



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2023
EMA/440934/2023 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 3-5 October 2023

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

3 October 2023, 09:00 – 5 October 2023, 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 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](#)).



Table of contents

| | |
|---|----------|
| Introduction..... | 5 |
| i. Adoption of the agenda | 5 |
| 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 3-5.10.2023. See October 2023 CVMP minutes (to be published post November 2023 CVMP meeting) | 5 |
| iii. Declaration of contacts between members and companies with regard to points on the agenda..... | 5 |
| iv. Adoption of the minutes of the previous meeting | 5 |
| 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..... | 5 |
| 1. Maximum residue limits | 5 |
| 1.1. Opinions | 5 |
| 1.2. Oral explanations..... | 5 |
| 1.3. List of outstanding issues..... | 5 |
| 1.4. List of questions | 5 |
| 1.5. Re-examination of CVMP opinions on maximum residue limits..... | 5 |
| 1.6. Other issues..... | 5 |
| 2. Marketing authorisations and extensions | 6 |
| 2.1. Opinions under Regulation (EU) 2019/6..... | 6 |
| 2.1. Opinions under Regulation (EC) No 726/2004 | 6 |
| 2.2. Oral explanations under Regulation (EU) 2019/6 | 6 |
| 2.2. Oral explanations under Regulation (EC) No 726/2004 | 6 |
| 2.3. List of outstanding issues under Regulation (EU) 2019/6 | 6 |
| 2.3. List of outstanding issues under Regulation (EC) No 726/2004 | 6 |
| 2.4. List of questions under Regulation (EU) 2019/6..... | 7 |
| 2.4. List of questions under Regulation (EC) No 726/2004..... | 7 |
| 2.5. Re-examinations of CVMP opinions under Regulation (EU) 2019/6 | 7 |
| 2.5. Re-examinations of CVMP opinions under Regulation (EC) No 726/2004 | 7 |
| 2.6. Other issues under Regulation (EU) 2019/6 | 7 |
| 3. Variations to marketing authorisations..... | 7 |
| 3.1. Opinions under Regulation (EU) 2019/6..... | 7 |
| 3.1. Opinions under Commission Regulation (EC) No 1234/2008..... | 8 |
| 3.2. Oral explanations under Regulation (EU) 2019/6 | 8 |
| 3.2. Oral explanations under Commission Regulation (EC) No 1234/2008 | 8 |
| 3.3. List of outstanding issues under Regulation (EU) 2019/6 | 9 |
| 3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008 | 9 |
| 3.4. List of questions under Regulation (EU) 2019/6..... | 9 |
| 3.4. List of questions under Commission Regulation (EC) No 1234/2008 | 9 |
| 3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6 | 10 |
| 3.5. Re-examinations of CVMP opinions on variations under Regulation (EC) No 726/2004 | 10 |
| 3.6. Other issues under Regulation (EU) 2019/6 | 10 |
| 3.6. Other issues under Commission Regulation (EC) No 1234/2008..... | 10 |

| | |
|---|-----------|
| 4. Referrals and related procedures | 10 |
| 4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6 | 10 |
| 4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6 | 10 |
| 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 | 10 |
| 4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure | 10 |
| 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..... | 10 |
| 4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6 | 10 |
| 4.7. Other issues..... | 11 |
| 5. Post-authorisation issues for marketing authorisations..... | 11 |
| 5.1. Pharmacovigilance under Regulation (EU) 2019/6..... | 11 |
| 5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004..... | 11 |
| 5.2. Post-authorisation measures under Regulation (EU) 2019/6..... | 11 |
| 5.2. Post-authorisation measures under Regulation (EC) No 726/2004..... | 11 |
| 5.3. Inspections and controls under Regulation (EU) 2019/6..... | 11 |
| 5.3. Supervision and sanctions under Regulation (EC) No 726/2004 | 11 |
| 5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6 | 11 |
| 6. Working parties | 11 |
| 6.1. Antimicrobials Working Party (AWP)..... | 11 |
| 6.2. Environmental Risk Assessment Working Party (ERAWP) | 11 |
| 6.3. Efficacy Working Party (EWP-V)..... | 11 |
| 6.4. Immunologicals Working Party (IWP) | 12 |
| 6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP) | 12 |
| 6.6. Novel Therapies & Technologies Working Party (NTWP) | 12 |
| 6.7. Pharmacovigilance Working Party (PhVWP-V)..... | 12 |
| 6.8. Quality Working Party (QWP) | 12 |
| 6.9. Scientific Advice Working Party (SAWP-V)..... | 12 |
| 6.10. Safety Working Party (SWP-V)..... | 12 |
| 6.11. Other working party and scientific group issues | 12 |
| 7. Other scientific matters | 13 |
| 7.1. MRL issues..... | 13 |
| 7.2. Environmental risk assessment | 13 |
| 7.3. Antimicrobial resistance..... | 13 |
| 7.4. Pharmacovigilance | 13 |
| 7.5. Vaccine antigen master file (VAMF) certification..... | 13 |
| 7.6. Platform technology master file (PTMF) certification | 13 |
| 7.7. Other issues..... | 13 |
| 8. Co-operation with other EU or International bodies..... | 13 |
| 8.1. VICH..... | 13 |
| 8.2. Codex Alimentarius..... | 13 |
| 8.3. Other EU bodies and international organisations | 14 |

