



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 March 2026
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Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 10-12 March 2026

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

10 March 2026, 09:00 – 12 March 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 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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Introduction

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- 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 10-12/03/2026. See 03/2026 CVMP minutes (to be published post 04/2026 CVMP meeting) Declaration of contacts between members and companies with regard to points on the agenda.
- 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 06 Mar 26	09.30-15.00
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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

1.4.1. Substance – EMEA/V/MRL/006954/FULL/0001 – bovine

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. *Salmonella infantis* vaccine \(live\) – EMEA/V/C/006646/0000 – chickens](#)

Indication: for active immunisation of healthy chickens to reduce faecal excretion and colonisation of internal organs with *Salmonella infantis*.

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[2.1.2. Bluetongue virus vaccine \(inactivated\) - EMEA/V/C/006821/0000 – sheep, cattle](#)

Indication: for active immunisation of sheep to reduce viraemia, preventing mortality and to reduce clinical signs caused by the serotype 3 of the bluetongue virus. For active immunisation of cattle against the serotype 3 of the bluetongue virus.

Accelerated assessment

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 interleukin-5 vaccine \(recombinant protein, conjugate\) - EMEA/V/C/006180/0000 – horses](#)

Indication: for the active immunisation of horses affected by a hyper-eosinophilic condition to normalise the level of eosinophil immune cells in blood and reduce clinical signs by induction of antibodies against equine Interleukin-5.

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. Porcine circovirus type 2d, ORF2 capsid protein – EMEA/V/C/006873/000 – 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 adoption

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

2.4.2. Double-stranded RNA with nucleotide sequence complementary to the calmodulin mRNA of *Varroa destructor* - EMEA/V/C/006823/0000 – honey bees

Indication: for reduction of varroa mite (*Varroa destructor*) infestation to prevent varroosis in honey bees during the productive season or in the autumn going into overwintering.

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information, new active substance report

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

No items

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

Variation requiring assessment: to add turkeys as a new target species; 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 decision

Need for oral explanation

Action: For adoption

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

[3.3.2. 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 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. BTVPUR – bluetongue virus vaccine \(inactivated\) \(multistrain: 1-2 strains out of a set of 4\) - EMA/VRA/0000322270 – species](#)

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

List of questions, comments on the product information

[3.4.2. 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 adoption

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

[3.4.3. 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

List of questions, comments on the product information

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

Variation requiring assessment: to change in the pack size of the finished product; change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data – to update the product information to include home use following the addition of the pack size. / Quality-related changes.

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

[3.6.1 Mometamax Ultra - gentamicin / posaconazole / mometasone furoate - EMA/VRA/0000300844 – dogs](#)

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

Action: For information

Letter of withdrawal of application

4. Referrals and related procedures

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

[4.1.1. Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep - EMA/REF/0000271819](#)

Efficacy, anti-parasitic resistance

Rapporteur: A. Golombiewski, Co-Rapporteur: C. Muñoz Madero

Scope: List of outstanding issues

Action: For discussion

Rapporteur's assessment report including co-rapporteur's critique

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

4.6.1. Quarter-based selective dry cow therapy – EMA/REF/0000285673

Antimicrobial resistance

Rapporteur: A. Golombiewski, Co-Rapporteur: M. Leppänen

Scope: Opinion

Action: For adoption

CVMP scientific advice, CVMP Assessment Report

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

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. Librela – bedinvetmab

Outcome of the signal management process

Rapporteur: F. Hasslung-Wikström, Co-Rapporteur: J. Poot

Action: For adoption

CVMP Assessment Report

5.1.2. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate

Outcome of the signal management process

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

Action: For adoption

CVMP Assessment Report

[5.1.3. Mometamax Ultra – gentamicin / posaconazole / mometasone furoate](#)

Outcome of the signal management process

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

Action: For adoption

CVMP Assessment Report

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

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

[5.4.1. Syvazul BTV 3 – bluetongue virus vaccine \(inactivated\) - EMA/S/0000309717](#)

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

Rapporteur: R. Breathnach, Co-Rapporteur: J. Poot

Action: For adoption

Opinion

[5.4.2. Vectormune HVT-AIV – avian influenza vaccine \(live recombinant\) - EMA/VRA/0000314905](#)

