedding and lesions caused by infection with PCV2.

Action: For adoption

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

2.4.2. Maropitant citrate– EMEA/V/C/006951/0000 – dogs

Indication: prevention of nausea induced by chemotherapy in dogs. Prevention of vomiting induced by motion sickness in dogs. Prevention and treatment of vomiting, in conjunction with maropitant solution for injection and in combination with other supportive measures in dogs.

Action: For adoption

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

2.4.3. *Streptococcus suis* vaccine (recombinant protein) - EMEA/V/C/006952/0000 – pigs

Indication: for the passive immunisation of progeny by active immunisation of pregnant gilts and sows to reduce clinical signs, septicaemia, (poly) serositis and mortality in piglets due to infection caused by IgM protease group A strains of *Streptococcus suis.*

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

Action: For adoption

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

2.5. Re-examinations of CVMP opinions

2.5.1. Scovella – 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.

Request for re-examination

Action: For adoption

Appointment of Rapporteurs

Action: For agreement

Composition and documents for AHEG; re-examination timetable

2.6. Other issues

No items

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Mometamax Ultra – gentamicin / posaconazole / mometasone furoate - EMA/VRA/0000350766 – dogs

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

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion; product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. Cimalgex – cimicoxib - EMA/VRA/0000349171 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process. In addition, the MAH took the opportunity to introduce minor editorial changes.

Rapporteur: H. Bremer

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. Upcard – torasemide - EMA/VRA/0000326002 – dogs

Variation requiring assessment: to add a new pharmaceutical form: oral solution.

Rapporteur: C. Muñoz Madero, Co-Rapporteur: P. McNeill

Action: For decision

Need for oral explanation

Action: For adoption

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

3.3.2. 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 decision

Need for oral explanation

Action: For adoption

List of outstanding issues*;* comments on the product information

3.3.3. 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 decision

Need for oral explanation

Action: For adoption

List of outstanding issues*;* comments on the product information

3.4. List of questions

3.4.1. Lotilaner / Milbemycin Elanco – lotilaner / milbemycin oxime- EMA/VRA/0000344590 – dogs

Variation requiring assessment: to change the legal status from "subject to prescription" to "not subject to prescription". In addition, the MAH takes the opportunity to propose a change in the adverse events section relating to "muscle tremor".

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsár

Action: For adoption

List of questions, comments on the product information

3.4.2. Tessie – tasipimidine – EMA/VRA/0000345377 – dogs

Variation requiring assessment: to modify the indication for use and to amend the product information as regards the age and bodyweight of target population, duration of treatment and administration instructions (including updated pictograms).

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

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. Clevor – ropinirole - EMA/VRA/0000321228 – dogs

Rapporteur: C. Muñoz Madero

Action: For endorsement

Request for an extension of clock stop

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

4.4.1. Vetmedin 1.5 mg/ml oral solution for dogs

Procedure scope: Potential lack of efficacy

Rapporteur:, Co-Rapporteur:

Action: For discussion

Request from the European Commission under Article 58(4) of Regulation (EU) 2019/6, appointment of rapporteur, co-rapporteur and peer reviewers

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. Veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications – EMA/REF/0000290626

Procedure scope: antimicrobial resistance

Rapporteur: S. Louet, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

Revised timetable

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. Galliprant – grapiprant – EMA/VS/0000347299

Outcome of the signal management process (signal for Gastric perforation, Intestinal perforation, Gastrointestinal ulceration)

Rapporteur: K. Baptiste, Co-Rapporteur: E. Dewaele

Action: For adoption

CVMP Assessment Report

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)

6.1.1. Appointment of a new AWP member – call for nominations

Action: For endorsement

6.1.2. Concept paper on a revision of the CVMP Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

6.3.1. Concept paper on the revision of the guideline on pharmaceutical fixed combination products

Action: For adoption

6.3.2. Call for nominations for EWP chair

Action: For information

6.4. Immunologicals Working Party (IWP)

6.4.1. Draft revised (administrative) Guideline on data requirements for changes to the strain composition of authorised influenza vaccines in line with WOAH recommendations

Action: For adoption

6.4.2. Draft revised (administrative) Guideline on data requirements to support in-use stability claims for veterinary vaccines

Action: For adoption

6.5. 3Rs Working Party (3RsWP)

6.5.1. Appointment of a new 3RsWP member – call for nominations

Action: For endorsement

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 1 July 2026

Action: For information

6.6.2. Concept paper on Quality and Safety aspects of interference RNA and antisense oligonucleotide therapies as veterinary medicines

Action: For adoption

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Election of PhVWP-V vice-chair

Action: For decision

6.7.2. Verbal report on PhVWP-V meeting

Action: For information

6.7.3. Appointment of a new additional PhVWP-V member with expertise in surveillance

Action: For endorsement

Call for nominations for a 5th additional PhVWP-V member with specific scientific competence in surveillance and signal management.

