4 November 2022
EMA/866843/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 8-10 November 2022

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

8 November 2022, 09:00 – 10 November 2022, 13:00 - Room 1D 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

Table of contents

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 8-10 November 2022. See November 2022 CVMP minutes (to be published post December 2022 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)	Mon 7 Nov 2022	10.00 - 13.00 CET

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 and extensions

2.1. Opinions under Regulation (EU) 2019/6

No items

2.1. Opinions under Regulation (EC) No 726/2004

2.1.1. EMEA/V/C/005538/0000 – dogs

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

2.2. Oral explanations under Regulation (EC) No 726/2004

No items

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

No items

2.3. List of outstanding issues under Regulation (EC) No 726/2004

2.3.1 Coxevac – Coxiella burnetii vaccine (inactivated) - EMEA/V/C/000155/X/0015 - cattle, goat

Rapporteur: C. Miras, Co-Rapporteur: C. Muñoz Madero

Action: For decision

Need for 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

2.4.1. EMEA/V/C/006117/0000 – dogs

Action: For adoption

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

2.4. List of questions under Regulation (EC) No 726/2004

No items

2.5. Re-examinations of CVMP opinions under Regulation (EU) 2019/6

No items

2.5. Re-examinations of CVMP opinions under Regulation (EC) No 726/2004

No items

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

No items

2.6. Other issues under Regulation (EC) No 726/2004

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Rabitec – Rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0010/G – foxes and raccoon dogs

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

Rapporteur: E. Werner

Action: For adoption

CVMP opinion CVMP assessment report, product information

3.1.2. Versican Plus Pi/L4R (EMEA/V/C/003682/VRA/0018) – dogs

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

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Versican Plus DHPPi/L4R (EMEA/V/C/002759/VRA/0019) – dogs

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

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.4. ProteqFlu – Equine influenza vaccine (live recombinant) – EMEA/V/C/000073/VRA/0025 – horses

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

3.1.5. ProteqFlu-Te - Equine influenza vaccine (live recombinant) and tetanus vaccine - EMEA/V/C/000074/VRA/0033 - horses

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

3.1.6. Apoquel – Oclacitinib maleate - EMEA/V/C/002688/VRA/0024 – 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

3.1.7. Semintra – Telmisartan – EMEA/V/C/002436/VRA/0016/G – cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD templates/ Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1. Opinions under Commission Regulation (EC) No 1234/2008

No items

3.2. Oral explanations under Regulation (EU) 2019/6

No items

3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

No items

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

3.3.1. Zeleris – Florfenicol/meloxicam - EMEA/V/C/004099/VRA/0005/G – cattle

Variation requiring assessment: to add a new therapeutic indication and to align the product information with version 9.0 of the QRD template

Rapporteur: A. Golombiewski, Co-Rapporteur: F. Božić

Action: For adoption

List of outstanding issues, comments on the product information

3.3.2. Suvaxyn PRRS MLV – Porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0006/G – pigs

Variation requiring assessment: efficacy-related changes

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

Action: For adoption

List of outstanding issues, comments on the product information

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

No items

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

3.4.1. Bravecto Plus – Fluralaner/moxidectin – EMEA/V/C/004440/VRA/0023/G – cats

Variation requiring assessment: to add a new therapeutic indication and to align the product information with version 9.0 of the QRD template

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

Action: For adoption

List of questions, comments on the product information

3.4.2. Librela – Bedinvetmab – EMEA/V/C/005180/VRA/0005/G – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to process the changes following assessment of the PSUR

Rapporteur: F. Hasslung Wikström

Action: For adoption

List of questions, comments on the product information

3.4.3. Innovax-ND-IBD - Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant) - (EMEA/V/C/004422/VRA/0010) – chickens and embryonated chicken eggs

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

3.4.4. Trocoxil – Mavacoxib - EMEA/V/C/000132/VRA/0021 – dogs

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

3.4.5. Simparica Trio – Sarolaner/moxidectin/pyrantel embonate - EMEA/V/C/004846/VRA/0010 – dogs

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

Rapporteur: R. Breathnach

Action: For adoption

List of questions, comments on the product information

3.4.6. BTVPUR – Bluetongue virus vaccine (inactivated) - EMEA/V/C/002231/VRA/0026/G – 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

3.4.7. Aservo EquiHaler – Ciclesonide - EMEA/V/C/004991/VRA/0007/G – horses

Variation requiring assessment: update the package leaflet following the outcome of the CVMP assessment of the 3rd PSUR (var. G.I.15.z), and align the product information with version 9.0 of the QRD template (var. G.I.18)

Rapporteur: K. Baptiste

Action: For adoption

List of questions, comments on the product information

3.4. List of questions under Commission Regulation (EC) No 1234/2008

No items

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

No items

3.5. Re-examinations of CVMP opinions on variations under Commission Regulation (EU) No 726/2004

No items

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

No items

3.6. Other issues under Commission Regulation (EC) No 1234/2008

No items

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

4.1.1. Veterinary medicinal products containing N-methyl pyrrolidone as an excipient – EMEA/V/A/146

Scope: User/ target animal safety

Rapporteur: A. Golombiewski, Co-Rapporteur: C. Bergman

Action: For decision

Need for outstanding issues

Action: For discussion

Rapporteur's assessment report including co-rapporteur's critique

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

5.1.1. Solensia - Frunevetmab – EMEA/V/C/005197 - cats

Recommendation for regulatory actions as an outcome of signal detection activities

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.2. Equilis Prequenza Te - Equine influenza (inactivated) and tetanus vaccine – EMEA/V/C/000095 - horses

Recommendation for regulatory actions as an outcome of signal detection activities

