13 June 2023
EMA/CVMP/270634/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 15-16 May 2023 meeting

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

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).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

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 15-17 May 2023

The attendance list was completed and competing interests were identified for the May 2023 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were 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 took 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 the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the April 2023 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

Information relating to briefing meetings taking place with applicants/marketing authorisation holders cannot be released at the present time as it is deemed to be commercially confidential.

1. Maximum residue limits

1.1. Opinions

- The Committee adopted by consensus (26 members present and eligible to vote) a revised CVMP opinion including the EPMAR and the CVMP assessment report, recommending the extension of MRLs to chickens for **Ketoprofen** (EMEA/V/MRL/003652/EXTN/0004). Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009 and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee agreed to extrapolate the conclusions to poultry. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the request from the European Commission for reconsideration of the CVMP opinion, the report from the EU Reference Laboratory, the revised rapporteur's EPMAR, the comments received from CVMP members and the revised summary of the opinion for publication.

1.2. Oral explanations

- There were no items for discussion.

1.3. Lists of outstanding issues

- There were no items for discussion.

1.4. List of questions

- There were no items for discussion.

1.5. Re-examination of CVMP opinions on maximum residue limits

- There were no items for discussion.

1.6. Other issues

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for **Eluracat** (EMEA/V/C/005948/0000), recommending the granting of a marketing authorisation. The product is for body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee adopted the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine (EMEA/V/C/005992/0000), for rabbits. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/006099/0000), for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted the comments received from CVMP members.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new vaccine (EMEA/V/C/006142/0000), for chickens.

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

- There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/VRA/0012), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Forceris** (EMEA/V/C/004329/VRA/0006/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Ypozane** (EMEA/V/C/000112/VRA/0007/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Chanaxin** (EMEA/V/C/000112/VRA/0001), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Naxcel** (EMEA/V/C/000079/VRA/0043), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. In addition, translation errors and the name of the marketing authorisation holder were corrected in the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Reconcile** (EMEA/V/C/000133/VRA/0042), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Strangvac** (EMEA/V/C/005309/VRA/0005), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and the product information and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Nobivac DP Plus** (EMEA/V/C/005251/VRA/0003/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to implement the outcome of a procedure concerning risk management measures in pharmacovigilance. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment (subject to a worksharing procedure) for **Prevexxion RN, Prevexxion RN+HVT+IBD** (EMEA/V/C/WS2437), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/VRA/0044), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Librela** (EMEA/V/C/005180/VRA/0008), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Canigen L4** (EMEA/V/C/004079/VRA/0011), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Nobivac L4** (EMEA/V/C/002010/VRA/0014), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **MiPet Easecto** (EMEA/V/C/004732/VRA/0012), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. In addition the name of the marketing authorisation holder was corrected in the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Simparica** (EMEA/V/C/003991/VRA/0023), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. In addition the name of the marketing authorisation holder was corrected in the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment (subject to a worksharing procedure) for **Purevax RCP FeLV, Purevax RCPCh FeLV, Purevax RC, Purevax RCP, Purevax RCPCh** (EMEA/V/C/WS2449), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment (subject to a worksharing procedure) for **Versican Plus DHPPi/L4R, Versican Plus Pi/L4R** (EMEA/V/C/WS2436), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Porcilis ColiClos** (EMEA/V/C/002011/VRA/0015), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee adopted a list of outstanding issues and agreed comments on the draft product information for a grouped variation requiring assessment for **NexGard Combo** (EMEA/V/C/005094/VRA/0007/G), to add two new therapeutic indications and to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of outstanding issues and agreed comments on the draft product information for a variation requiring assessment for **Tessie** (EMEA/V/C/005427/VRA/0001) to amend the product information as regards interactions with other medicinal products.

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

- There were no items for discussion.

