14 April 2023
EMA/171689/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 18–20 April 2023

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

13 April 2023, 09:00 – 15 April 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).

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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 18-20.04.2023. See April 2023 CVMP minutes (to be published post May 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

Scientific Advice Working Party (virtual)	Fri 14 Apr 2023	10.00-13.00 CEST

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance – EMEA/V/C/MRL/EXPL/003450

Action: For adoption

CVMP opinion including EPMAR

Action: For information

Summary of opinion

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

No items

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

2.3.1. EMEA/V/C/005972/0000 – cats

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

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

2.3.1. EMEA/V/C/005132/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

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

2.4.1. EMEA/V/C/006118/0000 – chickens

Action: For adoption

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

2.4.2. EMEA/V/C/006142/0000 – chickens

Action: For adoption

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

2.4.3. EMEA/V/C/006175/0000 – cattle

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

2.6.1. EMEA/V/C/005993/0000 – dogs

Action: For adoption

Request for an extension of the clock stop

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. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. 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 based on the outcome of signal detection activities

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. Gumbohatch – Avian infectious bursal disease vaccine (live) - EMEA/V/C/004967/VRA/0009 – chickens

Variation requiring assessment: to amend the indication

Rapporteur: J. G. Beechinor

Co-Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information, CVMP assessment report

Action: For information

Summary of opinion

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

Variation requiring assessment: efficacy-related changes

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

SL: J. Pozo

Action: For adoption

CVMP opinion, CVMP 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. 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 outstanding issues, comments on 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. Nobilis IB 4-91 – avian infectious bronchitis vaccine - EMEA/V/C/000036/VRA/0029/G - chickens

Variation requiring assessment: to include information on onset of immunity and duration of immunity to the product information and to align it with version 9.0 of the QRD template

Rapporteur: C. Miras, Co-Rapporteur: P. Pasquali

Action: For adoption

List of questions, comments on the product information

3.4.2. EMEA/V/C/WS2429 – CircoMax, CircoMax Myco – pigs

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information of CircoMax and CircoMax Myco

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

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

5.1.1. Neptra – florfenicol/terbinafine hydrochloride/mometasone furoate – EMA/V/C/004735 - dogs

Recommendation for regulatory actions as an outcome of signal management activities

Rapporteur: C. Muñoz Madero

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

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)

No items

6.4. Immunologicals Working Party (IWP)

No items

6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

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)

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. VICH GLs 7, 12, 13, 14, 15, 16, 19, 20, 21 on anthelmintics

Action: For endorsement

Draft EU comments to comments received at step 4

8.1.2 VICH GL47 on laboratory animal comparative metabolism studies

Action: For decision

Request to CVMP members to nominate an adviser to support the review of VICH GL47 on laboratory animal comparative metabolism studies

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

9.1.1. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for turkeys

9.1.2. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for horses

9.1.3. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal for dogs

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 13 April 2023

Presenter: F. Wikström

Action: For information

11. CMDv

No items

12. Legislation

Information on certain topics discussed under section 12 cannot be released at the present time as it is deemed to be confidential

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Zolvix – Monepantel – EMEA/V/C/000154/VRA/0031 – sheep

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMEA/V/C/005272/VRA/0003 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

Equilis Te – tetanus vaccine - EMEA/V/C/000093/VRA/0011/G - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the outcome signal management activities: to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet)

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Equilis Prequenza – equine influenza vaccine (inactivated) - EMEA/V/C/000094/VRA/0016/G - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the outcome of signal management activities: to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet)

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Equilis Prequenza Te – equine influenza (inactivated) and tetanus vaccine - EMEA/V/C/000095/VRA/0019/G - horses

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the outcome of signal management activities: to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet)

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

CircoMax Myco - EMEA/V/C/005184/VRA/0004/G – porcine circovirus vaccine (inactivated) and Mycoplasma hyopneumoniae vaccine (inactivated) - pigs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

Versican Plus DHPPi – Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) - EMEA/V/C/003679/VRA/0015 – dogs

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

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Prevexxion RN – EMEA/V/C/005058/VRA/0007 – 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 questions, comments on the product information

Versican Plus DHPPi/L4 – Canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) - EMEA/V/C/003678/VRA/0017 – dogs

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

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate - EMEA/V/C/000140/VRA/0025 – 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

SevoFlo – sevoflurane - EMEA/V/C/000072/VRA/0026 – dogs, cats

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

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

Letifend - EMEA/V/C/003865/REC/016

Post-authorisation recommendation

Rapporteur: C. Muñoz Madero

Action: For endorsement

Rapporteur's assessment report

Cytopoint – EMEA/V/C/003939/REC/019

Post-authorisation recommendation

Rapporteur: R. Breathnach

Action: For endorsement

Rapporteur's assessment report

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

The need for comments on draft 3 of VICH guideline on pharmaceutical development

Action: For endorsement

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

Action: For adoption

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

VICH status of guidelines

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

9.3. Regulatory matters

Invented names

10. Organisational matters

Revised consolidated 3-year work plan for the veterinary domain

Action: For endorsement

Consolidated 3-year work plan for the veterinary domain

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 20-21 April 2023, minutes of the CMDv meeting held on 23-24 March 2023

Annex to 18-20 April 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
April 2023	18-20						26		17		
May 2023	15-17	23-24					30-31		12		2-3
June 2023	13-15		21-22	7-8			21	26-28	12	22-23	27-28
July 2023	11-13						11-12		10		
Sept 2023	5-7	19-20					26-27	18-20	4		19-20