



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 March 2026
EMA/CVMP/65896/2026 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 14-16 April 2026

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

14 April 2026, 09:00 – 16 April 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](#)).



Table of contents

Introduction	6
i. Adoption of the agenda.	6
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 14-16/04/2026. See 04/2026 CVMP minutes (to be published post 05/2026 CVMP meeting).....	6
iii. Declaration of contacts between members and companies with regard to points on the agenda.....	6
iv. Adoption of the minutes of the February meeting.....	6
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).	6
1. Maximum residue limits	6
1.1. Opinions	6
1.2. Oral explanations.....	6
1.3. List of outstanding issues.....	6
1.4. List of questions	6
1.5. Re-examination of CVMP opinions on maximum residue limits.....	6
1.6. Other issues.....	6
2. Marketing authorisations	7
2.1. Opinions.....	7
2.1.1. Feline calicivirus, feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia), feline chlamydiosis (live) and feline leukaemia vaccine (RNA particle) vaccine - EMEA/V/C/006520/0000 – cats	7
2.2. Oral explanations.....	7
2.3. List of outstanding issues.....	7
2.4. List of questions	7
2.4.1. Newcastle disease and avian infectious bronchitis vaccine (live) - EMEA/V/C/006870/0000 – chickens.....	7
2.4.2. Avian infectious bronchitis vaccine (live) - EMEA/V/C/006871/0000 – chickens.....	8
2.4.3. Newcastle disease vaccine (live) - EMEA/V/C/006872/0000 – chickens	8
2.4.4. <i>Salmonella</i> Enteritidis vaccine (live) – EMEA/V/C/006875/0000 – chickens.....	8
2.4.5. Florfenicol / mometasone furoate / terbinafine – EMEA/V/C/006831/0000 – dogs	8
2.4.6. 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	8
2.5. Re-examinations of CVMP opinions	8
2.6. Other issues.....	9
2.6.1. Omeprazole - EMEA/V/C/006776/000 – horses	9
2.6.2. Equine interleukin-5 vaccine (recombinant protein, conjugate) - EMEA/V/C/006180/0000 – horses.....	9
2.6.3. Fuzapladib sodium – EMEA/V/C/006499/0000 – dogs	9
3. Variations to marketing authorisations	9
3.1. Opinions.....	9
3.1.1. Solensia – frunevetmab - EMA/VRA/0000334838 - cats	9
3.1.2. Startvac – <i>Staphylococcus aureus</i> and coagulase-negative staphylococci and <i>Escherichia coli</i> J5 vaccine (inactivated) - EMA/VRA/0000288186 – cattle.....	9
3.2. Oral explanations.....	10

3.3. List of outstanding issues.....	10
3.4. List of questions	10
3.4.1. Upcard – torasemide - EMA/VRA/0000326002 – dogs.....	10
3.4.2. Firocoxib CP-Pharma – firocoxib - EMA/VRA/0000326568 – dogs	10
3.5. Re-examinations of CVMP opinions on variations requiring assessment.....	10
3.6. Other issues.....	10
4. Referrals and related procedures	11
4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6	11
4.1.1. Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep - EMA/REF/0000271819	11
4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6	11
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	11
4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure	11
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.....	11
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	11
4.7. Other issues.....	11
5. Post-authorisation issues for marketing authorisations.....	12
5.1. Pharmacovigilance	12
5.1.1. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate	12
5.2. Post-authorisation measures	12
5.3. Inspections and controls.....	12
5.4. Re-examination of limited markets and exceptional circumstances authorisations	12
5.4.1. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/S/0000321438 .	12
5.5. Others.....	12
6. Working parties	12
6.1. Antimicrobials Working Party (AWP).....	12
6.1.1. Verbal report on AWP meeting held on 17-18 March 2026	12
6.1.2. 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	13
6.2. Environmental Risk Assessment Working Party (ERAWP)	13
6.3. Efficacy Working Party (EWP-V).....	13
6.4. Immunologicals Working Party (IWP)	13
6.5. 3Rs Working Party (3RsWP)	13
6.6. Novel Therapies & Technologies Working Party (NTWP)	13
6.6.1. Verbal report on NTWP meeting held on 9-10 April 2026.....	13
6.7. Pharmacovigilance Working Party (PhVWP-V).....	13
6.7.1. Verbal report on PhVWP-V meeting	13
6.8. Quality Working Party (QWP)	13
6.8.1. Verbal report on QWP meetings February and March 2026	13
6.8.2. Guideline on development and manufacture of synthetic peptides – overview of comments	13
6.8.3. CVMP Annex to VICH GL18 on residual solvents	13

