4 October 2024
EMA/CVMP/425782/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 8-10 October 2024

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

8 October 2024, 09:00 – 10 October 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 8-10/10/2024. See 09/2024 CVMP minutes (to be published post 10/2024 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 04 Oct 24	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 under Regulation (EU) 2019/6

2.1.1. EMEA/V/C/006102/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006311/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006296/0000 – chickens

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/006230/0000 – cats

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

2.3.2. EMEA/V/C/006142/0000 – chickens

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

2.3.3. EMEA/V/C/006288/0000 – chickens

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

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

Action: For decision

Need for oral explanation

Action: For adoption

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

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

Action: For decision

Need for oral explanation

Action: For adoption

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/006499/0000 – dogs

Action: For adoption

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

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

Action: For adoption

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1 Bovilis Nasalgen-C – Bovine coronavirus vaccine, (live attenuated) - EMEA/V/C/005906/VRA/0002 – cattle

Variation requiring assessment: to add wording to the product information to indicate that Bovilis Nasalgen-C can be used during pregnancy.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2 Eluracat – capromorelin tartrate - EMEA/V/C/005948/VRA/0002/G – cats

Variation requiring assessment: to implement the outcome of the MAH's signal management process and to move a warning from special precautions section to contraindications.

Rapporteur: R. Carapeto García

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

No items

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

3.3.1. Rheumocam – meloxicam - EMEA/V/C/000121/VRA/0038 – cats

Variation requiring assessment: to add a new strength

Rapporteur: S. Louet, Co-Rapporteur: N.C. Kyvsgaard

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.3.2. 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 decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

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

3.4.1. Innovax-ND-H5 - Newcastle disease, avian influenza and Marek's disease vaccine (live recombinant) - EMEA/V/C/006362/VRA/0001 – chickens and chicken embryonated eggs

Variation requiring assessment: to fulfil two outstanding specific obligations for Innovax-ND-H5 as agreed during the granting of the marketing authorisation

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leitner

Action: For adoption

List of questions, comments on the product information

3.4.2. Porcilis ColiClos - *E. coli* and C. perfringens vaccine (inactivated) - EMEA/V/C/002011/VRA/0018/G – pigs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner, Co-Rapporteur: K. Lehmann

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

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

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

No items

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

No items

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

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

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 the AWP meeting held on 24-25 September 2024

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

6.3.1. Revision of the guideline on anticoccidials used for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a)

Action: For adoption

Guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances

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 26-27 September 2024

Action: For information

6.6.2. Concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations

Action: For adoption

6.6.3. NTWP Horizon scanning 2024

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V 24-25 September 2024 meeting

Action: For information

6.7.2. Verbal report on PhVWP-V Interested Parties meeting held on 25 September 2024

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (July and September 2024)

Action: For information

6.8.2. Q&A on Ph. Eur. general chapter 2.2.46 Chromatographic separation techniques

Action: For adoption

6.8.3. Draft guideline on stability testing for variations for VMPs

Presenter: M-H Sabinotto

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

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

Action: For information

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

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

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 a veterinary medicinal product for exotic animals

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

No items

10. Organisational and strategic matters

10.1. Stakeholders' consultation on the 3-year work plan for the veterinary domain (2025-2027)

Action: For adoption

Overview of comments

11. CMDv

No items

12. Legislation

12.1. Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets

Action: For adoption

Guideline and overview of comments

12.2. Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For adoption

Guideline and overview of comments

12.3. Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For adoption

Guideline and overview of comments

12.4. Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For adoption

Guideline and overview of comments

12.5. Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets

Action: For adoption

Guideline and overview of comments

12.6. QRD template update to v.9.1

Action: For adoption

QRD veterinary product-information ANNOTATED template version 9.1

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

Action: For discussion

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

12.8. 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 and from the secretariat

- assessment of non-immunological substances identified by aquaculture sector as important for the treatment of fish
- high-level assessment of other non-immunological substances
- list of pathogenic agents and reflections on inclusion of immunological substances

13. AOB

13.1. AOB

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Bovela – bovine viral diarrhoea vaccine (modified live) - EMA/VRA/0000224205 – cattle, sheep

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Enteroporc Coli AC – Neonatal piglet colibacillosis (recombinant, inactivated) and *Clostridium perfringens* vaccine (inactivated) - EMEA/V/C/005149/VRA/0006/G – pigs

Variation requiring assessment: quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Mometamax Ultra – gentamicin / posaconazole / mometasone furoate – EMEA/V/C/004987/VRA/0003 – dogs

Variation requiring assessment: to update the instructions for use in the product information

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion, CVMP assessment report, product information

EMEA/V/C/WS2667/G – Cortavance, Easotic – hydrocortisone aceponate, hydrocortisone aceponate / gentamicin – dogs

Variation requiring assessment: quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Poulvac Procerta HVT-IBD – live recombinant turkey herpes virus, strain HVT-IBD, expressing the VP2 protein of infectious bursal disease virus - EMEA/V/C/006000/VRA/0001/G – chickens and embryonated chicken eggs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Zycortal – desoxycortone pivalate - EMEA/V/C/003782/VRA/0014 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: H. Bergendahl

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

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

List of questions, comments on the product information

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

List of questions, comments on the product information

Sedadex – dexmedetomidine - EMA/VRA/0000224259 – dogs, cats

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

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

Variation requiring assessment: quality related changes

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

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

Variation requiring assessment

Rapporteur: A. Golombiewski

Action: For adoption

List of questions, included in the rapporteur assessment report

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

6.5. 3Rs Working Party (3RsWP)

Adopted Minutes of May 3RsWP plenary meeting held on 21-22 May 2024

Action: For information

Adopted Minutes of May 3RsWP plenary meeting held on 21-22 May 2024

Adopted agenda of September 3RsWP plenary meeting held on 21-22 September 2024

Action: for information

Adopted agenda of September 3RsWP plenary meeting held on 21-22 September 2024

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 endorsement for sign off at step 6 by the VICH Steering Committee.

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