15 May 2023
EMA/CVMP/221092/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 18-20 April 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 the addition of a new item under point 3.1.

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 18-20.04.2023

The attendance list was completed and competing interests were identified for the April 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 March 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 (27 members present and eligible to vote) the CVMP opinion including the EPMAR recommending the extrapolation of MRLs to bovine and ovine milk for **rafoxanide** (EMEA/V/MRL/EXPL/003450). The Committee agreed to further extrapolate the bovine MRLs to all ruminants except ovine. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the report from the EU Reference Laboratory, a peer review report, the comments received from CVMP members and the 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

- 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.

2.1. 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 scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/005972/0000), for cats. The Committee agreed to invite the applicant for an oral explanation at its September 2023 meeting. The Committee noted a peer review report and the comments received from CVMP members.

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

- 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 product (EMEA/V/C/005132/0000), for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted peer review reports and the comments received from CVMP members.

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 vaccine (EMEA/V/C/006118/0000), for chickens. The Committee noted a peer review report 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/006142/0000), for chickens. The Committee noted a peer review report 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/006175/0000), for cattle. The Committee noted a peer review report and the comments received from CVMP members.

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 product (EMEA/V/C/005993/0000), for dogs.

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 (29 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a variation requiring assessment for **Melovem** (EMEA/V/C/00152/VRA/0015), recommending the variation of the marketing authorisation to implement quality-related changes. 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 (29 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a grouped variation requiring assessment for **Proteq West Nile** (EMEA/V/C/002005/VRA/0018/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to update the product information based on the outcome of signal detection activities. 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 (29 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information, for a variation requiring assessment for **Gumbohatch** (EMEA/V/C/004967/VRA/0009), recommending the variation of the marketing authorisation to amend the indication by adding the future layer chickens. 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 (29 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, for a variation requiring assessment (subject to a worksharing procedure) for **Vaxxitek HVT+IBD**, **Prevexxion RN+HVT+IBD**, **Prevexxion RN** (EMEA/V/C/WS2386), recommending the variation of the marketing authorisation to implement efficacy-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 **Zolvix** (EMEA/V/C/000154/VRA/0031), 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 variation requiring assessment (subject to a worksharing procedure) for **Purevax RCPCh, Purevax RCP FeLV, Purevax RCP, Purevax RCPCh FeLV** (EMEA/V/C/WS2376/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 the product information, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Contacera** (EMEA/V/C/002612/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.
- 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 **Onsior** (EMEA/V/C/000127/VRA/0035), 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 **Cerenia** (EMEA/V/C/000106/VRA/0043), 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 **Letifend** (EMEA/V/C/003865/VRA/0029), recommending the variation of the marketing authorisation to implement quality-related changes. 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 variation requiring assessment (subject to a worksharing procedure) for **Suiseng Diff/A** and other related nationally authorised products (EMEA/V/C/WS2395), concerning efficacy-related changes.

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 grouped variation requiring assessment for **Nobilis IB 4-91** (EMEA/V/C/000036/VRA/0029/G), to include information on onset of immunity and duration of immunity to the product information and 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 (subject to a worksharing procedure) for **CircoMax** and **CircoMax Myco** (EMEA/V/C/WS2429.
- The Committee adopted a list of questions for a variation requiring assessment for **Mhyosphere PCV ID** (EMEA/V/C/005272/VRA/0003), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Equilis Te** (EMEA/V/C/000093/VRA/0011/G), to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities: to add the adverse event

'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet).

- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Equilis Prequenza** (EMEA/V/C/000094/VRA/0016/G), to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities: to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet).
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Equilis Prequenza Te** (EMEA/V/C/000095/VRA/0019/G), to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities: to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet).
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **CircoMax Myco** (EMEA/V/C/005184/VRA/0004/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 **Versican Plus DHPPi** (EMEA/V/C/003679/VRA/0015), 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 **Prevexxion RN** (EMEA/V/C/005058/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 **Versican Plus DHPPi/L4** (EMEA/V/C/003678/VRA/0017), 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 **Easotic** (EMEA/V/C/000140/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 **SevoFlo** (EMEA/V/C/000072/VRA/0026), to align the product information with version 9.0 of the QRD template.

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

- There were no items for discussion.

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 was informed of the publication on the EMA website of a news announcement as well as an updated questions and answers document for the Article 82 referral procedure for **veterinary medicinal products containing N-methyl pyrrolidone as an excipient** (EMEA/V/A/146).

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 endorsed a recommendation for changes to the product information for **Neptra** (EMEA/V/C/004735) as outcome of signal management 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 **Letifend** (EMEA/V/C/003865/REC/016) which is considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Cytopoint** (EMEA/V/C/003939/REC/019) 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

- There were no items for discussion.

