31 October 2024
EMA/CVMP/493417/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 5-7 November 2024

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

5 November 2024, 09:00 – 7 November 2024, 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 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 5-7/11/2024. See 10/2024 CVMP minutes (to be published post 11/2024 CVMP meeting)

iii. Declaration of contacts between members and companies with regard to points on the agenda.

iv. Adoption of the minutes of the previous 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 (room 0A)	Mon 04 Nov 24	16.00-19.00

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance – EMEA/V/MRL/003652/MODF/0005 – bovine, porcine, *Equidae*

Action: For adoption

CVMP opinion including EPMAR, CVMP assessment report

Action: For information

Summary of opinion

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/003052/MODF/0002 – bovine and ovine

Action: For adoption

Scientific Overview and List of questions

1.4.2. Substance – EMEA/V/MRL/003125/MODF/0005 – all ruminants and *Salmonidae*

Action: For adoption

Scientific Overview and List of questions

1.5. Re-examination of CVMP opinions on maximum residue limits

No items

Other issues

No items

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

2.1.1. EMEA/V/C/006249/0000 – dogs, cats

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.2. Oral explanations under Regulation (EU) 2019/6

2.2.1. EMEA/V/C/006306/0000 – chickens and chicken embryonated eggs

Action: Oral explanation to be held on 5 November 2024 at 14:30

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

2.3. List of outstanding issues under Regulation (EU) 2019/6

2.3.1. EMEA/V/C/006389/0000 – dogs, cats

Action: For adoption

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

2.3.2. EMEA/V/C/006300/0000 – cats

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 under Regulation (EU) 2019/6

2.4.1. EMEA/V/C/006480/0000 – dogs

Action: For adoption

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

2.4.2. EMEA/V/C/006457/0000 – dogs

Action: For adoption

List of questions, comments on the product information

2.4.3. EMEA/V/C/006455/0000 – dogs

Action: For adoption

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

2.4.4. EMEA/V/C/006522/0000 – chickens

Action: For adoption

List of questions, comments on the product information

2.4.5. EMEA/V/C/006513/0000 – cats

Action: For adoption

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

2.5. Re-examinations of CVMP opinions under Regulation (EU) 2019/6

No items

2.6. Other issues under Regulation (EU) 2019/6

No items

2.6.1. EMEA/V/C/006230/0000 – cats

Action: For decision

Extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. MS-H Vaccine – mycoplasma synoviae (live) - EMA/VRA/0000229456 – chickens

Variation requiring assessment: to correct the pharmaceutical dose form and route of administration to align with the update of the definition of the EDQM standard term.

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.2. MS-H Vaccine – mycoplasma synoviae (live) - EMA/VRA/0000229769 – chickens

Variation requiring assessment: to amend section 3.5. of the Summary of Product Characteristics.

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.3. Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMA/VRA/0000221746 – dogs

Variation requiring assessment: to add a new therapeutic indication.

Rapporteur: R. Breathnach, Co-Rapporteur: E. Dewaele

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.4. Rabitec – rabies vaccine (live) - EMEA/V/C/004387/VRA/0013/G – foxes, raccoon dogs and dogs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.2. Oral explanations under Regulation (EU) 2019/6

No items

3.3. List of outstanding issues under Regulation (EU) 2019/6

No items

3.4. List of questions under Regulation (EU) 2019/6

No items

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

No items

3.6. Other issues under Regulation (EU) 2019/6

No items

4. Referrals and related procedures

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

No items

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

No items

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

No items

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

No items

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

No items

4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) 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 under Regulation (EU) 2019/6

5.1.1. Daxocox – enflicoxib – EMA/VS/0000175158

Signal assessment

Rapporteur: R. Breathnach, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

Draft rapporteur's assessment report

5.1.2. Senvelgo – velagliflozin - EMA/VS/0000225318

Annual statement assessment

Rapporteur: K. Baptiste, Co-Rapporteur: M. O'Grady

Action: For adoption

Draft rapporteur's assessment report

5.2. Post-authorisation measures under Regulation (EU) 2019/6

No items

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

No items

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

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)

6.1.2. AWP work plan for 2025

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 16-17 October 2024

Action: For information

6.2.2. ERAWP work plan for 2025

Action: For discussion

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 15-16 October 2024

Action: For information

6.3.2. EWP-V work plan for 2025

Action: For discussion

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 21-22 October 2024

Action: For information

6.4.2. IWP interested parties meeting

Action: For information

6.4.3. IWP-V work plan for 2025

Action: For discussion

6.4.4. Guideline on live recombinant vector vaccines for veterinary use

Action: For discussion

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2025

Action: For discussion

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V held 23 October 2024 meeting

