6 September 2024
EMA/420270/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 10-12 September 2024

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

10 September 2024, 09:45 – 12 September 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 10-12 September 2024. See 07/2024 CVMP minutes (to be published post 09/2024 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

Scientific Advice Working Party (virtual)	Fri 6 Sep 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 – EMA/V/MRL/004380/EXTN/0002

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/005993/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/006131/0000 – pigs

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

2.3. 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/006461/0000 – cattle, sheep, goats, pigs, horses, dogs, cats

Action: For adoption

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

2.4.2. EMEA/V/C/005987/0000 – chickens

Action: For adoption

List of questions, comments on the product information

2.4.3. EMEA/V/C/006481/0000 – dogs

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

2.6.1. EMEA/V/C/006147/0000 – horses

Withdrawal at D120

Action: For information

Letter of withdrawal

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1 NexGard Combo – esafoxolaner / eprinomectin / praziquantel - EMEA/V/C/005094/VRA/0010 – cats

Variation requiring assessment: to implement changes in the product information to further clarify the method of administration.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.2 YURVAC RHD – rabbit haemorrhagic disease and RHDV2 vaccine (recombinant) – EMEA/V/C/005992 – rabbits

Variation requiring assessment: addition of a new therapeutic indication.

Rapporteur: R. Carapeto Garcia, Co-rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP assessment report, product information

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

3.4.2. Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMA/VRA/0000221746 – dogs

Variation requiring assessment: to add a new therapeutic indication.

Rapporteur: R. Breathnach, Co-Rapporteur: E. Dewaele

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

4.7.1. Referrals under Regulation (EU) 2019/6

No items

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

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. Others

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)

No items

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

No items

6.8. Quality Working Party (QWP)

6.8.1. Guideline on risk management requirements for elemental impurities in veterinary medicinal products

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 6 September 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

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.2. EU enlargement – European Medicines Regulatory Network (EMRN) support to candidate and potential candidate countries

Action: For information

7.3.3. Update on the scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of resistance in *Aspergillus* spp.

Action: For information

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. Revision of VICH GLs 7, 12, 13, 14, 15, 16, 19, 20, 21 on efficacy of anthelmintics

Action: For endorsement

VICH GL7(R) on Efficacy of anthelmintics – general requirements

VICH GL12(R) on Efficacy of anthelmintics – specific recommendations for bovines

VICH GL13(R) on Efficacy of anthelmintics – specific recommendations for ovines

VICH GL14(R) on Efficacy of anthelmintics – specific recommendations for caprines

VICH GL15(R) on Efficacy of anthelmintics – specific recommendations for equines

VICH GL16(R) on Efficacy of anthelmintics – specific recommendations for porcines

VICH GL19(R) on Efficacy of anthelmintics – specific recommendations for canines

VICH GL20(R) on Efficacy of anthelmintics – specific recommendations for felines

VICH GL21(R) on Efficacy of anthelmintics – specific recommendations for chickens

8.2. Codex Alimentarius

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 veterinary medicinal product for honey bees.

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for European sea bass.

9.1.3. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for dogs

9.1.4. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for cats.

9.1.5. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for exotic animals.

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

9.3. Regulatory matters

10. Organisational and strategic matters

11. CMDv

11.1. Verbal report from CMDv chair on the 27-28 June and 25-26 July 2024 CMDv meetings

Action: For information

12. Legislation

12.1. Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6

Action: For adoption

Guideline

12.2. Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6

Action: For adoption

Guideline

12.3. Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of the Regulation (EU) 2019/6

Action: For adoption

Guideline

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

1. Maximum Residue Limits

1.6 Other issues

Lidocaine– EMEA/V/MRL/003649/EXTN/0002 – porcine species

Action: For adoption

Corrigendum to the EPMAR

Lidocaine– EMEA/V/MRL/003649/EXTN/0003 – bovine species

Action: For adoption

Corrigendum to the EPMAR

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Cimalgex – cimicoxib - EMEA/V/C/000162/VRA/0010 – dogs

Variation requiring assessment: 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

Novem – meloxicam- EMEA/V/C/000086/VRA/0029 – cattle, pigs

Variation requiring assessment: 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

Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) – EMEA/V/C/004276/VRA/0012/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Locatim – immunoglobulins against *Escherichia coli F5* - EMEA/V/C/000041/VRA/0027 – cattle

