29 November 2024
EMA/558441/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 3-5 December 2024

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

3 December 2024, 09:00 – 5 December 2024, 13:00 – virtual and room 2C

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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Table of contents

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 3-5/12/2024. See 11/2024 CVMP minutes (to be published post 12/2024 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 (virtual)	Fri 29 Nov 24	10.00-13.00 (TBC)

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 under Regulation (EU) 2019/6

2.1.1. EMEA/V/C/006309/0000 – Atlantic salmon

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

Action: For adoption

CVMP opinion, CVMP assessment report, product information, vPTMF certificate

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006234/0000 – cattle, pigs, 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

No items

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

2.3.1. EMEA/V/C/006235/0000 – dogs

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. EMEA/V/C/006247/0000 – sea bream

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/005890/0000 – cats

Action: For adoption

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

2.4.2. EMEA/V/C/006535/0000 - dogs

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Librela – bedinvetmab - EMA/VRA/0000234237 – dogs

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

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Action: For information

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

3.4.1. Nobivac L4, Nobivac LoVo L4 - canine leptospirosis vaccine (inactivated) - WS/2673 – dogs

Variation requiring assessment: to add new therapeutic indications

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

Action: For adoption

List of questions, comments on the product information

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

3.6.1 Vectra 3D – dinotefuran / pyriproxyfen / permethrin - EMEA/V/C/002555/VRA/0026/G – dogs

Variation requiring assessment: to add a new therapeutic indication and to update the pharmacodynamics section of the SPC

Rapporteur: A. Golombiewski, Co-Rapporteur: H. Bremer

Action: For information

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

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

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 under Regulation (EU) 2019/6

5.1.1. Librela – bedinvetmab - EMA/VRA/0000234237 – dogs

Signal assessment

Rapporteur: F. Hasslung Wikström, Co-Rapporteur: J. Poot

Action: For adoption

Draft Rapporteur's assessment report

5.1.2. Senvelgo – velagliflozin - EMA/VS/0000225318 - cats

Annual statement assessment

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

Action: For re-adoption

CVMP assessment report

5.1.3 Targeted signal management (TSM) report for injectable veterinary medicinal products and anaphylactic reactions in cattle

Final TSM Report

Action: For adoption

Final 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 adoption

6.1.3. Verbal report on AWP meeting held on 26 and 27 November 2024

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. ERAWP work plan for 2025

Action: For adoption

6.2.2. Update of relevant guidance documents in order to align them with provisions outlined in Regulation (EU) 2019/6

Action: For adoption

Guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater

6.3. Efficacy Working Party (EWP-V)

6.3.2. EWP-V work plan for 2025

Action: For adoption

6.4. Immunologicals Working Party (IWP)

6.4.1. Guideline on live recombinant vector vaccines for veterinary use

Action: For adoption

Overview of comments from public consultation of the revised guideline

6.4.2. Concept paper for the revision of the Guideline on the requirements for combined vaccines and associations of IVMPs

Action: For adoption

6.4.3. Concept paper for the development of a Guideline on quality aspects of mRNA vaccines for veterinary use

Action: For adoption

6.4.4. IWP-V work plan for 2025

Action: For adoption

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP meeting and nominations

Action: For decision

6.5.2. 3Rs WP work plan for 2025-2027

Action: For discussion

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2025

Action: For adoption

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting

Action: For information

6.7.2. PhVWP-V workplan for 2025

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (October and November 2024)

Action: For information

6.8.2. QWP workplan for 2025-2027

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 29 November 2024

Action: For information

6.9.3. SAWP-V work plan for 2025

Action: For adoption

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 14-15 November 2024

Action: For information

6.10.2. SWP-V work plan 2025

Action: For adoption

6.11. Other working party and scientific group issues

6.11.1. Verbal report on the ESUAvet WG meeting held on 14 and 15 November 2024

Action: For information

6.11.2. ESUAvet WG work plan for 2025

Action: For adoption

6.11.3. Work plan for the drafting group on veterinary biosimilars

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

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp.

