18 November 2022
EMA/CVMP/871224/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 4-6 October 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 the addition of additional nominations for each co-opted member up for election, under point 10.

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 October 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. 16 or more members of the 31 members

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

eligible to vote were present. Furthermore, absolute majority requires that 16 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the September 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

- There were no items for discussion.

1.2. Oral explanations

- There were no items for discussion.

1.3. Lists of outstanding issues

- There were no items for discussion.

1.4. List of questions

- There were no items for discussion.

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

- There were no items for discussion.

1.6. Other issues

- There were no items for discussion.

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

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

- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Meloxoral** (EMEA/V/C/000151/X/0015), recommending the extension of the marketing authorisation to add a new pharmaceutical form for 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 majority (25 members in favour out of the 28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Mometamax Ultra** (EMEA/V/C/005528/0000), recommending the granting of a marketing authorisation. The product is intended for the treatment of otitis externa caused by mixed infections with bacteria susceptible to gentamicin and fungi susceptible to Posaconazole, in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation. K. Baptiste and N. Kyvsgaard signed a divergent position not supporting the aforementioned 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.

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

- The Committee heard an oral explanation from the applicant, concerning an application for a new vaccine (EMEA/V/C/005538/0000), intended for the active immunisation of dogs. The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues to be addressed during the oral explanation. The adoption of the opinion is foreseen for the November 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 a marketing authorisation application for a new vaccine (EMEA/V/C/005906/0000) for calves. The Committee agreed that an oral explanation would not be requested. The Committee noted the peer review reports and the comments received from CVMP members.
- The Committee adopted a list of remaining outstanding issues and agreed comments on the draft product information for a marketing authorisation for a new vaccine (EMEA/V/C/005860/0000) for chickens. The Committee agreed to invite the applicant for an oral explanation in February 2023. The Committee noted the comments received from CVMP members.
- The Committee adopted the updated 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/005905/0000) for chickens. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the updated 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/005944/0000) for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

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/006045/0000), for cows. 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/005992/0000), for rabbits. 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

- There were no items for discussion.

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

- The Committee was informed of the formal notification from Zoetis of their decision to withdraw the application for a new marketing authorisation for **Versiguard SARS CoV2** (EMEA/V/C/005988/0000), for the active immunisation of mink. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

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 **Equip WNV** (EMEA/V/C/000137/VRA/0028), 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 grouped variation requiring assessment for **CircoMax** (EMEA/V/C/005185/VRA/0001/G), recommending the variation of the marketing authorisation to remove from the product information the warning regarding the absence of safety data during pregnancy and lactation and 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 grouped variation requiring assessment for **CircoMax Myco** (EMEA/V/C/005184/VRA/0002/G), recommending the variation of the marketing authorisation to remove from the product information the warning regarding the absence of safety data during pregnancy and lactation, and 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 **Bovela** (EMEA/V/C/003703/VRA/0023/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 revised product information, for a variation requiring assessment for **Exzolt** (EMEA/V/C/004344/VRA/0014/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Arti-Cell Forte** (EMEA/V/C/004727/VRA/0010), 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 (28 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Zenalpha** (EMEA/V/C/005465/VRA/0003), recommending the variation of the marketing authorisation to implement quality-related changes. Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Broadline** (EMEA/V/C/002700/VRA/0034), 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

- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a type II variation (subject to a worksharing procedure) for **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R** (EMEA/V/C/xxxx/WS2184), 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, the CVMP assessment report, and the product information for a type II variation for **Simparica Trio** (EMEA/V/C/004846/II/0007/G), recommending the variation of the marketing authorisation to update SPC section 5.1 regarding the onset of efficacy for *Ixodes ricinus* ticks. 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, the CVMP assessment report, and the product information for a type II variation (subject to a worksharing procedure) for **Simparica** and **MiPet Easecto** (EMEA/V/C/xxxx/WS2217), recommending the variation of the marketing authorisation to add a new therapeutic indication for reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* ticks for 28 days after treatment. The MAH also took the opportunity to update the product information for MiPet Easecto following a PSUR recommendation. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

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 variation requiring assessment for **Credelio Plus** (EMEA/V/C/005325/VRA/0005), to add a new therapeutic indication.
- The Committee adopted a list of questions and scientific overview and agreed comments on the draft product information for a variation requiring assessment for **Melovem** (EMEA/V/C/00152/VRA/0015), to implement quality-related changes.
- 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 **Porcilis PCV ID** (and other nationally authorised products) (EMEA/V/C/WS2294), to update the product information.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Simparica Trio** (EMEA/V/C/004846/VRA/0009/G), to add new therapeutic indications.
- The Committee adopted the Rapporteur's Assessment Report including list of questions for a variation requiring assessment for **Suprelorin** (EMEA/V/C/000109/VRA/0037), to implement 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

- The Committee was informed of the formal notification from Orion of their decision to withdraw the application for a type II variation application for **Sileo** (EMEA/V/C/003764/II/0022), concerning the addition of a new therapeutic indication. More information about this application

and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

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

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

- The Committee started a follow-up assessment procedure of the conditions on the marketing authorisations for **veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses** (EMEA/V/A/116) that have been applied with Commission Implementing Decision C(2017) 6577 of 25 September 2017, in the context of a referral procedure under Article 35 of Directive 2001/82/EC for the aforementioned products. The committee appointed R. Carapeto as rapporteur and A. Golombiewski as co-rapporteur, and four CVMP members as peer reviewers for the procedure. The Committee adopted the timetable for the procedure.

