

5 October 2026
EMA/222110/2026 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 6-8 October 2026

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

6 October 2026, 09:00 – 8 October 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 VICH 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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- 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 02 Oct 26	10.00-13.00
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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 – EMA/V/MRL/003011/MODF/0002 – equidae

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. 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 and product information

Action: For information

Summary of opinion, summary of opinion

[2.1.2. Lumpy skin disease vaccine \(live\) - EMEA/V/C/007001/0000 – cattle](#)

Indication: for the prophylactic immunisation of cattle for the control of lumpy skin disease.

Action: For adoption

CVMP opinion, CVMP Assessment report and product information

Action: For information

Summary of opinion

2.2. Oral explanations

[2.2.1. Verdinexor - EMEA/V/C/005902/0000 – dogs](#)

Indication: for the treatment of lymphoma in dogs.

Action: Oral explanation to be held on 6 October 2026 at 14:15 CEST

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

[2.2.2. 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: Oral explanation to be held on 6 October 2026 at 11:00 CEST

Rapporteurs' assessment of additional data from applicant presentation from the applicant

2.3. List of outstanding issues

[2.3.1. Florfenicol / mometasone furoate / terbinafine – EMEA/V/C/006831/0000 – dogs](#)

Indication: treatment of acute canine otitis externa or acute exacerbations of recurrent otitis externa caused by mixed infections of *Staphylococcus pseudintermedius* and *Malassezia pachydermatis*.

Action: For adoption

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

[2.3.2. Porcine circovirus vaccine \(recombinant\) and *Mycoplasma hyopneumoniae* vaccine \(inactivated\) - EMEA/V/C/006603/0000 – pigs](#)

Indication: for the active immunisation of pigs to reduce viraemia, the duration of viraemia, the virus load in lungs and lymphoid tissues, the nasal and faecal viral shedding and the lymphoid lesions and its incidence caused by PCV-2 infection. To reduce the severity of the clinical signs and the lung lesions caused by *Mycoplasma hyopneumoniae*. To reduce the loss of body weight at the end of the fattening period and increase in the average daily weight gain (ADWG).

Action: For decision

Need for oral explanation

Action: For adoption

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

[2.3.3. 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 adoption

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

2.4. List of questions

No items

2.5. Re-examinations of CVMP opinions

[2.5.1. Scovella – velagliflozin – EMA/V/C/006610 – horses](#)

Indication: product intended 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.

Rapporteur: J. Poot, Co-Rapporteur: S. Louet

Action: For adoption

List of questions to the Ad Hoc Expert Group (AHEG); composition of the AHEG

2.6. Other issues

[2.6.1. Equimezon – equine adipose-derived mesenchymal stem cells - EMEA/V/C/006680/0000 – horses](#)

Rapporteur: K. Baptiste, Co-rapporteur: M. Leppänen

Action: For endorsement

Request from the applicant for a further extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions

[3.1.1. 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 adoption

CVMP opinion, CVMP assessment report, product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

[3.4.1. CircoMax – porcine circovirus vaccine \(inactivated recombinant\) – EMA/VRA/0000363711 – pigs](#)

Variation requiring assessment: to add 'pigs for reproduction' as a new subcategory of the target species and to introduce efficacy claims specific for pregnant gilts and sows. The product information is updated accordingly.

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: F. Marsilio

Action: For adoption

List of questions, comments on the product information

[3.4.2. Ecovaxxin MS – *Mycoplasma synoviae* vaccine \(live\) – EMA/VRA/0000363577 – chickens](#)

Variation requiring assessment: to extend the licensed duration of immunity from 17 weeks to 44 weeks.

Rapporteur: C. Miras

Action: For adoption

List of questions, comments on the product information

3.4.3. Bluevac 3 – bluetongue virus vaccine (inactivated)- EMA/VRA/0000363701 – sheep and cattle

Variation requiring assessment: to change the indication in sheep and cattle, from the reduction to the prevention of viraemia, to add reduction of clinical signs in cattle and to update the posology of the primary vaccination for sheep from two-doses to one-single dose.

Rapporteur: E. Werner, Co-Rapporteur: C. Munoz Madero

Action: For adoption

List of questions, comments on the product information

3.4.4. Prevexxion RN – Marek's disease vaccine (live recombinant) – chickens

Variation requiring assessment: to add a new route of administration (*in ovo*). Additionally, the marketing authorisation holder takes the opportunity to provide editorial changes to several parts of the dossier.

Rapporteur: E. Dewaele, Co-Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

3.4.5. Strangvac – *Streptococcus equi* vaccine (recombinant proteins)- EMA/VRA/0000365393 – horses

Variation requiring assessment: to extend the duration of immunity (DoI).