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

- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **RenuTend** (EMEA/V/C/005428/VRA/0001) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Clynav** (EMEA/V/C/002390/VRA/0016) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Tulaven** (EMEA/V/C/005153/VRA/0007/G), concerning quality-related changes.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Enteroporc Coli AC** (EMEA/V/C/005149/VRA/0005/G), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Dexdomitor** (EMEA/V/C/000070/VRA/0045) to align the product information with version 9.0 of the QRD template.
- The Committee adopted comments on the draft product information for a variation requiring assessment for **Zactran** (EMEA/V/C/000129/VRA/0048) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions, and agreed comments on the draft product information, for a variation requiring assessment for **Palladia** (EMEA/V/C/000150/VRA/0019), to align the product information with version 9.0 of the QRD template. In addition, the name of the marketing authorisation holder in the product information and minor translation discrepancies in the different languages are corrected.
- The Committee adopted a list of questions and agreed comments on the draft product information, for a variation requiring assessment for **Panacur AquaSol** (EMEA/V/C/002008/VRA/0023) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information, for a variation requiring assessment for **Ypozane** (EMEA/V/C/000112/VRA/0006) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information, for a grouped variation requiring assessment for **Zuprevo** (EMEA/V/C/002009/VRA/0017/G) to align the product information with version 9.0 of the QRD template and to implement the outcome of a signal management procedure.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee agreed to a request from the MAH for an extension to the clock-stop for a variation requiring assessment (subject to a worksharing procedure) for **CircoMax, CircoMax Myco** (EMEA/V/C/WS2429).

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

- There were no items for discussion.

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

- There were no items for discussion.

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

- There were no items for discussion.

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

- There were no items for discussion.

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

- There were no items for discussion.

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

- There were no items for discussion.

4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6

- There were no items for discussion.

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.

4.7.1. Referrals under Regulation (EU) 2019/6

- The Committee noted the question and answer document for publication for the Article 33(4) referral procedure for **Catophos 100mg/ml+0.05mg/ml solution for injection for horses, cattle, dogs and cats** (EMEA/V/A/147).
- The Committee noted the question and answer document for publication for the Article 33(4) referral procedure for **Vey Tosal 100mg/ml+0.05mg/ml solution for injection for horses, cattle, dogs and cats** (EMEA/V/A/148).

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

- There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

Information relating to certain pharmacovigilance topics, and 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

- The Committee adopted a recommendation for changes in the product information in the sections on adverse events for **Apoquel** (EMEA/V/C/002688) as an outcome of signal detection activities.

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

- There were no items for discussion.

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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Mometamax Ultra** (EMEA/V/C/004987/REC/001) which is considered fulfilled.

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

- There were no items for discussion.

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

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

- There were no items for discussion.

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

- There were no items for discussion.

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)

- The Committee discussed the question and answer document on the guideline on the SPC for VMPs containing antimicrobial substances – antibiotic clinical breakpoints that may be included in section 4.2 of the SPC for generic VMPs. The adoption of the guideline is foreseen for the June 2023 meeting of the Committee.
- The Committee noted the call for nominations for two new AWP experts. The deadline for submission of nominations is 2 June 2023.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the overview of comments received on the draft "Reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs" (EMA/CVMP/ERA/31905/2021), following the close of the public consultation.

6.3. Efficacy Working Party (EWP-V)

- There were no items for discussion.

6.4. Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 24-25 April 2023, and noted the agenda of the meeting, together with the minutes of the IWP meeting held on 21-22 November 2022.
- The Committee discussed the draft concept paper for the revision of the guideline on live recombinant vector vaccines for veterinary use for public consultation. The adoption of the concept paper is foreseen for the June 2023 meeting of the Committee.
- The Committee noted the call for nominations for the upcoming election of the Chair of the IWP.

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

- There were no items for discussion.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee received a verbal report from the NTWP chair on the meeting held on 26 April 2023, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy (EMA/CVMP/NTWP/179287/2022) and the overview of comments received during public consultation. The adoption of the guideline is foreseen for the June 2023 meeting of the Committee.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 26 April 2023 and noted the agenda of the meeting together with a summary record.

