13 February 2024
EMA/CVMP/111854/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 13-14 February 2024

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 remotely.

Adoption of the Agenda

The Committee adopted the agenda with no modifications. There was an additional announcement regarding the publication, in the Official Journal, of the European Commission's Guidance to Applicants.

i. 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 13-14 February 2024

The attendance list was completed and competing interests were not identified for the February 2024 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).

ii. 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.

iii. Adoption of the minutes of the previous meeting

The minutes of the January 2024 meeting were adopted with no amendments.

iv. 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

2.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for **Alcort** (EMEA/V/C/006143/0000), recommending the granting of a marketing authorisation. The product is for the alleviation of clinical signs associated with atopic dermatitis and for symptomatic treatment of inflammatory and pruritic dermatoses in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Lexylan** (EMEA/V/C/006103/0000), recommending the granting of a marketing authorisation. The product is intended for the treatment of metritis, interdigital dermatitis, wounds and abscesses, treatment of septicemic mastitis in addition to an intramammary therapy, in cattle; infections of the respiratory tract, the urogenital system, the skin, soft tissues, and the gastrointestinal system, in dogs, and infections of the respiratory tract, the urogenital system, the skin and soft tissues, in

cats. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Divence Penta** (EMEA/V/C/006175/0000), recommending the granting of a marketing authorisation. The product is a vaccine intended for the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia, clinical signs and lung lesions caused by bovine respiratory syncytial virus and parainfluenza virus 3; to reduce virus shedding, hyperthermia and clinical signs caused by infectious bovine rhinotracheitis virus; to reduce viremia, hyperthermia and leukopenia caused by bovine viral diarrhoea virus 1 and bovine viral diarrhoea virus 2 and virus shedding caused by bovine viral diarrhoea virus 2; and for the active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of bovine viral diarrhoea virus (type 1 and 2). The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

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/005989/0000) for chickens. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report.
- 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/006160/0000) for turkeys. The Committee agreed that an oral explanation would not be requested. The Committee noted peer review reports 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/006043/0000), for chickens. The Committee agreed that an oral explanation would not be requested. The Committee noted peer review reports.

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

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product, (EMEA/V/C/006102/0000), for dogs. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/006306/0000), for chickens. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product, (EMEA/V/C/006356/0000), for dogs. The Committee noted peer review reports and the comments received from CVMP members.

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 new product, (EMEA/V/C/006235/0000).

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (27 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/0006), recommending the variation of the marketing authorisation to implement the outcome of the MAH's signal management process to add adverse events in the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/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 (27 members present and eligible to vote) the CVMP opinion and the product information for **Credelio** and for **AdTab** and endorsed the rapporteur's assessment report for a variation requiring assessment (subject to a worksharing procedure, EMEA/V/C/WS2636), recommending the variation of the marketing authorisations to implement the outcome of the MAH's signal management process to add adverse events in the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Daxocox** (EMEA/V/C/005354/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 (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a grouped variations requiring assessment for **Gumbohatch** (EMEA/V/C/000083/VRA/0011/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 (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for grouped variations requiring assessment (subject to a worksharing procedure) for **Bovela** (EMEA/V/C/WS2564/G), recommending the variation of the marketing authorisation to quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/VRA/0007), 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 (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for grouped variations requiring assessment for **Librela** (EMEA/V/C/005180/VRA/0010/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 majority (27 members present and eligible to vote) the CVMP opinion, the product information and endorsed the rapporteur's assessment report for grouped variations requiring assessment for **Incurin** (EMEA/V/C/000047/VRA/0017), 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 (27 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, Purevax RCP FeLV** (EMEA/V/C/WS2586), recommending the variation of the marketing authorisations to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 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 **Draxxin** (EMEA/V/C/000077/VRA/0050), 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 (27 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 **Lydaxx** (EMEA/V/C/005199/VRA/0006), 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 (27 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 **Tulissin** (EMEA/V/C/005073/VRA/0009), 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 manufacturer responsible for batch release was corrected. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 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 **Ovugel** (EMEA/V/C/005219/VRA/0001), 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 (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Increxxa** (EMEA/V/C/005305/VRA/0006), 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 (27 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 **Aivlosin** (EMEA/V/C/000083/VRA/0096), 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 (27 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 **Suprelorin** (EMEA/V/C/000083/VRA/0040), 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 (27 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report for grouped variations requiring assessment for **Profender** (EMEA/V/C/000097/VRA/0054/G), recommending the variation of the marketing authorisation to implement quality-related changes. 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 list of outstanding issues and agreed comments on the draft product information for a variation requiring assessment for **MS-H vaccine** (EMEA/V/C/000161/VRA/0019), to align the product information with version 9.0 of the QRD template.

