14 June 2022
EMA/CVMP/587361/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 10-12 May 2022 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

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 10-12 May 2022

The attendance list was completed and competing interests were identified for the May 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 April 2022 meeting were adopted with minor 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 majority (21 members in favour out of the 25 members present and eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to chickens for **ketoprofen** (EMEA/V/MRL/003652/EXTN/0004). Furthermore, the Committee agreed to extrapolate the conclusions to poultry. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. E. Werner, L. Nepejchalová, N. C. Kyvsgaard, and S. Louet signed a divergent position not supporting the aforementioned recommendation. The Committee noted 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

- The Committee discussed the rapporteur's assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the extension of MRLs to fin fish for a substance, (EMEA/V/MRL/003477/EXTN/0004) and adopted a list of outstanding issues that should be addressed in writing. The adoption of the opinion is foreseen for September 2022.

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

- There were no items for discussion.

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 vaccine (EMEA/V/C/005538/0000), for dogs. The Committee agreed to invite the applicant for an oral explanation in July 2022. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/005528/0000), for dogs. The Committee agreed to invite the applicant for an oral explanation in September 2022. The Committee noted a peer review report and the comments received from CVMP members.

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

- There were no items for discussion.

2.4. List of questions under Regulation (EC) No 726/2004

- 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/005988/0000), for minks. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/005902), for dogs. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/005905/0000), for chickens. The Committee noted a peer review report and the comments received from CVMP members.

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

- There were no items for discussion.

2.5. 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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a variation requiring assessment application for **Vectormune ND** (EMEA/V/C/003829/VRA/0016), recommending the variation of the marketing authorisation to modify the product information to add the compatibility claim on the simultaneous use of Vectormune ND with another product. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 application for **Apoquel** (EMEA/V/C/002688/VRA/0023), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report and the product information, for a variation requiring assessment application for **Innovax ND IBD** (EMEA/V/C/004422/VRA/0009), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 application for **Sileo** (EMEA/V/C/003764/VRA/0024), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 application for **Zenalpha** (EMEA/V/C/005465/VRA/0001), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

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, the CVMP assessment report and the product information for a grouped type II variation application for **Suprelorin** (EMEA/V/C/000109/II/0032/G), recommending the variation of the marketing authorisation to add a new therapeutic indication (in female dogs) and to add a non-food producing target species (cats, for use in males). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application for **Credelio Plus** (EMEA/V/C/005325/II/0004), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 type II variation application for **Fortekor Plus** (EMEA/V/C/00280/II/0021/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and Annex B and endorsed the rapporteur's assessment report, for a grouped type II variation application (subject to a worksharing procedure) for **Canigen L4 and Novibac L4** (EMEA/V/C/xxxx/WS2160/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 type II variation application for **Innovax ND ILT** (EMEA/V/C/005190/II/0003/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

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 for a variation requiring assessment for **Nexgard** (EMEA/V/C/002729/VRA/0036), 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 **Circomax** (EMEA/V/C/005185/VRA/0001/G), to align the product information with the latest QRD template, version 9.0.
- 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/0002/G), to align the product information with the latest QRD template, version 9.0.
- The Committee adopted a list of questions for a variation requiring assessment for **Tulinovet** (EMEA/V/C/005076/VRA/0004), concerning quality-related changes.

- The Committee adopted a list of questions for a variation requiring assessment for **Loxicom** (EMEA/V/C/000141/VRA/0041), 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

- The Committee considered the notification from Germany for a referral for **veterinary medicinal products containing N-methyl-pyrrolidone (NMP) as an excipient**. The referral concerns user safety. The Committee agreed to start a referral procedure (EMEA/V/A/146) under Article 82 of Regulation (EU) 2019/6 and appointed A. Golombiewski as rapporteur and C. Bergman as co-rapporteur, and two CVMP members as peer reviewers for the procedure. The Committee adopted the list of questions to stakeholders (EMA/CVMP/232862/2022) and the timetable (EMA/CVMP/154238/2022) and noted the list of products concerned by the procedure (EMA/188372/2022).

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 35 of Directive 2001/82/EC

- There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

5.1. Pharmacovigilance under Regulation (EU) 2019/6

- The Committee endorsed a recommendation for changes to the product information for **Cerenia** (EMEA/V/C/000106) as the outcome of signal detection activities.
- The Committee endorsed a recommendation for changes to the product information for **Nasym** (EMEA/V/C/004897) as the outcome of signal detection activities.

5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

- The Committee adopted the CVMP assessment report on the PSUR for the period 01.02.2021 – 31.07.2021 for **Aservo EquiHaler** (EMEA/V/C/004991) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report on the PSUR for the period 01.06.2021 – 30.11.2021 for **Librela** (EMEA/V/C/005180) with a recommendation to amend the product information.

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

Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

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

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

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)

- There were no items for discussion.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the updated questions and answers document on the implementation of the CVMP guideline on environmental impact assessment for VMPs in support of the VICH guidelines GL6 and GL38 (EMA/CVMP/ERA/172074/2008).

