2 September 2022
EMA/723776/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 6-8 September 2022

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

Tuesday, 6 September 2022, 09:00 – Thursday, 8 September 2022, 13:00 - Room 1C 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 6-8.09.2022. See September 2022 CVMP minutes (to be published post October 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)	Monday 5 Sep 2022	10.00-13.00 CEST

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance – EMEA/V/MRL/003477/EXTN/0004 – fin fish

Action: For adoption

CVMP opinion including EPMAR, CVMP assessment report

Action: For information

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

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

2.2.1. EMEA/V/C/005528/0000 – dogs

Action: Oral explanation to be held on 6 September 2022 at 14:00

Action: For discussion

Rapporteurs' assessment of responses to the list of outstanding issues, 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/005577/0000 – pigs

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/005972/0000) – cats

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

2.6.1. EMEA/V/C/005132/0000 – dogs

Action: For decision

Request from applicant to further extend the clock-stop

2.6.2. EMEA/V/C/005835/0000 – dogs

Action: For information

Letter of withdrawal of the marketing authorisation application

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 Improvac - gonadotropin releasing factor analogue diphtheria toxoid conjugate - EMEA/V/C/000136/VRA/0039/G - pigs

Grouped variation requiring assessment including update to the product information with version 9.0 of the QRD template

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2 Improvac – gonadotropin releasing factor analogue diphtheria toxoid conjugate - EMEA/V/C/000136/VRA/0040 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.1.3. Porcilis PCV ID – Porcine circovirus vaccine (inactivated) - EMEA/V/C/003942/VRA/0006 – pigs

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

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.4. Solensia – Frunevetmab - EMEA/V/C/005179/VRA/0003 – cats

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

Rapporteur: R. Breathnach

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 align the product information with version 9.0 of the QRD template / Quality-related changes

Rapporteur: K. Boerkamp

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. Rabitec – rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0010/G – foxes and raccoon dogs

Grouped variation requiring assessment procedure including update to 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

3.4.2. Apoquel – Oclacitinib maleate - EMEA/V/C/002688/VRA/0024 – 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. ProteqFlu – Equine influenza vaccine (live recombinant) – EMEA/V/C/000073/VRA/0025 – horses

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

Rapporteur: C. Miras

Action: For adoption

Comments on the product information

3.4.4. ProteqFlu-Te - Equine influenza vaccine (live recombinant) and tetanus vaccine - EMEA/V/C/000074/VRA/0033 - horses

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

Rapporteur: C. Miras

Action: For adoption

Comments on the product information

3.4.5. EMEA/V/C/WS2280/G - NexGard, Nexgard Spectra – 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 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

No items

4.7.1. Referrals under Regulation (EU) 2019/6

No items

4.7.2. Referrals under Article 33(4) of Directive 2001/82/EC

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

Scope : Bioequivalence

Rapporteur: *to be appointed*

Co-Rapporteur: *to be appointed*

Action: For discussion and decision

Notification from the Czech Republic under Article 33(4) of Directive 2001/82/EC.

Appointment of rapporteur, co-rapporteur and peer reviewers

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

Scope : Bioequivalence

Rapporteur: *to be appointed*

Co-Rapporteur: *to be appointed*

Action: For discussion and decision

Notification from the Czech Republic under Article 33(4) of Directive 2001/82/EC.

Appointment of rapporteur, co-rapporteur and peer reviewers

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. 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)

No items

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

No items

6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

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

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

7.5. Vaccine antigen master file (VAMF) certification

No items

7.6. Platform technology master file (PTMF) certification

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 adviser in VICH EWG EWG on Safety of biologicals

Action: For endorsement

8.1.2. Concept paper proposing development of VICH GL on implementation of in vitro methods to replace animal batch potency tests in veterinary immunologicals – draft 2

Action: For endorsement

8.2. Codex Alimentarius

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

Action: For discussion

Summary and conclusions of 94th JECFA meeting, CCRVDF 26 – extrapolation proposals

8.3. Other EU bodies and international organisations

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

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

Action: For discussion

Invitation and draft agenda

11. CMDv

11.1. Verbal report from CMDv Chair

Verbal report from the CMDv chair on the CMDv meetings held on 16-17 June 2022 and 14-15 July 2022

Action: For information

12. Legislation

12.1. Article 37(2)(j) of Regulation (EU) 2019/6

Action: For adoption

Revised draft reflection paper on Article 37(2)(j) of Regulation (EU) 2019/6, overview of comments

12.2. 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 discussion

12.3. 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 information

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

Verbal feedback

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/xxxxx/WS2257

Poulvac E. coli – Avian colibacillosis vaccine (live) – chicken, turkey

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/xxxx/WS2265

Vaxxitek HVT+IBD, Prevexxion RN+HVT+IBD and Prevexxion RN – chicken

Variation requiring assessment: Quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, Vaxxitek HVT+IBD product information, Prevexxion RN+HVT+IBD product information, Prevexxion RN product information

Action: For endorsement

Rapporteur's assessment report

Evicto – selamectin - EMEA/V/C/004973/VRA/0004/G - cats, dogs

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Tulinovet – Tulathromycin - EMEA/V/C/005076/VRA/0004 – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Clynav – Salmon pancreas disease vaccine (recombinant DNA plasmid) - EMEA/V/C/002390/VRA/0013 – Atlantic salmon

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Clynav – Salmon pancreas disease vaccine (recombinant DNA plasmid) - EMEA/V/C/002390/VRA/0014 – Atlantic salmon

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

EMEA/V/C/xxxx/WS2281

Porcilis PCV M Hyo - pigs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner, Co-Rapporteur: M. Leppanen

Action: For adoption

Rapporteur's assessment report including List of questions

Rabitec – rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0009 – foxes and raccoon dogs

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

Simparica Trio – Sarolaner / Moxidectin / Pyrantel - EMEA/V/C/004846/VRA/0008 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

Rhiniseng – Porcine progressive atrophic rhinitis vaccine (inactivated) - EMEA/V/C/000160/VRA/0012 – pigs

Variation requiring assessment: Quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

List of questions

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

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

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

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

BTVPUR - EMEA/V/C/002231/REC/024

Rapporteur: C. Muñoz Madero, Co-Rapporteur: P. Pasquali

Action: For endorsement

Rapporteur's assessment report

Versican Plus L4 - EMEA/V/C/003680/REC/13, Versican Plus Pi/L4 - EMEA/V/C/003683/REC/14, Versican Plus Pi/L4R - EMEA/V/C/003682/REC/15, Versican Plus DHPPi/L4 - EMEA/V/C/003678/REC/18, Versican Plus DHPPi/L4R - EMEA/V/C/002759/REC/18

Rapporteur: E. Werner, Co-Rapporteur: G. Kulcsár

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

9. Procedural and regulatory matters

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

9.3. Regulatory matters

Invented names

Annex to 6-8 September 2022 CVMP Agenda

CVMP Working Parties dates 2022-2023

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Sept 2022	6-8	20-21				15-16	27-28	19-21	5		
Oct 2022	4-6		19-20	12-13					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										