4 October 2022
EMA/CVMP/799298/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 6-8 September 2022 meeting

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

Note on access to documents

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

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session

The attendance list was completed and competing interests were identified for the September 2022 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.

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.

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iv. Adoption of the minutes of the previous meeting

The minutes of the July 2022 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 (24 members present and eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of the MRL entry for **praziquantel** to fin fish (EMEA/V/MRL/003477/EXTN/0004). Furthermore, with reference to Article 5 of Regulation (EC) No 470/2009, and in line with the criteria laid down in Commission Regulation (EU) 2017/880, the Committee recommended extrapolation of the "No MRL required" entry established in ovine species to other ruminants except cattle. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the rapporteur's assessment report of responses to the list of outstanding issues, the rapporteur's EPMAR, 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

- The Committee heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/005528/0000). The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the October 2022 CVMP meeting.

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

- There were no items for discussion.

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

- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for an application for a new product, (EMEA/V/C/005577/0000), for pigs. The Committee noted a peer review report 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 product (EMEA/V/C/005972/0000), for cats. The Committee noted peer review reports 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 a further extension to the clock-stop for a new product (EMEA/V/C/005132/0000).
- The Committee was informed of the formal notification from Boehringer Ingelheim Vetmedica GmbH of their decision to withdraw the application for a new marketing authorisation for dogs (EMEA/V/C/005835/0000).

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a grouped variation requiring assessment for **Improvac** (EMEA/V/C/000136/VRA/0039/G), recommending the variation of the marketing authorisation to extend the inter-dose interval from 4 to 8 weeks, and to reduce the minimum age of vaccination accordingly (from 14 to 10 weeks of age) in female pigs and 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 noted the summary of the opinion for publication.

- 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 **Improvac** (EMEA/V/C/000136/VRA/0040), 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 (25 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Porcilis PCV ID** (EMEA/V/C/003942/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 (26 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Solensia** (EMEA/V/C/005179/VRA/0003), 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 (25 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Exzolt** (EMEA/V/C/004344/VRA/0014/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 **Poulvac E. coli** and other related nationally authorised products (EMEA/V/C/xxxxxx/WS2257), 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 the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment (subject to a worksharing procedure) for **Vaxxitek HVT+IBD, Prevexxion RN+HVT+IBD** and **Prevexxion RN** (EMEA/V/C/xxxx/WS2265), 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 the product information and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Evicto** (EMEA/V/C/004973/VRA/0004/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 **Tulinovet** (EMEA/V/C/005076/VRA/0004), 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 **Clynav** (EMEA/V/C/002390/VRA/0013), 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 **Clynav** (EMEA/V/C/002390/VRA/0014), 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

- There were no items for discussion.

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 **Rabitec** (EMEA/V/C/004387/VRA/0010/G), including an update to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and comments on the draft product information for a variation requiring assessment for **Apoquel** (EMEA/V/C/002688/VRA/0024), to align the product information with version 9.0 of the QRD template.
- The Committee adopted comments on the draft product information for a variation requiring assessment for **ProteqFlu** (EMEA/V/C/000073/VRA/0025), to align the product information with version 9.0 of the QRD template.
- The Committee adopted comments on the draft product information for a variation requiring assessment for **ProteqFlu-Te** (EMEA/V/C/000074/VRA/0033), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment (subject to a worksharing procedure) for **NexGard** and **Nexgard Spectra** (EMEA/V/C/WS2280/G), to add two new therapeutic indications and to amend the product information.
- The Committee adopted a rapporteur's assessment report including list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Porcilis PCV M Hyo** and other related nationally authorised products (EMEA/V/C/xxxx/WS2281), concerning quality-related changes.

- The Committee adopted a list of questions for a variation requiring assessment for **Rabitec** (EMEA/V/C/004387/VRA/0009), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Simparica Trio** (EMEA/V/C/004846/VRA/0008), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Rhiniseng** (EMEA/V/C/000160/VRA/0012), concerning quality-related changes.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Bluevac BTV** (EMEA/V/C/000156/VRA/0011/G), concerning quality-related changes.

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 (EU) 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) 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

- There were no items for discussion.

4.7.2. Referrals under Article 33(4) of Directive 2001/82/EC

- The Committee considered the notification from Czechia for a referral procedure for **Catophos 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats**. The referral concerns the granting of a waiver for a bioequivalence study for the intramuscular and subcutaneous routes of administration. The Committee agreed to start a referral procedure (EMEA/V/A/147) under Article 33(4) of Directive 2001/82/EC and appointed A. Golombiewski as rapporteur and L. Nepejchalová as co-rapporteur, and three CVMP members as peer reviewers for the procedure. The Committee adopted a list of questions and the timetable for the procedure.
- The Committee considered the notification from Czechia for a referral procedure for **Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats**. The referral concerns the granting of a waiver for a bioequivalence study for the intramuscular and subcutaneous routes of administration. The Committee agreed to start a referral procedure (EMEA/V/A/148) under Article 33(4) of Directive 2001/82/EC and appointed A. Golombiewski as rapporteur and L. Nepejchalová as co-rapporteur, and three CVMP members as peer reviewers for the procedure. The Committee adopted a list of questions and the timetable for the procedure.

5. Post-authorisation issues for marketing authorisations

Information relating 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

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

- There were no items for discussion.

