9 February 2024
EMA/63473/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 13-15 February 2024

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

Tuesday 13 February 2024, 09:00 – Thursday 15 February 2024, 13:00 – virtual and room 2C

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).

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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 13-15 February 2024. See February 2024 CVMP minutes (to be published post March 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

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/006143/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006103/0000 – dogs, cattle, cats

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006175/0000 – cattle

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/005989/0000 – chickens

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/006160/0000 – turkeys

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/006043/0000 – chickens

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/006102/0000 – dogs

Action: For adoption

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

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

Action: For adoption

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

2.4.3. EMEA/V/C/006356 – 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. Strangvac – Recombinant protein CCE from *Streptococcus equi*, Recombinant protein Eq85 from *Streptococcus equi*, Recombinant protein IdeE from *Streptococcus equi* – EMEA/V/C/005309/VRA/0006 - horses

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

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2. Syvazul BTV – Bluetongue virus vaccine (inactivated) - EMEA/V/C/004611/VRA/0008 – sheep, cattle

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.1.3. EMEA/V/C/WS2636 – Credelio, AdTab – lotinaner – 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 of AdTab and Credelio

Action: For endorsement

Rapporteur's assessment report

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

No items

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

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

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

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)

No items

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on the PhVWP-V meeting held on 23-24 January 2024

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings

Action: For information

6.8.2. Guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water - draft annex on compatibility studies between veterinary medicinal products and biocidal products

Action: For adoption

Draft Annex on compatibility studies between veterinary medicinal products and biocidal products; overview of comments received during the public consultation

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 9 February 2024

Action: For information

6.10. Safety Working Party (SWP-V)

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

No items

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

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 horses

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. Verbal report on Veterinary Domain meeting held on 1 February 2024

Presenter: F. Hasslung Wikström

Action: For information

10.2. CVMP Interested Parties meeting

Action: For decision

11. CMDv

11.1. Verbal report from CMDv Chair

Action: For information

Draft agenda of the CMDv meeting to be held on 15-16 February 2024; minutes of the CMDv meeting held on 18-19 January 2024

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

2. Marketing authorisations and extensions

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

EMEA/V/C/006235/0000 – dogs

Action: For decision

Request for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Daxocox – enflicoxib - EMEA/V/C/005354/VRA/0001 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Gumbohatch – Avian infectious bursal disease vaccine (live) - EMEA/V/C/000083/VRA/0011/G – chickens

Variation requiring assessment: quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2564/G - Bovela - bovine viral diarrhoea vaccine (modified live) - cattle

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Syvazul BTV – Bluetongue virus vaccine (inactivated, multistrain) - EMEA/V/C/004611/VRA/0007 – sheep, cattle

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Librela – bedinvetmab - EMEA/V/C/005180/VRA/0010/G – dogs

Variation requiring assessment: quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Incurin – estriol - EMEA/V/C/000047/VRA/0017 – dogs

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

EMEA/V/C/WS2586 - Purevax RCP, Purevax RCP FeLV – sheep, cattle

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Draxxin – tulathromycin – EMEA/V/C/000077/VRA/0050 – cattle, pigs, sheep

Variation requiring assessment: to align the product information with version 9.0 of the QRD template. In addition, the MAH took the opportunity to correct the name of the marketing authorisation holder in the product information.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Lydaxx – tulathromycin - EMEA/V/C/005199/VRA/0006 – cattle, pigs, sheep

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

Rapporteur's assessment report

Tulissin – tulathromycin – EMEA/V/C/005073/VRA/0009 – cattle, pigs, sheep

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

Ovugel – triptorelin acetate - EMEA/V/C/005219/VRA/0001 - pigs

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

Rapporteur's assessment report

Increxxa – tulathromycin – EMEA/V/C/005305/VRA/0006 – cattle, pig, sheep

Variation requiring assessment: quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Aivlosin – tylvalosin - EMEA/V/C/000083/VRA/0096 – pigs

