16 January 2024
EMA/24929/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 5-7 December 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).

The meeting was held in-person

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 5-7 December 2023

The attendance list was completed and competing interests were identified for the December 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).

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.

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

iv. Adoption of the minutes of the previous meeting

The minutes of the November 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

- There were no items for discussion.

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

- There were no items for discussion.

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee adopted the scientific overview including 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/006175/0000) for cattle. The Committee agreed that an oral explanation would not be requested. The Committee noted the rapporteur's joint assessment report of the list of questions and the comments received from CVMP members.
- The Committee adopted the scientific overview including 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/005887/0000) for chickens. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report.

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

- There were no items for discussion.

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

- There were no items for discussion.

2.6. 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 vaccine (EMEA/V/C/006288/0000).

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion, product information and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Zactran** (EMEA/V/C/000129/VRA/0056/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 (24 members present and eligible to vote) the CVMP opinion, product information and endorsed the rapporteur's assessment report for a variation requiring assessment for **Broadline** (EMEA/V/C/002700/VRA/0035), 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 (24 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 **Bovilis Nasalgen-C, Nobilis IB 4-91, Porcilis AR-T DF, Nobilis IB Primo QX, Nobivac DP Plus, Porcilis ColiClos, Nobivac Bb, Nobivac Myxo-RHD Plus** (EMEA/V/C/WS2559), 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 (24 members present and eligible to vote) the CVMP opinion, the product information and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Tulinovet** (EMEA/V/C/005076/VRA/0005/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 (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Vectra 3D** (EMEA/V/C/002555/VRA/0024), 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 (24 members present and eligible to vote) the CVMP opinion, the product information and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Solensia** (EMEA/V/C/005179/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 (24 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 **Arti-Cell Forte** and **RenuTend** (EMEA/V/C/WS2512), 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 (29 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a variation requiring assessment for **Bravecto** (EMA/V/C/002526/VRA/0059), recommending the variation of the marketing authorisation to add a new pharmaceutical form, 150 mg/ml powder and solvent for suspension for injection, for dogs. 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, the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Solensia** (EMEA/V/C/000047/VRA/0008), recommending the variation of the marketing authorisation to implement the outcome of the MAH's signal management process, to include "skin disorders" as a rare adverse event. 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, the CVMP assessment report and the product information for grouped variations requiring assessment for **Frontpro** (EMEA/V/C/005126/VRA/0014/G), recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of tick infestations with *Ixodes hexagonus* and to align the wording of the indications for use with applicable CVMP guidelines, to update SPC section 3.7 to allow the use of the product in breeding, pregnant and lactating female dogs, and to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

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

- There were no items for discussion.

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

- The Committee adopted a CVMP list of outstanding issues and agreed comments on the draft product information for a variation requiring assessment for **Strangvac** (EMEA/V/C/005309/VRA/0006), to implement the outcome of the MAH's signal management process.

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

- The Committee adopted a list of questions for a variation requiring assessment for **Aivlosin** (EMEA/V/C/00083/VRA/0095) 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 **Suprelorin** (EMEA/V/C/000083/VRA/0040), to align the product information with version 9 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 **Incurin** (EMEA/V/C/000047/VRA/0017), to align the product information with version 9 of the QRD template.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Gumbohatch** (EMEA/V/C/000083/VRA/0011/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 **Zulvac BTV** (EMEA/V/C/004185/VRA/0006), to align the product information with version 9.0 of the QRD template. Additionally, the MAH took the opportunity to process editorial changes and make a correction in the name of the marketing authorisation holder in the product information.
- The Committee adopted a list of questions for a grouped variation requiring assessment (subject to a worksharing procedure) for **Bovela** (EMEA/V/C/WS2564/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 **Eurican Herpes 205** (EMEA/V/C/000059/VRA/0032), 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 **Draxxin** (EMEA/V/C/00077/VRA/00050), to align the product information with version 9.0 of the QRD template. In addition, the MAH took the opportunity to correct the name of the marketing authorisation holder in the product information.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Lydaxx** (EMEA/V/C/005199/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 variation requiring assessment for **Tulissin** (EMEA/V/C/005073/VRA/0009), to align the product information with version 9.0 of the QRD template. In addition, the MAH took the opportunity to correct the name of the manufacturer responsible for batch release.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Aivlosin** (EMEA/V/C/000083/VRA/0094/G), to add information to section 4.7 of the SPC and section 12 of the package leaflet on use during pregnancy, lactation or lay and to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for a variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/VRA/0008), 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 **Prevexxion RN+HVT+IBD** (EMEA/V/C/005057/VRA/0009), to add a new route of administration.