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.3. Equilis Prequenza - Equine influenza vaccine (inactivated) – EMEA/V/C/000094 - horses

Recommendation for regulatory actions as an outcome of signal detection activities

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.4. Equilis Te - Tetanus vaccine for horses – EMEA/V/C/000093 - horses

Recommendation for regulatory actions as an outcome of signal detection activities

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.5. Nobivac DP Plus - Canine distemper vaccine (live, attenuated) and canine parvovirus vaccine (live) – EMEA/V/C/005251 - dogs

Recommendation for regulatory actions as an outcome of signal detection activities

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

No items

5.2. Post-authorisation measures under Regulation (EU) 2019/6

No items

5.2. Post-authorisation measures under Regulation (EC) No 726/2004

No items

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

No items

5.3. Supervision and sanctions under Regulation (EC) No 726/2004

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)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

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

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP-V)

No items

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

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

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

8.1.1. VICH Guideline on GMP for active pharmaceutical ingredients

Action: For endorsement

Draft Guideline on GMP for active pharmaceutical ingredients in VMPs

8.1.2. Concept paper proposing development of a Global Regulatory Dossier Format for VMPs

Action: For endorsement

Concept paper for a Global Regulatory Dossier Framework for VMPs

8.1.3. VICH Steering Committee and VICH Outreach Forum meetings

Action: For information

8.2. Codex Alimentarius

8.2.1. Preparation for 26th CCRVDF meeting, scheduled for 12-17 February 2023

Action: For discussion

8.3. Other EU bodies and international organisations

8.3.1. Development of a harmonised approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides in food of animal origin

Action: For discussion

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

9.2. 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. Veterinary Domain verbal report

Verbal report from the chair of the Veterinary Domain on the meeting held on 27 October 2022

Action: For information

10.2. CVMP Interested Parties meeting

Action: For decision

10.3. CVMP work plan for 2023

Action: For discussion

CVMP work plan for 2023

10.4. 2nd Veterinary Big Data Stakeholder Forum

Action: For information

11. CMDv

11.1. Verbal report from CMDv Chair

Verbal report from the CMDv chair on the CMDv meetings held on 8-9 September 2022 and 6-7 October 2022

Action: For information

12. Legislation

12.1. Draft reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations

Action: For adoption

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

1. Maximum Residue Limits

1.6. Other issues

Substance – fin fish

Action: For information

Letter of withdrawal of application

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

EMEA/V/C/xxxx/WS2281 - Porcilis PCV M Hyo – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Simparica Trio – Sarolaner / moxidectin / pyrantel embonate - EMEA/V/C/004846/VRA/0011 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Lydaxx – Tulathromycin - EMEA/V/C/005199/VRA/0003 – cattle, pig, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Lydaxx – Tulathromycin - EMEA/V/C/005199/VRA/0004 – cattle, pig, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Librela – bedinvetmab - EMEA/V/C/005180/VRA/0006 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Onsior – robenacoxib - EMEA/V/C/000127/VRA/0034 – dogs and cats

Variation requiring assessment: Quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Convenia – cefovecin - EMEA/V/C/000098/VRA/0037 – dogs and cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Simparica Trio – sarolaner/moxidectin/pyrantel embonate - EMEA/V/C/004846/VRA/0008 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Rhiniseng – Porcine progressive atrophic rhinitis vaccine (inactivated) – EMEA/V/C/000160/VRA/0012 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

EMEA/V/C/xxxx/WS2286 - Purevax RCP FeLV/Purevax RCP – cats

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

List of questions, comments on the product information of Purevax RCP and Purevax RCP FeLV

Halocur – halofuginone lactate - EMEA/V/C/000040/VRA/0017 – calves

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

EMEA/V/C/xxxx/WS2330 - Versican Plus Pi/L4R; Versican Plus Pi/L4; Versican Plus DHPPi/L4; Versican Plus DHPPi/L4R; Versican Plus L4 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

Rapporteur's assessment report including list of questions

EMEA/V/C/xxxx/WS2316/G - Vectormune FP ILT; Vectormune FP ILT + AE – chickens

Variation requiring assessment: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

Rapporteur's assessment report including list of questions

Syvazul BTV – Bluetongue virus vaccine (inactivated) – EMEA/V/C/004611/VRA/0005/G – sheep, cattle

Variation requiring assessment: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions

Suvaxyn PRRS MLV - Porcine respiratory and reproductive syndrome virus vaccine (live) EMEA/V/C/004276/VRA/0007 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

Mhyosphere PCV ID – Mycoplasma hyopneumoniae and porcine circovirus vaccine (inactivated, recombinant) – EMEA/V/C/005272/VRA/0002 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

3.6 Other issues under Regulation (EU) 2019/6

3.6.1 Rabitec – rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0009 – foxes and raccoon dogs

Rapporteur: E. Werner

Action: For information

Letter of withdrawal from the applicant

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

CircoMax Myco – REC 002.6

Rapporteur: N. C. Kyvsgaard, Co-Rapporteur: P. Pasquali

Action: For adoption

Rapporteur's assessment report

6. Working parties

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

7. Other scientific matters

7.4 Other scientific matters for PhV

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

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

9.3. Regulatory matters

Annex to 8-10 November 2022 CVMP Agenda

CVMP Working Parties dates 2022-2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Nov 2022	8-10	22-23			21-22	14	29-30	21-23	7	17-18	
Dec 2022	6-8								5		
Jan 2023	17-19						24-25		13		
Feb 2023	14-16			21-22		23	22		13		28
Mar 2023	21-23	14-15	29-30				28-29	6-8	20		1