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

Rapporteur: C. Miras

Action: For adoption

List of questions

[5.4.3. 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

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. Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in animals in the European Union: development of resistance and impact on public and animal health

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 24-25 February 2026

Action: For information

6.2.2. Appointment of a new ERAWP member – call for nominations

Action: For endorsement

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

Action: For decision

6.2.4. Updated guideline on the plant testing strategy for veterinary medicinal products

Action: For adoption

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 17 February 2026

Action: For information

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Risk Management Plan (RMP) template for novel therapies

Action: For discussion / adoption

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held in February 2026

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 6 March 2026

Action: For information

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

6.11.1. Concept paper on the development for guidance on demonstration of biosimilarity of biological veterinary medicinal products

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

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

8.1.1. Concept paper proposing development of a VICH GL to parallel ICH Q9

Action: For discussion

8.1.2. Concept paper proposing a revision of VICH GL 57: marker residue depletion studies to establish product withdrawal periods in aquatic species

Action: For discussion

8.1.3. VICH GL 61 on Pharmaceutical Development

Action: For endorsement

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. CVMP recommendation for veterinary medicinal product for dogs 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

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

Action: For decision

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 25 February 2026

Action: For information

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

Action: For adoption

CVMP session agenda, CVMP-CMDv session agenda

10.3. Veterinary Medicine Safety Day campaign, 8 April 2026

Action: For information

10.4. EMA veterinary assessor day

Action: For information

11. CMDv

No items

12. Legislation

12.1. European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6: guidance concerning five substances not included in Commission Implementing Regulation (EU) 2025/901

Action: For discussion

Draft report

12.2. European Commission's request under Article 141(1)(f) of Regulation (EU) 2019/6: guidance on scientific issues in relation to Articles 107(6) and 114(3)

Action: For discussion

13. Any other business

13.2. Meeting highlights

Action: For comments

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

[Coxevac – *Coxiella burnetii* vaccine \(inactivated\) - EMA/VRA/0000308623 – cattle, goats, sheep](#)

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Vectormune ND / Vectormune FP ILT + AE / Vectormune HVT-AIV / Newflend ND H9 / Ultifend ND IBD / Vectormune FP ILT \(WS\) – EMA/VRA/0000290574 – chickens](#)

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion **Action:** For endorsement

Rapporteur's assessment report

[Halagon – halofuginone - EMA/VRA/0000309721 – cattle](#)

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

[Stelfonta – tigilanol tiglate - EMA/VRA/0000301147 – dogs](#)

Variation requiring assessment: to align the product information with version 9.1 of the QRD template and make additional minor editorial changes.

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.3. List of outstanding issues

[Veraflox – pradofloxacin – EMA/VRA/0000301203 – dogs, cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of outstanding issues

3.4. List of questions

[Credelio Plus – lotilaner / milbemycin oxime – EMA/VRA/0000322260 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

List of questions

[Locatim – bovine concentrated lactoserum containing specific immunoglobulins G against *E. coli* F5 \(K99\) adhesin \$\geq 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

List of questions, comments on the product information

[Draxxin – tulathromycin - EMA/VRA/0000314905 – cattle, pigs, sheep](#)

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

[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

List of questions, comments on the product information

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

Cevac Reomune - EMA/PAM/0000324337

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

CVMP Rapporteur's assessment report

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

List of veterinary products to be tested in the Sampling and Testing Programme 2027

Action: For adoption

6. Working parties

6.7 Pharmacovigilance Working Party (PhVWP-V)

Endorsement of new Swedish PhVWP-V member (replacement of previous member)

Action: For adoption

Endorsement of new Spanish PhVWP-V member (replacement of previous member)

Action: For adoption

Endorsement of new Romanian PhVWP-V member (replacement of previous member)

Action: For adoption

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

Questions & Answers on the Implementation of 3DP Technology

Action: For adoption

6.10 Other working party and scientific group issues

Dosage Review and Adjustment of established Antibiotics (ADRA) tWP: meeting minutes – 16.01.2026

Action: For information

7. Other scientific matters

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

10. Organisational and strategic matters

11. CMDv

Reports from CMDv

Action: To note