- The Committee adopted by consensus (28 members present and eligible to vote) a revision of the CVMP opinion and the CVMP assessment report for the referral procedure under Article 35 of Directive 2001/82/EC for **veterinary medicinal products containing toltrazuril to be administered orally to chickens** (EMEA/V/A/144). In the revised opinion, a sentence of the agreed product information was slightly amended. The Norwegian CVMP member agreed with the above-mentioned recommendation.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

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

- 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 received a verbal report from the AWP chair on the meeting held on 20-21 September 2022, and noted the minutes of the AWP meeting held on 24-25 May 2022.
- The Committee discussed the call for nominations for two experts for the AWP, together with the selection procedure and draft timetable.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the draft reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs. The adoption of the reflection paper is foreseen for the November 2022 meeting of the Committee.

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 discussed the draft revised guideline on the development and data requirements of potency tests for cell-based therapy products and the relation to clinical efficacy. The adoption of the guideline is foreseen for the November 2022 meeting of the Committee.
- The Committee was informed that the discussion on the draft revised guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy is foreseen for the November 2022 meeting of the Committee.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 27-28 September 2022, and noted the agenda of the meeting.
- The Committee discussed the draft PhVWP-V work plan for 2023. The adoption of the work plan is foreseen for the December 2022 meeting of the Committee.
- The Committee received a verbal report from the PhVWP-V chair on the PhVWP-V Interested Parties meeting held on 28 September 2022, and noted the agenda of the meeting.

6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 19-21 September 2022, and noted the agenda of the meeting, together with the minutes of the QWP meeting held on 27-29 June 2022, and the agenda of the joint GMDP IWG/QWP meeting held on 21 September 2022.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V Chair on the meeting held on 30 September 2022 and noted the agenda of the meeting, together with the minutes of the meeting held on 5 September 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 amend the existing entry for **pentaerythrityl tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]** in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009, under the heading of excipients, allowing for cutaneous use. This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.
- 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.55).

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 endorsed the EU comments on the draft proposal for revising the scope of the VICH guideline on pharmaceutical combination products.
- The Committee endorsed the draft section on dissolution testing conditions for the new VICH GL on in vitro dissolution testing.
- The Committee noted the draft agenda for the VICH Steering Committee meeting to be held on 14-17 November 2022, in Washington (USA).

8.2. Codex Alimentarius

- There were no items for discussion.

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 CVMP elected R. Breathnach as CVMP co-opted member with relevant scientific competence in clinical veterinary practice, for a three-year mandate.
- The CVMP elected M. O'Grady as CVMP co-opted member with relevant scientific competence in quality, for a three-year mandate.
- The Committee was informed that the 2nd Veterinary Big Data Stakeholder Forum is due to be held on 23 November 2022, and noted the draft agenda of the meeting.
- The Committee finalised the agenda for the Presidency CVMP and Joint CVMP/CMDv meetings to be held under the Czech Presidency of the EU, on 12-13 October 2022 in Prague, Czechia.

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 6-7 October 2022, the minutes of the meeting held on 8-9 September 2022, and the draft agenda of the CMDv-Interested Parties meeting to be held on 7 October 2022.

12. Legislation

- The Committee adopted a reflection paper on the criteria for determining if an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU) 2019/6 (EMA/CVMP/116512/2021), following the close of the public consultation. The comments received during the consultation period (EMA/CVMP/352510/2022) were taken into account in the finalisation of the reflection paper.
- The Committee endorsed the drafting group membership and terms of reference for the implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the good manufacturing practice for veterinary medicinal products and active substances used as starting materials.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the October 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 October 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	
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	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	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	
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	
BG	Nadya Ognyanova Vladimirova	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
NL	Kim Boerkamp	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
PL	Ewa Augustynowicz	Full involvement	
RO	Lollita Taban	Full involvement	
SI	Boris Kolar	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.			
AT	Haru Kroneis	Full involvement	
BE	Sandy Vermout	Full involvement	
FR	Mariette Saléry	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
DK	Anne H. Buur	Full involvement	
DE	Christopher Janich	Full involvement	
FR	Jean-Christoph Faucon	Full involvement	
BE	Koen Brusselmans	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Jukka Pakkanen	Full involvement	
FI	Tommi Nurminen	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Lennart Åkerblom	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Mats Welin	Full involvement	
DE	Kathrin Schmidt	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Jana Fluksová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Jitka Chumchalová	Full involvement	
ES	Alberto de Prado Lopez	Full involvement	
ES	Rosario Bullido Gomez-Heras	Full involvement	
ES	Susana Casado Hernández	Full involvement	
ES	Maria Jose Ferrer Montesa	Full involvement	
DE	Anja Pfalzgraff	Full involvement	
DE	Caroline Bitterlich	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Thilo Nölke	Full involvement	
DE	Anke Finnah	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	Sandra Schack	Full involvement	
DE	Henriette Rau	Full involvement	
DE	Monika Hofmann	Full involvement	
DK	Kirsten Brolin Thomsen	Full involvement	
DK	Malene Nissen	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Susan Reid	Full involvement	
ES	Carlos Ballesteros Vicente	Full involvement	
ES	Ana Isabel Olías Molero	Full involvement	
DE	Kathrin Dietze	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
3RsWP	Sarah Adler-Flindt *(veterinary vice chair)*
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