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Letifend – canine leishmaniasis vaccine (recombinant protein) – EMEA/V/C/003865/VRA/0030 – dogs

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

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Respiporc FLU3 – swine influenza vaccine (inactivated) - EMEA/V/C/000153/VRA/0024/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Equilis West Nile – West Nile fever vaccine (inactivated recombinant) - EMEA/V/C/002241/VRA/0009 – horses

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

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMEA/V/C/005309/VRA/0007/G – horses

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMEA/V/C/005272/VRA/0005/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Respiporc FLU3 – swine influenza vaccine (inactivated) - EMEA/V/C/000153/VRA/0025 – 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

Purevax FeLV – feline leukaemia vaccine (live recombinant) - EMEA/V/C/000056/VRA/0032 – 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

Rheumocam – meloxicam - EMEA/V/C/000121/VRA/0039 – cats, dogs, cattle, pigs, horses

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

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Inflacam – meloxicam - EMEA/V/C/002497/VRA/0030 – cats, dogs, cattle, pigs, horses

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

Rapporteur: S. Louet

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Felpreva – tigolaner / emodepside / praziquantel - EMEA/V/C/005464/VRA/0008 – cats

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

Metacam – meloxicam - EMEA/V/C/000033/VRA/0153 – cats, cattle, dogs, guinea pigs, horses, pigs

Variation requiring assessment: 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

Panacur AquaSol - fenbendazole - EMEA/V/C/002008/VRA/0024/G – pigs, chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Cerenia – maropitant / maropitant citrate - EMEA/V/C/000106/VRA/0045 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Simparica, Simparica Trio – sarolaner, moxidectin, pyrantel embonate – EMEA/VRA/0000175976 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: J. Beechinor

Action: For adoption

CVMP opinion, rapporteur's assessment report

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

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

CVMP opinion

Action: For endorsement

Zenalpha – medetomidine hydrochloride/vatinoxan hydrochloride– EMEA/VRA/0000223452 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, Rapporteur's assessment report

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

NexGard Combo – esafoxolaner / eprinomectin / praziquantel - EMEA/V/C/005094/VRA/0009 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

Rexxolide – tulathromycin – EMA/VRA/0000221089 – cattle, pigs, sheep

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

Rapporteur: S. Louet

Action: For adoption

List of questions, comments on the product information

Ecoporc Shiga – genetically modified STx2e antigen vaccine - EMEA/V/C/002588/VRA/0014 – pigs

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

Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

Equisolon – prednisolone - EMEA/V/C/002382/VRA/0012 - horses

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

Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

EMEA/V/C/WS2730 - Eurican L4 - cattle

Variation requiring assessment: quality-related changes.

Rapporteur: E. Kollár-Nagy

Action: For adoption

Rapporteur's assessment report including list of questions

Eurican L4 - canine leptospirosis vaccine (inactivated) – EMEA/V/C/005944/VRA/0002 - cattle

Variation requiring assessment: quality-related changes.

Action: For adoption

Rapporteur's assessment report including list of questions

Profender – praziquantel / emodepside - EMEA/V/C/000097/VRA/0056/G - cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

List of questions

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

Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMEA/V/C/004735/VRA/0010 – dogs

Rapporteur: C. Muñoz Madero

Action: For information

Withdrawal letter from the applicant

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance under Regulation (EU) 2019/6

Senvelgo – velagliflozin - EMEA/V/C/005972 – direct animal healthcare professional communication (DaHPC) and topic-specific communication plan

Action: For information

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

Nobivac L4 – EMEA/V/C/002010/REC/004

Rapporteur: E. Dewaele

Action: For endorsement

Rapporteur's assessment report

Trilocur – EMEA/V/C/006128/REC/001

Rapporteur: M. O'Grady

Action: For endorsement

Rapporteur's assessment report

Trilorale – EMEA/V/C/006124/REC/001

Rapporteur: M. O'Grady

Action: For endorsement

Rapporteur's assessment report

Neoleish – EMEA/V/C/005538/REC/002.1

Rapporteur: C. Miras

Action: For endorsement

Rapporteur's assessment report

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS – EMEA/V/VAMF/0001-0008

Rapporteur: J. Poot

Action: For endorsement

Rapporteur's assessment report

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

6.8 Quality Working Party (QWP)

7. Other scientific matters

7.7. Other issues

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

9.3. Regulatory matters

Invented names

12. Legislation