12 January 2024
EMA/19707/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 16-18 January 2024

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

16 January 2024, 09:00 – 18 January 2024, 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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Table of contents

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 16-18.11.2024. See January 2024 CVMP minutes (to be published post February 2024 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

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

No items

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

No items

2.2. Oral explanations under Regulation (EU) 2019/6

No items

2.3. List of outstanding issues under Regulation (EU) 2019/6

2.3.1. EMEA/V/C/006222/0000 – cattle

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

2.4.1. EMEA/V/C/006311/0000 - dogs

Action: For adoption

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

2.4.2. EMEA/V/C/006309/0000 – Atlantic salmon

Action: For adoption

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

2.4.3. EMEA/V/C/006296/0000 – chickens

Action: For adoption

List of questions, comments on the product information

2.5. Re-examinations of CVMP opinions under Regulation (EU) 2019/6

No items

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

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Metacam – meloxicam - EMEA/V/C/000033/VRA/0151/G – cats

Variation requiring assessment: to modify the indication for use in cats and make related changes to the product information

Rapporteur: H. Bremer

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

3.3. List of outstanding issues under Regulation (EU) 2019/6

No items

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

3.4.1. Bluevac BTV - Bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3) - EMEA/V/C/000156/VRA/0012/G – cattle, sheep

Variation requiring assessment: to change the multistrain dossier to allow up to two different inactivated bluetongue virus serotypes in the final product (bivalent vaccine) and quality-related changes

Rapporteur: E. Werner, Co-Rapporteur: F. Marsilio

Action: For adoption

List of questions, comments on the product information

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

No items

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

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 35 of Directive 2001/82/EC

Veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses – EMEA/V/A/116 – follow-up assessment

Scope: risk to the environment due to PBT properties of moxidectin

Rapporteur: R. Carapeto, Co-Rapporteur: A. Golombiewski

Action: For adoption

CVMP assessment report

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

No items

5.2. Post-authorisation measures under Regulation (EU) 2019/6

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

No items

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

No items

5.5. Other issues

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)

6.1.1. Election of the Chair of the AWP

Action: For decision

Nomination(s) received:

D. Bouchard

6.1.2. AWP work plan for 2024

Action: For adoption

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. ERAWP work plan for 2024

Action: For adoption

6.3. Efficacy Working Party (EWP-V)

6.3.1. Revised Guideline on data requirements for veterinary medicinal products for zootechnical purposes

Action: For adoption

6.3.2. EWP-V work plan for 2024

Action: For adoption

6.4. Immunologicals Working Party (IWP)

6.4.1. IWP-V work plan for 2024

Action: For adoption

6.4.2. Guideline on plasmid DNA vaccines for veterinary use

Action: For adoption

6.4.3. Revised Guideline on live recombinant vector vaccines for veterinary use

Action: For adoption

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2024

Action: For adoption

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report from PhVWP-V meeting held on 19 December 2023

Action: For information

6.7.2. PhVWP-V work plan for 2024

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Q&A on assessment of quality of finished products containing known active substances

Action: For adoption

6.8.2. Q&A on how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV)

Action: For adoption

6.8.3. QWP work plan for 2024-2026

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 12 January 2024

Action: For information

6.9.2. SAWP-V work plan for 2024

Action: For adoption

6.10. Safety Working Party (SWP-V)

6.10.1. Guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances

Action: For adoption

6.10.2. SWP-V work plan for 2024

Action: For adoption

6.10.3. Overview of comments received on Concept paper on the revision of the Guideline on user safety of topically administered veterinary medicinal products (EMA/CVMP/SWP/721059/2014)

Action: For information

6.11. Other working party and scientific group issues

6.11.1. ESUAvet WG – revised work plan for 2023/2024

Action: For adoption

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

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

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

8.2. 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

Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for cats

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. Update on IRIS for core Regulatory Procedures

Action: For information

11. CMDv

No items

12. Legislation

12.1. Verbal report on the work progress of the expert group for the Scientific advice on Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months

Action: For information

12.2. Verbal report on the work progress of the expert group for the Scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with article 114(1)

Action: For information

12.3 Verbal report on the work progress of the working group for the implementation of Section I.1.7 of Annex II to Regulation (EU) 2019/06

Action: For information

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

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

EMEA/V/C/006142/0000 – chickens

Action: For adoption

Request for an extension of the clock stop

3.1. Opinions under Regulation (EU) 2019/6

EMEA/V/C/WS2477 - Fevaxyn Pentofel/Suvaxyn CSF Marker/ Suvaxyn PRRS MLV – Feline panleucopenia, calicivirosis, rhinotracheitis leukaemia and chlamydosis vaccine (inactivated) / Classical swine fever vaccine (live, recombinant) / Porcine respiratory and reproductive syndrome virus vaccine (live)— cats, pigs

