30 September 2022
EMA/795167/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 4-6 October 2022

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

4 October 2022, 09:00 – 6 October 2022, 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 4-6 October 2022. See October 2022 CVMP minutes (to be published post November 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)	Fri 30 Sept 2022	10.00-13.00 CEST

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

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/000151/X/0015 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/005528/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

Action: To note

Divergent position from K. Baptiste

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

No items

2.2. Oral explanations under Regulation (EC) No 726/2004

2.2.1. EMEA/V/C/005538/0000 – dogs

Action: **Oral explanation** to be held on **4 October 2022 at 14:30 CEST**

Action: For discussion

Rapporteurs' assessment of responses to list of outstanding issues to be addressed during the oral explanation, comments on the product information, presentation from the applicant

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/005906/0000 – cattle

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/005860/0000 – chickens

Action: For adoption

List of additional outstanding issues

2.3.3 EMEA/V/C/005905/0000 - chickens

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3.4. EMA/V/C/005944/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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

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

2.4.1. EMEA/V/C/006045/0000 – cattle

Action: For adoption

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

2.4.2. EMEA/V/C/005992/0000 – rabbits

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Equip WNV – West Nile fever vaccine (inactivated) – EMEA/V/C/000137/VRA/0028 – horses

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

3.1.2 CircoMax – porcine circovirus vaccine (inactivated recombinant) - EMEA/V/C/005185/VRA/0001/G - pigs

Grouped variation requiring assessment including alignment of 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

3.1.3 CircoMax Myco - porcine circovirus vaccine (inactivated, recombinant) and mycoplasma hyopneumonia vaccine (inactivated) - EMEA/V/C/005184/VRA/0002/G - pigs

Grouped variation requiring assessment including alignment of 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

3.1.4. Bovela – Bovine viral diarrhoea vaccine (modified live) - EMEA/V/C/003703/VRA/0023/G - cattle

Variation requiring assessment: Quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.5. Exzolt – Fluralaner – EMEA/V/C/004344/VRA/0014/G - chicken

Grouped variation requiring assessment: to update the product information in line with version 9.0 of the QRD template / Quality-related changes

Rapporteur: K. Boerkamp

SL: C. Griffin

Action: For adoption

Revised product information

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

3.1.1. 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

CVMP opinion, CVMP assessment report, product information

3.1.2. 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

CVMP opinion, CVMP assessment report, product information for Simparica and MiPet Easecto

Action: For information

Summary of opinion

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. Credelio Plus – lotilaner / milbemycin oxime – EMEA/V/C/005325/VRA/0005 – dogs

Variation requiring assessment: to add a new therapeutic indication

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

Action: For adoption

List of questions, comments on the product information

3.4.2. 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 questions and scientific overview, comments on the product information

3.4.3. EMEA/V/C/WS2294 – Porcilis PCV ID – pigs

Variation requiring assessment: to update the product information

Rapporteur: J. Poot

Action: For adoption

List of questions, comments on the product information

3.4.4. Simparica Trio – sarolaner/moxidectin/pyrantel embonate - EMEA/V/C/004846/VRA/0009/G – dogs

Variation requiring assessment: to add new therapeutic indications

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

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 Commission Regulation (EU) 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

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

Veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses – EMEA/V/A/116

Risk to the environment due to PBT properties of moxidectin

Rapporteur: *to be appointed*, Co-Rapporteur: *to be appointed*

Scope: Appointment of rapporteurs and peer reviewers for the follow-up assessment

Action: For decision

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

No items

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

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)

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

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. EU comments on draft proposal for revising the scope of VICH general guideline on pharmaceutical combination products

Action: For endorsement

8.1.2. EU adviser in VICH EWG on Safety of biologicals

Action: For endorsement

8.1.3. Periodic review of VICH guidelines

Action: For endorsement

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

8.3.1. Request to EFSA for a scientific opinion on vaccination against highly pathogenic avian influenza - Nomination of CVMP expert for EFSA mandate

Action: For decision

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

10.1 Appointment of co-opted members

Action: For decision

Clinical Veterinary Practice

- Nominations received for:

- R. Breathnach

Quality

- Nominations received for:

- M. O'Grady

10.3. CVMP/CMDv Informal meeting under the Czech Presidency, Prague, 11 – 13 October 2022

Action: For information

Agenda

11. CMDv

No items

12. Legislation

12.1. Draft reflection paper on Article 37(2)(j) of Regulation (EU) 2019/6

Action: For adoption

12.2. Implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the good manufacturing practice for veterinary medicinal products and active substances used as starting materials

Action: For endorsement

Drafting group membership and terms of reference

12.3. Scientific guidelines for limited market products deemed not eligible for authorisation under Article 23 of Regulation 2019/6

Action: For decision

12.4. 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

2. Marketing authorisations and extensions

2.6. Other issues under Regulation (EC) No 726/2004

EMEA/V/C/005988/0000 - mink

Action: For information

Letter of withdrawal of the marketing authorisation application

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Arti-Cell Forte – allogeneic equine peripheral blood-derived chondrogenic induced mesenchymal stem cells – EMEA/V/C/004727/VRA/0010 – horses

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Zenalpha – medetomidine hydrochloride/vatinoxan hydrochloride - EMEA/V/C/005465/VRA/0003 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Broadline – fipronil / methoprene / eprinomectin / praziquantel - EMEA/V/C/002700/VRA/0034 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

EMEA/V/C/xxxx/WS2184
Versican Plus Pi/L4R and Versican Plus DHPPi/L4R – dogs

Worksharing variation: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information for Versican Plus DHPPi L4R and Versican Plus Pi L4R

Action: For endorsement

Rapporteur's assessment report

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

Suprelorin – Deslorelin acetate - EMEA/V/C/000109/VRA/0037 – cats, dogs and ferrets

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

Rapporteur's assessment report including list of questions

3.6. Other issues under Commission Regulation (EC) No 1234/2008

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

Rapporteur: F. Hasslung Wikström, Co-rapporteur: P. McNeill

Action: For information

Letter of withdrawal from the applicant

4. Referrals and related procedures

4.7. Other issues

Veterinary medicinal products containing toltrazuril to be administered orally to chickens – Article 35 of Directive 2001/82/EC (EMEA/V/A/144)

Referral scope: *Consumer safety*

Rapporteur: J. Poot, Co-Rapporteur: S. Louet

Action: For adoption

Revised CVMP opinion, revised CVMP assessment report

5. Post-authorisation issues for marketing authorisations

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

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

6. Working parties

6.11. Other working party and scientific group issues

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

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

Invented names

10. Organisational and strategic matters

2nd Veterinary Big Data Stakeholder Forum

Action: For information

Draft agenda

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 6-7 October 2022, minutes of the CMDv meeting held on 8-9 September 2022; draft agenda of the CMDv-Interested Parties meeting to be held on 7 October 2022

Annex to 4-6 October 2022 CVMP Agenda

CVMP Working Parties dates 2022-2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Oct 2022	4-6		19-20	18-19					30 Sept		
Nov 2022	8-10	22-23			21-22	14	29-30	21-23	7	17-18	
Dec 2022	6-8								5		
Jan 2023	17-19						24-25				
Feb 2023	14-16			21-22		23	22				