



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 November 2023
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Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 7-9 November 2023

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

Tuesday 7 November 2023, 09:00 – Thursday 9 November 2023, 13:00 - Room 1D 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 ongoing 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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- 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 7-9.11.2023. See November 2023 CVMP minutes (to be published post December 2023 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)

Mon 6 Nov 2023

10.00-13.00 CET

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 and extensions

2.1. Opinions under Regulation (EU) 2019/6

No items

2.1. Opinions under Regulation (EC) No 726/2004

No items

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

No items

2.2. Oral explanations under Regulation (EC) No 726/2004

No items

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

[2.3.1. EMEA/V/C/006103/0000 – dogs, cattle, 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/006128/0000 – dogs](#)

Action: For decision

Need for oral explanation

Action: For adoption

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

[2.3.3. EMEA/V/C/006124/0000 – dogs](#)

Action: For decision

Need for oral explanation

Action: For adoption

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

2.3. List of outstanding issues under Regulation (EC) No 726/2004

No items

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

[2.4.1. EMEA/V/C/006131/0000 – pigs](#)

Action: For adoption

List of questions, comments on the product information

[2.4.2. EMEA/V/C/006289/0000 – pigs](#)

Action: For adoption

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

2.4. List of questions under Regulation (EC) No 726/2004

No items

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

No items

2.5. Re-examinations of CVMP opinions under Regulation (EC) No 726/2004

No items

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

No items

2.6. Other issues under Regulation (EC) No 726/2004

No items

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Suvaxyn Circo+MH RTU – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) - EMEA/V/C/003924/VRA/0021 – pigs

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

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1. Opinions under Commission Regulation (EC) No 1234/2008

No items

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

No items

3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

No items

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

No items

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

No items

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

3.4.1. 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

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

Action: For adoption

List of questions, comments on the product information

3.4.2. Increxxa – tulathromycin – EMEA/V/C/005305/VRA/0006 – cattle, pigs, sheep

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

Rapporteur's assessment report including list of questions

3.4. List of questions under Commission Regulation (EC) No 1234/2008

No items

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

No items

3.5. Re-examinations of CVMP opinions on variations under Regulation (EC) No 726/2004

No items

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

No items

3.6. Other issues under Commission Regulation (EC) No 1234/2008

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

4.4.1. Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs – procaine benzylpenicillin – EMEA/V/A/149

Scope: environmental risk assessment

Rapporteur: S. Louet, Co-Rapporteur: P. McNeill

Action: For discussion

Rapporteur's assessment report including co-rapporteur's critique

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

4.7.2.1. 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 persistent, bioaccumulative, toxic (PBT) properties of moxidectin

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

Action: For discussion

Rapporteur's assessment report including co-rapporteur's critique on the responses to the list of questions

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

5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

No items

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

5.2.1. HorStem – final study report on post-marketing surveillance study - EMEA/V/C/004265/REC/011

Rapporteur: A. Golombiewski, Co-rapporteur: C. Muñoz Madero

Action: For adoption

CVMP assessment report

5.2. Post-authorisation measures under Regulation (EC) No 726/2004

No items

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

No items

5.3. Supervision and sanctions under Regulation (EC) No 726/2004

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)

6.1.1. Overview of comments received on 'Concept paper for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals' (EMA/CVMP/AWP/933451/2022)

Action: For discussion

6.1.2. Draft AWP Work plan 2024

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 11–12 October 2023

Action: For information

6.2.2. Q&A on the implementation of the CVMP guideline on environmental impact assessment for VMPs in support of VICH GLs 6 and 38

Action: For adoption

6.2.3. Reflection paper on the environmental risk assessment of ectoparasiticide veterinary medicinal products used in cats and dogs

Action: For adoption

6.2.4. Draft ERAWP Work plan 2024

Action: For discussion

6.2.5. Upcoming election of the Vice-Chair of the ERAWP

Action: For information

Call for nominations

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP meeting held on 10-11 October 2023

Action: For information

6.4. Immunologicals Working Party (IWP)

6.4.1. IWP interested parties meeting

Action: For information

6.5. 3Rs Working Party (3RsWP)

6.5.1. Concept paper for the revision of the "Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches" (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)

Action: For adoption

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

[6.7.1. Verbal report on PhVWP-V meeting held on 25 October 2023](#)

Action: For information

[6.7.2. Draft PhVWP-V work plan for 2024](#)

Action: For discussion

6.8. Quality Working Party (QWP)

[6.8.1. Addendum to the guideline on the use of near infrared spectroscopy \(NIRS\)](#)

