



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 June 2026
EMA/137917/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 16-18 June 2026

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

16 June 2026, 09:00 – 18 June 2026, 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 ongoing 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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- iii. Declaration of contacts between members and companies with regard to points on the agenda
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Scientific Advice Working Party (virtual)	Fri 12 Jun 26	10.00-13.00 CEST
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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. 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: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[2.1.2. 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](#)

Indication: for active immunisation of cats to prevent mortality, and reduce clinical signs and virus excretion caused by infection with feline herpesvirus type 1 (FHV); to reduce the clinical signs and virus excretion caused by infection with feline calicivirus (FCV); to prevent mortality, clinical signs, leucopenia and virus excretion caused by infection with feline panleucopenia virus (FPL); to reduce the clinical signs and bacterial excretion caused by infection with *Chlamydia felis*; and to prevent persistent viraemia and clinical signs caused by feline leukaemia virus (FeLV)

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[2.1.3. Feline leukemia \(RNA particle\) vaccine - EMEA/V/C/006683/0000 – cats](#)

Indication: for active immunisation of cats to reduce persistent viraemia and clinical signs caused by feline leukemia virus (FeLV).

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[2.1.4. Feline calicivirosis, feline rhinotracheitis, feline panleukopenia \(live\) and feline leukemia \(RNA particle\) vaccine - EMEA/V/C/006682/0000 – cats](#)

Indication: for active immunisation of cats against feline calicivirus, feline herpesvirus type 1, feline panleukopenia virus and feline leukemia virus.

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. Equine umbilical cord-derived mesenchymal stem cells - EMEA/V/C/006713/0000 – dogs, cats

Indication: for clinical remission of symptoms associated with inflammatory bowel disease (IBD) in dogs and cats.

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. Verdinexor - EMEA/V/C/005902/0000 – dogs

Indication: for the treatment of lymphoma in 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. Gacovetug - EMEA/V/C/006842/0000 – pigs

Indication: for the protection/prophylaxis against post-weaning diarrhoea caused by F4-positive enterotoxigenic *Escherichia coli* (F4-ETEC).

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. Buprenorphine hydrochloride - EMEA/V/C/006917/0000 – mice, rats, rabbits (non-food-producing)

Action: For endorsement

Request from the applicant for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions

No items

3.2. Oral explanations

No items

3.3. List of outstanding issues

[3.3.1. Firocoxib CP-Pharma – firocoxib - EMA/VRA/0000326568 – dogs](#)

Variation requiring assessment: to add horses as a new target species.

Rapporteur: K. Boerkamp, Co-Rapporteur: L. Nepejchalová

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. Clevor – ropinirole - EMA/VRA/0000321228 – dogs](#)

Variation requiring assessment: quality-related changes.

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues; comments on the product information

[3.3.3. Mirataz – mirtazapine – EMA/VRA/0000326548 – cats](#)

Variation requiring assessment: to update the product information on the basis of new target animal safety data.

Rapporteur: S. Louet, Co-Rapporteur: M. Glanda

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues; comments on the product information

[3.3.4. Vectormune HVT-AIV – avian influenza vaccine \(live recombinant\) - EMA/VRA/0000321340 – chickens](#)

Variation requiring assessment: to add turkey as a new target species and to add a new strength

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

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues; comments on the product information

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

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. Innovax-ND-H5 – avian influenza vaccine (live recombinant) - EMA/S/0000340084

Scope: to apply for the annual 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 AWP meeting held on 2-3 June 2026

Action: For information

6.1.2. Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species – overview of comments

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 3-4 June 2026

Action: For information

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 26 May 2026

Action: For information

6.4. Immunologicals Working Party (IWP)

6.4.1. Election of IWP chair

Action: For decision

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 adoption

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 adoption

6.4.4. Guideline on data requirements for changes to the strain composition of authorised influenza vaccines in line with OIE recommendations