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Guideline on stability testing for variations for VMPs

Action: For adoption

Guideline on stability testing for variations for VMPs; overview of comments

6.8.2. QWP workplan for 2025-2027

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 4 November 2024

Action: For information

6.9.7. SAWP-V work plan for 2025

Action: For discussion

6.10. Safety Working Party (SWP-V)

6.10.1. Safety WG work plan for 2025

Action: For discussion

6.11. Other working party and scientific group issues

6.11.1. ESUAvet annual report draft outline

Action: For adoption

6.11.2. ESUAvet WG work plan for 2025

Action: For discussion

6.11.3. Draft Work Plan for the drafting group on veterinary biosimilars

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

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

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.

7.6.1. EMEA/V/VPTMF/0001

Action: For adoption

vPTMF Assessment report

Action: For endorsement

vPTMF certificate

7.7. Other issues

No items

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

No items

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.1.1. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for dogs

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

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.2. CVMP work plan 2025

Action: For adoption

CVMP work plan 2025

10.4. Update on the signal management process for CAPs

Action: For information

11. CMDv

11.1 Verbal report from the CMDv Chair on the meetings held on 19-20 September and 17-18 October

Action: For information

12. Legislation

12.1. Revision of the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products

Action: For adoption

Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products; overview of comments

12.2. Verbal report on the work progress of the expert group for the scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with Article 114(1)

Action: For information

Verbal report from the expert group's chair

12.3. QRD template update to v.9.1

Action: For adoption

QRD veterinary product-information ANNOTATED template version 9.1

12.4. Implementation plan for the QRD template v.9.1

Action: For information

Implementation plan for the QRD template v.9.1

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Rexxolide – tulathromycin – EMA/VRA/0000221089 – cattle, pigs, sheep

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Equisolon – prednisolone - EMEA/V/C/002382/VRA/0012 - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Baycox Iron – toltrazuril / iron(III) ion - EMA/VRA/0000230683 – pigs

Variation requiring assessment: quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, CVMP assessment report

WS2730 – Eurican L4 - dogs

Variation requiring assessment: quality-related changes

Rapporteur: E. Kollár-Nagy

Action: For adoption

CVMP opinion

RenuTend – tesrivetcel - EMEA/V/C/005428/VRA/0005/G – horses

Variation requiring assessment: quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

List of outstanding issues under Regulation (EU) 2019/6

Profender – praziquantel / emodepside – EMEA/V/C/000097/VRA/0056/G – cats, dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of outstanding issues

3.4. List of questions under Regulation (EU) 2019/6

Hydrocortisone aceponate Ecuphar – hydrocortisone aceponate - EMA/VRA/0000166782 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: S. Louet

Action: For adoption

List of questions, comments on the product information

Clevor – ropinirole - EMA/VRA/0000227231 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions, comments on the product information

Bluevac BTV – bluetongue virus vaccine (inactivated) - EMEA/V/C/000156/VRA/0013– cattle, sheep

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

Quadrisol – vedaprofen – EMEA/V/C/000032/VRA/0039 – horses

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

Strangvac – Streptococcus equi vaccine (recombinant proteins) – EMEA/V/C/005309/VRA/0008/G – horses

Variation requiring assessment: quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.2 Post-authorisation measures under Regulation (EU) 2019/6

Rabitec – EMEA/V/C/004387/REC/013

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's assessment report

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

ERA ESEC Expert nominations

6.5. 3Rs Working Party (3RsWP)

Minutes of the tOEG - 3RsWP - Batch release testing meeting held on 6 September 2024

Action: For information

Agenda of the tOEG - 3RsWP - Batch release testing meeting held on 18 October 2024

Action: For information

Agenda of the New Approach Methodologies ESEC webinar held on 16 October 2024

Action: For information

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

List of nominations for the Quality Chemical ESEC

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH Revision of VICH GLs 7, 12, 13, 14, 15, 16, 19, 20, 21 on efficacy of anthelmintics

The final guidelines are now presented for adoption for publication.

VICH Revision of VICH GL8 Stability testing for medicated premixes

The revised guideline is presented for endorsement for sign off at step 3 by Steering Committee for public consultation

VICH status of guidelines

Action: For information

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