1 December 2023
EMA/550532/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 5-7 December 2023

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

5 December 2023, 09:00 – 7 December 2023, 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 5-7 December 2023. See December 2023 CVMP minutes (to be published post January 2023 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

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

1. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

No items

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/006175/0000 – cattle

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.2. EMEA/V/C/005887/0000 – chickens

Action: For decision

Need for an oral explanation

Action: For adoption

CVMP 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. Bravecto – fluralaner – EMA/V/C/002526/VRA/0059 – dogs

Variation requiring assessment: to add a new pharmaceutical form for dogs

Rapporteur: K. Boerkamp, Co-Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.2. Solensia – frunevetmab - EMEA/V/C/000047/VRA/0008 – cats

Variation requiring assessment: to implement the outcome of the MAH's signal management process. In addition, the MAH included some minor editorial changes in SPC section 10 and PL sections 7 and 15 linked to the QRD template version 9.0.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Frontpro – afoxolaner - EMEA/V/C/005126/VRA/0014/G - dogs

Variation requiring assessment: to add a new therapeutic indication, to update SPC section 3.7, and to align the product information with version 9.0 of the QRD template.

Rapporteur: K. Boerkamp

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. 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

List of outstanding issues, product information

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

3.4.1. Draxxin – tulathromycin – EMEA/V/C/00077/VRA/00050 – 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

List of questions, comments on the product information

3.4.2. 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

List of questions, comments on the product information

3.4.3. 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. In addition, the MAH took the opportunity to correct the name of the manufacturer responsible for batch release

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions, comments on the product information

3.4.4. Aivlosin – tylvalosin - EMEA/V/C/000083/VRA/0094/G – chickens, pheasants, turkeys, pigs

Variation requiring assessment: to add information to section 4.7 of the SPC and section 12 of the package leaflet on use during pregnancy, lactation or lay and to align the product information with version 9.0 of the QRD template.

Rapporteur: H. Bremer

Action: For adoption

List of questions, comments on the product information

3.4.5. 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

List of questions

3.4.6. Prevexxion RN+HVT+IBD – infectious bursal disease and Marek's disease vaccine (live recombinant) – EMEA/V/C/005057/VRA/0009 – chickens

Variation requiring assessment: to add a new route of administration

Rapporteur: F. Klein, Co-rapporteur: E. Werner

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

4.4.1. Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs – procaine benzylpenicillin – EMEA/V/A/149

Scope: environmental risk assessment

Rapporteur: S. Louet, Co-Rapporteur: P. McNeill

Action: For adoption

CVMP reply to EC; CVMP assessment report

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 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

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)

6.1.1. Verbal report on the AWP meeting held on 28-29 November 2023

Action: For information

6.1.2. Draft AWP Work plan 2024

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Election of the Vice-Chair of the ERAWP

Action: For decision

Nomination(s) received:

B. Kolar

6.3. Efficacy Working Party (EWP-V)

6.3.1. Guideline on the conduct of pharmacokinetic studies in target animal species

Action: For adoption

Revised guideline on the conduct of pharmacokinetic studies in target animal species; overview of comments received on the guideline on the conduct of pharmacokinetic studies in target animal species

6.3.3. EWP-V work plan for 2024

Action: For discussion

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 14-15 November 2023

Action: For information

6.4.2. IWP-V work plan for 2024

Action: For discussion

6.4.3. Guideline on plasmid DNA vaccines for veterinary use

Action: For discussion

Draft guideline on plasmid DNA vaccines for veterinary use, overview of comments received during public consultation

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 24 November 2023

Action: For information

6.6.2. NTWP work plan 2024

Action: For discussion

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 28-29 November 2023

Action: For information

6.7.2. Revised Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD)

Action: For adoption

6.7.3 Revised questions and answers (Q&A) on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL))

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meeting held on 30-31 October 2023

Action: For information

6.8.3. QWP work plan 2024-2026

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Election of new members of SAWP-V

Action: For decision

Nomination(s) received:

E. den Hertog, M. Leitner, R. Belmar, F. Moya, P. McNeill, T. Neumann, C. Kühne, H. Ait Lbacha,

K. Just Andersen, F. Alleman, V. Devesa

6.9.2. Verbal report on SAWP-V meeting held on 1 December 2023

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 16 November 2023

Action: For information

6.10.3. SWP-V work plan for 2024

Action: For discussion

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

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Questionnaire - review and adjustment of dosage regimens

Action: For adoption

7.3.2. Thirteenth ESVAC report: Sales of veterinary antimicrobial agents in 31 European countries in 2022. Trends from 2010 to 2022

Action: For information

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.

