10 February 2025
EMA/52364/2025 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 11-13 February 2025

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

11 February 2025, 09:00 – 13 February 2025, 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 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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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 11-13 February 2025. See 01/2025 CVMP minutes (to be published post 02/2025 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 07 Feb 25	10.00-13.00 (TBC)

1. Maximum residue limits

1.1. Opinions

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

Action: For adoption

CVMP opinion including EPMAR

Action: For information

Summary of opinion

1.2. Oral explanations

No items

1.3. List of outstanding issues

1.3.1. Substance – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues

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/005345/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: To note

Action: For information

Summary of opinion

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

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

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

2.3.1. EMEA/V/C/006442/0000 – chickens, embryonated chicken eggs

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/006356 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.3. EMEA/V/C/006439/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

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

Action: For decision

Need for oral explanation

Action: For adoption

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

2.4. List of questions

2.4.1. EMEA/V/C/006595/0000 – rabbits

Action: For adoption

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

2.5. Re-examinations of CVMP opinions

No items

2.6. Other issues

No items

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Innovax-ND-H5 - avian influenza 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

CVMP opinion, CVMP assessment report, product information

3.1.2. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. Simparica Trio – sarolaner / moxidectin / pyrantel embonate – EMA/VRA/0000240712 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one

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

Action: For adoption

CVMP opinion, assessment report, product information

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

No items

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

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/advice under Articles 141(1)(c), 141(1)(e) or 141(1)(i) of Regulation (EU) 2019/6

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

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

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

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)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.3.1. Revision of efficacy guidelines in line with the definitions in Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis and prophylaxis

Action: For adoption

- Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances; overview of comments received on the draft revised guideline during public consultation
- Revised guideline on the conduct of efficacy studies for intramammary products for use in cattle; overview of comments received on the draft revised guideline during public consultation

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP meeting

Action: For information

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 28-29 January 2025

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (December 2024 and January 2025)

Action: For information

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 7 February 2025

Action: For information

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

6.11.2. European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group

Verbal report on the ESUAvet WG meeting held on 6 and 7 February 2025

Action: For information

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.

7.5.1. EMEA/V/VAMF/00010

Action: For adoption

VAMF evaluation report and list of questions

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

No items

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 cats

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

10.3. Verbal report on Veterinary Domain meeting held on 21 January 2025

Action: For information

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 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 adoption

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

2. Marketing authorisations and extensions

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

EMEA/V/C/006499/0000 – dogs

Action: For decision

Request for an extension of clock stop

EMEA/V/C/006234/0000 – cattle, pigs, dogs, cats

Action: For information

Product information corrected following the omission of Annex II at opinion stage

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Fortekor Plus – pimobendan / 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

CVMP opinion, product information

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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, 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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: to align the product information with version 9.1 of the QRD template

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Ingelvac CircoFLEX vaccine – porcine circovirus vaccine (inactivated) - EMEA/V/C/000126/VRA/0040 – pigs

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

Rapporteur: F. Marsilio

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Prozinc – insulin human – EMEA/V/C/002634/VRA/0030 – cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

ReproCyc ParvoFLEX – porcine parvovirosis vaccine (inactivated) - EMEA/V/C/004858/VRA/0007 – pigs

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

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, comments on the product information

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

Newflend ND H9 – Newcastle disease and avian influenza vaccine (live, recombinant) - EMEA/V/C/005860/VRA/0003 – chickens

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

Rapporteur: J. Poot

Action: For adoption

List of questions, comments on the product information

Zycortal – desoxycortone pivalate- EMA/VRA/0000240475– dogs

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

Rapporteur: H. Bergendahl

Action: For adoption

List of questions, comments on the product information

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

6.5 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

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

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

12. Legislation