6.3. Efficacy Working Party (EWP-V)

- The Committee discussed the draft revised guideline on data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats, and the overview of comments received during the public consultation of the draft guideline. The adoption of the revised guideline is foreseen for the June 2022 meeting of the Committee.
- The Committee postponed the discussion on the revised concept paper on the revision of the guideline for veterinary medicinal products for zootechnical purposes to its June 2022 meeting.

6.4. Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 28-29 April 2022, and noted the agenda of the meeting, together with the minutes of the IWP meeting held on 17-18 November 2021.
- The Committee discussed the draft revised guideline on requirements for the production and control of immunological veterinary medicinal products and the overview of comments received during the public consultation of the draft revised guideline. The adoption of the revised guideline is foreseen for the June 2022 meeting of the Committee.
- The Committee adopted the revised questions and answers on data requirements for multi-strain dossiers for inactivated veterinary vaccines.

6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- There were no items for discussion.

6.6. Novel therapies & Technologies Working Party (NTWP)

- There were no items for discussion.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 28 April 2022, and noted the agenda of the meeting, and a summary record of the PhVWP-V meeting held on 29-30 March 2022.

6.8. Quality Working Party (QWP)

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee elected unanimously Dr Frida Hasslung Wikström as chair of the SAWP-V for a second three-year mandate.

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 6 May 2022, and noted the agenda of the meeting, together with the minutes of the SAWP-V meeting held on 8 April 2022.

6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

6.11. Other working party and scientific group issues

- The Committee adopted the provisional mandate of the quality innovation group (QIG), a newly formed Operational Expert Group within the Quality Domain, and noted the call for nomination of members of the QIG.

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential.

7.1. MRL issues

7.2. Environmental risk assessment

- There were no items for discussion.

7.3. Antimicrobial resistance

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

- The Committee adopted a draft procedural advice for vaccine platform technology master file (vPTMF) certification for a 2-month period of public consultation.

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

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

- The Committee agreed to the transfer of all (co-)rapporteurships and peer review responsibilities from Dr Judita Hederová to Dr Eva Chobotová.

9.3. Regulatory matters

10. Organisational and strategic matters

- The CVMP elected unanimously Mr Gerrit Johan Schefferlie as CVMP Chair for a three-year mandate starting on 14 June 2022.
- The Committee received a verbal report from the chair of the Veterinary Domain (VetD) on the meeting held on 5 May 2022, and noted the agenda of the meeting and the minutes of the meeting held on 10 March 2022.
- The Committee noted the agenda of the CVMP/CMDv meeting under the French Presidency, to be held on 31 May - 1 June 2022 in Saint Malo, France.
- The Committee noted the agenda of the EMA Veterinary Info Day to be held on 12-13 May 2022 (link).

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 12-13 May 2022 and the minutes of the meeting held on 12-13 April 2022.

12. Legislation

- The Committee adopted a revised template (scientific overview and LoQ) for the assessment of an informed consent application (EMA/68300/2022) under Article 21 of Regulation (EU) 2019/6.
- The Committee received a verbal report from the chair of the drafting group on the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6 and discussed comments from stakeholders, received during the public consultation period, on the respective concept paper. The Committee agreed to draft a guideline to elaborate on the scientific criteria within the various provisions of Article 34 of Regulation (EU) 2019/6.
- The Committee adopted the manual for reporting antimicrobial use data reporting per animal categories (numerator) to the Agency (EMA/757638/2021).
- The Committee received an 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)).

- The Committee adopted the proposal for an amendment to the EMA advice on the designation of antimicrobials or groups of antimicrobials to be reserved for treatment of certain infections in humans, in relation to implementing measures under Article 37(5) of Regulation (EU)2019/6.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the May 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 May 2022 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Svetoslav Valentinov Branchev	Full involvement	4.1 one item
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	J. Gabriel Beechinor	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	
SK	Eva Chobotová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie **VICE CHAIR**	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
IE	Paul McNeill	Full involvement	
IT	Antonio Battisti	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	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	Mariette Saléry	Full involvement	
IE	Hannah Byrne	Full involvement	
FR	Anne Marie Jacques	Full involvement	
FR	Nathalie Bridoux	Full involvement	
FR	Martine Redureau	Full involvement	
FR	Jean Christophe Faucon	Full involvement	
FR	Carole Cousin	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Pascale Macours	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Anne Sagnier	Full involvement	
DK	Malene Nissen	Full involvement	
DK	Alma Fejzic	Full involvement	
DK	Gar Fai Pang	Full involvement	
DK	Sille Graa Andreasen	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Kirsten Brolin Thomsen	Full involvement	
FR	Gerard Moulin	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Hanna Bremer	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Jitka Chumchalová	Full involvement	
CZ	Jana Fluksová	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Eva Vernerová	Full involvement	
ES	Sonia Gil Morales	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Kathrin Schmidt	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Roswitha Merkel	Full involvement	
DE	Werner Terhalle	Full involvement	
DE	Thilo Nölke	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Birgit Kegel	Full involvement	
DE	Judith Romberg	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Susana Casado	Full involvement	
IE	Gavin Ryan	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Tatyana Devine	Full involvement	
FR	Caroline Guittre	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
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