| | |
|---|-----------|
| 9. Procedural and regulatory matters | 14 |
| 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 | 14 |
| 9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers | 14 |
| 9.3. Regulatory matters | 14 |
| 10. Organisational and strategic matters | 14 |
| 11. CMDv..... | 14 |
| 12. Legislation | 15 |
| 13. Any other business | 15 |
| 14. Annex..... | 16 |

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 3-5.10.2023. See October 2023 CVMP minutes (to be published post November 2023 CVMP meeting)
- iii. Declaration of contacts between members and companies with regard to points on the agenda.
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Scientific Advice Working Party (virtual)

Mon 2 Oct 2023

10.00-13.00 CEST

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance – EMEA/V/MRL/003420/EXTN/0004 – chickens

Action: For adoption

CVMP opinion including EPMAR, CVMP assessment report

Action: For information

Summary of opinion

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

2.1.1. EMEA/V/C/005628/0000 – dogs

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. EMEA/V/C/005972/0000 – cats

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. EMEA/V/C/006045/0000 – cattle

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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/006143 – 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/0006254/0000 - dogs

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

2.6.1. EMEA/V/C/005993/0000 – dogs

Action: For decision

Request from the applicant for a further extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Fortekor Plus – pimobendan / benazepril hydrochloride - EMEA/V/C/002804/VRA/0023/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[3.1.2. EMEA/V/C/WS2395 – Suiseng Diff/A – *Clostridioides difficile* and *Clostridium perfringens* vaccine \(inactivated\) – pigs](#)

Variation requiring assessment: to add the associated use of the vaccine Suiseng Diff/A with the vaccine Suiseng Coli/C

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

[3.1.3. EMEA/V/C/WS2429 – CircoMax, CircoMax Myco – pigs](#)

Variation requiring assessment: to add the option of administering CircoMax Myco and CircoMax intramuscularly, using needle-free devices

Rapporteur: N. C. Kyvsgaard

Action: For adoption

CVMP opinion, product information of CircoMax and CircoMax Myco, CVMP assessment report

Action: For information

Summary of opinion

[3.1.4. Porcilis PCV ID – Porcine circovirus vaccine \(inactivated\) - EMEA/V/C/003942/VRA/0008 – pigs](#)

Variation requiring assessment: to extend the duration of immunity

Rapporteur: J. Poot

Action: For adoption

CVMP opinion, product information, CVMP assessment report

Action: For information

Summary of opinion

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

3.3.1. Bravecto – fluralaner – EMA/V/C/002526/VRA/0059 – dogs

Variation requiring assessment: to add a new pharmaceutical form

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

Action: For adoption

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

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. Frontpro – afoxolaner – EMEA/V/C/005126/VRA/0014/G – dogs

Variation requiring assessment: to add a new therapeutic indication, to update SPC section 3.7, and to align the product information with version 9.0 of the QRD template

Rapporteur: K. Boerkamp

Action: For adoption

List of questions, comments on the product information

3.4.2. EMEA/V/C/WS2512 - Arti-Cell Forte, RenuTend – tenogenic primed equine peripheral blood-derived mesenchymal stem cells; chondrogenic induced equine peripheral blood-derived mesenchymal stem cells - horses

Variation requiring assessment: Quality-related changes

Rapporteur: F. Hasslung Wikström

Action: For adoption

List of questions

3.4.3. Strangvac – Recombinant protein CCE from *Streptococcus equi*, Recombinant protein Eq85 from *Streptococcus equi*, Recombinant protein IdeE from *Streptococcus equi* - EMEA/V/C/005309/VRA/0006 – horses

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

Rapporteur: M. Blixenkroner-Møller

Action: For adoption

List of questions, comments on the product information

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: *to be appointed*, Co-Rapporteur: *to be appointed*