7.7. Other issues

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

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. VICH GL22 on reproduction toxicity

Action: For endorsement

Updated GL22 for endorsement for sign off at EWG level

8.1.5. Feedback from VICH Steering Committee and Forum meetings of 13-16 November 2023

Action: For information

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

No items

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. Draft CVMP work plan for 2024

Action: For adoption

CVMP work plan for 2024

11. CMDv

11.1. Verbal report from CMDv Chair on the CMDv meetings held on 5-6 October 2023 and 9-10 November 2023

Action: For information

Draft agenda of the CMDv meeting to be held on 7-8 December 2023; minutes of the CMDv meeting held on 9-10 November 2023

12. Legislation

12.1. Scientific advice on the implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the GMP for veterinary medicinal products and active substances used as starting materials

Action: For adoption

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

Action: For adoption

12.3. 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

12.4. 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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Zactran – gamithromycin - EMEA/V/C/000129/VRA/0056/G – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Rapporteur's assessment report

Broadline – fipronil, (s)-methoprene, eprinomectin, praziquantel - EMEA/V/C/002700/VRA/0035 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Rapporteur's assessment report

EMEA/V/C/WS2559 – Bovilis Nasalgen-C, Nobilis IB 4-91, Porcilis AR-T DF, Nobilis IB Primo QX, Nobivac DP Plus, Porcilis ColiClos, Nobivac Bb, Nobivac Myxo-RHD Plus – cattle, chickens, pigs, dogs, rabbits

Variation requiring assessment: Quality-related changes

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Tulinovet – tulathromycin – EMEA/V/C/005076/VRA/0005/G – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Vectra 3D – dinotefuran / pyriproxyfen / permethrin - EMEA/V/C/002555/VRA/0024 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Solensia - frunevetmab – EMEA/V/C/005179/VRA/0007/G – cats

Variation requiring assessment: Quality related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, comments on the product information

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2512 - Arti-Cell Forte, RenuTend – tenogenic primed equine peripheral blood-derived mesenchymal stem cells; chondrogenic induced equine peripheral blood-derived mesenchymal stem cells - horses

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP Opinion

Action: For endorsement

Rapporteur's assessment report

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

Aivlosin – tylvalosin - EMEA/V/C/00083/VRA/0095 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: H. Bremer

Action: For adoption

List of questions

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

List of questions, comments on the product information

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

List of questions, product information

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

List of questions

Zulvac BTV - Bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3) – EMEA/V/C/004185/VRA/0006 – sheep, cattle

Variation requiring assessment: to align the product information with version 9.0 of the QRD template. Additionally, the MAH took the opportunity to process editorial changes and make correction in the name of the Marketing Authorisation Holder (from Zoetis Belgium S.A. to Zoetis Belgium).

Rapporteur: F. Klein

Action: For adoption

List of questions, comments on the product information

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

List of questions

Eurican Herpes 205 – Canine herpes vaccine (inactivated subunit) - EMEA/V/C/000059/VRA/0032 – dogs

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

Rapporteur: J. G. Beechinor

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

6.5 CVMP/CHMP Working Party on the application of the 3Rs (3RsWP)

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

10. Organisational and strategic matters

Regulatory Procedure Management for Product lifecycle management product overview for Network

Action: For information

Annex to 5-7 December 2023 CVMP Agenda

CVMP Working Parties dates 2023-2024

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	3RsWP
Dec 2023	5-7						19	4-6	1		
Jan 2024	16-18						23-24	15-16	12		
Feb 2024	13-15			20-21			21	12-13	9	21-22	
Mar 2024	12-14	5-6	20-21				26-27	11-13	8		
Apr 2024	16-18						25	15-16	12		