Variation requiring assessment: quality-related changes

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Suprelorin – deslorelin acetate - EMEA/V/C/000083/VRA/0040 – dogs, cats

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

Profender – praziquantel/emodepside - EMEA/V/C/000097/VRA/0054/G – dogs, cats

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

MS-H vaccine - *Mycoplasma synoviae* (live)– EMEA/V/C/000161/VRA/0019 – chickens

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

Rapporteur: F. Klein

Action: For adoption

List of outstanding issues, comments on the product information

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

Apoquel – oclacitinib maleate – EMEA/V/C/002688/VRA/0027 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

Convenia – cefovecin – EMEA/V/C/000098/VRA/0038 – cats, dogs

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

Evant – *Eimeria acervulina, Eimeria maxima, Eimeria mitis, Eimeria praecox, Eimeria tenella* (vaccine live) – EMEA/V/C/004902/VRA/0004 – chickens

Variation requiring assessment: quality-related changes

Rapporteur: G. Beechinor

Action: For adoption

List of questions

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

List of questions, comments on the product information

Arti-Cell Forte – allogeneic equine peripheral blood-derived chondrogenic induced mesenchymal stem cells - EMEA/V/C/004727/VRA/0014 – horses

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

Rapporteur: F. Hasslung Wikström

Action: For adoption

List of questions, comments on the product information

Cortavance – hydrocortisone aceponate - EMEA/V/C/000110/VRA/0016 – 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

Syvazul BTV – Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 3) - EMEA/V/C/004611/VRA/0009 – sheep, cattle

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

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

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

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

List of questions, comments on the product information

UpCard – torasemide - EMEA/V/C/003836/VRA/0009 – 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

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

List of questions, comments on the product information

Tessie – tasipimidine - EMEA/V/C/005427/VRA/0002 – dogs

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

Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

Advocate – imidacloprid /moxidectin - EMEA/V/C/000076/VRA/0049 – cats, ferrets, dogs

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

Rapporteur: M. Leppänen

Action: For adoption

List of questions, comments on the product information

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

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

Neoleish – Canine leishmaniasis vaccine (recombinant DNA plasmid) - EMEA/V/C/005538/VRA/0001/G – dogs

Variation requiring assessment: quality-related changes and to align the product information to the latest QRD version 9.0

Rapporteur: C. Miras

Action: For adoption

List of questions

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

List of questions, comments on the product information

Coxevac – *Coxiella burnetii* vaccine - EMEA/V/C/000155/VRA/0016/G – cattle, goats, sheep

Variation requiring assessment: quality-related changes

Rapporteur: C. Miras

Action: For adoption

List of questions

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

Neptra – florfenicol, terbinafine hydrochloride, mometasone furoate - EMEA/V/C/004735/VRA/0008 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For information

Letter of withdrawal of the variation

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

5.5. Other issues

6. Working parties

6.5. 3Rs Working Party (3RsWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL61 on Pharmaceutical Development

Following sign-off by the Expert Working Group CVMP is now asked to endorse sign-off at the Steering Committee level (step 3)

Action: For endorsement

VICH GL22(R) on reproduction toxicity

Following sign-off at the Steering Committee level (step 3), the draft guideline is now presented for sign off for public consultation (step 4)

Action: For adoption

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

9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

Transfer of (co-)rapporteurships responsibilities

Action: For decision

T-M. Muhonen to K. Lehmann and M. Leppänen

M. Leppänen to K. Lehmann

9.3. Regulatory matters

Invented names

Annex to 13-15 February 2024 CVMP Agenda

CVMP Working Parties dates 2024

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	3RsWP
Feb 2024	13-15			20-21			21	12-13	9		
Mar 2024	12-14	5-6	18-19				26-27	11-13	8	21-22	
Apr 2024	16-18						25	15-16	12		
May 2024	21-23	28-29		28-29			28-29	23-24	17		