6.8. Quality Working Party (QWP)

- There were no items for discussion.

6.9. Scientific Advice Working Party (SAWP-V)

- There were no items for discussion.

6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

6.11. Other working party and scientific group issues

- There were no items 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

- There were no items for discussion.

7.2. Environmental risk assessment

- There were no items for discussion.

7.3. Antimicrobial resistance

- The Committee discussed the draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators.

7.4. Pharmacovigilance

- There were no items for discussion.

7.5. Vaccine antigen master file (VAMF) certification

- There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

7.7. Other issues

- There were no items for discussion.

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

- The Committee endorsed EU comments on VICH GL22 Reproduction testing, and the EU discussion paper on Extended One-Generation Reproductive Toxicity Study (EOGRTS) implementation.
- The Committee endorsed the EU comments on the revision of VICH GL23 on Genotoxicity testing, and the draft revised VICH GL23 including EU comments.
- The Committee discussed the draft *in vitro* dissolution guideline for immediate release solid oral veterinary dosage forms including draft EU comments, and comments from the QWP. CVMP members were requested to submit any comments in writing by 26 May. Final EU comments will be adopted at the June 2023 meeting.
- The Committee adopted the updated GL18(R2) Impurities: residual solvents in new veterinary medicinal products, active substances and excipients (EMA/CVMP/VICH/502/1999). The revised guideline will be published for implementation.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- There were no items for discussion.

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

- The Committee considered the request for limited market classification for a veterinary medicinal product for cats and dogs. The Committee classified the product as not intended for a limited market and not eligible for authorisation under 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

10. Organisational and strategic matters

- The Committee adopted the agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held on 30-31 May 2023 in Uppsala, Sweden.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 23-24 March 2023 and 20-21 April 2023, and noted the draft minutes of the April meeting as well as the draft agenda of the meeting to be held on 16-17 May 2023.

12. Legislation

- The Committee discussed a scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall be used in accordance with these articles subject to certain conditions. The adoption of the advice is expected for the June 2023 meeting of the Committee. An *ad-hoc* CVMP meeting to further discuss the document is planned for 1 June 2023.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the May 2023 CVMP meeting, the draft news highlights were circulated for members to provide comments within 24 hours.

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the May 2023 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	Paul McNeill	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Eva Chobotová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
Co-opted	Carina Bergman	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
NL	Kim Boerkamp	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Els Dewaele	Full involvement	
DE	Christine Schwarz	Full involvement	
FR	Laetitia Le Letty	Full involvement	
FR	Marie-Hélène Sabinotto	Full involvement	
IE	Gavin Ryan	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Alma Moffett	Full involvement	
DE	Christopher Janich	Full involvement	
DE	Haru Kroneis	Full involvement	
DE	Sonja Beken	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
CZ	Eva Pomezná	Full involvement	
FR	Anne Marie Jacques	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Kathrin Schmidt	Full involvement	
FR	Mathilde Harvey	Full involvement	
FR	Anne Sagnier	Full involvement	
DE	Christina Bredtmann	Full involvement	
DE	Wiebke Weiher	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Katariina Kivilahti-Mäntylä	Full involvement	
ES	Patricia Vera Luque	Full involvement	
ES	María Domínguez Nicolás	Full involvement	
ES	Luis Agote Casado	Full involvement	
ES	Ramón Lorenzo Gómez	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Jitka Chumchalová	Full involvement	
DE	Maike Gömmel	Full involvement	
DE	Sandra Schack	Full involvement	
ES	María José Ferrer Montesa	Full involvement	
ES	Alberto de Prado López	Full involvement	
ES	Rosario Bullido Gómez-Heras	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Petra Kubová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Dana Halová	Full involvement	
DE	Jens Schönfeld	Full involvement	
DE	Heike Kaspar	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WP	Sarah Adler-Flindt
PhVWP-V	Els Dewaele
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

European Medicines Agency support
Meeting run with support from the relevant EMA staff