6.8.4. Update to Q&A on reduced testing.....	13
Action: For adoption	13
6.9. Scientific Advice Working Party (SAWP-V).....	14
6.10. Safety Working Party (SWP-V).....	14
6.10.1. Verbal report on SWP-V meeting held on 19-20 March 2026	14
6.10.2. Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances	14
6.10.3. Guideline on user safety for pharmaceutical veterinary medicinal products	14
6.10.4. Guideline on user safety of topically administered veterinary medicinal products	14
6.11. Other working party and scientific group issues	14
6.11.1. Concept paper on the development for guidance on demonstration of biosimilarity of biological veterinary medicinal products	14
7. Other scientific matters	14
7.1. MRL issues.....	14
7.2. Environmental risk assessment	14
7.3. Antimicrobial resistance.....	14
7.4. Pharmacovigilance	14
7.5. Vaccine antigen master file (VAMF) certification.....	14
7.6. Platform technology master file (PTMF) certification	15
7.7. Other issues.....	15
8. Co-operation with other EU or International bodies.....	15
8.1. VICH.....	15
8.1.1. Concept paper proposing development of a VICH GL to parallel ICH Q9	15
8.1.2. Concept paper proposing a revision of VICH GL 57: marker residue depletion studies to establish product withdrawal periods in aquatic species.....	15
8.2. Codex Alimentarius.....	15
8.3. Other EU bodies and international organisations	15
9. Procedural and regulatory matters	15
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	15
9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers	16
9.2.1. Summary of eligibility and table of offers from rapporteurs	16
9.2.6. Decision on the application under exceptional circumstances	16
9.2.7. Decision on the application under exceptional circumstances	16
9.2.8. Decision on the accelerated assessment request	16
9.3. Regulatory matters	16
10. Organisational and strategic matters	16
10.1. Veterinary Strategic Focus Group NCA Capacity Survey – outcome and recommendations..	16
11. CMDv.....	16
11.1. Verbal report from CMDv chair on the CMDv meeting held on 18-19 March 2026	16
12. Legislation	16
12.1. 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)	16
12.2. European Commission’s request under Article 141(1)(f) of Regulation (EU) 2019/6: request concerning five substances not included in Commission Implementing Regulation (EU) 2025/901	17

13. Any other business	17
13.2. Meeting highlights.....	17
14. Annex.....	18

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 14-16/04/2026. See 04/2026 CVMP minutes (to be published post 05/2026 CVMP meeting).
- iii. Declaration of contacts between members and companies with regard to points on the agenda.
- iv. Adoption of the minutes of February meeting.
- 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 (virtual)

Fri 10 Apr 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. 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

2.2. Oral explanations

No items

2.3. List of outstanding issues

No items

2.4. List of questions

2.4.1. Newcastle disease and avian infectious bronchitis vaccine (live) - EMEA/V/C/006870/0000 – chickens

Indication: active immunisation of chickens to reduce the presence of virus in the trachea and the detrimental effect on the ciliary activity caused by infection with strains of the Massachusetts serotype of avian infectious bronchitis virus, which may be manifested in respiratory clinical signs.

Active immunisation of chickens to reduce clinical signs and mortality, together with viral shedding caused by infection with Newcastle disease virus.

Action: For adoption

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

[2.4.2. Avian infectious bronchitis vaccine \(live\) - EMEA/V/C/006871/0000 – chickens](#)

Indication: active immunisation of chickens to reduce the presence of virus in the trachea and the detrimental effect on the ciliary activity caused by infection with strains of the Massachusetts serotype of avian infectious bronchitis virus, which may be manifested in respiratory clinical signs

Action: For adoption

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

[2.4.3. Newcastle disease vaccine \(live\) - EMEA/V/C/006872/0000 – chickens](#)

Indication: active immunisation of chickens to reduce clinical signs and mortality, together with viral shedding caused by infection with Newcastle disease virus

Action: For adoption

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

[2.4.4. *Salmonella* Enteritidis vaccine \(live\) – EMEA/V/C/006875/0000 – chickens](#)

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

Action: For adoption

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

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

Indication: treatment of acute canine otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of susceptible strains of bacteria sensitive to florfenicol (*Staphylococcus pseudintermedius*) and fungi sensitive to terbinafine (*Malassezia pachydermatis*).

Action: For adoption

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

[2.4.6. 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: vaccine intended 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 adoption

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. Omeprazole - EMEA/V/C/006776/000 – horses

Action: For endorsement

Request from the applicant to extend the clock stop

2.6.2. 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 endorsement

Request from the applicant for an extension of clock stop

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

Action: For endorsement

Request from the applicant for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Solensia – frunevetmab - EMA/VRA/0000334838 - cats

Variation requiring assessment: to implement the outcome of the MAH's signal management process. Additionally, the MAH introduces some editorial and formatting changes, and the product information is aligned with version 9.1 of the QRD template.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. Startvac – *Staphylococcus aureus* and coagulase-negative staphylococci and *Escherichia coli* J5 vaccine (inactivated) - EMA/VRA/0000288186 – cattle

Variation requiring assessment: to allow the current vaccination schedule to be administered independently of the parturition date and administration of booster doses every three months.

