2 December 2022
EMA/918919/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 6 – 8 December 2022

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

6 December 2022, 09:00 – 8 December 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 6-8 December 2022. See December 2022 CVMP minutes (to be published post January 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

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2.1. Opinions under Regulation (EC) No 726/2004

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Action: For adoption

CVMP opinion, CVMP assessment report, product information

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

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

No items

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

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Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4.2. EMEA/V/C/006000/0000 – chickens and embryonated chicken eggs

Action: For adoption

Scientific overview and list of questions, comments on the product information

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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

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

Variation requiring assessment: to update the product information

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.2. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. 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

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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, Nexgard Spectra - EMEA/V/C/WS2280/G – dogs

Variation requiring assessment: to add two new therapeutic indications, and to amend the product information

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

Action: For adoption

List of outstanding issues, comments on the product information for NexGard and Nexgard Spectra

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

Variation requiring assessment: quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

List of questions

3.4.2. 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

List of questions, comments on the product information

3.4.3. Zolvix – monepantel – EMEA/V/C/000154/VRA/0030 – sheep

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

3.4.4. 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

List of questions, comments on the product information

3.4.5. 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

List of questions , comments on the product information

3.4.6. Versican Plus Pi/L4 – canine parainfluenza virus vaccine (live) and canine leptospirosis vaccine (inactivated) - EMEA/V/C/003683/VRA/015 - 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

3.4.7. Prevomax – maropitant - EMEA/V/C/004331/VRA/0013 – dogs, cats

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

3.4.8. Lotilaner Elanco – lotilaner - EMEA/V/C/006030/VRA/0001 – dogs, cats

Variation requiring assessment: to change the legal status

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

Action: For adoption

List of questions, comments on the product information

3.4.9. Gumbohatch - EMEA/V/C/004967/VRA/0008/G – chickens

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

3.4.10. Evanovo - EMEA/V/C/005819/VRA/0001 – chickens

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

Rapporteur: M. O'Grady

Action: For adoption

List of questions, comments on the product information

3.4.11 Galliprant – grapiprant - EMEA/V/C/004222/VRA/0018 – dogs

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

Rapporteur: K. Baptiste

Action: For adoption

List of questions, comments on the product information

3.4.12. Procox – toltrazuril/emodepside - EMEA/V/C/002006/VRA/032 – dogs

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

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

4.1.1. Veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection – EMEA/V/A/145

Scope: Dose rate and duration, risk of AMR development

Rapporteur: A. Golombiewski, Co-Rapporteur: K. Baptiste

Action: For adoption

List of outstanding issues

Action: For discussion

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

4.1.2. Veterinary medicinal products containing N-methyl pyrrolidone as an excipient – EMEA/V/A/146

Scope: User/ target animal safety

Rapporteur: A. Golombiewski, Co-Rapporteur: C. Bergman

Action: For adoption

CVMP opinion, CVMP assessment report

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

*Information relatin*g 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. Bravecto – fluralaner – EMA/V/C/002526 - dogs

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: K. Boerkamp

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.2. Felpreva – tigolaner / emodepside / praziquantel – EMA/V/C/0005464 - cats

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: A. C. Golombiewski

Action: For endorsementVeterinary signal assessment report and PhVWP-V recommendation

5.1.3. Improvac – gonadotropin releasing factor analogue diphtheria toxoid conjugate – EMA/V/C/000136 - pigs

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: N. C. Kyvsgaard

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.4. Proteq West Nile - West Nile fever vaccine (live recombinant) – EMA/V/C/002005 - horses

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: C. Miras

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.5. Procox - toltrazuril/emodepside – EMA/V/C/002006 - dogs

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: F. Hasslung Wikström

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.6. Zuprevo – tildipirosin - EMA/V/C/002009 - cattle

Recommendation for regulatory actions as an outcome of signal detection activities

