10 January 2025
EMA/11086/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 14-15 January 2025

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

14 January 2025, 09:00 – 15 January 2025, 18:00 - Room 1C and virtual

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

Disclaimer

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CVMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CVMP members and the work the Committee undertakes.

Declaration of interests

In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP Secretariat at the start of meeting.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to 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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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	Fri 10 Jan 25	Written procedure

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

No items

1.3. List of outstanding issues

1.3.1. Substance – EMA/V/MRL/004380/EXTN/0002 - *salmonidae* and other fin fish

Action: For decision

Need for oral explanation

Action: For discussion

Scientific overview

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. EMEA/V/C/006575/0000 – cattle, sheep

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

Summary of opinion

2.1.2. EMEA/V/C/006623/0000 – cattle and sheep

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

Summary of opinion

2.1.3. EMEA/V/C/006501/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

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. EMEA/V/C/006180/0000 – horses

Rapporteur: F. Hasslung-Wikström, Co-Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

2.4.2. EMEA/V/C/006589/0000 – chickens

Action: For adoption

List of questions, comments on the product information

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

2.6.1. EMEA/V/C/006300/0000 – cats

Action: For decision

Request for an extension of the clock stop

3. Variations to marketing authorisationss

3.1. Opinions

No items

3.2. Oral explanations

No items

3.3. List of outstanding issues

No items

3.4. List of questions

3.4.1. NexGard Combo – esafoxolaner / eprinomectin / praziquantel – EMEA/V/C/005094/VRA/0012/G – cats

Variation requiring assessment: addition of a therapeutic indication and modification of an approved one

Rapporteur: A. Golombiewski, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

3.4.2. Pexion – imepitoin - EMEA/V/C/002543/VRA/0019/G – dogs

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

3.4.3. Veraflox – pradofloxacin - EMA/VRA/0000236570 – dogs and cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and the EMA Guideline on the SPC for antimicrobial medicinal products (EMA/CVMP/383441/2005-Rev.1 Corr)

Rapporteur: A. Golombiewski

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

No items

4.2. Union interest referral under Article 82 based on Article 129(3)

No items

4.3. Procedure under Article 70(11) 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) on a CMDv review procedure

No items

4.5. Request from the European Commission under Article 130(4) 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)

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

4.7.1. Referrals under Regulation (EU) 2019/6

No items

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

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

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. Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals

Action: For adoption

Guideline on AMR risk assessment; guideline AMR Risk assessment - overview of comments (2018)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Upcoming election for chair of ERAWP

Action: For information

Call for nominations

6.3. Efficacy Working Party (EWP-V)

6.3.1. Guideline on data requirements for veterinary medicinal products for zootechnical purposes

Action: For adoption

Revised guideline on data requirements for veterinary medicinal products for zootechnical purposes; overview of comments received on the draft guideline during public consultation

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 18 December 2024

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 10 January 2025

Action: For information

6.10. Safety Working Party (SWP-V)

No items

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

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

8.3.1 Invitation to participate in development of an EU framework on aggregate exposure assessment to chemicals

Action: For decision

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

9.1.1. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for broiler chickens

9.1.2. 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

10. Organisational and strategic matters

No items

11. CMDv

11.1 Verbal report from the CMDv Chair on the meetings held on 14-15 November and 12-13 December

Presenter: L. le Letty

Action: For information

CMDv report

Report for Release July-September 2024 (EMA/CMDv/477668/2024)

12. Legislation

12.1. 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

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

WS2769 – Porcilis AR-T DF – Porcilis ColiClos – Porcilis Porcoli Diluvac Forte – pigs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2767 – Nobivac Bb + MRP, DCP, NAP – cattle, cattle and pigs

Variation requiring assessment: quality related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, Annex B

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions

Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0019 – chickens

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

Rapporteur: F. Klein

Action: For adoption

List of questions, comments on the product information

Quadrisol – vedaprofen - EMEA/V/C/000032/VRA/0040 – horses

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

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

Sevohale – sevoflurane - EMA/VRA/0000236258 – dogs and cats

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

Rapporteur: J.G. Beechinor

Action: For adoption

List of questions, comments on the product information

Profender, Procox, Felpreva (WS) - EMA/VRA/0000224998 – cats, dogs

Variation requiring assessment: quality related changes

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

WS2768 - Porcilis ColiClos, Porcilis Porcoli Diluvac Forte, Porcilis AR-T DF - E. coli and C. perfringens vaccine (inactivated) to provide passive immunity to pigs, Porcine progressive atrophic rhinitis vaccine (inactivated) - pigs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

Rapporteur's assessment report including list of questions

EMEA/V/C/WS2760 – Forceris, Gleptosil – pigs

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.3 Inspections and controls

6. Working parties

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

NC and NAMs ESEC nominations

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH status of guidelines

Action: For information

VICH status of guidelines

9. Procedural and regulatory matters

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

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters