11 March 2022
EMA/154330/2022 – draft 3
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 15-17 March 2022

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

15 March 2022, 09:00 – 17 March 2022, 13:00 - Room 15-B and virtual

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

Disclaimer

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CVMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CVMP members and the work the Committee undertakes.

Declaration of interests

In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP Secretariat at the start of meeting.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 15-17 March 2022. See March 2022 CVMP minutes (to be published post April 2022 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 **5**

2.1. Opinions under Regulation (EU) 2019/6 5

2.1. Opinions under Regulation (EC) No 726/2004 5

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 6

2.4. List of questions under Regulation (EC) No 726/2004 6

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

2.5. Re-examinations of CVMP opinions under Regulation (EC) No 726/2004 6

2.6. Other issues under Regulation (EU) 2019/6 7

2.6. Other issues under Regulation (EC) No 726/2004 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 7

3.2. Oral explanations under Regulation (EU) 2019/6 7

3.2. Oral explanations under Commission Regulation (EC) No 1234/2008 7

3.3. List of outstanding issues under Regulation (EU) 2019/6 7

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008 7

3.4. List of questions under Regulation (EU) 2019/6 7

3.4. List of questions under Commission Regulation (EC) No 1234/2008 8

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6 8

3.5. Re-examinations of CVMP opinions on variations under Commission Regulation (EU) No 726/2004 8

3.6. Other issues under Regulation (EU) 2019/6 8

3.6. Other issues under Commission Regulation (EC) No 1234/2008 8

4. Referrals and related procedures 8
4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6 8
4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6 8
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 8
4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure 8
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 9
4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6 9
4.7. Other issues 9
5. Post-authorisation issues for marketing authorisations 9
5.1. Pharmacovigilance under Regulation (EU) 2019/6 9
5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004 9
5.2. Post-authorisation measures under Regulation (EU) 2019/6 9
5.2. Post-authorisation measures under Regulation (EC) No 726/2004 9
5.3. Inspections and controls under Regulation (EU) 2019/6 9
5.3. Supervision and sanctions under Regulation (EC) No 726/2004 9
5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6 10
6. Working parties 10
6.1. Antimicrobials Working Party (AWP) 10
6.2. Environmental Risk Assessment Working Party (ERAWP) 10
6.3. Efficacy Working Party (EWP-V) 10
6.4. Immunologicals Working Party (IWP) 10
6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG) 10
6.6. Novel Therapies & Technologies Working Party (NTWP) 10
6.7. Pharmacovigilance Working Party (PhVWP-V) 10
6.8. Quality Working Party (QWP) 10
6.9. Scientific Advice Working Party (SAWP-V) 10
6.10. Safety Working Party (SWP) 10
6.11. Other working party and scientific group issues 10
7. Other scientific matters 10
7.1. MRL issues 10
7.2. Environmental risk assessment 10
7.3. Antimicrobial resistance 11
7.4. Pharmacovigilance 11
7.5. Vaccine antigen master file (VAMF) certification 11
7.6. Platform technology master file (PTMF) certification 11
7.7. Other issues 11
8. Co-operation with other EU or International bodies 11
8.1. VICH 11
8.2. Codex Alimentarius 12
8.3. Other EU bodies and international organisations 12

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

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 15-17 March 2022. See March 2022 CVMP minutes (to be published post April 2022 CVMP meeting)

iii. Declaration of contacts between members and companies with regard to points on the agenda.

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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 14 Mar 2022	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

No items

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

2.3.1. EMEA/V/C/005829/0000 – dogs

Action: For decision

Need for an oral explanation

Action: For adoption

CVMP scientific overview and list of outstanding issues

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

No items

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

2.4.1. EMEA/V/C/005906/0000 – cattle

Action: For adoption

CVMP scientific overview and list of questions

2.4.2. Coxevac – Coxiella burnetii vaccine (inactivated) - EMEA/V/C/000155/X/0015 - cattle, goat

Extension to add a new target species

Rapporteur: C. Miras, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP scientific overview and list of questions

