11 February 2022
EMA/96832/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 15-17 February 2022

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

15 February 2022, 09:00 – 17 February 2022, 13:00 - Room 15B 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 15-17 February 2022. See (current) February 2022 CVMP minutes (to be published post March 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 expert's 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 14 Feb 2022	10.00 - 13.00

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 – EMEA/V/MRL/005739/FULL/0001 – Equidae

Action: For information

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. EMA/V/C/005606/0000 – cattle, pigs, sheep

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/005428/0000 – horses

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

No items

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

2.4.1. EMA/V/C/005944/0000 – dogs

Action: For adoption

CVMP scientific overview and 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

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

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

Variation: to add a new therapeutic indication and target species

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

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

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

No items

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

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

Scope: Notification

Action: For decision

Notification from Germany under Article 82 of Regulation (EU) 2019/6

Appointment of rapporteur, co-rapporteur and peer reviewers

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

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. Neptra – florfenicol/terbinafine hydrochloride/mometasone furoate – EMEA/V/C/004735

Rapporteur: C. Muñoz Madero

Action: For endorsement

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

5.1.2. Nobivac Myxo-RHD Plus – Live myxoma vectored RHD virus strain 009, Live myxoma vectored RHD virus strain MK1899 – EMEA/V/C/004989

Rapporteur: E. Werner

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 GMP and pharmacovigilance inspections 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

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)

6.1.1. Election of the chair of AWP

Action: For decision

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.2. Election of the chair of ERAWP

Action: For decision

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.8. Quality Working Party (QWP)

6.8.1 Election of the veterinary vice-chair of the QWP

Action: For decision

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP)

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

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

7.7.1. Temporary approach to deal with nitrosamine impurities in VMP applications

Action: For endorsement

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. Draft VICH GL on Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

Action: For endorsement

EU comments on latest draft of the guideline

8.1.2. VICH Discussion Document – Global Regulatory Dossier Framework for VMPs

Action: For endorsement

Discussion Document – Global Regulatory Dossier Framework with EU comments

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

8.3.1. New mandate on the request for the fourth Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report

Action: For information

8.3.2. Request from the European Commission for a scientific report on the impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.

Action: For information

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and 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

9.1.6. EMA MUMS / Limited Markets Policy – 12th Annual Report

Action: For endorsement

12th annual report on Veterinary MUMS / Limited Markets, for adoption by Management Board on 16-17 March 2022

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

No items

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Consolidated 3-year work plan for the Veterinary Domain

Action: For adoption

Consolidated 3-year work plan for the Veterinary Domain

11. CMDv

11.1. Verbal report from CMDv Chair

Verbal report from the CMDv chair on the CMDv meetings held on 9-10 December 2021 and 20-21 January 2022

Action: For information

Agenda of the CMDv meeting to be held on 17-18 February 2022; minutes of the CMDv meeting held on 20-21 January 2022

12. Legislation

12.1. Scientific advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans for the implementing act to Regulation (EU) 2019/6

Action: For adoption

Scientific advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans for the implementing act to Regulation (EU) 2019/6

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

Action: For adoption

Draft reflection paper on criteria for determining that an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU) 2019/6

12.3. Article 34 of Regulation (EU) 2019/6

Action: For adoption

Establishment of a drafting group for the elaboration of guidance on the application of Article 34 of Regulation (EU) 2019/6 regarding the classification of veterinary medicinal products and interpreting the criteria for determining the prescription status

12.4. Article 44 (2) of Regulation (EU) 2019/6

Action: For adoption

Procedural advice – extended assessment time for initial marketing authorisation applications of 90 days

12.6. 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 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))

13. Any other business

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/005579/0000 – dogs

Action: For decision

Request from applicant to extend clock-stop for 3 months

EMEA/V/C/005132/0000 – dogs

Action: For decision

Request from the applicant for a further extension of the clock stop

3. Variations to marketing authorisations

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

EMEA/V/C/xxxx/WS2201
Purevax RCPCh FeLV, Purevax RCP FeLV, Purevax RCP, Purevax RC and Purevax RCPCh -
– cat

