12 July 2024
EMA/329607/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting of 16-18 July 2024

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

16 July 2024, 09:00 – 18 July 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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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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 16-18/07/2024. See 06/2024 CVMP minutes (to be published post 07/2024 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 0B)	Mon 15 Jul 24	15.00-18.00 (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

1.4.1. Lidocaine – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: For adoption

Scientific overview and list of questions

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/0006254/0000 - dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006118/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006289/0000 – pigs

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

No items

2.3.1. EMEA/V/C/006102/0000 – 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/006296/0000 – chickens

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/006131/0000 – pigs

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/006306/0000 – chickens and chicken embryonated eggs

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/006336/0000 – pigs

Action: For adoption

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

2.4.2. EMEA/V/C/006358/0000 – 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

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Clomicalm – clomipramine hydrochloride - EMEA/V/C/000039/VRA/0042/G – dogs

Variation requiring assessment: to align the product information with the version 9.0 of the QRD template and to update the adverse events section due to the outcome of signal management.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. EMEA/V/C/WS2690 - Profender – cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Posatex – posaconazole / mometasone furoate / orbifloxacin - EMEA/V/C/000122/VRA/0031/G – 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, CVMP assessment report, product 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. 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.

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

Action: For adoption

List of questions, comments on the product information

3.4.2. 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 adoption

Scientific overview and 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. 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, embryonated chicken eggs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

Request for an extension of the clock-stop

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

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

5.2. 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. Other issues

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)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 25–26 June 2024

Action: For information

6.3. Efficacy Working Party (EWP-V)

6.3.1. Concept paper on the revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats

Action: For adoption

6.3.2. Concept paper on the revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees

Action: For adoption

6.3.3. Concept paper on the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products

Action: For adoption

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

No items

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 19 June and 9-10 July 2024 meetings

Action: For information

6.7.2. Revised VeDDRA documents

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (May and June 2024)

Action: For information

6.8.2. Draft guideline on development and manufacture of synthetic oligonucleotides

Action: For adoption

6.8.3. Q&A on co-processed excipients

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 15 July 2024

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 27-28 June 2024

Action: For information

6.10.2. Concept paper on the revision of the guideline on user safety for pharmaceutical veterinary medicinal products

Action: For adoption

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.

7.6.1. EMEA/V/VPTMF/0001

Action: For adoption

Assessment report and list of outstanding issues

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

8.3.1. EC mandate on the development of a harmonised tool for calculating human dietary exposure to residues from veterinary medicinal products, feed additives and pesticides

Action: For information

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. Verbal report on Veterinary Domain meeting held on 3 July 2024

Action: For information

10.6. Update on IRIS for core Regulatory Procedures

Action: For information

11. CMDv

No items

12. Legislation

12.2. Scientific advice on Article 115 (5) of Regulation (EU) 2019/6 as regards the 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

Verbal report from the Chair of the working group

Action: For adoption

Scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding the 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

12.3. 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

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

Introduction

i. Adoption of the updated agenda of June CVMP meeting

1. Maximum Residue Limits

1.6. Other issues

EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For decision

Request for an extension of clock stop

2. Marketing authorisations and extensions

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

EMEA/V/C/005993/0000 – dogs

Action: For decision

Request for an extension of clock stop

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

Action: For decision

Request for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Eluracat – capromorelin tartrate – EMEA/V/C/005948/VRA/0001 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Carapeto Garcia

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0018 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

WS2682 - Versican Plus DHPPi/L4R, Versican Plus Pi/L4, Versican Plus Pi/L4, Versican Plus Pi/L4R, Versican Plus L4 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

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

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bergendahl

Action: For adoption

List of questions

Locatim – immunoglobulins against *Escherichia coli F5* - EMEA/V/C/000041/VRA/0027– cattle

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

List of questions

Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) – EMEA/V/C/004276/VRA/0012/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions

Felpreva – tigolaner / emodepside / praziquantel - EMEA/V/C/005464/VRA/0008 – cats

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

Rapporteur: A. Golombiewski

Action: For adoption

List of questions, comments on the product information

Rheumocam – meloxicam - EMEA/V/C/000121/VRA/0039 – cats, dogs, cattle, pigs, horses

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

Inflacam – meloxicam - EMEA/V/C/002497/VRA/0030 – cats, dogs, cattle, pigs, horses

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

Mhyosphere PCV ID – mycoplasma hyopneumoniae and porcine circovirus vaccine (inactivated, recombinant) - EMEA/V/C/005272/VRA/0005/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions

WS2667 – Cortavance, Easotic – hydrocortisone aceponate; hydrocortisone aceponate/gentamicin – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

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

Bravecto – EMEA/V/C/002526/REC/023-025

Rapporteur: K. Boerkamp

Action: For endorsement

Rapporteur's assessment report

Rapporteur: F. Hasslung Wikström

Action: For endorsement

Rapporteur's assessment report

5. Post-authorisation issues for marketing authorisations

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

6. Working parties

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9.3. Regulatory matters

Invented names