6 May 2022
EMA/258586/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 10-12 May 2022

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

10 May 2022, 09:00 – 12 May 2022, 13:00 - Room 1C EMA, 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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Introduction

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 10-12 May 2022. See May 2022 CVMP minutes (to be published post June 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)	Friday 6 May 2022	10.00-13.00 CEST

1. Maximum residue limits

1.1. Opinions

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

Action: For adoption

CVMP opinion including EPMAR, CVMP AR

Action: For information

Summary of opinion

Action: To note

Divergent position

1.2. Oral explanations

No items

1.3. List of outstanding issues

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

Action: For adoption

List of outstanding issues

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/005538/0000 – dogs

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/005528/0000 – dogs

Action: For decision

Need for oral explanation

Action: For adoption

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/005988/0000 - mink

Action: For adoption

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

2.4.2. EMEA/V/C/005902/0000 – dogs

Action: For adoption

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

2.4.3. EMEA/V/C/005905/0000 - chickens

Action: For adoption

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

2.6.1. EMEA/V/C/005132/0000 – dogs

Action: For decision

Request from the applicant for a waiver for data during MAA evaluation

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0016 – chickens

Variation requiring assessment: to modify the product information

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, CVMP assessment report, product information

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

3.1.1. 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: For adoption

CVMP opinion, CVMP assessment report, product information

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

Variation requiring assessment: to align the product information with the latest QRD template, version 9.0.

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

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

Variation requiring assessment: to align the product information with the latest QRD template, version 9.0.

Rapporteur: N.C Kyvsgaard

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 N-methyl-pyrrolidone (NMP) as an excipient – EMEA/V/A/146

Scope: User safety

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

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

No items

5. Post-authorisation issues for marketing authorisations

5.1. Pharmacovigilance under Regulation (EU) 2019/6

5.1.1. Cerenia – maropitant - EMEA/V/C/000106

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

Rapporteur: N. Kyvsgaard

Action: For endorsement

P-SMEG evaluation endorsed by the PhVWP-V

5.1.2. Nasym – live attenuated bovine respiratory syncytial virus (BRSV), strain Lym-56 – EMEA/V/C/004897

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

Rapporteur: J. G. Beechinor

Action: For endorsement

P-SMEG evaluation endorsed by the PhVWP-V

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

5.1.1. Aservo EquiHaler – ciclesonide – EMEA/V/C/004991

Rapporteur: K. Baptiste

Action: For discussion and adoption

CVMP assessment report on the PSUR for the period 01.02.2021-31.07.2021

5.1.2. Librela – bedinvetmab – EMEA/V/C/005180

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP assessment report on the PSUR for the period 01.06.2021-30.11.2021

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)

No items

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)

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)

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

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. Concept paper on implementation of *in-vitro* methods to replace animal batch potency in veterinary immunologicals

Action: For discussion

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

No items

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. Election of the Chair of the Committee for Veterinary Medicinal Products (CVMP)

Action: For decision

Nomination(s) received:

G. J. Schefferlie

10.2. Veterinary Domain verbal report

Verbal report from the chair of the Veterinary Domain on the meeting held on 5 May 2022

Action: For information

Agenda of the meeting held on 5 May 2022 and minutes of the meeting held on 10 March 2022

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

Action: For information

Agenda

Background information: N/a

11. CMDv

No items

12. Legislation

12.1. Article 21 of Regulation (EU) 2019/6 - Informed consent (template)

Action: For adoption

Revised template: scientific overview and LoQ for an informed consent application

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

Action: For information

Verbal report on the drafting group for the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6

Action: For discussion

Comments from stakeholders on the concept paper on the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6

12.3. Antimicrobial use (AMU) data reporting per animal categories (numerator). Manual for reporting the data to the Agency

Action: For discussion

Manual for AMU reporting per animal categories (numerator)

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

Documents for silent adoption and information

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Apoquel – Oclacitinib maleate – EMEA/V/C/002688/VRA/0023 – Dog

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Innovax ND IBD – Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant) – EMEA/V/C/004422/VRA/0009 – chicken, chicken (embryonated eggs)

Variation requiring assessment: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

Sileo – dexmedetomidine hydrochloride - EMEA/V/C/003764/VRA/0024 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Zenalpha – medetomidine hydrochloride/vatinoxan hydrochloride - EMEA/V/C/005465/VRA/0001 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

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

Variation: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Variation: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, Annex B

Action: For endorsement

Rapporteur's assessment report

Action: For information

Innovax ND ILT – Marek's disease vaccine, Newcastle disease vaccine & infectious laryngotracheitis vaccine (live recombinant) – EMEA/V/C/005190/II/0003/G – poultry

Variation: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Tulinovet – tulathromycin - EMEA/V/C/005076/VRA/0004 – cattle, pig, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

List of questions

Loxicom – meloxicam - EMEA/V/C/000141/VRA/0041 – dog

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions

Nexgard – Afoxolaner - EMEA/V/C/002729/VRA/0036 – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: K. Boerkamp

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

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

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

10. Organisational and strategic matters

10.1. EMA Veterinary Info Day 2022

Action: For information

EMA Veterinary Info Day to be held on 12-13 May 2022; agenda (link)

11. CMDv

11.1. Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 12-13 May 2022; minutes of the CMDv meeting held on 12-13 April 2022

Annex to 10-12 May 2022 CVMP Agenda

CVMP Working Parties dates 2022

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
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		
Sept 2022		20-21						19-21	2		
Oct 2022				11-12					30 Sep		