14 June 2024
EMA/281901/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 18-20 June 2024

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

18 June 2024, 09:00 – 20 June 2024, 13:00 – virtual and room 2C

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 18-20/06/2024. See 05/2024 CVMP minutes (to be published post 06/2024 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

2.1.1. EMEA/V/C/006260/0000 - cattle

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

2.3.1. EMEA/V/C/006249/0000 – dogs, cats

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.3.2. EMEA/V/C/006311/0000 – 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

2.4.1. EMEA/V/C/006442/0000 – chickens, embryonated chicken eggs

Action: For adoption

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

2.4.2. EMEA/V/C/006439/0000 – dogs

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/006288/0000 – chickens

Action: For adoption

Request from the applicant for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. 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: K. Lehmann

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.2. Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0011/G – pigs

Variation requiring assessment: to change the product information related to the use in lactating sows and to align the product information with version 9.0 of the QRD template.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.3. Daxocox – enflicoxib - EMEA/V/C/005354/VRA/0003/G – dogs

Variation requiring assessment: to add two new tablet strengths and to amend the dosing table for the currently approved tablet strengths.

Rapporteur: R. Breathnach, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

3.1.4. Credelio / Adtab – lotilaner - EMA/VRA/0000177859 – cats, dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion; Credelio product information; AdTab 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

3.4.1. Stronghold Plus – selamectin / sarolaner - EMA/VRA/0000174657 – cats

Variation requiring assessment: to add a new therapeutic indication.

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

Action: For adoption

List of questions, comments on 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

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

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)

6.1.1. Election of the Vice-chair of AWP

Presenter: J. Schefferlie

Action: For decision

Nomination(s) received:

6.1.2. Verbal report on the AWP meeting held on 28-29 May 2024

Action: For information

6.2. Environmental Risk Assessment Working Party (ERAWP)

No items

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP meeting

Action: For information

6.3.2. Revision of efficacy guidelines in line with the definitions in Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis and prophylaxis

Action: For adoption

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting on meeting held on 7 June 2024

Action: For information

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 28-29 May 2024

Action: For information

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting to be held on 14 June 2024

Action: For information

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

6.11.2. Verbal report on the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group meeting held on 22-23 May 2024

Action: For information

6.11.3. Updated Workplan of the ESUAvet Working Group

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

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

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

Action: For endorsement

- VICH GL7 revised at step 5 - EU comments; responses to comments GL7 - EU comments
- VICH GL12 revised at step 5 - EU comments; responses to comments GL12 - EU comments
- VICH GL13 revised at step 5 - EU comments; responses to comments GL13 - EU comments
- VICH GL14 revised at step 5 - EU comments; responses to comments GL14 - EU comments
- VICH GL15 revised at step 5 - EU comments; responses to comments GL15 - EU comments
- VICH GL16 revised at step 5 - EU comments; responses to comments GL16 - EU comments
- VICH GL19 revised at step 5 - EU comments; responses to comments GL19 - EU comments
- VICH GL20 revised at step 5 - EU comments; responses to comments GL20 - EU comments
- VICH GL21 revised at step 5 - EU comments; responses to comments GL21 - EU comments

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

8.3.1. Call for volunteers to contribute to the development of the calculation tool for human dietary exposure to residues from veterinary medicinal products, feed additives and pesticides

Action: For decision

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

No items

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

9.3. Regulatory matters

9.3.1. Q&A Paper on Product Classification

Action: For adoption

10. Organisational and strategic matters

10.1 Joint resolution regarding scientific committee conduct

Action: For information

10.2. Targeted stakeholder consultation - Draft consolidated 3-year work plan for the veterinary domain (2025-2027)

Action: For discussion

11. CMDv

11.1. Verbal report on the CMDv meetings held on 25-26 April 2024 and 30-31 May 2024

Action: For information

12. Legislation

12.1. 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

Verbal report

Action: For discussion

Draft scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding 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.

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 discussion

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

2. Marketing authorisations

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

EMEA/V/C/006332/0000 – dogs

Action: For adoption

Request from the applicant for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

MS-H Vaccine – *Mycoplasma synoviae* (live) - EMEA/V/C/000161/VRA/0021/G - chickens

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Leucofeligen FeLV/RCP, Leucogen, Nobivac LeuFel – feline calicivirosis vaccine, feline viral rhinotracheitis vaccine, feline infectious enteritis (feline panleucopenia) vaccine (live), feline leukaemia vaccine (recombinant protein), feline leukaemia vaccine (inactivated) – WS2580 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Ingelvac CircoFLEX – porcine circovirus vaccine (inactivated) - EMEA/V/C/000126/VRA/0039 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: F. Marsilio

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMEA/V/C/004735/VRA/0009 – 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

WS2680 - Proteq West Nile, Oncept IL-2, Prevexxion RN, ProteqFlu-Te, ProteqFlu, Purevax RCPCh FeLV, Purevax RC, Vaxxitek HVT+IBD, Purevax RCPCh, Purevax RCP FeLV, Purevax FeLV, Prevexxion RN+HVT, Prevexxion RN+HVT+IBD, Purevax RCP, Purevax Rabies - cats

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

WS2668 - Prevexxion RN, Vaxxitek HVT+IBD, Prevexxion RN+HVT, Prevexxion RN+HVT+IBD – chickens, embryonated chicken eggs

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

CVMP opinion

Prevexxion RN product information, Vaxxitek HVT+IBD product information, Prevexxion RN+HVT product information, Prevexxion RN+HVT+IBD product information

Action: For endorsement

Rapporteur's assessment report

Exzolt – fluralaner - EMEA/V/C/004344/VRA/0017 – chickens

Variation requiring assessment: quality related changes.

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Letifend – canine leishmaniasis vaccine (recombinent protein) – EMEA/V/C/003865 – dogs

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

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

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

List of questions, comments on the product information

Poulvac Procerta HVT-IBD – live recombinant turkey herpes virus, strain HVT-IBD, expressing the VP2 protein of infectious bursal disease virus - EMEA/V/C/006000/VRA/0001/G – chickens, embryonated chicken eggs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

List of questions, comments on the product information

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

List of questions

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

Variation requiring assessment: quality-related changes.

Rapporteur: J. Beechinor

Action: For adoption

Rapporteur's assessment report including list of questions

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

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

List of questions

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

Osurnia – terbinafine / florfenicol / betamethasone acetate – EMEA/V/C/003753/VRA/0026/G – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For decision

Request from the applicant for an extension of clock stop

Osurnia – terbinafine / florfenicol / betamethasone acetate - EMEA/V/C/003753/VRA/0027 – dogs

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

Rapporteur: S. Louet

Action: For information

Letter of withdrawal of application

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.3. Inspections and controls under Regulation (EU) 2019

6. Working parties

6.2. Environmental Risk assessment Working Party (ERAWP)

6.5. 3Rs Working Party (3RsWP)

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL23(R2) – Safety: Genotoxicity testing

Action: For adoption

VICH GL23 Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing (revision 2)

9.3. Regulatory matters

Invented names