6.8. Quality Working Party (QWP)

6.8.1. Election of QWP veterinary vice-chair

Action: For decision

6.8.2. Q&A on post-approval change management protocols for VMPs

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 10 July 2026

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting

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

No items

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

9.2. CVMP recommendation for veterinary medicinal product for dogsEligibility 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

9.3.2. Classification request

Action: For adoption

9.3.3. Classification request

Action: For adoption

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 26 June 2026

Action: For information

10.2. CVMP/CMDv Informal meeting under the Irish EU Presidency

Action: For discussion

10.3. Network resources – identification of areas in which NCAs currently use risk-based approaches

Action: For discussion

10.4 Committees meeting schedule for 2027

Action: For information

11. CMDv

No items

12. Legislation

No items

13. Any other business

13.1. Meeting highlights

Action: For comments

13.2. Extension of the EMA OPEN initiative to veterinary medicinal products

Action: For information

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

Profender – praziquantel / emodepside - EMA/VRA/0000323435 (WS) – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Nexgard, Nexgard Spectra, Frontpro – afoxolaner, afoxolaner / milbemycin oxime EMA/VRA/0000347906 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Cortavance/ Easotic/ Cortotic – hydrocortisone - EMA/VRA/0000333848 (WS) – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Cirbloc M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) - EMA/VRA/0000288333 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Brucellin Aquilon – Brucella abortus, strain AQ1302, protein extract - EMA/VRA/0000343835 – pigs

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

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

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

NexGard Combo / Broadline – fipronil / (S)-methoprene / eprinomectin / praziquantel, esafoxolaner / eprinomectin / praziquantel – EMA/VRA/0000291062 – cats

Variation requiring assessment: quality related changes.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

VeroBlue-3 – Bluetongue virus vaccine (inactivated) – EMA/VRA/0000350624 – sheep

Variation requiring assessment: to delay SOB1 from Q2 2026 to Q3 2026.

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Reconcile – fuoxetine - EMA/VRA/0000322711– dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.2 List of outstanding issues

Credelio Plus – lotilaner / milbemycin oxime – EMA/VRA/0000322260 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

List of outstanding issues

3.4. List of questions

NexGard Combo and Broadline – eprinomectin – EMA/VRA/0000335335 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

Librela – bedinvetmab - EMA/VRA/0000344161 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

List of questions

Action: For endorsement

Rapporteur's assessment report

Profender / Procox / non-CAPs (WS) – EMA/VRA/0000340567 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

Rapporteur's assessment report with the list of questions

Bravecto Plus / Bravecto TriUno – fluralaner / moxidectin / pyrantel - EMA/VRA/0000337982 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

Rapporteur's assessment report with the 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

5.2 Post-authorisation measures

Respiporc FLU3 – EMA/PAM/0000343528 – pigs

Post-authorisation recommendation

Rapporteur: M. Blixenkrone-Møller

Action: For endorsement

Rapporteur's Assessment Report

Stelfonta - EMA/PAM/0000347862 – dogs

Post-authorisation recommendation

Rapporteur: K. Boerkamp

Action: For endorsement

Rapporteur's assessment report

BioBhyo – EMA/PAM/0000349244 - pigs

Post-authorisation recommendation

Rapporteur: R. Carapeto García

Action: For endorsement

Rapporteur's Assessment Report

5.3 Inspections and controls under Regulation (EU) 2019/6

Pharmacovigilance Inspections Programme – 2026 revision

Action: For adoption

6. Working parties

6.5. 3Rs Working Party (3RsWP)

Minutes of the 3RsWP annual stakeholders meeting held on 31 March 2026

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

Endorsement of new Dutch PhVWP-V member

Action: For adoption

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

6.11. Other working party and scientific group issues

6.11.1 Pharmacovigilance inspectors working group - VGVP Module on Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files – Rev 1 for public consultation

Action: For adoption

6.11.2 Minutes of the Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party meetings held in May and June 2026

Action: For information

Minutes of the ADRA tWP meeting held on 13 May 2026 Minutes of the ADRA tWP – Pharmacokinetics subgroup meeting held on 11 June 2026

Minutes of the ADRA tWP meeting held on 24 June 2026

7. Other scientific matters

7.5 Vaccine antigen master file (VAMF) certification

EMEA/V/VAMF/0002/VRA/0001

Rapporteur: J. Poot

Action: For adoption

VAMF variation evaluation report and list of questions

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

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