10 February 2023
EMA/68188/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 14-16 February 2023

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

14 February 2023, 09:00 – 16 February 2023, 12:00 - 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).

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iii. Declaration of contacts between members and companies with regard to points on the agenda.

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Scientific Advice Working Party (virtual)	Fri 10 Feb 23	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

1.4.1. Substance – EMEA/V/MRL/003420/EXTN/0004 – chicken

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 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/005906/0000 – cattle

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. Coxevac – *Coxiella burnetii* vaccine (inactivated) - EMEA/V/C/000155/X/0015 - cattle, goats

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/005905/0000 - chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.4. EMA/V/C/005944/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.5. EMEA/V/C/006117/0000 – 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

No items

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

2.4.1. EMEA/V/C/006143/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

2.4.2. EMEA/V/C/006146/0000 – chickens

Action: For adoption

CVMP 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. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.4. Lotilaner Elanco – lotilaner - EMEA/V/C/006030/VRA/0001 – dogs, cats

Variation requiring assessment: to change the legal status

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsár

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.5. 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 update the product information following the outcome of the CVMP assessment on the PSUR

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.6. Gumbohatch - EMEA/V/C/004967/VRA/0008/G – chickens

Grouped variation requiring assessment including the alignment of the product information with version 9.0 of the QRD template

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

Rapporteur's assessment report

3.1.7. BTVPUR – bluetongue virus vaccine (inactivated) - EMEA/V/C/002231/VRA/0026/G – sheep and cattle

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to amend SPC section 3.6 and PL section 7 as recommended by the PhVWP-V CAPs surveillance

Rapporteur: C. Muñoz Madero

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. Melovem – meloxicam – EMEA/V/C/00152/VRA/0015 – horses

Variation requiring assessment: Quality related changes

Rapporteur: R. Breathnach, Co-rapporteur: N. C. Kyvsgaard

Action: For adoption

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

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

No items

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

3.4.1. Cerenia – maropitant - EMEA/V/C/000106/VRA/0043 – 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

3.4.2. EMEA/V/C/WS2395 – Suiseng Diff/A – *Clostridioides difficile* and *Clostridium perfringens* vaccine (inactivated) – pigs

Variation requiring assessment: Efficacy-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions, comments on the product information

3.4.3. EMEA/V/C/WS2386 – Vaxxitek HVT+IBD, Prevexxion RN+HVT+IBD, Prevexxion RN - chickens

Variation requiring assessment: Efficacy-related changes

Rapporteur: B. Urbain, Co-Rapporteur: E. Werner

Action: For adoption

List of questions

3.4.4. Proteq West Nile – West Nile fever vaccine (live recombinant) – EMEA/V/C/002005/VRA/0018/G – horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to update the product information as outcome of signal detection activities

Rapporteur: C. Miras

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 Regulation (EC) 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

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

4.7.1. Referrals under Regulation (EU) 2019/6

No items

4.7.2. Referrals under Article 33(4) of Directive 2001/82/EC

4.7.2.1. Catophos 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats – EMEA/V/A/147

Scope: Bioequivalence

Rapporteur: A. Golombiewski, Co-Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP assessment report

4.7.2.2. Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats – EMEA/V/A/148

Scope: Bioequivalence

Rapporteur: A. Golombiewski, Co-Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP assessment report

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

No items

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

No items

5.2. 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)

No items

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)

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

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

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

8.1.1. Draft guideline on Good manufacturing practice guide for active pharmaceutical ingredients used in VMPs

Action: For information

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

No items

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 2 February 2023

Action: For information

Agenda of the meeting held on 2 February 2023 and minutes of the meeting held on 27 October 2022

11. CMDv

No items

12. Legislation

12.1. Article 115(5) of Regulation (EU) 2019/6 - request from the EC on support of the revision of the implementing act for the establishment of a list of substances which are essential for the treatment of equine species

Action: For adoption

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/006103/0000 – dogs, cattle, cats

Action: For adoption

Request for an extension of the clock stop

EMEA/V/C/005948/0000 – cats

Action: For adoption

Request for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

EMEA/V/C/WS2286 - Purevax RCP FeLV; Purevax RCP - cats

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information of Purevax RCP and Purevax RCP FeLV

Action: For endorsement

Rapporteur's assessment report

Action: For information

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: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Procox – toltrazuril/emodepside - EMEA/V/C/002006/VRA/0032 – dogs

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

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Librela – bedinvetmab - EMEA/V/C/005180/VRA/0004/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Naxcel – ceftiofur - EMEA/V/C/000079/VRA/0042 – horses, cattle, pigs

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Suprelorin – Deslorelin acetate - EMEA/V/C/000109/VRA/0039 – ferrets, dogs, cats

Variation requiring assessment: Quality-related changes

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Equip WNV – West Nile fever vaccine (inactivated) - EMEA/V/C/000137/VRA/0029 – horses

Variation requiring assessment: Quality-related changes

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Equip WNV – West Nile fever vaccine (inactivated) - EMEA/V/C/000137/VRA/0030 - horses

Variation requiring assessment: Quality-related changes

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Galliprant – grapiprant - EMEA/V/C/004222/VRA/0018 – dogs

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

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Zolvix – monepantel – EMEA/V/C/000154/VRA/0030 – sheep

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

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Evanovo - EMEA/V/C/005819/VRA/0001 – chickens

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

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Aservo EquiHaler – ciclesonide - EMEA/V/C/004991/VRA/0007/G – horses

Variation requiring assessment: to update the package leaflet following the outcome of the CVMP assessment of the 3rd PSUR and to align the product information with version 9.0 of the QRD template

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Contacera – meloxicam - EMEA/V/C/002612/VRA/0015 – cattle, pigs and 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

Syvazul BTV – Bluetongue virus vaccine (inactivated) - EMEA/V/C/004611/VRA/0006 – sheep, cattle

Variation requiring assessment: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

Rapporteur's assessment report including List of Questions

EMEA/V/C/WS2376/G – Purevax RC, Purevax RCP FeLV, Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP – cats

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

List of questions

Kriptazen – Halofuginone – EMEA/V/C/004868/VRA/0007/G – cattle

Variation requiring assessment: Quality-related changes

Rapporteur: A. Wachnik-Święcicka

Action: For adoption

List of questions, comments on the product information

Onsior – robenacoxib - EMEA/V/C/000127/VRA/0035 – cats, 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

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

Mirataz – EMEA/V/C/004733/REC/007

Rapporteur: S. Louet

Action: For endorsement

Rapporteur's Assessment Report

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

6.11. Other WP issues

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL35 (Pharmacovigilance: electronic standards for transfer of data) and GL42 (Pharmacovigilance: data elements for submission of adverse event reports)

Action: For adoption

Draft revised VICH GL18 on residual solvents

Action: For endorsement

8.3. Other EU bodies and international organisations

Public discussion on the WHO Medically Important Antimicrobial List, 7th Revision

Action: For information

Public discussion on the WHO Medically Important Antimicrobial List, 7th Revision (link)

9. Procedural and regulatory matters

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

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

Veterinary Domain Training Plan 2023

Action: For adoption

Veterinary Domain Training Plan 2023

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 16-17 February 2023 EMA/CMDv/46371/2023, minutes of the CMDv meeting held on 19-20 January 2023

Annex to 14-16 February 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Feb 2023	14-16			7-8		23	22		10		28
Mar 2023	21-23	14-15	29-30				28-29	6-8	20	30-31	1
April 2023	18-20						26		14		
May 2023	15-17								12		
June 2023	13-15										