17 May 2024
EMA/237161/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 21-23 May 2024

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

21 May 2024, 09:00 – 23 May 2024, 13:00 - Room 2C and virtual

Health & Safety Information Test

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 21-23 May 2024. See April 2024 CVMP minutes (to be published post May 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 17 May 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/006043/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/005989/0000 – 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/006234/0000 – cattle, pigs, dogs, cats

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/0006254/0000 - dogs

Action: For adoption

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

2.3.3. EMEA/V/C/005345/0000 – dogs

Action: For adoption

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

2.3.4. EMEA/V/C/006289/0000 – pigs

Action: For decision

Need for oral explanation

Action: For adoption

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

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

No items

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. Bluevac BTV - Bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3) - EMEA/V/C/000156/VRA/0012/G – cattle, sheep

Variation requiring assessment: efficacy and quality-related changes

Rapporteur: E. Werner, Co-Rapporteur: F. Marsilio

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

No items

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

3.4.1. 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 validation of 4 pharmacovigilance signals

Rapporteur: A. Golombiewski

Action: For adoption

List of questions, comments on the product information

3.4.2. Posatex – posaconazole / mometasone furoate / orbifloxacin - EMEA/V/C/000122/VRA/0031/G – dogs

Variation requiring assessment: to update the product information and 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

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

No items

4.7.1. Referrals and related procedures under Regulation (EU) 2019/6

4.7.1. Article 130(4) recommendation: direct animal healthcare professional communication (DaHPC) and topic-specific communication plan: Kexxtone 32.4 g continuous-release intraruminal device for cattle – monensin – EMA/V/A/150

Scope: benefit-risk balance

Rapporteur: C. Muñoz Madero, Co-rapporteur: J.G. Beechinor

Action: For endorsement

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)

6.1.1. Election of the Vice-chair of AWP

Action: For decision

Nomination(s) received:

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 24-25 April 2024

Action: For information

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 meeting held on 25 April 2024

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings

Action: For information

6.8.2. QWP 3-year workplan 2025-2027

Action: For information

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 17 May 2024

Action: For information

6.10. Safety Working Party (SWP-V)

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

No items

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

8.1.4. Nomination of EU speakers for VICH Conference in November 2024

Action: For endorsement

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. Verbal report on Veterinary Domain meeting held on 8 May 2024

Action: For information

10.2. Agenda of the CVMP Interested Parties meeting

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 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

12.2. 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

13.1. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Isemid – torasemide – EMEA/V/C/004345/VRA/0006 – 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

Virbagen Omega – feline interferon omega (recombinant) – EMEA/V/C/000061/VRA/0011 – dogs, cats

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

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Forceris – toltrazuril / iron(iii) ion - EMEA/V/C/004329/VRA/0007 – pigs (piglets)

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

Porcilis AR-T DF – porcine progressive atrophic rhinitis vaccine (inactivated) - EMEA/V/C/000055/VRA/0019 – pigs (sows), pigs (sows, nullipar)

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

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Contacera – meloxicam - EMEA/V/C/002612/VRA/0017 – horses, cattle, pigs

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Vectra 3D – dinotefuran / pyriproxyfen / permethrin – EMEA/V/C/002555/VRA/0025 – dogs

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

Vectra Felis – dinotefuran / pyriproxyfen – EMEA/V/C/002746/VRA/0020 - cats

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

Rabitec – rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0012 – foxes and raccoon dogs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

MS-H Vaccine – Mycoplasma synoviae (live) - EMEA/V/C/000161/VRA/0020 – chickens

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Circovac – Porcine circovirus vaccine (inactivated) - EMEA/V/C/000114/VRA/0021 – 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

Nobivac LoVo L4 – canine *Leptospira* vaccine - EMEA/V/C/005628/VRA/0001 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: E. Dewaele

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Locatim – immunoglobulins against Escherichia coli F5 antigen, Bovine - EMEA/V/C/000041/VRA/0026 – cattle (newborn calves)

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Tulissin – tulathromycin - EMEA/V/C/005073/VRA/0010/G – cattle, pigs, sheep

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Felpreva – tigolaner, emodepside, praziquantel - EMEA/V/C/005464/VRA/0007 – cats

Variation requiring assessment: quality-related changes

Rapporteur: C. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.4. List of questions 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

List of questions

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

List of questions

Osurnia – terbinafine / florfenicol / betamethasone acetate - EMEA/V/C/003753/VRA/0027 – 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

Nobilis IB Primo QX – avian infectious bronchitis vaccine (live) - EMEA/V/C/002802/VRA/0012/G - chickens

Variation requiring assessment: quality-related changes

Rapporteur: C. Miras

Action: For adoption

Rapporteur's assessment report including list of questions

Action: For endorsement

Solensia – frunevetmab – EMEA/V/C/005179/VRA/0009/G – cats

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

Rapporteur's assessment report including list of questions

Meloxoral - EMA/VRA/0000174596 – dogs, cats

Variation requiring assessment:quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

Rapporteur's assessment report including list of questions

3.6 Other issues under Regulation (EU) 2019/6

Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMEA/V/C/004846/VRA/0015/G – dogs

Rapporteur: R. Breathnach

Action: For endorsement

Rapporteur's 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

6.5. 3Rs Working Party (3RsWP)

6.8 Quality Working Party (QWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL23 (R2) Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing

Action: For endorsement

9.3. Regulatory matters

Invented names

12. Legislation

Publication in the Official Journal of the EU the DA on oral administration

Commission Delegated Regulation (EU) 2024/1159 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals has been published today in the

(https://eur-lex.europa.eu/eli/reg_del/2024/1159/oj)

Action: For information