Variation: To implement changes in section 4.6 of the SPC that were approved in the 10th PSURs assessment (PSUR covering period 01 March 2018 - 28 February 2021)

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

EMEA/V/C/xxxx/WS2215/G
Metacam – Meloxicam - cattle and horse
Novem – Meloxicam - cattle

Variation: Quality-related changes

Rapporteur: C. Bergman

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Tulissin – tulathromycin - EMEA/V/C/005073/II/0005 – cattle, pig, sheep

Variation: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Forceris – toltrazuril/iron(iii) ion - EMEA/V/C/004329/II/0004/G – pig (piglet)

Variation: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Strangvac - Streptococcus equi vaccine (recombinant proteins) - EMEA/V/C/005309/II/0002

Variation: Quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Veraflox – Pradofloxacin – EMEA/V/C/000159/II/0024/G – cats, dogs

Variation: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Fortekor Plus – Pimobendan/benazepril hydrochlorid – EMEA/V/C/00280/II/0021/G – dogs

Variation: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions

Credelio Plus – Lotilaner / milbemycin oxime – EMEA/V/C/005325/II/0004 – dogs

Variation: Quality-related changes

Rapporteur: Rory Breathnach

Action: For adoption

List of questions

EMEA/V/C/xxxx/WS2160/G
Canigen L4, Nobivac L4 – Canine leptospirosis vaccine (inactivated) - dogs

Variation: Quality-related changes

Rapporteur: B. Urbain

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

Arti-Cell Forte – Mesenchymal stem cells derived from peripheral blood, chondrogenic induced, allogeneic, equine – EMEA/V/C/004727

Rapporteur: F. Hasslung Wikström

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.04.2021-30.09.2021

Comfortis – spinosad – EMEA/V/C/002233

Rapporteur: A. Golombiewski

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.10.2020-30.09.2021

Daxocox – enflicoxib – EMEA/V/C/005354

Rapporteur: R. Breathnach

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 20.04.2021-31.10.2021

ProteqFlu – Influenza A/equi-2/Ohio/03 [H3N8] recombinant Canarypox virus (vCP2242), Influenza A/equi-2/Newmarket/2/93 [H3N8] recombinant Canarypox virus (vCP1533) – EMEA/V/C/000073

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.10.2018-30.09.2021

ProteqFlu-Te – Influenza A/equi-2/Ohio/03 [H3N8] recombinant Canarypox virus (vCP2242), Influenza A/equi-2/Newmarket/2/93 [H3N8] recombinant Canarypox virus (vCP1533), Clostridium tetani toxoid – EMEA/V/C/000074

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.10.2018-31.09.2021

Simparica Trio – sarolaner / moxidectin / pyrantel embonate – EMEA/V/C/004846

Rapporteur: R. Breathnach

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.04.2021-30.09.2021

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

Purevax RCP – EMEA/V/C/000090/REC/023.1
Purevax RC - EMEA/V/C/000091/REC/023.1
Purevax RCPCh - EMEA/V/C/000088/REC/025.1

Post-authorisation recommendation

Rapporteur: B. Urbain

Action: For endorsement

Rapporteur's assessment report

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

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

6. Working parties

6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

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

VICH Guidance for members of Expert Working Groups

Action: For information

VICH Guidance on Procedure for Expert Working Groups

Action: For information

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

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

9.3. Regulatory matters

Annex to 15-17 February CVMP Agenda

CVMP Working Parties dates 2022

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
February 2022	15-17			22-23				28 Feb- 2 Mar	14		
March 2022	15-17	22-23	2-3						14	31	
April 2022	11-13				28-29				8	1	
May 2022	10-12	24-25		17-18					6 or 10		
June 2022	14-16							27-29	10, 13 or 14		