Action: For discussion

6.4.5. Guideline on data requirements to support in-use stability claims for veterinary vaccines

Action: For discussion

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

Action: For discussion

6.6.2. Call for interest for new Novel Therapies (NTs) European Specialised Expert Community (ESEC) members

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Election of PhVWP-V chair

Action: For decision

6.7.2. Verbal report on PhVWP-V meeting held on 27 May 2026

Action: For information

6.7.3. Verbal report on PhVWP-V-PhV IWG Interested parties meeting

Action: For information

6.7.4. Revised VeDDRA documents

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held in April and May 2026

Action: For information

6.8.2. Call for nominations for QWP chair

Action: For information

6.8.3. Call for nominations for QWP veterinary vice-chair

Action: For information

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 12 June 2026

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1 Appointment of a new SWP member – call for nominations

Action: For endorsement

6.11. Other working party and scientific group issues

6.11.1 Procedures complementing the Working Parties (WPs) mandate

Action: For discussion

6.11.2 Verbal report on the ESUAvet mandate revision

Action: For endorsement

6.11.3. CVMP guidance on ERA for biological other than immunological VMPs

Action: For discussion

6.11.4. Status update on the work of the Dosage Review and Adjustment of established Antibiotics (ADRA) temporary Working Party

Action: For information

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

Action: For adoption

7.3.2. Update on the 5th joint inter-agency antimicrobial consumption and resistance analysis (JIACRA) report

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.

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

9.2. 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 information

9.2.4. Decision on the accelerated assessment request and application under exceptional circumstances

Action: For decision

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

10. Organisational and strategic matters

10.1. CVMP/CMDv Informal meeting under the Cyprus EU Presidency, Vienna, 28-29 April 2026

Action: For adoption

CVMP session minutes, CVMP-CMDv session minutes

10.2. Presentations given at the CVMP plenary meeting

Action: For discussion

11. CMDv

11.1. Verbal report on CMDv meeting held on 22-23 April and 24-25 May 2026

Action: For information

12. Legislation

No items

13. Any other business

No items

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

[Bluevac BTV - Bluetongue virus vaccine \(inactivated\) - EMA/VRA/0000309935 – cattle and sheep](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4R, Versican Plus Pi/L4 – canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis and rabies vaccine (inactivated), canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated), canine leptospirosis vaccine (inactivated), canine parainfluenza virus vaccine (live) and canine leptospirosis and rabies vaccine (inactivated), canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) - EMA/VRA/0000293810 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information Versican Plus DHPPi/L4R, product information Versican Plus DHPPi/L4, product information Versican Plus L4, product information Versican Plus Pi/L4, product information Versican Plus Pi/L4R

Action: For endorsement

Rapporteur's assessment report

3.3. List of outstanding issues

[Rabitec – rabies vaccine \(live, oral\) - EMA/VRA/0000326391– foxes and raccoon dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of outstanding issues, product information

3.4. List of questions

[Loxicom – meloxicam – EMA/VRA/0000340368 – dogs](#)

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

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

List of questions

[Vectormune FP ILT – fowlpox and avian infectious laryngotracheitis vaccine \(live, recombinant\) - EMA/VRA/0000338802 – chickens](#)

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

Rapporteur: J. Poot

Action: For adoption

List of questions, comments on the product information

3.6. Other issues

No items

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

[Suvaxyn PRRS MLV – EMA/PAM/0000341362](#)

Rapporteur: E. Werner

Action: For endorsement

CVMP rapporteur's assessment report

5.3 Inspections and controls

6. Working parties

6.5 3Rs Working Party (3RsWP)

[Agenda of the 3RsWP plenary meeting held on 2 June – 3 June 2026](#)

Action: For information

[Minutes of the 3RsWP plenary meeting held on 1 April 2026](#)

Action: For information

6.7 Pharmacovigilance Working Party (PhVWP-V)

Endorsement of new Italian PhVWP-V member

Action: For adoption

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

List of nominations for the Quality Chemical ESEC

6.10 Safety Working Party (SWP-V)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

Transfer of rapporteurship (Slovenia)

Action: For adoption

Transfer of rapporteurship from K. Straus to U. Peunik and M. Ogriz