12 May 2023
EMA/219677/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 15-17 May 2023

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

Monday 15 May 2023, 09:00 – Wednesday 17 May 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 15-17 May 2023. See May 2023 CVMP minutes (to be published post June 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

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance – EMEA/V/MRL/003652/EXTN/0004 – chickens

Action: For adoption

CVMP opinion including EPMAR, revised CVMP assessment report

Action: For information

Revised 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

2.1.1. EMEA/V/C/005948/0000 – cats

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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/005992/0000 – rabbits

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/006099/0000 – dogs

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

No items

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

No items

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. Hiprabovis IBR Marker Live – Infectious bovine rhinotracheitis vaccine (live) – EMEA/V/C/000158/VRA/0012 – cattle

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

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. NexGard Combo – esafoxolaner/eprinomectin/praziquantel - EMEA/V/C/005094/VRA/0007/G – cats

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

Rapporteur: A. Golombiewski, Co-Rapporteur: N. C. Kyvsgaard

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.3.2. Tessie – tasipimidine - EMEA/V/C/005427/VRA/0001 – dogs

Variation requiring assessment: to amend the product information as regards the interactions with other medicinal products

Rapporteur: K. Boerkamp

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. RenuTend - tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells - EMEA/V/C/005428/VRA/0001 - 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

Action: For information

3.4.2. Clynav – EMEA/V/C/002390/VRA/0016 – Atlantic salmon

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

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

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. Apoquel (EMA/V/C/002688) - oclacitinib maleate – dogs

Recommendation for regulatory actions as an outcome of signal management activities

Rapporteur: R. Breathnach

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)

No items

6.4. Immunologicals Working Party (IWP)

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)

No items

6.9. Scientific Advice Working Party (SAWP-V)

No items

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

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 GL22 Reproduction testing

Action: For endorsement

Draft EU comments; draft EU discussion on Extended One-Generation Reproductive Toxicity Study (EOGRTS) implementation

8.1.2. VICH GL23 Genotoxicity testing

Action: For endorsement

Draft EU discussion on revision of VICH GL23; draft revised VICH GL23 including EU comments

8.1.3. Draft VICH *in vitro* dissolution guideline for immediate release solid oral veterinary dosage forms

Action: For discussion

Draft *in vitro* dissolution guideline for immediate release solid oral veterinary dosage forms

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 cats and dogs

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

9.3. Regulatory matters

9.3.2. Change in the process for adoption Commission Decisions on variations

Action: For information

10. Organisational and strategic matters

10.1. CVMP/CMDv Informal meeting under the Swedish Presidency, Uppsala, 30 – 31 May 2023

Action: For adoption

Agenda of CVMP/CMDv Informal meeting under the Swedish Presidency

11. CMDv

11.1. Verbal report from CMDv Chair

Verbal report from CMDv Chair on the CMDv meetings held on 23-24 March 2023 and 20-21 April 2023

Presenter: L. Le Letty

Action: For information

Draft agenda of the CMDv meeting to be held on 16-17 May 2023; minutes of the CMDv meeting held on 20-21 April 2023

12. Legislation

12.3. Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall be used in accordance with these articles subject to certain conditions

Action: For discussion

Scientific advice

12.5. CVMP reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (EMA/CVMP/64911/2021)

Action: For information

Reflection paper

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 – sheep

Action: For information

Letter of withdrawal of application

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

EMEA/V/C/006142/0000 – chickens

Action: For adoption

Request for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Forceris – Toltrazuril/Iron(III) ion - EMEA/V/C/004329/VRA/0006/G – pigs (piglets)

Variation requiring assessment: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Ypozane – osaterone acetate - EMEA/V/C/000112/VRA/0007/G - dogs

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Chanaxin – tulathromycin - EMEA/V/C/000112/VRA/0001 – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: M. O' Grady

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Naxcel – ceftiofur - EMEA/V/C/000079/VRA/0043 – cattle, pigs

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

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Reconcile – fluoxetine - EMEA/V/C/000133/VRA/0042 - dogs

