10 June 2022
EMA/583174/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 14-16 June 2022

Chair: G. J. Schefferlie

14 June 2022, 09:00 – 16 June 2022, 13:00 - Room 1B 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 14.06.2022-16.06.2022. See June 2022 CVMP minutes (to be published post July 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

1. Maximum residue limits

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No items

1.3. List of outstanding issues

No items

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1.6. Other issues

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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

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/005816/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/005819/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.4. EMEA/V/C/005829/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

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2.3. List of outstanding issues 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

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

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

No items

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2.5. Other issues under Regulation (EU) 2019/6

No items

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

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3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Circovac – adjuvanted inactivated vaccine against porcine circovirus type 2- EMEA/V/C/000114/VRA/0020/G – pigs

Variation requiring assessment: to change the product information

Rapporteur: P. Pasquali

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.2. Nobilis IB 4-91 – avian infectious bronchitis vaccine (live, attenuated) - EMEA/V/C/000036/VRA/0028 – chickens

Variation requiring assessment: to add a new claim

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.3. Credelio – lotilaner - EMEA/V/C/004247/VRA/0021 – dogs, 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. Opinions under Commission Regulation (EC) No 1234/2008

3.1.1. Bravecto – fluralaner – EMEA/V/C/002526/II/0054/G – dogs

Variation: to add two new therapeutic indications

Rapporteur: K. Boerkamp, Co-Rapporteur: R. Breathnach

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

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No items

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

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

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

Variation requiring assessment: efficacy-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

3.4.2. Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0006/G – pigs

Variation requiring assessment: efficacy-related changes

Rapporteur: E. Werner, Co-rapporteur: F. Klein

Action: For adoption

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

3.4.3. 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

List of questions, comments on the product information

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3.5. Re-examinations of CVMP opinions on variations under Commission Regulation (EU) No 726/2004

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

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No items

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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 35 of Directive 2001/82/EC

Veterinary medicinal products containing toltrazuril to be administered orally to chickens – EMEA/V/A/144

Scope: Consumer safety

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

Action: For decision

Need for outstanding issues

Action: For discussion

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

5. Post-authorisation issues for marketing authorisations

5.1. Pharmacovigilance under Regulation (EU) 2019/6

5.1.1. Cardalis - benazepril hydrochloride/spironolactone – EMEA/V/C/002524

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

Rapporteur: C. Muñoz Madero

Action: For endorsement

P-SMEG recommendations endorsed by the PhVWP-V

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

5.1.1. Suprelorin – deslorelin acetate - EMEA/V/C/000109

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

Rapporteur: N. C. Kyvsgaard

Action: For endorsement

Rapporteur's assessment and final recommendation (signal analysis with DLP 31.12.2021)

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

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)

No items

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)

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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

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. Call for Chair of VICH Metabolism and Residue Kinetics Expert Working Group

Action: For discussion

8.1.2. Draft guideline: Good manufacturing practice guide for active pharmaceutical ingredients used in veterinary medicinal products

Action: For information

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

Action: For endorsement

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

10. Organisational and strategic matters

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

Action: For decision

Nomination(s) received

F. Hasslung Wikström

10.2. Appointment of a CVMP co-opted member at the July 2022 CVMP meeting

Action: For discussion

Identification of expertise necessary for CVMP to complement its expertise and appointment of a co-opted member, CVMP list of expertise 2022

11. CMDv

11.1. Verbal report from CMDv Chair

Verbal report from the CMDv chair on the CMDv meetings held on 12-13 April 2022 and 12-13 May 2022

Action: For information

Draft agenda of the CMDv meeting to be held on 16-17 June 2022; minutes of the CMDv meeting held on 12-13 May 2022; minutes of the CMDv-Interested Parties meeting held on 18 March 2022; draft agenda of the CMDv-Interested Parties meeting to be held on 17 June 2022

12. Legislation

12.1. Generics of nationally authorised reference products: information on reference product - procedure and templates

Action: For endorsement

Procedure to request and circulate minimum information on reference product (RP)

12.3 Article 34 of Regulation (EU) 2019/6

Action: For discussion

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

12.4. Guideline on quality data requirements for applications for non-biological products intended for limited markets (applicable to applications submitted under either Article 8 or Article 23 of Regulation (EU) 2019/6)

Action: For information

Verbal update on work progress of QWP concerning the preparation of the guideline

12.5. Guideline on safety and residues data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For information

Verbal update on work progress of SWP-V concerning the preparation of the guideline

12.6. Guideline on efficacy and target animal safety data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For information

Verbal update on work progress of EWP concerning the preparation of the guideline

12.7. Guideline on quality data requirements for applications for biological products (including IVMPs) intended for limited markets (applicable to applications submitted under either Article 8 or Article 23 of Regulation (EU) 2019/6)

Action: For information

Verbal update on work progress of IWP concerning the preparation of the guideline

12.8. Guideline on safety and efficacy data requirements for applications for IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For information

Verbal update on work progress of IWP concerning the preparation of the guideline

12.9 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))

Presenter: G. Moulin

Action: For information

Background information: N/a

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

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

EMEA/V/C/005538/0000 – dogs

Action: For decision

Request for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Felpreva – tigolaner/emodepside/praziquantel - EMEA/V/C/005464/VRA/0001 – cats

Variation requiring assessment: quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Onsior – robenacoxib - EMEA/V/C/000127/VRA/0033 – cats, dogs

Variation requiring assessment: quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Suprelorin – deslorelin acetate – EMEA/V/C/000109/VRA/0035 – dogs, ferrets

Variation requiring assessment: quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

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

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

Variation requiring assessment: quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

List of questions

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

Variation requiring assessment: quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

List of questions, comments on the product information

Zenalpha – Medetomidine hydrochloride/Vatinoxan hydrochloride - EMEA/V/C/005465/VRA/0002 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

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: J. G. Beechinor

Action: For decision

Request for an extension of clock stop

Simparica Trio – sarolaner/moxidectin/pyrantel embonate - EMEA/V/C/004846/II/0007/G – dogs

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

Action: For decision

Request for an extension of clock stop

EMEA/V/C/xxxx/WS2217

Simparica, MiPet Easecto – sarolaner – dogs

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

Action: For decision

Request for an extension of clock stop

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

Librela – EMEA/V/C/005180/REC/005

Rapporteur: F. Hasslung Wikström

Action: For endorsement

Rapporteur's assessment report

Clynav - EMEA/V/C/002390/REC/011

Rapporteur: J. G. Beechinor

Action: For endorsement

Rapporteur's assessment report

Letifend - EMEA/V/C/003865/REC/015

Rapporteur: C. Muñoz Madero

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

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 14-16 June 2022 CVMP Agenda

CVMP Working Parties dates 2022

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
June 2022	14-16		28-29			9		27-29	13		
July 2022	12-14								8		
Sept 2022	6-8	20-21				15-16		19-21	2, 5, or 6		
Oct 2022	4-6		19-20	11-12					30 Sep, 3 or 4 Oct		
Nov 2022	8-10	22-23			23-24	14		21-23	2, 5 or 6	17-18	