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

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

Rapporteur's assessment report

Action: For information

Summary of opinion

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

[3.4.1. 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 adoption

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

[3.4.2. 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

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

[3.4.3. 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 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

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: Opinion

Action: For adoption

CVMP Assessment Report, CVMP opinion

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

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. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate

Outcome of the signal management process

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: C. Muñoz Madero

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. Vectormune HVT-AIV – avian influenza vaccine (live recombinant) - EMA/S/0000321438

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

Rapporteur: C. Miras; Co-rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP Rapporteur's Assessment Report

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 17-18 March 2026

Action: For information

6.1.2. 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 adoption

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)

No items

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 9-10 April 2026

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings February and March 2026

Action: For information

6.8.2. Guideline on development and manufacture of synthetic peptides – overview of comments

Action: For adoption

6.8.3. CVMP Annex to VICH GL18 on residual solvents

Action: For adoption

6.8.4. Update to Q&A on reduced testing

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 19-20 March 2026

Action: For information

6.10.2. Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances

Action: For discussion

6.10.3. Guideline on user safety for pharmaceutical veterinary medicinal products

Action: For discussion

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

Action: For discussion

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 adoption

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

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 adoption

Draft concept paper including EU comments

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 adoption

Draft concept paper including EU comments

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

No items

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

9.2.6. Decision on the application under exceptional circumstances

Action: For decision

9.2.7. Decision on the application under exceptional circumstances

Action: For decision

9.2.8. Decision on the accelerated assessment request

Action: For decision

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.1. Veterinary Strategic Focus Group NCA Capacity Survey – outcome and recommendations

Action: For information

11. CMDv

11.1. Verbal report from CMDv chair on the CMDv meeting held on 18-19 March 2026

Action: For information

12. Legislation

12.1. 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 adoption

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

Action: For adoption

Guidance under Article 141(1)(f)

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

1. Maximum Residue Limits

1.6. Other issues

[Substance – EMEA/V/MRL/003649/MODF/0004 – porcine](#)

Action: For adoption

Editorial correction to the CVMP Opinion including EPMAR

3. Variations to marketing authorisations

3.1. Opinions

[EMA/VRA/0000320723 – Nobilis IB 4-91, Porcilis AR-T DF, Nobivac Bb, Porcilis ColiClos, Nobilis IB Primo QX, Nobivac Myxo-RHD Plus, Nobivac DP Plus, Bovilis Nasalgen-C - pigs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[BTVPUR – Bluetongue virus vaccine \(inactivated\) - EMA/VRA/0000326031 – sheep and cattle](#)

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Zenrelia – ilunocitinib - EMA/VRA/0000309679 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Tulissin – tulathromycin - EMA/VRA/0000316055 – cattle, pigs, sheep](#)

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Rhiniseng – porcine progressive atrophic rhinitis vaccine \(inactivated\) - EMA/VRA/0000322270 – pigs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkron-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[EMA/VRA/0000304883 – Prevexxion RN / Prevexxion RN+HVT / Prevexxion RN+HVT+IBD / Vaxxitek HVT+IBD / non-CAPs – chickens](#)

Variation requiring assessment: quality-related changes

Rapporteur: E. Dewaele

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[EMA/VRA/0000322708 – Clynav – Atlantic salmon](#)

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[EMA/VRA/0000334631 – Zenrelia – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[EMA/VRA/0000321357 – Zenalpha – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Coxatab – firocoxib - EMA/VRA/000326232 – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.3. List of outstanding issues

[MA/VRA/0000293810 - 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 \(inactivated\) – dogs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.4. List of questions

[NexGard Combo /Broadline – fipronil / \(S\)-methoprene / eprinomectin / praziquantel, esafoxolaner / eprinomectin / praziquantel – VRA/0000291062 – cats](#)

Variation requiring assessment: quality related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

[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 questions, comments on the product information

[Portela – relfovetmab – EMA/VRA/0000334629 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: M. Leitner

Action: For adoption

Rapporteur's assessment report with the list of questions

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

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

Rabitec – rabies vaccine (live, oral) - EMA/PAM/0000326224 – dogs, foxes, raccoon dogs

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

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

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

Publication on past and future 3Rs activities at EMA

Action: For information

Link to the article: <https://doi.org/10.1016/j.namjnl.2026.100086>

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

6.11. Other working party and scientific group issues

Minutes of the Dosage Review and Adjustment of established Antibiotics (ADRA) meetings held in February 2026

Action: For information

7. Other scientific matters

7.1 MRL issues

Request on whether a full MRL evaluation is required in accordance with Commission regulation (EU) 2018/782 for reCG (recombinant equine Chorionic Gonadotropin) - cattle, sheep and pigs

Action: For adoption

Summary of assessment

Action: For information

CVMP assessment report and summary of assessment

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9.3. Regulatory matters

Invented names

10. Organisational & Strategic Matters

Veterinary Assessors Day 2026

Action: For information

Draft agenda