12 April 2024
EMA/158463/2024 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 16-18 April 2024

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

16 April 2024, 09:00 – 18 April 2024, 13:00 – virtual and rooms 2C/2B

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 16-18 April 2024. See April 2024 CVMP minutes (to be published post May 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)	12 April 2024	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 (ketoprofen) – EMEA/V/MRL/003652/MODF/0005 – bovine, porcine, equidae

Action: For adoption

Scientific overview and list of questions, call for scientific data for use in CVMP assessment work of ketoprofen

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/006160/0000 – turkeys

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/005993/0000 – dogs

Action: For adoption

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

2.3.2. EMEA/V/C/006118/0000 – chickens

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

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

Action: For decision

Need for oral explanation

Action: For adoption

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/006389/0000 – dogs, cats

Action: For adoption

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

2.4.2. EMEA/V/C/006332/0000 – dogs

Action: For adoption

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

2.4.3. EMEA/V/C/006362/0000 – chickens

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

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

No items

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

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

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

4.5.1. Kexxtone 32.4 g continuous-release intraruminal device for cattle – monensin – EMA/V/A/150

Scope: Benefit-risk balance

Action: Oral explanation

Action: For discussion

Rapporteurs assessment report

Background information: request from the European Commission under Article 130(4) of Regulation (EU) 2019/6; list of questions

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

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)

6.2.1. Verbal report on ERAWP meeting held on 18-19 March 2024

Action: For information

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

No items

6.5. 3Rs Working Party (3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Draft concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations

Action: For adoption

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on the PhVWP-V meeting held on 26-27 March 2024

Action: For information

6.8. Quality Working Party (QWP)

6.8.1. Draft guideline on stability testing for variations for VMPs

Action: For adoption

6.8.2. Addendum to the guideline on the use of near infrared spectroscopy (NIRS)

Action: For adoption

Addendum to the guideline on the use of near infrared spectroscopy (NIRS) on defining the scope of an NIRS procedure after public consultation; overview of comments

6.8.3. Q&A on nitrosamines limits on CEPs

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

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

Action: For information

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 21-22 March 2024

Action: For information

6.10.2. Election of the Chair of the SWP-V

Action: For decision

Nomination(s) received:

C. Bergman

6.11. Other working party and scientific group issues

6.11.1. European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group - Draft Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations

Action: For adoption

6.11.3. Active substance master file working group – update of ASMF worksharing procedure guideline

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

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

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

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

9.3. Regulatory matters

No items

10. Organisational and strategic matters

10.1. Agenda of the CVMP Interested Parties meeting to be held on 22 May 2024

Action: For discussion

11. CMDv

11.1. Verbal report on the CMDv meetings held on 15-16 February 2024 and 14-15 March 2024

Action: For information

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

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

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

EMEA/V/C/006102/0000 – dogs

Action: For endorsement

Request for an earlier submission of the responses to the list of questions

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Neoleish – canine leishmaniasis vaccine (recombinant DNA plasmid) - EMEA/V/C/005538/VRA/0001/G – dogs

Variation requiring assessment: quality-related changes and 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 endorsement

Rapporteur's assessment report

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

Variation requiring assessment: quality-related changes

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Convenia – cefovecin – EMEA/V/C/000098/VRA/0038 – cats, dogs

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

Evant – *Eimeria acervulina, Eimeria maxima, Eimeria mitis, Eimeria praecox, Eimeria tenella* (vaccine live) – EMEA/V/C/004902/VRA/0004 – chickens

Variation requiring assessment: quality-related changes

Rapporteur: G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMEA/V/C/004846/VRA/0015/G – dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Coxevac – *Coxiella burnetii* vaccine - EMEA/V/C/000155/VRA/0016/G – cattle, goats, sheep

Variation requiring assessment: quality-related changes

Rapporteur: C. Miras

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Advocate – imidacloprid / moxidectin - EMEA/V/C/000076/VRA/0049 – cats, ferrets, dogs

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

Rapporteur: M. Leppänen

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Tessie – tasipimidine - EMEA/V/C/005427/VRA/0002 – dogs

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

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

UpCard – torasemide - EMEA/V/C/003836/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

Arti-Cell Forte – allogeneic equine peripheral blood-derived chondrogenic induced mesenchymal stem cells - EMEA/V/C/004727/VRA/0014 – horses

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

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Cortavance – hydrocortisone aceponate - EMEA/V/C/000110/VRA/0016 – dogs

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

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

MS-H vaccine - *Mycoplasma synoviae* (live)– EMEA/V/C/000161/VRA/0019 – chickens

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

Rapporteur: F. Klein

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Syvazul BTV – Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 3) - EMEA/V/C/004611/VRA/0009 – sheep, cattle

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

NexGard – Afoxolaner - EMA/VRA/0000166782 – dogs

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

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion, comments on the product information

Action: For endorsement

Rapporteur's assessment report

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

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

List of questions, comments on the product information

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

List of questions

Action: For endorsement

Rapporteur's assessment report

Prozinc – insulin human - EMEA/V/C/002634/VRA/0028 – cats, dogs

Variation requiring assessment: quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

Mhyosphere PCV ID – EMEA/V/C/005272/REC/004

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)

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

9.3. Regulatory matters

Invented names