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

No items

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

3.1.1. Advocate – imidacloprid/moxidectin - EMEA/V/C/000076/II/0046 – cats

Variation: to add a new therapeutic indication

Rapporteur: T. M. Muhonen, Co-Rapporteur: J. P. Duarte Da Silva

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

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

No items

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

3.4.1. Bravecto – fluralaner – EMEA/V/C/002526/II/0054/G – dogs

Variation: to add two new therapeutic indications

Rapporteur: G. J. Schefferlie, Co-Rapporteur: R. Breathnach

Action: For adoption

List of questions

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 Commission Regulation (EU) 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

3.6.1. Suprelorin – Deslorelin – EMEA/V/C/000109/II/0032/G – cats

Rapporteur: N. C. Kyvsgaard, Co-Rapporteur: J. P. Duarte Da Silva

Action: For endorsement

Request from the applicant for an oral explanation

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

5. Post-authorisation issues for marketing authorisations

5.1. Pharmacovigilance under Regulation (EU) 2019/6

No items

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

5.1.1. Mhyosphere PCV ID – Mycoplasma hyopneumoniae, strain 7304 (Nexhyon), expressing the capsid protein of porcine circovirus type 2a, inactivated – EMEA/V/C/005272

Rapporteur: E. Werner

Action: For adoption

Rapporteur's evaluation on the PSUR for the period 01.04.2021-30.09.2021

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

Information relating to GMP and pharmacovigilance inspections will not be published as it would undermine the purpose of such inspections

No items

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

Information relating to supervision and sanctions will not be published as it would undermine the purpose of such inspections.

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)

No items

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.4. Immunologicals Working Party (IWP)

No items

6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

No items

6.6. Novel Therapies & Technologies Working Party (NTWP)

No items

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

6.10. Safety Working Party (SWP)

6.11. Other working party and scientific group issues

No items

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

7.7.1. Draft procedural advice for veterinary vaccine antigen master file (VAMF) certification

Action: For discussion

Draft procedural advice for veterinary vaccine antigen master file (VAMF) certification, overview of comments received during public consultation

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.1.1. Revision of VICH Guidelines on efficacy of anthelmintics

Action: For endorsement

Revised guidelines to sign off at Expert working group level (step 2):
- VICH GL07(R) - Anthelmintics - General requirements
- VICH GL12(R) - Anthelmintics – Bovines
- VICH GL13(R) - Anthelmintics – Ovines
- VICH GL14(R) - Anthelmintics – Caprines
- VICH GL15(R) - Anthelmintics – Equines
- VICH GL16(R) - Anthelmintics – Porcines
- VICH GL19(R) - Anthelmintics – Canines
- VICH GL20(R) - Anthelmintics – Felines
- VICH GL21(R) - Anthelmintics – Chickens

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

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

9.2. 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. Veterinary Domain verbal report

Verbal report from the chair of the Veterinary Domain on the meeting held on 10 March 2022

Presenter: G. J. Schefferlie

Action: For information

Agenda of the meeting held on 10 March 2022 and minutes of the 13 January 2022 meeting

11. CMDv

No items

12. Legislation

12.1. Article 34 of Regulation (EU) 2019/6

Action: For adoption

Concept paper on the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6

12.2. Guideline on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species

Action: For adoption

Guideline on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species and overview of comments received

12.3. Revision of the CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products (EMEA/CVMP/248499/2007)

Action: For endorsement

12.5. Scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))

Action: For information

Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))

12.6. EMA Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products

Action: For information

EMA advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans - in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products (link)

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

Documents for silent adoption and information

3. Variations to marketing authorisations

3.1 Opinions under Regulation (EU) 2019/6

3.1.1. Coliprotec F4/F18 - Porcine post-weaning diarrhoea vaccine (live) - EMEA/V/C/004225/VRA/0010 – pigs

Variation: Quality-related changes

Rapporteur: E. Augustynowicz

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

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

Cepedex – dexmedetomidine - EMEA/V/C/004376/II/0006 – cat, dog

Variation: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

BTVPUR - Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 4) - EMEA/V/C/002231/II/0025/G – cattle, sheep

Variation: Quality-related changes

Rapporteur: C. Muñoz Madero

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Porcilis ColiClos – *E. coli* and *C. perfringens components* – EMEA/V/C/002011/II/0013 – pigs

Variation: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Inflacam, Rheumocam – meloxicam– EMEA/V/C/WS295 – dogs

