

7 September 2026
EMA/201652/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 8-10 September 2026

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

8 September 2026, 09:00 – 10 September 2026, 13:00 - Room 1D and virtual

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 8-10.09.2026. See 07.2026 CVMP minutes (to be published post 09.2026 CVMP meeting).
- iii. Declaration of contacts between members and companies with regard to points on the agenda.
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Scientific Advice Working Party (virtual)
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Fri 04 Sep 26

10.00-13.00

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

2.1.1. 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, and virus shedding caused by porcine circovirus type 2 (PCV2) infection.

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. *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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

Indication: reduction of clinical signs of non-food responsive chronic inflammatory enteropathies (CIEs) in dogs.

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion, rapporteurs' joint assessment of additional data from applicant

2.2. Oral explanations

2.2.1. 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: Oral explanation to be held on 8 September 2026 at 14.15

Rapporteurs' assessment of responses to LoOI, comments on the product information

2.3. List of outstanding issues

2.3.1. Canine distemper, canine adenovirus, canine parainfluenza virus vaccine (live), canine parvovirus vaccine (live, recombinant) and canine leptospirosis vaccine (inactivated) - EMEA/V/C/006876/0000 – dogs

Indication: for the active immunisation of dogs from 6 weeks of age onwards to prevent or reduce symptoms or lesions caused by CDV, CAV1, CAV2, CPV, CPi, *Leptospira interrogans* and *L. kirschneri*.

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. *Streptococcus suis* vaccine (recombinant protein) - EMEA/V/C/006777/0000 – pigs

Indication: for passive immunisation of progeny by active immunisation of pregnant sows and gilts to reduce clinical signs, mortality, bacterial load and pathological lesions in serosae, joints and organs which are associated with *Streptococcus suis* belonging to IdeSsuis genotype 1.1.

Action: For decision

Need for oral explanation

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

2.3.3. Fuzapladib sodium – EMEA/V/C/006499/0000 – dogs

Indication: for the treatment of clinical signs associated with acute pancreatitis.

Action: For decision

Need for oral explanation

Action: For adoption

Additional list of outstanding issues

Action: For endorsement

Rapporteurs' assessment

2.4. List of questions

No items

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

[2.6.1. Canine adipose-derived mesenchymal stem cells - EMEA/V/C/006457/0000 – dogs](#)

Action: For decision

Request from the applicant for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions

[3.1.1. 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

CVMP Opinion, scientific overview, product information

[3.1.2. Inovax ND-H5 – avian influenza vaccine \(live recombinant\) - EMA/VRA/0000360413 – chickens](#)

Variation requiring assessment: to fulfil the specific obligation concerning stability data, by providing the missing data required to support the 36-month shelf-life of the finished product. The product information is to be updated accordingly.

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

Action: For adoption

CVMP opinion, CVMP assessment report, product information

[3.1.3. Credelio / AdTab – lotilaner - EMA/VRA/0000350956 – dogs](#)

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information for Credelio and product information for AdTab

Action: For endorsement

Rapporteur's assessment report

[3.1.4. 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

CVMP opinion, CVMP assessment report, product information

[3.1.5. 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 adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[3.1.6. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate - EMA/VRA/0000365315 – dogs](#)

Variation requiring assessment: to implement the outcome of the MAHs signal management process.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[3.1.7. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[3.1.8. Galliprant – grapiprant – EMA/VRA/0000363588 – dogs](#)

Variation requiring assessment: to implement the outcome of the MAH's signal management process. The MAH also took the opportunity to align the product information with version 9.1 of the QRD template.

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion, product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

[3.4.1. Credelio – lotilaner - EMA/VRA/0000358561 – cats](#)

Variation requiring assessment: change(s) to therapeutic indication(s) in cats - addition of a new therapeutic indication or modification of an approved one: treatment of ear mite infestations (*Otodectes cynotis*).

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

Action: For adoption

List of questions, comments on the product information

[3.4.2. Hepizovac – epizootic haemorrhagic disease vaccine \(inactivated\) - EMA/VRA/0000356582 – cattle](#)

Variation requiring assessment: to fulfil the specific obligation regarding the stability studies (up to 21 months) to confirm the accepted shelf life of 18 months under the recommended storage conditions for the finished product.

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

Action: For adoption

List of questions, comments on the product information

3.4.3. Orbyk EHD – epizootic haemorrhagic disease vaccine (recombinant protein) EMA/VRA/0000358791 – cattle

Variation requiring assessment: to fulfil the following obligations of the marketing authorisation under exceptional circumstances: to provide the complete validation report for the potency test in the finished product; to support the in-use shelf life of 10 hours by potency data.

Rapporteur: E. Werner, Co-Rapporteur: J. Poot

Action: For adoption

List of questions

3.4.4. Syvazul BTV 3 - Bluetongue virus vaccine (inactivated) - EMA/VRA/0000359275 – sheep

Variation requiring assessment: to fulfil two SOBs: completion of the development of the ELISA potency test for the BTV 3 antigen and to provide the study of duration of immunity in sheep.