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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **BTVPUR** (EMEA/V/C/002231/REC/024) which is now considered fulfilled.

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Versican Plus L4** (EMEA/V/C/003680/REC/13), **Versican Plus Pi/L4** (EMEA/V/C/003683/REC/14), **Versican Plus Pi/L4R** (EMEA/V/C/003682/REC/15), **Versican Plus DHPPi/L4** (EMEA/V/C/003678/REC/18) and **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/REC/18) which is now considered fulfilled.

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

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

- Status report on PSURs for centrally authorised veterinary medicinal products

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 adopted the draft concept paper on a guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6 (EMA/CVMP/AWP/201064/2022) for a 4-month public consultation.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

6.3. Efficacy Working Party (EWP-V)

- The Committee confirmed the appointment of two new members of the Efficacy Working Party: Luis Agote and Erik den Hertog.

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 in Regulatory Testing of Medicinal Products (J3RsWP)

- The Committee endorsed the appointment of Sonja Beken and Sarah Adler-Flindt as Chair and Vice-Chair of the Joint CVMP/CHMP Working Party on the application of the 3Rs in Regulatory Testing of Medicinal Products (J3RsWP).

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 31 August 2022, and noted the agenda of the meeting.
- The Committee adopted a revision of the questions and answers on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL)) (EMA/CVMP/150343/2016 – Rev.5).

6.8. Quality Working Party (QWP)

- The Committee adopted a draft concept paper on the development of a guideline on synthetic peptides for a 3-month public consultation.
- The Committee adopted a draft concept paper on the development of a guideline on synthetic oligonucleotides for a 3-month public consultation.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 5 September 2022, and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting held on 8 July 2022.

6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

6.11. Other working party and scientific group issues

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

- The Committee agreed to include **mannosylated chitosan** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients (EMA/CVMP/318299/2022).
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.54).

7.2. Environmental risk assessment

- There were no items for discussion.

7.3. Antimicrobial resistance

- There were no items for discussion.

7.4. Pharmacovigilance

- The Committee was informed on the EU Veterinary Pilot Signal Management Expert Group (P-SMEG) process description.

7.5. Vaccine antigen master file (VAMF) certification

- There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

7.7. Other issues

- There were no items for discussion.

8. Co-operation with other EU or International bodies

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

8.1. VICH

- The Committee endorsed the second draft of a concept paper proposing development of VICH GL on implementation of *in vitro* methods to replace animal batch potency tests in veterinary immunologicals.

8.2. Codex Alimentarius

8.3. Other EU bodies and international organisations

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

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 discussed the upcoming appointment of CVMP co-opted members at the October 2022 CVMP meeting, as the mandates of M. O'Grady and R. Breathnach will expire in November 2022. The Committee agreed to appoint two co-opted members, retaining the same areas of expertise (i.e. quality and clinical veterinary practice). A call for nominations will be launched by the secretariat shortly after the September 2022 CVMP meeting.
- The Committee discussed the draft agenda of the joint CVMP/CMDv Presidency meeting under the Czech Presidency, to be held on 11-13 October 2022 in Prague, Czechia.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meeting held on 16-17 June 2022 and 14-15 July 2022, and noted the draft minutes of the meeting held on 14-15 July 2022 as well as the draft agenda of the meeting to be held on 8-9 September 2022.

12. Legislation

- The Committee was informed about request from the European Commission for the Agency to provide scientific advice relevant to the implementing measures referred to in Article 93(2) of Regulation (EU) 2019/6 with regards to the good manufacturing practice for veterinary medicinal products and active substances used as starting materials. The Committee agreed on the workplan and timetable of the drafting group tasked with developing the scientific advice.
- The Committee received a verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6)).

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the September 2022 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 September 2022 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	
BG	Svetoslav Valentinov Branchev	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	
HU	Gábor Kulcsár	Full involvement	
IE	Paul McNeill	Full involvement	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	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	
HR	Hrvoje Pasavovic	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
LU	Caroline Coner	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.			
FR	Gérard Moulin	Full involvement	
BE	Sonja Beken	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Anja Pfalzgraff	Full involvement	
DE	Jana Fischer	Full involvement	
FI	Svenja Rieke	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Malin Öhlund	Full involvement	
FR	Jean-Christophe Faucon	Full involvement	
FR	Nathalie Bridoux	Full involvement	
FR	Martine Redureau	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Carole Cousin	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
DK	Theis Moeslund Jensen	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DK	Yen Ngoc Pham	Full involvement	
DK	Kirsten Brolin Thomsen	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Malene Nissen	Full involvement	
DE	Martina Kern	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Kathrin Schirmann	Full involvement	
DE	Thilo Nölke	Full involvement	
DE	Roswitha Merkel	Full involvement	
ES	Maria Jose Ferrer Montesa	Full involvement	
ES	Carlos Ballesteros Vicente	Full involvement	
ES	Rosario Bullido Gomez-Heras	Full involvement	
IE	Sarah Hanley	Full involvement	
CZ	Eva Pomezná	Full involvement	
DK	Mette Madsen	Full involvement	
NO	Ragnhild Holter Mehli	Full involvement	
ES	Susana Casado Hernández	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
ES	Raúl Belmar Liberato	Full involvement	
ES	Sonia Gil Morales	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