Variation: Quality-related changes

Rapporteur: S. Louet

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

ProteqFlu-Te – equine influenza (live recombinant) and tetanus vaccine - EMEA/V/C/000074/II/0032/G – horses

Variation: Quality-related changes

Rapporteur: C. Miras

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Recocam – meloxicam - EMEA/V/C/002247/II/0017 – cattle, pigs, horses

Variation: Quality-related changes

Rapporteur: J. G. Beechinor

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

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

ProZinc – insulin human - EMEA/V/C/002634/II/0025 – cat, dog

Variation: Quality-related changes

Rapporteur: R. Breathnach

Action: For adoption

List of questions

EMEA/V/C/xxxx/WS2184

Versican Plus Pi/L4R and Versican Plus DHPPi/L4R – dogs

Variation: Quality-related changes

Rapporteur: E. Werner

Action: For adoption

List of questions

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

Clevor – Ropinirole – EMEA/V/C/004417

Rapporteur: C. Muñoz Madero

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.05.2021-31.10.2021

Cytopoint – Lokivetmab – EMEA/V/C/003939

Rapporteur: R. Breathnach

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.11.2020-31.10.2021

Forceris – Toltrazuril/Iron (III) ion – EMEA/V/C/004329

Rapporteur: C. Muñoz Madero

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.05.2021-31.10.2021

Leucogen & Nobivac LeuFel – Purified p45 FeLV-envelope antigen – EMEA/V/C/000144 & EMEA/V/C/004778

Rapporteur: E. Werner

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.11.2018-31.10.2021

Procox – Toltrazuril/Emodepside – EMEA/V/C/002006

Rapporteur: F. Hasslung Wikström

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.11.2018-31.10.2021

Veraflox – Pradofloxacin – EMEA/V/C/000159

Rapporteur: A. Golombiewski

Action: For endorsement

Rapporteur's evaluation on the PSUR for the period 01.11.2018-31.10.2021

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

CircoMax Myco – EMEA/V/C/005184/REC/002

Post-authorisation recommendation

Rapporteur: N. C. Kyvsgaard

Action: For endorsement

Rapporteur's assessment report

Suvaxyn Circo+MH RTU – EMEA/V/C/003924/REC/007

Suvaxyn Circo - EMEA/V/C/004242/REC/015

Post-authorisation recommendation

Rapporteur: F. Klein

Action: For endorsement

Rapporteur's assessment report

Vectormune FP ILT + AE - EMEA/V/C/005077/REC/007

Rapporteur: J. Poot, Co-Rapporteur: C. Muñoz Madero

Action: For endorsement

Rapporteur's assessment report

MiPet Easecto - EMEA/V/C/004732/REC/006, Simparica - EMEA/V/C/003991/REC/014

Rapporteur: J. G. Beechinor, Co-Rapporteur: K. Boerkamp

Action: For endorsement

Rapporteur's assessment report

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

Information relating to GMP and pharmacovigilance inspections will not be published as it would undermine the purpose of such inspections

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

Information relating to supervision and sanctions will not be published as it would undermine the purpose of such inspections.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

Revision of EFSA guidance on the use of the Benchmark Dose approach in risk assessment

Action: For information

Draft revised guidance and public consultation until 11 April 2022 (link)

9. Procedural and regulatory matters

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

9.3. Regulatory matters

11. CMDv

11.1. Report from the Chair of CMDv

Action: For information

Draft agenda of the CMDv meeting to be held on 17-18 March 2022; minutes of the CMDv meeting held on 17-18 February 2022; minutes of the CMDv-Interested Parties meeting held on 21 January 2022; agenda of the CMDv-Interested Parties meeting to be held on 18 March 2022

Annex to 15-17 March 2022 CVMP Agenda

CVMP Working Parties dates 2022

CVMP WPs dates	CVMP	AWP	ERAWP	EWP	IWP	NTWP	PhVWP	QWP	SAWP	SWP	J3RsWG
March 2022	15-17	22-23	2-3						14	31	
April 2022	11-13				28-29				8	1	
May 2022	10-12	24-25		17-18		18-19			6 or 10		
June 2022	14-16							27-29	10, 13 or 14		
July 2022	12-14								8, 11, or 12		