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

- The Committee adopted a list of questions for a variation requiring assessment for **Apoquel** (EMEA/V/C/002688/VRA/0027) 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 **Convenia** (EMEA/V/C/000098/VRA/0038), 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 **Evant** (EMEA/V/C/004902/VRA/0004) 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 **Isemid** (EMEA/V/C/004345/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 **Arti-Cell Forte** (EMEA/V/C/004727/VRA/0014), 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 **Cortavance** (EMEA/V/C/000110/VRA/0016), 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 **Syvazul BTV** (EMEA/V/C/004611/VRA/0009), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for grouped variations requiring assessment for **Simparica Trio** (EMEA/V/C/004846/VRA/0015/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 **Vectra 3D** (EMEA/V/C/002555/VRA/0025), 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 **UpCard** (EMEA/V/C/003836/VRA/0009), 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 **Forceris** (EMEA/V/C/004329/VRA/0007), 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 **Tessie** (EMEA/V/C/005427/VRA/0002), 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 **Advocate** (EMEA/V/C/000076/VRA/0049), 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 **Contacera** (EMEA/V/C/002612/VRA/0017), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for grouped variations requiring assessment for **Neoleish** (EMEA/V/C/005538/VRA/0001/G), concerning quality-related changes and to align the product information to the latest QRD version 9.0.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Vectra Felis** (EMEA/V/C/002746/VRA/0020), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for grouped variations requiring assessment for **Coxevac** (EMEA/V/C/000155/VRA/0016/G), concerning quality-related changes.

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

- The Committee was informed of the formal notification from Elanco GmbH of their decision to withdraw the application for a variation requiring assessment for **Neptra** (EMEA/V/C/004735/VRA/0008), concerning quality-related changes.

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.

4.6. 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

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.

5.5. Other issues

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)

- There were no items for discussion.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

6.3. Efficacy Working Party (EWP-V)

- There were no items for discussion.

6.4. Immunologicals Working Party (IWP)

- There were no items for discussion.

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

6.6. Novel therapies & Technologies Working Party (NTWP)

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 23-24 January 2024 and noted the agenda of the meeting, together with the draft summary record of the January 2024 PhVWP-V meeting.

6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meetings held on 4-6 December 2023 and 15-16 January 2024, and noted the respective agendas of the meetings, together with the minutes of the QWP meeting held on 4-6 December 2023 and on 30-31 October 2023.
- The Committee adopted the annex to the guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water on compatibility studies between veterinary medicinal products and biocidal products and the overview of comments received during public consultation.
- The Committee was informed of the mandate, objectives and rules of procedure for Quality Domain Chemical ESEC and the open call for nominations.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 9 February 2024, and noted the agenda of the meeting together with the final minutes of the SAWP-V meeting held on 12 January 2024.

6.10. Safety Working Party (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

7.2. Environmental risk assessment

- There were no items for discussion.

7.3. Antimicrobial resistance

- There were no items for discussion.

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

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 draft VICH guideline GL61 on Pharmaceutical Development for sign-off by the VICH Steering Committee at step 3 of the VICH process.
- The Committee adopted the draft VICH guideline VICH GL22(R) on reproduction toxicity for release for public consultation at step 4 of the VICH process.

8.2. Codex Alimentarius

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

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

- The Committee agreed to the transfer of all (co-)rapporteurships and peer review responsibilities from T-M. Muhonen to K. Lehmann and M. Leppänen.

9.3. Regulatory matters

10. Organisational and strategic matters

- The Committee received a verbal report from the chair of the Veterinary Domain (VetD) on the meeting held on 1 February 2024, and noted the agenda of that meeting and the minutes of the meeting held on 26 October 2023.
- The Committee endorsed the proposal for a face-to-face CVMP Interested Parties meeting on 22 May 2024.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 7-8 December 2023 and 18-19 January 2024, and noted the minutes of the meeting held on 18-19 January 2024 as well as the draft agenda of the meeting to be held on 15-16 February 2024.

12. Legislation

- The Committee received a verbal report on the progress made by the expert group developing scientific advice on Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances that 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 from 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 February 2024 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 February 2024 meeting, *which was held remotely (participants with an asterisk * attended in person).*

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	Els Dewaele	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	
IE	Paul McNeill	Full involvement	
IT	Fulvio Marsilio	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 (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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
BG	Nadya Ognyanova Vladimirova	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Christine Miras	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Hanna Bremer	Full involvement	
NO	Knud Sveen 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.			
DK	Mariette Salery	Full involvement	
DE	Anke Finnah	Full involvement	
ES	Veronica Devesa	Full involvement	
BE	Sonja Beken	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
CZ	Eva Pomezna	Full involvement	
IE	Bryan Deane	Full involvement	
IE	Susan Reid	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Monika Hofmann	Full involvement	
DE	Dagmar Sommer	Full involvement	
DE	Brigitte Küchler	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Uta Herbst	Full involvement	
ES	Mercedes Ureña Montilla	Full involvement	
ES	Luis González Rivas	Full involvement	
ES	Jaime García Sánchez	Full involvement	
ES	Maria Jose Ferrer	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Maria Esperanza Herreros Avila	Full involvement	
ES	Susana Casado	Full involvement	
ES	Alberto de Prado	Full involvement	
ES	Luis Agote Casado	Full involvement	
ES	Leyre Sanchez Sanchez de Rojas	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
DE	Jana Schimanski	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	Thea Neumann	Full involvement	
DE	Nadine Matzmohr	Full involvement	
BE	Michel Goret	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Nathalie Bridoux	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
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