Action: For adoption

Scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp.

7.3.2. CVMP Strategy on antimicrobials 2026-2030

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.

7.6.1. EMEA/V/PTMF/0003

Action: For adoption

Assessment report and list of questions

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

8.1.2. Feedback from VICH Steering Committee, Forum and Conference meetings of 10-15 November 2024

Action: For information

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

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Appointment of co-opted members

Action: For election

Nomination(s) received:

- Antimicrobial resistance – K. Baptiste
- Environmental risk assessment

10.2. Verbal report on Veterinary Domain meeting held on 22 October 2024

Action: For information

10.3. Consolidated 3-year work plan for the veterinary domain (2025-2027)

Action: For adoption

10.4. P-SMEG final report and signal management process recommendations

Action: For information

P-SMEG final report, recommendations for processes related to signal management and surveillance

11. CMDv

No items

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

12.2 Update with regards the scientific advice on Article 115(5) of Regulation (EU) 2019/6 - list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months

Action: For information

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

Annex

1. Maximum residue limits

1.6. Other issues

Substance (ketoprofen) – EMEA/V/MRL/003652/MODF/0005 – bovine, porcine, *Equidae*

Action: For information

2. Marketing authorisations

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

EMEA/V/C/005902 – dogs

Action: For decision

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

NexGard Combo – esafoxolaner / eprinomectin / praziquantel - EMEA/V/C/005094/VRA/0009 – cats

Variation requiring assessment: quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Osurnia – terbinafine / florfenicol/ betamethasone acetate – EMEA/V/C/003753/VRA/0026/G – dogs

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Bonqat – pregabalin – EMEA/V/C/005489/VRA/0006 – cats

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

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2703 - Zeleris, Florkem – cattle, cattle and pigs

Variation requiring assessment: quality related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

WS2753 - Prevexxion RN+HVT, Prevexxion RN+HVT+IBD, Prevexxion RN – Marek's disease vaccine (live recombinant) infectious bursal disease and Marek's disease vaccine (live recombinant) - Marek's disease vaccine (live recombinant) – chickens

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Pexion – imepitoin – EMEA/V/C/002543/VRA/0018 – dogs

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

Ecoporc Shiga – genetically modified STx2e antigen vaccine - EMEA/V/C/002588/VRA/0014 – pigs

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

Cerenia – maropitant / maropitant citrate – EMEA/V/C/000106/VRA/0046 – dogs, cats

Variation requiring assessment: quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Fortekor Plus – pimobendane / benazepril hydrochloride – EMEA/V/C/002804/VRA/0024 – dogs

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

Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

ProZinc – insulin human - EMEA/V/C/002634/VRA/0030 – cats and dogs

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 product information

Increxxa – tulathromycin - EMA/VRA/0000231564 – cattle, pigs and sheep

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

Rapporteur: A.C. Golombiewski

Action: For adoption

List of questions, comments on the product information

Suvaxyn PRRS MLV - porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0013/G – pigs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Cardalis – benazepril hydrochloride / spironolactone - EMEA/V/C/002524/VRA/0015 – 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

Sileo – dexmedetomidine hydrochloride - EMEA/V/C/003764/VRA/0026 – dogs

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

Rapporteur: H. Bremer

Action: For adoption

List of questions, comments on the product information

Felpreva – tigolaner / emodepside / praziquantel - EMA/VRA/0000227250 – cats

Variation requiring assessment: quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

List of outstanding issues, included in the rapporteur assessment report

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

RESPIVAC aMPV – EMEA/V/C/006160/REC/001

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

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

6.11. Other working party and scientific group issues

Nomination to the new HMA/EMA Joint Network Data Steering Group

Action: For information

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

Revision of VICH GL8 on Stability testing for medicated premixes

VICH GL8(R) on Stability testing of for medicated premixes

Action: For adoption

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

11. CMDv

Report from the Chair of CMDv

Action: To note