8 April 2022
EMA/213330/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 11-13 April 2022

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

11 April 2022, 09:00 – 13 April 2022, 13:00 - Room 15-B 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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i. Adoption of the agenda

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session to be held 11-13 April 2022. See April 2022 CVMP minutes (to be published post May 2022 CVMP meeting)

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

iv. Adoption of the minutes of the previous meeting

v. Topics and experts' participation in discussions, rapporteur's meetings and breakout sessions held in advance or in the margins of the present CVMP meeting

Scientific Advice Working Party (virtual)	8 April 2022	10.00–13.00 CEST

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

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

Action: **Oral explanation** to be held on **11 April 2022 at 14:00 CEST**

Rapporteurs' assessment of responses to list of outstanding issues, rapporteur's EPMAR, presentation from the applicant

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

No items

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

2.3.1. EMEA/V/C/005816/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.1. EMEA/V/C/005829/0000 – chickens

Action: For decision

Need for oral explanation

Action: For adoption

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

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

No items

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

2.4.1. EMEA/V/C/005948/0000 – cats

Action: For adoption

List of questions, comments on the product information

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

No items

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

3.1.1. Gumbohatch – live attenuated infectious bursal disease virus - EMEA/V/C/004967/II/0005/G - chickens

Variation: Quality-related changes

Rapporteur: J.G. Beechinor

Action: For adoption

CVMP opinion, product information, CVMP assessment report

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

No items

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

3.2.1. Suprelorin – Deslorelin – EMEA/V/C/000109/II/0032/G – cats

Variation: to add a new therapeutic indication and to add a non-food producing target species

Rapporteur: N. C. Kyvsgaard, Co-Rapporteur: J. P. Duarte Da Silva

Action: **Oral explanation** to be held on **12 April 2022 at 10.55 CEST**

Rapporteurs' assessment of responses to list of outstanding issues, comments on the product information, presentation from the applicant

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. Prevomax – maropitant - EMEA/V/C/004331/VRA/0012 – cats, dogs

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

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

3.4.1. Sileo – Dexmedetomidine - EMEA/V/C/003764/II/0022 – dogs

Variation: to modify the approved indication

Rapporteur: F. Hasslung Wikström, Co-rapporteur: J. G. Beechinor

Action: For adoption

List of questions, comments on the product information

3.4.2. Simparica Trio – sarolaner/moxidectin/pyrantel embonate - EMEA/V/C/004846/II/0007/G – dogs

Variation: to add a new therapeutic indication and to update SPC section 5.1

Rapporteur: R. Breathnach, Co-Rapporteur: B. Urbain

Action: For adoption

List of questions, comments on the product information

3.4.3. EMEA/V/C/xxxx/WS2217, Simparica, MiPet Easecto – sarolaner – dogs

Variation: to add a new therapeutic indication

Rapporteur: J. G. Beechinor, Co-Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

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

No items

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

No items

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

No items

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

5. Post-authorisation issues for marketing authorisations

5.1. Pharmacovigilance under Regulation (EU) 2019/6

No items

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

5.1.1. Stelfonta – Tigilanol tiglate – EMEA/V/C/005018

Rapporteur: K. Boerkamp

Action: For adoption

Revised CVMP Assessment Report on the 3rd PSUR for the period 01.02.2021-31.07.2021

5.1.2. BTVPUR – bluetongue-virus serotype-1 antigen/bluetongue virus serotype 8 antigen– EMEA/V/C/002231

Rapporteur: C. Muñoz Madero

Action: For endorsement

Recommendation for changes to the SPC as an outcome of signal detection activities

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

Information relating to GMP and pharmacovigilance inspections will not be published as it would undermine the purpose of such inspections

No items

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

Information relating to supervision and sanctions will not be published as it would undermine the purpose of such inspections.

No items

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

No items

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

No items

6.5. Joint CHMP/CVMP 3Rs Working Party (J3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

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

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.7. Other issues

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.1.1. VICH GL 49 on Validation of Analytical Methods used in Residue Depletion Studies

Action: For endorsement

Draft EU comments on the proposed revised guideline

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

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

Action: For adoption

Draft report of the working group

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

10.4. EMA Veterinary Info Day 2022

Action: For information

EMA Veterinary Info Day to be held on 12-13 May 2022; draft programme

10.6. CVMP/CMDv Informal meeting under the French Presidency, Saint Malo, France 31 May – 1 June 2022

Action: For information

Invitation and agenda

11. CMDv

11.1. Verbal report from CMDv Chair

Verbal report from the CMDv chair on the CMDv meetings held on 17-18 February 2022 and 17-18 March 2022

Action: For information

Agenda of the CMDv meeting to be held on 12-13 April 2022; minutes of the CMDv meeting held on 17-18 March 2022

12. Legislation

12.3. 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

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

Documents for silent adoption and information

3. Variations to marketing authorisations

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

EMEA/V/C/xxxx/WS2036 - Purevax RC, Purevax RCP FeLV, Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP – cats

Variation: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

NexGard Spectra – afoxolaner / milbemycin oxime - EMEA/V/C/003842/II/0031 – dogs

Variation: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Bonqat – pregabalin - EMEA/V/C/005489/II/0002/G – cats

Variation: Quality-related changes

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Suprelorin – deslorelin acetate - EMEA/V/C/000109/II/0033 – dogs and ferrets

Variation: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Rabitec – rabies vaccine (live, oral) - EMEA/V/C/004387/II/0007/G – fox, raccoon dogs

Variation: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

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

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

List of questions

Felpreva – Tigolaner/Emodepside/Praziquantel - EMEA/V/C/005464/VRA/0001 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

Rapporteur's assessment report including list of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

Gumbohatch – Live attenuated infectious bursal disease virus (IBDV), strain 1052 – EMEA/V/C/004967

Rapporteur: J. G. Beechinor

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.06.2021-30.11.2021

HorStem – Equine umbilical cord mesenchymal stem cells – EMEA/V/C/004265

Rapporteur: A. Golombiewski

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.07.2021-31.12.2021

SevoFlo – Sevoflurane – EMEA/V/C/000072

Rapporteur: J. G. Beechinor

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.12.2020-31.11.2021

Virbagen Omega – Recombinant omega interferon of feline origin – EMEA/V/C/000061

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.12.2018-30.11.2021

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

Nobivac DP Plus – EMEA/V/C/005251/REC/005

Rapporteur: E. Werner

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

8.1.1. Revision of VICH Guidelines on efficacy of anthelmintics

Action: For endorsement

Revised guidelines for sign off at Steering Committee level (step 3):
- VICH GL07(R) - Anthelmintics - General requirements
- VICH GL12(R) - Anthelmintics – Bovines
- VICH GL13(R) - Anthelmintics – Ovines
- VICH GL14(R) – Anthelmintics – Caprines
- VICH GL15(R) - Anthelmintics – Equines
- VICH GL16(R) - Anthelmintics – Porcines
- VICH GL19(R) - Anthelmintics – Canines
- VICH GL20(R) - Anthelmintics – Felines
- VICH GL21(R) - Anthelmintics – Chickens

9. Procedural and regulatory matters

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

Annex to 11-13 April 2022 CVMP Agenda

CVMP Working Parties dates 2022

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWG
April 2022	11-13				28-29				8	1	
May 2022	10-12	24-25		17-18		18-19			6		
June 2022	14-16		29-30					27-29	13		
July 2022	12-14								8 or 12		
Sept 2022		20-21						19-21	2, 5, or 6		