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

- There were no items for discussion.

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

- 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

- The Committee adopted by majority (25 members present and eligible to vote) the CVMP reply to the European Commission and the CVMP assessment report for the procedure for **Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs** (EMEA/V/A/149) concluding that the restriction of the use of this veterinary medicinal product to pigs weighing 25 kg or less could be removed. A. Golombiewski, N.C. Kyvsgaard, S. Louet, and K. Baptiste signed divergent views not supporting the aforementioned conclusion. The Norwegian CVMP member supported one of the divergent views.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

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 received a verbal report from the AWP chair on the meeting held on 28-29 November 2023 and noted the agenda of the meeting. The Committee was informed that C. Schwarz will step down as chair of the AWP by the end of 2023 and thanked her for the valuable contribution to the CVMP during her tenure as AWP Chair.
- The Committee discussed the draft AWP work plan for 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee re-elected Boris Kolar as vice-chair of the ERAWP for a further 3-year mandate.

6.3. Efficacy Working Party (EWP-V)

- The Committee adopted the revised guideline on the conduct of pharmacokinetic studies in target animal species (EMA/CVMP/EWP/133/1999-Rev.1) and the overview of comments received (EMA/CVMP/EWP/326568/2018) following the close of the public consultation.
- The Committee discussed the draft revised guideline on data requirements for veterinary medicinal products for zootechnical purposes. The adoption for release for public consultation is foreseen for the January 2024 CVMP meeting.
- The Committee discussed the draft EWP-V work plan for 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.

6.4. Immunologicals Working Party (IWP)

- The Committee received a verbal report on the meeting held on 14-15 November 2023, and noted the agenda of the meeting.
- The Committee discussed the draft IWP-V work plan for 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.

- The Committee discussed the draft guideline on plasmid DNA vaccines for veterinary use and the overview of comments received following public consultation. The adoption of the guideline is foreseen for the January 2024 meeting of the Committee.
- The Committee discussed the draft revised guideline on live recombinant vector vaccines for veterinary use. The adoption for release for public consultation is foreseen for the January 2024 CVMP meeting.

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

- The Committee noted the members of the non-clinical (NC) and new approach methodologies (NAMs) European Specialised Expert Community (ESEC) endorsed by CHMP/PROM at its December 2023 plenary meetings.
- The Committee noted the minutes of the 3RsWP meeting held on 19 September 2023 together with the agenda of the 3RsWP meeting held on 22–23 November 2023.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee received a verbal report from the NTWP chair on the meeting held on 24 November 2023, and noted the minutes of the meeting held on 29 August 2023.
- The Committee discussed the NTWP work plan for 2024. The adoption of the work plan is foreseen for the January 2024 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 8-29 November 2023, and noted the agenda of the meeting.
- The Committee adopted the revised guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD) (EMA/CVMP/PhVWP/399363/2023) and the overview of comments received (EMA/CVMP/PhVWP/470818/2023) following the close of the public consultation. The new guideline comes into effect in December 2023.
- The Committee adopted the revised question and answer document on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL)) (EMA/CVMP/150343/2016-Rev.4).

6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 30-31 October 2023, and noted the agenda of the meeting together with the minutes of the QWP meeting held on 5-6 October 2023.
- The Committee discussed QWP work plan 2024-2026. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee elected P. McNeill and M. Leitner as SAWP-V members.
- The Committee received a verbal report from the SAWP-V chair on the meeting held on 1 December 2023, and noted the agenda of the meeting.
- The Committee adopted the scientific advice report on an existing veterinary medicinal product for dogs.

- The Committee adopted the scientific advice report on the development of new veterinary medicinal product for dogs.

6.10. Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 16 November 2023, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances (EMA/CVMP/SWP/591282/2023) and the overview of comments received during public consultation. This guideline, which was already discussed by the Committee in June 2022 following the close of the public consultation, has been on hold on request of the Commission since then, and is now undergoing finalisation. The adoption of the guideline is foreseen for the January 2024 meeting of the Committee.
- The Committee discussed SWP-V work plan 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.
- The Committee appointed Trijntje van de Velde-Koerts, Uta Herbst and Thierry Godard as members of the SWP-V.

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 adopted the questionnaire on review and adjustment of dosage regimens which was prepared to follow up the recommendations made in the reflection paper in order to establish a list of priority candidate products on review and adjustment of dosage regimens. Submission of stakeholders' feedback is expected by 1 June 2024.
- The Committee noted the Thirteenth ESVAC (European Surveillance of Veterinary Antimicrobial Consumption) report on sales of veterinary antimicrobial agents in 31 European countries in 2022 - *trends from 2010 to 2022* (link).