Action: For discussion

Request from the European Commission under Article 54(8) of regulation (EU) 2019/6, appointment of rapporteur, co-rapporteur and peer reviewers

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) 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

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

No items

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

No items

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)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

No items

6.4. Immunologicals Working Party (IWP)

6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Election of the Vice-Chair of PhVWP-V

Action: For decision

6.7.2. Verbal report on PhVWP-V meeting held on 26-27 September 2023

Action: For information

6.7.3. Verbal report on PhVWP-V Interested parties meeting held on 27 September 2023

Action: For information

6.7.4. Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD)

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meeting held on 4-5 September 2023

Action: For information

6.8.2. Concept paper on a GL on stability testing for variations for VMPS

Action: For adoption

6.8.3. Guideline on development and manufacture of synthetic peptides

Action: For adoption

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

6.11.1. Quality Innovation Group - Q&A on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing

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

7.3.1. Draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators

Action: For adoption

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

8.1.4. 42nd VICH Steering Committee meeting – November 2023

Action: To note

Draft agenda for 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 large zoo animals (lions, leopards, cheetahs, tigers, bears, great apes, others)

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

9.2.1. Summary of eligibility requests and table of offers from rapporteurs

Action: For decision

9.3. Regulatory matters

No items

10. Organisational and strategic matters

11. CMDv

11.1. Verbal report from CMDv Chair on the CMDv meetings held on 16-17 July 2023 and 7-8 September 2023

Presenter: L. Le Letty

Action: For information

Draft agenda of the CMDv meeting to be held on 5-6 October 2023; minutes of the CMDv meeting held on 15-16 June 2023; minutes of the CMDv-Interested Parties meeting held on 16 June 2023 ([link](#)); draft agenda of the CMDv-Interested Parties meeting to be held on 6 October 2023

12. Legislation

13. Any other business

13.1. AOB

No items

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

1.6. Other issues

Substance (ketoprofen) – EMEA/V/MRL/003652/EXTN/0004 – chickens

Rapporteur: K. Boerkamp

Action: For information

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

EMEA/V/C/006147/0000 – horses

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

Clomicalm – clomipramine hydrochloride - EMEA/V/C/000039/VRA/0041/G – dogs

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Porcilis ColiClos/Porcilis PCV ID/Porcilis PCV/Porcilis PCV M Hyo/Porcilis Porcoli DF – Porcine circovirus vaccine (inactivated), *E. coli* vaccine (inactivated), porcine circovirus vaccine (inactivated), *E. coli* and *C. perfringens* vaccine (inactivated), porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMEA/V/C/WS2501 - pigs

Variation requiring assessment: Quality-related changes

Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

[Suvaxyn CSF Marker – classical swine fever vaccine \(live, recombinant\) - EMEA/V/C/002757/VRA/0011 – pigs](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and to implement editorial changes

Rapporteur: M. Blixenkron-Møller

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

[Tulinovet – tulathromycin – EMA/V/C/005076/VRA/0006 – dogs](#)

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

Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

[Vectra 3D – dinotefuran / pyriproxyfen / permethrin - EMEA/V/C/002555/VRA/0024 – dogs](#)

Variation requiring assessment: Quality-related changes

Rapporteur: A. Golombiewski

Action: For adoption

List of questions

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

[Solensia – EMEA/V/C/005179/REC/004](#)

Rapporteur: R. Breathnach

Action: For endorsement

Rapporteur's assessment report

5.3 Inspections controls under Regulation (EU) 2019/6

6. Working parties

6.5 Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

6.7 PhVWP-V

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL60 Good Manufacturing Practice for active ingredients used in VMPs

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

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

9.3. Regulatory matters

Invented names

Annex to 3-5 October 2023 CVMP Agenda

CVMP Working Parties dates 2023

| CVMP WPs dates | CVMP | AWP | ERAWP | EWP | IWP | NTWP | PhVWP | QWP | SAWP | SWP | J3RsWP |
|-----------------|-------|-------|-------|-------|-------|------|-------|-------|--------|-------|--------|
| Oct 2023 | 3-5 | | 11-12 | 10-11 | | | 25 | | 2 | | |
| Nov 2023 | 7-9 | 21-22 | | | 14-15 | | 28-29 | 13-15 | 6 | 16-17 | 14-15 |
| Dec 2023 | 5-7 | | | | | | 19 | | 1 or 4 | | |
| Jan 2024 | 16-18 | | | | | | | | | | |
| Feb 2024 | 13-15 | | | | | | | | | | |