Rapporteur: M. Blixenkrone-Møller, Co-Rapporteur: E. Werner

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

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

4.4.1. Vetmedin 1.5 mg/ml oral solution - pimobendan - EMA/REF/0000358452 - dogs

Procedure scope: Potential lack of efficacy.

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

Scope: Opinion

Action: For adoption

CVMP opinion, CVMP assessment report

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

5.1.1. Suprelorin – deslorelin acetate - EMA/VS/0000358954, EMA/VS/0000358963

Signals on lack of expected efficacy (LEE) and movement of implant.

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: J.P. Duarte Da Silva

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

5.4.1. Vaxxitek HVT+IBD+H5 – avian influenza vaccine (live recombinant) - EMA/S/0000365375

Scope: to apply for the annual re-examination of the marketing authorisation for Vaxxitek HVT+IBD+H5 in line with Article 27(3) of Regulation (EU) 2019/6.

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

Action: For adoption

CVMP opinion, CVMP Rapporteur's Assessment Report, product information

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 22-23 September 2026

Action: For information

6.1.2. Reflection paper on the use of macrolides, lincosamides and streptogramins in animals in the European Union

Action: For discussion

6.1.3 Reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

6.4.1. Reflection paper on the use of heat treatment to inactivate endogenous retroviruses in live immunological veterinary medicinal products

Action: For discussion

6.5. 3Rs Working Party (3RsWP)

6.5.1. Upcoming election of Vice-chair

Action: For information

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 16 September 2026

Action: For information

6.6.2. Call for nominations for a new NTWP member

Action: For endorsement

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting

Action: For information

6.7.2. Revised VGVP Module: signal management - Medically Important (MI) VeDDRA terms list

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 2 October 2026

Action: For information

6.9.2. Call for nominations for a new SAWP-V member

Action: For endorsement

6.10. Safety Working Party (SWP-V)

6.10.1. Appropriateness of subchronic and chronic toxicity studies in dogs for ADI derivation

Action: For discussion

Mandate to SWP-V to reflect on appropriateness of subchronic and chronic toxicity studies in dogs for ADI derivation

6.10.2. Development of a harmonised tool for calculating human dietary exposure (REDEX)

Action: For discussion

REDEX in the context of MRL procedures – status update

6.11. Other working party and scientific group issues

6.11.1. Expert groups mandate

Action: For discussion

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential

7.1. MRL issues

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Fifth (5th) JIACRA report

Action: For discussion

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.7. Other issues

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 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

9.2.2. Eligibility request

Action: For decision

9.2.3. Eligibility request

Action: For decision

9.2.4. Eligibility request

Action: For decision

9.2.5. Eligibility for the multi-strain dossier approach

Action: For decision

9.3. Regulatory matters

9.3.1. Classification request

Action: For adoption

CVMP decision letter

9.3.2. VMPs without outer packaging and ensuring compliance with the legislation

Action: For information

10. Organisational and strategic matters

10.1. Network Data Steering Group (NDSG) – CVMP representative

Action: For information

11. CMDv

No items

12. Legislation

No items

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

[Strangvac - Streptococcus equi vaccine \(recombinant proteins\) - EMA/VRA/0000365767 - horses](#)

Variation requiring assessment: quality related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Librela – bedinvetmab - EMA/VRA/0000344161 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Arti-Cell Forte, Renutend - EMA/VRA/0000361367 \(WS\) – horses](#)

Variations requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

[Nobivac DP Plus – canine distemper vaccine \(live, attenuated\) and canine parvovirus vaccine \(live, recombinant\) - EMA/VRA/0000358778 \(WS\) – dogs](#)

Rapporteur: E. Werner

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance

[Signal evaluation and recommendations](#)

Action: For adoption

Outcome of the signal management process, list of finalised signals

5.2 Post-authorisation measures

[Neoleish – EMA/PAM/0000367834](#)

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's assessment report

5.3. Inspections and controls under Regulation (EU) 2019

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. Agenda of the 3RsWP plenary held on 23, 24 September 2026](#)

Action: For information

6.6 Novel Therapies & Technologies Working Party (NTWP)

[Nomination of new Novel Therapies \(NTs\) ESEC expert](#)

Action: For endorsement

6.7 Pharmacovigilance Working party (PhVWP-V)

[Endorsement of new Croatian PhVWP-V member](#)

Action: For endorsement

6.8 Quality Working Party (QWP)

[Quality Chemical ESEC nominations](#)

Action: For adoption

7. Other scientific matters

7.5. Vaccine antigen master file (VAMF) certification

EMA/V/VAMF/0002/VRA/0001

Scope: quality-related changes.

Action: For adoption

VAMF variation evaluation report

Action: For endorsement

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