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Strangvac– *Streptococcus equi* vaccine (recombinant proteins)- EMEA/V/C/005309/VRA/0005 - horses

Variation requiring assessment: Quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

Nobivac DP Plus – EMEA/V/C/005251/VRA/0003/G – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the outcome of a procedure concerning risk management measures in pharmacovigilance.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2437 – Prevexxion RN, Prevexxion RN+HVT+IBD - chickens

Variation requiring assessment: Quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Vaxxitek HVT+IBD – Infectious bursal disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/000065/VRA/0044 – chickens

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

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Librela – bedinvetmab – EMEA/V/C/005180/VRA/0008 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Canigen L4 – canine *leptospira* vaccine (inactivated) - EMEA/V/C/004079/VRA/0011 – dogs

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

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Nobivac L4 – canine *leptospira* vaccine (inactivated) - EMEA/V/C/002010/VRA/0014 – dogs

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

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

MiPet Easecto – sarolaner – EMEA/V/C/004732/VRA/0012 – dogs

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

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Simparica – sarolaner – EMEA/V/C/003991/VRA/0023 – dogs

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

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2449 – Purevax RCP FeLV, Purevax RCPCh FeLV, Purevax RC, Purevax RCP, Purevax RCPCh - cats

Variation requiring assessment: Quality-related changes

Rapporteur: Bruno Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2436 – Versican Plus DHPPi/L4R, Versican Plus Pi/L4R - dogs

Variation requiring assessment: Quality-related changes

Rapporteur: Esther Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Porcilis ColiClos – *E. coli* and *C. perfringens* vaccine (inactivated) – EMEA/V/C/002011/VRA/0015 – pigs

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

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

Tulaven – tulathromycin - EMEA/V/C/005153/VRA/0007/G – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

Enteroporc Coli AC – EMEA/V/C/005149/VRA/0005/G – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions

Dexdomitor – dexmedetomidine - EMEA/V/C/000070/VRA/0045 – dogs, cats

Variation requiring assessment: 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

Zactran – gamithromycin - EMEA/V/C/000129/VRA/0048 – cattle, sheep, pigs

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

Rapporteur: N. C. Kyvsgaard

Action: For adoption

Comments on the product information

Palladia – toceranib - EMEA/V/C/000150/VRA/0019 – dogs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template. In addition, the applicant took the opportunity to correct the name of the marketing authorisation holder in the product information and to correct minor translation discrepancies in the different languages.

Rapporteur: H. Bremer

Action: For adoption

List of questions, comments on the product information

Panacur AquaSol – EMEA/V/C/002008/VRA/0023 – pigs, chickens

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

Ypozane – Osaterone acetate – EMEA/V/C/000112/VRA/0006 – 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

Zuprevo – tildipirosin - EMEA/V/C/002009/VRA/0017/G – cattle, pigs

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the outcome of a signal management procedure

Rapporteur: A. Golombiewski

Action: For adoption

List of questions, comments on the product information

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

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

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For decision

Request for an extension of clock stop

4. Referrals and related procedures

4.7. Other issues

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

Action: For information

Questions and answers for publication

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

Action: For information

Questions and answers for publication

5. Post-authorisation issues for marketing authorisations

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

Mometamax Ultra – EMEA/V/C/004987/REC/001

Rapporteur: K. Baptiste

Action: For endorsement

Rapporteur's assessment report

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

6. Working Parties

6.1 Antimicrobials Working Party (AWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL18(R2) Impurities: residual solvents in new veterinary medicinal products, active substances and excipients

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

9.3. Regulatory matters

Invented names

12. Legislation

Annex to 15-17 May 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
May 2023	15-17	23-24					30-31		No meeting		2-3
June 2023	13-15		21-22	7-8			21	26-28	9	22-23	27-28
July 2023	11-13						11-12		10		
Sept 2023	5-7	19-20					26-27	18-20	4		19-20
Oct 2023			11-12	10-11			25		29		
Nov 2023					14-15						