Variation requiring assessment: quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Rexxolide – tulathromycin - EMEA/V/C/005384/VRA/0005 – cattle, pigs and sheep

Variation requiring assessment: quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Halocur – halofuginone - EMEA/V/C/000040/VRA/0019 – cattle (newborn calf)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement the ATCvet code change for halofuginone

Rapporteur: S. Louet

Action: For adoption

List of questions, comments on the product information

Tulaven – tulathromycin - EMEA/V/005153/VRA/0008 – cattle, pigs, sheep

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

Rapporteur: A. Golombiewski

Action: For adoption

List of questions, comments on the product information

Coxatab – firocoxib – EMEA/V/C/005816/0001/G – dogs

Variation requiring assessment: quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

List of questions

Rabitec – Rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0012 – foxes and raccoon dogs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

Nobilis IB Primo QX – avian infectious bronchitis virus (live) - (EMEA/V/C/002802/VRA/0011) – chicken

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

Suiseng Diff/A – clostridioides difficile and *Clostridium perfringens* vaccine (inactivated) - EMEA/V/C/005596/VRA/0003 – pigs

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

Respiporc FLUpan H1N1– Porcine influenza vaccine (inactivated) – EMEA/V/003993/VRA/0017 – pigs

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

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

List of questions, comments on the product information

Respiporc FLUpan H1N1 - Porcine influenza vaccine (inactivated) - EMEA/V/C/003993/VRA/0016/G – pigs

Variation requiring assessment: quality-related changes

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

List of questions, comments on the product information

Purevax RCP FeLV - Feline calicivirosis vaccine (inactivated), feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia) vaccine (live), feline leukaemia vaccine (live recombinant) - EMEA/V/C/000089/VRA/0035 – cats

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

Rapporteur: E. Dewaele

Action: For adoption

List of questions, comments on the product information

Coliprotec F4/F18 - Porcine post-weaning diarrhoea vaccine (live) - EMEA/V/C/004225/VRA/0011 - pigs

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

Rapporteur: E. Augustynowicz

Action: For adoption

List of questions, comments on the product information

3.4.5. Purevax RCP - Feline calicivirosis vaccine (inactivated), feline viral rhinotracheitis, feline infectious enteritis (feline panleucopenia) vaccine (live) - EMEA/V/C/000090/VRA/0035 – cats

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

Rapporteur: E. Dewaele

Action: For adoption

List of questions, comments on product information

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.2 Post-authorisation measures under Regulation (EU) 2019/6

Prevexxion RN+HVT+IBD – EMEA/V/C/005057/REC/008

Rapporteur: F. Klein

Action: For endorsement

Rapporteur's assessment report

Clevor – EMEA/V/C/004417/REC/009

Rapporteur: C. Muñoz Madero

Action: For endorsement

Rapporteur's assessment report

Nobivac DP Plus – EMEA/V/C/005251/REC/006

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's assessment report

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

6. Working parties

6.5. 3Rs Working Party (3RsWP)

Non-Clinical Domain workplan for 2024, including priorities for the 3RsWP

Action: For adoption

Non-Clinical and New Approach Methodologies ESEC nominations endorsed/to be endorsed by CHMP at its December 2023/January 2024 plenary meeting, respectively

Action: For information

Batch Release Testing OEG — Final composition

Action: For adoption

Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/3Rs/164002/2016) — Revision of the reflection paper

Action: For information

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL22(R) - Reproduction: Studies to evaluate the safety of residues of veterinary drug in human food: reproduction studies

Action: For adoption

9. Procedural and regulatory matters

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

Transfer of (co-)rapporteurships responsibilities

Action: For decision

Transfer of (co-)rapporteurships responsibilities from:

B. Urbain to E. Dewaele and F. Klein

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 19-20 January 2024; minutes of the CMDv meeting held on 7-8 December 2023

12. Legislation

Proposal for a Regulation establishing a common data platform on chemicals

Action: For information

Annex to 16-18 January 2024 CVMP Agenda

CVMP Working Parties dates 2024

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	3RsWP
Jan 2024	16-18						23-24	15-16	12		
Feb 2024	13-15			20-21			21	12-13	9	21-22	
Mar 2024	12-14	5-6	20-21				26-27	11-13	8		
Apr 2024	16-18						25	15-16	12		
May 2024	21-23	28-29		28-29			28-29	23-24	17		