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 agreed on the call for nominations for two new experts for the AWP.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 29–30 March 2023, and noted the agenda of the meeting, together with the minutes from the meeting held on 19–20 October 2022.
- The Committee agreed on the call for nominations for a new expert for the ERAWP.

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 (J3RsWP)

- There were no items for discussion.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee noted the draft agenda of the upcoming Focus Group meeting on Bacteriophages on 11 May 2023.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the PhVWP-V product specific meeting held on 28-29 March 2023 and noted the agenda of the meeting.

6.8. Quality Working Party (QWP)

- The Committee adopted the QWP 3-year workplan (2023-2025). The Committee also adopted the call for nominations for members of the QWP and noted the proposed restructuring of the working party.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 14 April 2023, and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting held on 20 March 2023.

6.10. Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 30-31 March 2023, and noted the agenda of the meeting, together with the minutes of the meeting held on 17-18 November 2022.
- The Committee discussed the draft impact assessment from SWP-V of a change of model of consumer exposure.
- The Committee was informed of an ongoing public consultation on EFSA PRIMo4.

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

- 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

- 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 adopted the revised VICH guidelines GL35 Pharmacovigilance: electronic standards for transfer of data (EMA/CVMP/VICH/123940/2006) and VICH GL42 Pharmacovigilance: data elements for submission of adverse event reports (EMA/CVMP/VICH/355996/2005), for publication and implementation.
- The Committee endorsed the EU comments on the summary of comments and comments from animal welfare groups received at step 4 of the VICH process on the revised draft VICH guidelines 7, 12, 13, 14, 15, 16, 19, 20, 21 on efficacy of anthelmintics, following the end of the public consultation on the revised guidelines.
- The Committee agreed to use the joint expertise of the Safety Working Party to support the review of VICH GL47 on laboratory animal comparative metabolism studies.
- The Committee endorsed the absence of any need for comments on draft 3 of the VICH guideline on pharmaceutical development.

8.2. Codex Alimentarius

- There were no items for discussion.

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 and action plan of CVMP and working parties.

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 the veterinary medicinal product intended for turkeys. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

- The Committee considered the request for the veterinary medicinal product in horses. The Committee classified the product as intended for a limited market and not eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered the request for the veterinary medicinal product intended for dogs. The Committee classified the product as intended for a limited market and 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 received a verbal report from the chair of the Veterinary Domain (VetD) on the meeting held on 13 April 2023, and noted the agenda of the meeting and the minutes of the meeting held on 2 February 2023. The Committee noted the proposed draft agenda for the upcoming Presidency CVMP meeting under the Swedish presidency of the Council.
- The Committee endorsed the revised consolidated 3-year work plan for the VetD following the one-year review by VetD.
- The Committee discussed the consolidated list of agenda topics proposed by the CVMP Interest Parties for the CVMP Interested Parties meeting, due to be held on 24 May 2023.

11. CMDv

- The Committee noted the draft minutes of the meeting held on 23-24 March 2023, as well as the draft agenda of the meeting to be held on 20-21 April 2023.

12. Legislation

- The Committee received a verbal report from the expert group's chair on Scientific advice under Article 115(5) of Regulation (EU) 2019/6 with regards to 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 endorsed the survey to stakeholders which will be published on the EMA website with a deadline for completion by 30 June 2023.

13. Any other business

13.1. AOB

- No items for discussion

13.2. Meeting highlights

- Upon the completion of the April 2023 CVMP meeting, the draft news 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 April 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	Esther Werner	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	
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	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
IT	Antonio Battisti	Full involvement	
NL	Kim Boerkamp	Full involvement	
SK	Katarína Massányiová	Full involvement	
NO	Annelin Aksdal Bjelland	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	
FR	Marie-Hélène Sabinotto	Full involvement	
FR	Nathalie Bridoux	Full involvement	
DE	Nikola Lange	Full involvement	
ES	Nuria Sanchez	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Martine Redureau	Full involvement	
FR	Anne Chevance	Full involvement	
FR	Laetitia LeLetty	Full involvement	
ES	Susana Casado	Full involvement	
ES	Alberto de Prado	Full involvement	
ES	Rosario Bullido	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DK	Theis Moeslund Jensen	Full involvement	
DK	Yen Ngoc Pham	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Malene Nissen	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	John Aspegren	Full involvement	
FI	Stella Attia	Full involvement	
FI	Jukka Pakkanen	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Jenny Larsson	Full involvement	
DE	Babett Kobe	Full involvement	
DE	Sandra Schack	Full involvement	
DE	Heike Gyra	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	Monika Hofmann	Full involvement	
DE	Daniela Loos	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Judith Romberg	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Rhona McHugh	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Susan Reid	Full involvement	
IE	Tatyana Devine	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	---
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