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

- The Committee adopted the assessment report and list of questions for a platform technology master file (PTMF) certification procedure (EMEA/V/VPTMF/0001).

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

- The Committee endorsed the EU comments on version 3 of the draft guideline on target animal safety evaluation for veterinary monoclonal antibody products.
- The Committee endorsed the EU comments on the latest draft of the guideline for the evaluation of veterinary pharmaceutical products containing two or more active pharmaceutical ingredients in fixed combination: general principles.
- The Committee received a verbal report on the VICH Safety Expert Working Group meeting held on 9-10 November 2023.
- The Committee endorsed the updated VICH guideline GL22 on reproduction toxicity, for sign-off at the EWG level.
- The Committee received a verbal report on the VICH Steering Committee and Forum meetings of 13-16 November 2023.
- The Committee endorsed the draft VICH guideline 61 on Pharmaceutical Development (EMA/CVMP/VICH/841162/2023), for sign-off by the VICH Steering Committee at step 2 of VICH.

8.2. Codex Alimentarius

8.3. Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

- Status of active VICH guidelines.

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

- There were no items for discussion

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 draft CVMP work plan for 2024 (EMA/CVMP/475891/2023).
- The Committee noted the document on Regulatory Procedure Management for Product lifecycle management product overview for Network.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the CMDv meetings held on 5-6 October 2023 and 9-10 November 2023, and noted the minutes of the meeting held on 9-10 November 2023 as well as the draft agenda of the meeting held on 7-8 December 2023 together with the minutes of the CMDv-IP meeting held on 6 October 2023 (link).

12. Legislation

- The Committee adopted the scientific advice to the European Commission on the implementing measures under article 93(2) of regulation (EU) 2019/6 of the European Parliament and of the Council on Veterinary Medicinal Products, regarding the GMP for veterinary medicinal products and active substances used as starting materials (EMA/INS/GMP/533512/2023).
- The Committee adopted the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products (EMA/CVMP/248499/2007) for release for a 6-month period of public consultation.
- The Committee received a 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.
- The Committee received a 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).

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the December 2023 CVMP meeting, the draft meeting highlights was 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 December 2023 meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the participant attended remotely.
Additional experts participated in (part of) the meeting, either in-person or remotely.

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	
BG	Krasimir Zlatkov	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	
IT	Fulvio Marsilio	Full involvement	
IE	Paul McNeill	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 (Vice-Chair)	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	
DK	Merete Blixenkrone-Møller	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LU	Caroline Coner	Full involvement	
NL	Kim Boerkamp	Full involvement	
SI	Boris Kolar	Full involvement	
SE	Hanna Bremer	Full involvement	
NO	Knud Torjesen	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.			
SE	Johan Heldemar	Full involvement	
BE	Sandy Vermout	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Dusan Palic	Full involvement	
IE	Susan Reid	Full involvement	
FR	Damien Bouchard	Full involvement	
BE	Els Dewaele (in-person)	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Maike Gömmel	Full involvement	
DK	Kira Rosenkilde Underbjerg	Full involvement	
DE	Judith Romberg DE	Full involvement	
DE	Brigitte Küchler	Full involvement	
BE	Koenraad Brusselmans	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Benoit Courty	Full involvement	
FR	Thierry Godard	Full involvement	
FR	Béatrice Leroux	Full involvement	
FR	Mariette Salery	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Jukka Pakkanen	Full involvement	
ES	María Esperanza Herreros Avilés	Full involvement	
ES	Jaime García Sánchez	Full involvement	
ES	Alberto de Prado Lopez	Full involvement	
ES	Marta Martin Juarez	Full involvement	
ES	Susana Casado Hernández	Full involvement	
ES	Rosario Bullido Gomez-Heras	Full involvement	
ES	Mª Jose Ferrer Montesa	Full involvement	
DE	Christina Bredtmann	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Roswitha Merkel	Full involvement	
DE	Gunther Speichert	Full involvement	
DE	Kerstin Cramer	Full involvement	
ES	Ana Isabel Olías Molero	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Sarah Hanley	Full involvement	
CZ	Jana Fluksova	Full involvement	
RO	Vilma Dosedlová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Dana Halová	Full involvement	
ES	Luis Agote Casado	Full involvement	
FR	Caroline Guittré	Full involvement	
DE	Daniela Loos	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
ESUAVet WG	Sara Sacristan* *(CVMP co-chair)*
EWP-V	Cristina Muñoz Madero
J3Rs WP	Sarah Adler-Flindt* *(veterinary vice chair)*
PhVWP-V	James Mount*
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