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

[6.9.1. Verbal report on SAWP-V meeting held on 6 November 2023](#)

Action: For information

[6.9.2. Scientific advice report](#)

Action: For adoption

[6.9.3. Draft SAWP-V work plan for 2024](#)

Action: For discussion

[6.9.4. Upcoming election for new members of SAWP-V](#)

Action: For information

Call for nominations

6.10. Safety Working Party (SWP-V)

No items

6.11. Other working party and scientific group issues

[6.11.1. Verbal report on the ESUAvet WG meeting held on 29 September 2023](#)

Action: For information

[6.11.2. ESUAvet WG – revised workplan 2023/2024](#)

Action: For discussion

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

7.1.1. Request on whether a full MRL evaluation is required in accordance with Commission regulation (EU) 2018/782 for *Varroa destructor* calmodulin gene-specific double-stranded interfering RNA EP15

Action: For adoption

Summary of assessment, revised list of biological substances considered as not requiring an MRL evaluation as per Regulation (EU) No. 2018/782, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

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. VICH guideline (GL) between strength bio-waivers for veterinary immediate release solid oral dosage forms

Action: For endorsement

Draft VICH GL on between strengths bio-waivers for veterinary immediate release solid oral dosage forms, including EU comments

8.1.2. Concept paper on principles for technical guidance for the transition to in vitro methods for batch potency tests in veterinary immunologicals

Action: For endorsement

8.1.3. Revision of VICH GL49 on validation of analytical methods used in residue depletion studies – EU proposal

Action: For endorsement

8.1.5. 42nd VICH Steering Committee meeting – November 2023

Action: To note

Draft agenda for the VICH Steering Committee meeting

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 veterinary medicinal product for cats

9.1.2. Request for classification

Action: For classification

CVMP recommendation for veterinary medicinal product for horses

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

9.3. Regulatory matters

9.3.1. Quick response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures guidance

Action: For information

QR Code Veterinary guidance; QR code request form_rev. 1 draft

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting to be held on 26 October 2023

Action: For information

10.2. Draft CVMP work plan for 2024

Action: For discussion

11. CMDv

No items

12. Legislation

12.1. Scientific advice on the implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the GMP for veterinary medicinal products and active substances used as starting materials

Action: For discussion

12.2. Revision of the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products

Action: For discussion

Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products – draft

12.3. 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

12.4. 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

12.5 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

1. Maximum residue limits

1.6. Other issues

[1.6.1. Substance \(Azamethiphos \(extension to fin fish\)\) – EU/11/185/FVG – fin fish](#)

Action: For adoption

Corrigendum to the EPMAR

2. Marketing authorisations and extensions.

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

[EMEA/V/C/006230 – cats](#)

Action: For decision

Request from the applicant for an extension of the clock stop

[EMEA/V/C/006249 – dogs](#)

Action: For decision

Request from the applicant for an extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

[Credelio Plus – lotilaner/milbemycin oxime - EMEA/V/C/05325/VRA/0006 - dogs](#)

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

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

[Onsior – robenacoxib – EMEA/V/C/000127/VRA/0036 – dogs](#)

Variation requiring assessment: Quality-related changes

Rapporteur: K. Boerkamp

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Vepured – *E. coli* verotoxoid vaccine \(inactivated recombinant\) – EMEA/V/C/004364/VRA/0006 – pigs](#)

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

[Mhyosphere PCV ID – EMEA/V/C/005272/VRA/0004 – pigs](#)

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

[Ubac – *Streptococcus uberis* vaccine \(inactivated\) - EMEA/V/C/004595/VRA/0007 – cattle](#)

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

[Hiprabovis IBR Marker Live – infectious bovine rhinotracheitis vaccine \(live\) – EMEA/V/C/000158/VRA/0013 – cattle](#)

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

Rapporteur: B. Urbain

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[Eryseng – swine erysipelas vaccine \(inactivated\) - EMEA/V/C/002761/VRA/0010 – 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 endorsement

Rapporteur's assessment report

[Eryseng Parvo – porcine parvovirus vaccine \(inactivated\) and swine erysipelas vaccine \(inactivated\) - EMEA/V/C/002762/VRA/0015 – 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 endorsement

Rapporteur's assessment report

[Nasym – bovine respiratory syncytial virus vaccine \(live, attenuated\) – EMEA/V/C/004897/VRA/0005 - cattle](#)