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

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. 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: To note

Withdrawal letter

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 - pimobendan - EMA/REF/0000358452

Procedure scope: Potential lack of efficacy

Rapporteur: A. Golombiewski Co-Rapporteur: P. Falb

Action: For discussion

Revised rapporteur's assessment report including co-rapporteur critique

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

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 – recommendation from the Veterinary Domain

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 adoption

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.3.1. Election of Efficacy Working Party (EWP-V) chair

Action: For decision

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.5.1. Appointment of a new 3RsWP member– recommendation from the Non-Clinical Domain

Action: For endorsement

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management

Action: For adoption

6.7.2. Appointment of a new additional PhVWP-V member with expertise in surveillance – recommendation from the Veterinary Domain

Action: For endorsement

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held in June and July 2026

Action: For information

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

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 4 September 2026

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Guideline on user safety for pharmaceutical veterinary medicinal products

Action: For adoption

6.10.2. Guideline on user safety of topically administered veterinary medicinal products

Action: For adoption

6.10.3. Appointment of a new SWP-V member – recommendation from the Veterinary Domain

Action: For endorsement

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

7.7.1. Notification of an ITF briefing meeting

Innovation Task Force briefing meeting request

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

8.1.1. Revision of VICH GL8 on Stability Testing for Medicated Premixes – EU responses to public consultation comments

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 horses

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for Atlantic salmon

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 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. Appointment of rapporteurs

Action: For decision

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.1. Network Data Steering Group (NDSG) achievements

Action: For information

[10.2. iMAA and pre-submission activities in IRIS](#)

Action: For information

[10.3. New guidance for CVMP on how to work with IRIS iMAAs](#)

Action: For information

[10.4. Update on IE Presidency meetings for the CVMP / CMDv](#)

Action: For information

11. CMDv

[11.1. Verbal report on June and July CMDv meeting](#)

Action: For information

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

[Nobilis IB 4-91 / Nobilis IB Primo QX - avian infectious bronchitis vaccine \(live, attenuated\) / avian infectious bronchitis vaccine \(live\) - EMA/VRA/0000335790 – chickens](#)

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

CVMP Opinion, product information, Annex B

Action: For endorsement

Rapporteur's assessment report

[Porcilis AR-T DF / Porcilis Porcoli Diluvant Forte / Porcilis PCV / Porcilis PCV ID - EMA/VRA/0000332520 – pigs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP Opinion, Annex B

Action: For endorsement

Rapporteur's assessment report

[Solensia - frunevetmab - EMA/VRA/0000363671 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP Opinion, product information

Action: For endorsement

Rapporteur's assessment report

[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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[Eryseng Parvo - porcine parvovirus vaccine \(inactivated\) and swine erysipelas vaccine \(inactivated\) - EMA/VRA/0000343672 - pigs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Bovela / Purevax Rabies – rabies vaccine \(live recombinant\), bovine viral diarrhoea vaccine \(modified live\) - EMA/VRA/0000344586 – cattle](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Dewaele

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP FeLV, Purevax RCP, Purevax RC– calicivirus antigen - EMA/VRA/0000340558 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Dewaele

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[EMA/VRA/0000340567 – Profender, Procox & non-CAPs – cats, dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Lystralin – finrozole – EMA/VRA/0000337642 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[VeroBlue-3 – Bluetongue virus vaccine \(inactivated\) – EMA/VRA/0000363177 – sheep and cattle](#)

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion

3.4. List of questions

[Clynav – salmon pancreas disease vaccine \(recombinant DNA plasmid\) – EMA/VRA/0000358332 – Atlantic salmon](#)

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

List of questions

[Bluevac 3 – Bluetongue virus vaccine \(inactivated\) - EMA/VRA/0000360349 – sheep and cattle](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions

[Porcilis PCV M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine \(inactivated\) - EMA/VRA/0000358527 – pigs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions

[Arti-Cell Forte / RenuTend – alisvetcel / tesrivetcel - EMA/VRA/0000341950 – horses](#)

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

List of questions

3.6. Other issues

[NexGard Combo and Broadline – eprinomectin – EMA/VRA/0000335335 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

Request for an extension of clock stop.

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

Request for an extension of clock stop.

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

Action: For adoption

Request for an extension of clock stop.

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance

5.2 Post-authorisation measures

Rapporteur: M. Blixenkrone-Møller

Action: For endorsement

Rapporteur's assessment report

Rapporteur: J. Poot

Action: For endorsement

Rapporteur's assessment report

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's assessment report

Rapporteur: M. Blixenkrone-Møller

Action: For endorsement

Rapporteur's assessment report

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's assessment report

5.3 Inspections and controls

6. Working parties

6.5 3Rs Working Party (3RsWP)

6.5.1. NC and NAMs ESEC nominations

Action: For information

NC and NAMs ESEC nominations

6.5.2. Minutes of the 3RsWP meeting held on 02 and 03 June 2026

Action: For information

6.5.3. New Approach Methodologies OEG (NAMs OEG) nominations

Action: For information

New Approach Methodologies OEG (NAMs OEG) nominations.

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

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

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

9.3. Regulatory matters

Invented names