17 March 2023
EMA/CVMP/128829/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 21-23 March 2023

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

21 March 2023, 09:00 – 23 March, 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).

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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 21-23 March 2023. See March 2023 CVMP minutes (to be published post April 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)	Mon 20 Mar 2023	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

1.6.1. Substance – poultry

Action: For discussion

Request from the European Commission for reconsideration of the CVMP opinion

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/005860/0000 – chickens

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/006128/0000 – dogs

Action: For adoption

List of questions, comments on the product information

2.4.2. EMEA/V/C/006124/0000 – dogs

Action: For adoption

List of questions, comments on the product information

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

Action: For adoption

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

2.4.4. EMEA/V/C/005628/0000 – dogs

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 – fluralaner - EMEA/V/C/002526/VRA/0058 – dogs, cats

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

3.1.2. Stronghold – selamectin - EMEA/V/C/000050/VRA/0059 – cats, dogs

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

Rapporteur: J. G. Beechinor

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

No items

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. 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

Rapporteur: S. Louet

Action: For adoption

List of questions, comments on the product information

3.4.2. Cytopoint – lokivetmab - EMEA/V/C/003939/VRA/0016 – 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

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

Variation requiring assessment: to amend summary of product characteristics section 4.8

Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

3.4.4. 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 adoption

List of questions, comments on the product information

3.4.5. 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

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions, comments on the product information

3.4.6. 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

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

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 35 of Directive 2001/82/EC

4.7.2.1. Veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses – EMEA/V/A/116 – follow-up assessment

Scope: Risk to the environment due to PBT properties of moxidectin

Rapporteur: R. Carapeto, Co-Rapporteur: A. Golombiewski

Action: For decision and adoption

List of questions

Action: For discussion

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

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. Galliprant – grapiprant – EMA/V/C/004222 - dogs

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: K. Baptiste

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.3. Signal management approach by P-SMEG

Action: For discussion

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 (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

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 GL47 on laboratory animal comparative metabolism studies – nomination of an adviser

Action: For decision

8.1.2. Concept paper proposing development of VICH GL on technical requirements for in vitro methods for batch potency tests in veterinary immunologicals – draft 3

Action: For endorsement

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

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

9.3. Regulatory matters

10. Organisational and strategic matters

No items

11. CMDv

11.1. Verbal report from CMDv Chair on the CMDv meetings held on 19-20 January 2023 and 16 February 2023

Action: For information

12. Legislation

12.1. Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))

Action: For information

12.2. Verbal update on Article 115(5) of Regulation (EU) 2019/6 - Implementing measures as regards the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months

Action: For information

12.3. Draft 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 decision

Overview of comments from stakeholders

13. AOB

13.1. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Suprelorin – deslorelin acetate – EMEA/V/C/000109/VRA/0038 – dogs and cats

Variation requiring assessment: Quality-related changes

Rapporteur: N.-C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Leucofeligen FeLV/RCP – EMEA/V/C/WS2398 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Variation requiring assessment: Quality-related changes

Rapporteur: A. Wachnik-Święcicka

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Innovax-ILT - Marek's disease and avian infectious laryngotracheitis disease vaccine (live recombinant) - EMEA/V/C/003869/VRA/0010/G – chicken

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

Nexgard Combo – Esafoxolaner/Eprinomectin/Praziquantel – EMEA/V/C/005094/VRA/0008 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Masivet – masitinib - EMEA/V/C/000128/VRA/0022 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Purevax Rabies – rabies vaccine (live recombinant) - EMEA/V/C/002003/VRA/0017 – cats

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

Prevomax – maropitant – EMEA/V/C/04331/VRA/0014 – dogs, cats

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Nobilis Influenza H5N2 – avian influenza virus vaccine (inactivated) – EMEA/V/C/000118/VRA/0017 – chickens

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

Poulvac E. coli – avian colibacillosis vaccine (live) - EMEA/V/C/002007/VRA/0020 – chicken, turkeys

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

Porcilis PCV M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMEA/V/C/003796/VRA/0017 – 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

Versican Plus L4 – canine leptospirosis vaccine (inactivated) - EMEA/V/C/003680/VRA/0012 – 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

Versican Plus Pi – canine parainfluenza virus vaccine (live) - EMEA/V/C/003681/VRA/0013 – 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

Versican Plus Pi/L4 – canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) - EMEA/V/C/003683/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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

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

Variation requiring assessment: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For endorsement

Rapporteur's assessment report including List of Questions

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

Halocur – halofuginone - EMEA/V/C/000040/VRA/0018/G – calves

Rapporteur: S. Louet

Action: For information

Letter of withdrawal of application

Bravecto – fluralaner – EMEA/V/C/002526/VRA/0057 – dogs

Rapporteur: K. Boerkamp

Action: For information

Letter of withdrawal of application

4. Referrals and related procedures

5. Post-authorisation issues for marketing authorisations

5.3. Inspections and controls under Regulation (EC) No 726/2004

List of veterinary products to be tested in the Sampling and Testing Programme 2024

Action: For adoption

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

6. Working parties

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

Minutes of the 3RsWP plenary meeting held on 23 November 2022

Action: For information

Minutes of the 3RsWP plenary meeting held on 23 November 2022

6.11. Other working party and scientific group issues

Quality innovation group

Action: For information

QIG workplan for 2023: 2023 work plan for the Quality Innovation Group (QIG) - Consolidated workplan (europa.eu)

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 VMPs, active substances and excipients

Action: For endorsement

8.2 Codex Alimentarius

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 21-23 March 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
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			23-24					12		
June 2023	13-15									22-23	
July 2023	11-13						4-5		10		