Variation requiring assessment: to align the product information with version 9 of the QRD template

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[EMEA/V/C/WS2478 - Nobivac LeuFel, Leucogen – feline leukaemia vaccines \(inactivated\) - cats](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD templates. In addition, minor corrections have been applied to the product information for both products.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information Leucogen and Nobivac LeuFel

Action: For endorsement

Rapporteur's assessment report

[Rhiniseng – porcine progressive atrophic rhinitis vaccine \(inactivated\) - EMEA/V/C/000160/VRA/0013 – pigs](#)

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

Rapporteur: M. Blixenkroner-Møller

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[Evant - coccidiosis vaccine live – EMEA/V/C/004902/VRA/0003 – chickens](#)

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

[Meloxoral – meloxicam - EMEA/V/C/00151/VRA/0017 – dogs, 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

[Suvaxyn Circo – porcine circovirus vaccine \(inactivated recombinant\) - EMEA/V/C/004242/VRA/0011 – pigs](#)

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

Variation requiring assessment: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Startvac – *Staphylococcus aureus* and coagulase-negative staphylococci and *Escherichia coli* J5 vaccine \(inactivated\) – EMEA/V/C/000130/VRA/0009 – cattle](#)

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

[Eravac – Rabbit haemorrhagic disease vaccine \(inactivated\) - EMEA/V/C/004239/VRA/0008 – rabbits](#)

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

[Equioxx – firocoxib – EMEA/V/C/00142/VRA/0030 – horses](#)

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Evalon – coccidiosis vaccine \(live\) - EMEA/V/C/004013/VRA/0004 – chickens](#)

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

[Nobivac Myxo-RHD Plus – Myxomatosis and rabbit haemorrhagic viral disease vaccine \(live recombinant\) - EMEA/V/C/004989/VRA/0002 – rabbits](#)

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

[EMEA/V/C/WS2560](#)

[Simparica Trio / Felisecto Plus / MiPet Easecto / Simparica / Stronghold Plus – cats, dogs](#)

Variation requiring assessment: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

[OvuGel – triptorelin acetate- EMEA/V/C/05219/VRA/0001– pigs](#)

Variation requiring assessment: to align the product information with version 9 of the QRD template

Rapporteur: B. Urbain

Action: For adoption

List of questions, product information

Action: For endorsement

[Versican Plus DHPi/L4 – Versican Plus L4 – Versican Plus Pi/L4 - EMEA/V/C/WS2556 – dogs](#)

Variation requiring assessment: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

Rapporteur’s assessment report including list of questions

[Syvazul BTV – Bluetongue virus vaccine \(inactivated, multistrain\) - EMEA/V/C/004611/VRA/0007 – sheep, cattle](#)

Variation requiring assessment: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

List of questions

[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: B. Urbain

Action: For adoption

List of questions, comments on the product information

3.6 Other issues under Regulation (EU) 2019/6

[Fortekor Plus – pimobendan/benazepril hydrochloride - EMEA/V/C/002804/VRA/0023/G – dogs](#)

Rapporteur: N. C. Kyvsgaard

Action: To note

CVMP opinion

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

Yurvac RHD – EMEA/V/C/005992/REC/001

Post-authorisation recommendation

Rapporteur: R. Carapeto García

Action: For endorsement

Rapporteur's assessment report

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

6.5 CVMP/CHMP Working Party on the application of the 3Rs (3RsWP)

Non-clinical (NC) and New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC)

Agenda of the NC and NAMs ESEC kick-off meeting held on 18 October 2023

Action: For information

6.6 Novel Therapies & Technologies Working Party (NTWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9. Procedural and regulatory matters

9.3. Regulatory matters

Invented names

10. Organisational and strategic matters

CVMP/CMDv Presidency meeting under the Spanish Presidency, Malaga, 20 – 21 September 2023

Action: For adoption

Minutes

11. CMDv

Report from the Chair of CMDv

Action: To note

Draft agenda of the CMDv meeting to be held on 9-10 November 2023; minutes of the CMDv meeting held on 5-6 October 2023

Annex to 7-9 November 2023 CVMP Agenda

CVMP Working Parties dates 2023/2024

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWP
Nov 2023	7-9	21-22			14-15		28-29		6	16-17	14-15
Dec 2023	5-7						19	4-6	1		
Jan 2024	16-18						23-24	15-16	12		
Feb 2024	13-15			20-21			21	12-13	9		
Mar 2024	12-14	5-6	20-21				26-27	11-13	8		