Rapporteur: A. Golombiewski

Action: For endorsement

Veterinary signal assessment report and PhVWP-V recommendation

5.1.7. Hiprabovis IBR Marker Live – Infectious bovine rhinotracheitis vaccine (live) - EMEA/V/C/000158

Evaluation of answers to list of questions to MAH

Rapporteur: B. Urbain

Action: For information

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)

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)

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

7.3. Antimicrobial resistance

7.3.1. Twelfth ESVAC report: Sales of veterinary antimicrobial agents in 31 European countries in 2021. Trends from 2010 to 2021 (link)

Action: For information

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. EU comments on draft VICH GL on target animal safety of veterinary monoclonal antibody products (VMAP)

Action: For endorsement

8.1.2. EU comments on revised VICH GL 8 on stability testing for medicated premixes

Action: For endorsement

8.1.3. Draft revised VICH GL18 on residual solvents

Action: For endorsement

8.1.4. EU comments on draft VICH guideline on pharmaceutical development

Action: For endorsement

8.1.5. Feedback from VICH Steering Committee and Outreach Forum meetings of 14-17 November 2022

Action: For information

8.2. Codex Alimentarius

8.2.1. Preparation for 26th CCRVDF meeting scheduled for 12-17 February 2023

Action: For endorsement

8.3. Other EU bodies and international organisations

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

Action: For adoption

8.3.2. Request to EFSA for a scientific opinion on vaccination against highly pathogenic avian influenza – update and next actions

Action: For information

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

No items

10. Organisational and strategic matters

10.1. CVMP work plan for 2023

Action: For adoption

10.2. Update on IRIS for core regulatory procedures

Action: For information

11. CMDv

No items

12. Legislation

12.1 Article 34 of Regulation (EU) 2019/6

Action: For discussion

Draft guideline on the application of Article 34 of Regulation (EU) 2019/6, overview of comments

12.2 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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

EMEA/V/C/WS2329 – Purevax RC, Purevax RCP FeLV, Purevax RCPCh FeLV, BTVPUR, Eurican Herpes 205, Purevax RCPCh, Purevax RCP – cats, sheep, cattle, dogs

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2349 - Suvaxyn CSF Marker, Fevaxyn Pentofel and Suvaxyn PRRS MLV – cats, pigs

Variation requiring assessment: Quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/WS2355 – Panacur Aquasol – fenbendazole - pigs, chickens

Variation requiring assessment: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Solensia – frunevetmab – EMEA/V/C/005179/VRA/0005 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Mirataz - mirtazapine EMEA/V/C/004733/VRA-0004 – cats

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Imoxat – imidacloprid / moxidectin - EMEA/V/C/005597/VRA/0001/G – cats, dogs, ferrets

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

Procox – toltrazuril / emodepside – EMEA/V/C/002006/VRA/0034/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

Procox – toltrazuril / emodepside – EMEA/V/C/002006/VRA/0033/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Bluevac BTV – Bluetongue virus vaccine (inactivated) - EMEA/V/C/000156/VRA/0011/G – cattle, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Locatim – immunoglobulins against *Escherichia coli* F5 antigen - EMEA/V/C/000041/VRA/0023 – cattle

Variation requiring assessment: Quality-related changes

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Halocur – halofuginone - EMEA/V/C/000040/VRA/018/G – calves

Variation requiring assessment: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

Purevax RC, Purevax RCP and Purevax RCPCh – REC 023.2 – 025.2

Rapporteur: B. Urbain, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

Rapporteur's assessment report

7. Other scientific matters

7.7. Other issues

9. Procedural and regulatory matters

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

9.3. Regulatory matters

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 8-9 December 2022 minutes of the CMDv meeting held on 10-11 November 2022– *to be tabled*

Annex to 06-08 December 2023 CVMP Agenda

CVMP Working Parties dates 2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Dec 2022	6-8								5		
Jan 2023	17-19						24-25		16		
Feb 2023	14-16			7-8		23	22		13		28
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