8 March 2024
EMA/107153/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 12-14 March 2024

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

12 March 2024, 09:00 – 14 March 2024, 13:00 - Room 2C 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 12-14.03.2024. See March CVMP minutes (to be published post April 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 8 Mar 24	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

1.4.1. Substance – EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For adoption

Scientific overview and list of questions

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

2.1.1. EMEA/V/C/006222/0000 – cattle

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006128/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006124/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.4. EMEA/V/C/005887/0000 – chickens

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For endorsement

VAMF certificates

Action: For information

Summary of opinion

2.1.5. EMEA/V/C/006441/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report product, product information

Action: For information

Summary of opinion

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

No items

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

No items

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

2.4.1. EMEA/V/C/006300/0000 – cats

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

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

2.6.1. EMEA/V/C/005902/0000 – dogs

Action: For decision

Request for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Aivlosin – tylvalosin - EMEA/V/C/000083/VRA/0094/G – chickens, pheasants, turkeys, pigs

Variation requiring assessment: to add information to section 4.7 of the SPC and section 12 of the package leaflet on use during pregnancy, lactation or lay and to align the product information with version 9.0 of the QRD template

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

No items

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

3.3.1. Prevexxion RN+HVT+IBD– infectious bursal disease and Marek's disease vaccine (live recombinant) – EMEA/V/C/005057/VRA/0009 – chickens

Variation requiring assessment: to add a new route of administration

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

Action: For adoption

List of outstanding issues, product information

3.3.2. Rabitec - rabies vaccine (live, oral) – EMEA/V/C/004387/VRA/0011 – foxes and raccoon dogs

Variation requiring assessment: to add a new strength including a new target species, a new composition of the bait and new vaccine container

Rapporteur: E. Werner, Co-rapporteur: M. Leppänen

Action: For adoption

List of outstanding issues, comments on product information

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

No items

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

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

No items

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. Verbal report on the AWP meeting held on 5-6 March 2024

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP meeting held 20-21 February 2024

Action: For information

6.4. Immunologicals Working Party (IWP)

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Election of the Chair of the NTWP

Action: For decision

Nomination(s) received:

J. Poot

6.6.2. Election of the Vice-Chair of the NTWP

Action: For decision

Nomination(s) received:

S. Casado

6.6.3. Verbal report on NTWP meeting on meeting held on 28 February 2024

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on the PhVWP-V meeting held on 22 February 2024

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held on 15-16 January 2024 and 12-13 February 2024

Action: For information

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 8 March 2024

Action: For information

6.10. Safety Working Party (SWP-V)

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

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Fourth joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance

Action: For information

Published fourth joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance new item (link); JIACRA 4 report (link); simplified summary (link)

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

9.1.1. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for cage birds, homing pigeons, terrarium animals, small rodents, ferrets, rabbits, exotic animals and zoo-kept animals

9.1.2. Request for classification

Action: For classification

CVMP recommendation for a veterinary medicinal product for wild boars

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

11. CMDv

No items

12. Legislation

12.1. 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

12.2. 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

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

2. Marketing authorisations

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

EMEA/V/C/006247/0000 – sea bream

Action: For decision

Request for an extension of clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Purevax RCP FeLV - feline calicivirosis vaccine (inactivated), feline viral rhinotrachieitis, 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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Respiporc FluPan H1N1 – porcine influenza vaccine – EMEA/V/C/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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Tulaven – tulathromycin - EMEA/V/C/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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Zulvac BTV - Bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3) – EMEA/V/C/004185/VRA/0006 – sheep, cattle

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

Rapporteur: F. Klein

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Senvelgo – velagliflozin – EMEA/V/C/005972/VRA/0001 – cats

Variation requiring assessment: quality-related changes

Rapporteur: K. Baptiste

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

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

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, product information

Action: For information

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For information

Rapporteur's assessment report

Eurican Herpes 205 – canine herpes vaccine (inactivated subunit) - EMEA/V/C/000059/VRA/0032 – dogs

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

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Bovela - Bovine viral diarrhoea vaccine (modified live) - EMEA/V/C/003703/VRA/0026 – cattle

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Virbagen Omega – feline Interferon omega (recombinant) – EMEA/V/C/000061/VRA/0011 – dogs, cats

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

Tulissin – tulathromycin - EMEA/V/C/005073/VRA/0010/G – cattle, pigs, sheep

Variation requiring assessment: quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions

Nobivac LoVo L4 – canine *Leptospira* vaccine - EMEA/V/C/005628/VRA/0001 – dogs

Variation requiring assessment: quality-related change

Rapporteur: E. Dewaele

Action: For adoption

List of questions, comments on the product information

Simparica, Simparica Trio, Stronghold Plus, Felisecto Plus - EMA/VRA/0000166127

Variation requiring assessment: quality-related changes

Rapporteur: J.G. Beechinor

Action: For adoption

Rapporteur's assessment report including request for supplementary information

MS-H Vaccine – *Mycoplasma synoviae* (live) - EMEA/V/C/000161/VRA/0020 – chickens

Variation requiring assessment: quality-related changes

Rapporteur: F. Klein

Action: For adoption

List of questions

Porcilis AR-T DF – porcine progressive atrophic rhinitis vaccine (inactivated) - EMEA/V/C/000055/VRA/0019 – pigs (sows), pigs (sows, nullipar)

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

Solensia – frunevetmab – EMEA/V/C/005179/VRA/0009/G – cats

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

Rapporteur's assessment report including list of questions

EMEA/V/C/WS2628 – Versican Plus DHPPi/L4R, Versican Plus Pi/L4R – dogs

Variation requiring assessment: quality-related changes

Rapporteur: E. Werner

Action: For adoption

Rapporteur's assessment report including list of questions

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

Apoquel – oclacitinib maleate – EMEA/V/C/002688/VRA/0027 – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For information

Withdrawal letter from the applicant

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

Strangvac – EMEA/V/C/005309/REC/006

Rapporteur: M. Blixenkrone-Møller

Action: For endorsement

Rapporteur's assessment report

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

List of veterinary products to be tested in the Sampling and Testing Programme 2025

Action: For adoption

List of veterinary products to be tested in the Sampling and Testing Programme 2025

6. Working Parties

6.5 3Rs Working Party (3RsWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL 61 on pharmaceutical development

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

9.3. Regulatory matters

Invented names

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 14-15 March 2024; minutes of the CMDv meeting held on 15-16 February 2024