16 April 2024
EMA/CVMP/162270/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 12-13 March 2024 meeting

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

Note on access to documents

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

The meeting was held in-person.

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 12-13 March 2024

The attendance list was completed and competing interests were identified for the March 2024 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I).

Katarina Straus gave a proxy to Frane Bozic for the whole meeting.

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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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the February 2024 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

- The Committee adopted the scientific overview and list of questions for the modification of MRLs in bovine species for a substance (EMEA/V/MRL/005009/MODF/0003). The Committee noted a peer review report and the comments received from CVMP members.

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

- There were no items for discussion.

1.6. Other issues

- There were no items for discussion.

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **DIVENCE Tetra** (EMEA/V/C/006222/0000), recommending the granting of a marketing authorisation. The product is a vaccine for the active immunisation of cattle against bovine respiratory syncytial virus and parainfluenza-3 virus to reduce virus shedding, hyperthermia, clinical signs and lung lesions and against bovine viral diarrhoea virus (BVDV type 1 and 2) to reduce viremia, hyperthermia and leukopenia caused by BVDV-1 and BVDV-2 and virus shedding caused by BVDV-2; and for active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of BVDV (type 1 and 2). 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, the CVMP assessment report and the product information for **Trilocur** (EMEA/V/C/006128/0000), a hybrid of the decentralised product Vetoryl, recommending the

granting of a marketing authorisation. The product is intended for the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs. 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, the CVMP assessment report and the product information for **Trilorale** (EMEA/V/C/006124/0000), a hybrid of the decentralised product Vetoryl, recommending the granting of a marketing authorisation. The product is intended for the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs. 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, the CVMP assessment report and the product information for **Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS** (EMEA/V/C/005887/0000), recommending the granting of a marketing authorisation. The product is intended for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus, reduction of respiratory signs and egg drop caused by infectious bronchitis virus, reduction of mortality and clinical signs caused by Newcastle disease virus, passive immunisation of the progeny of the vaccinated chickens to reduce mortality and clinical signs of disease caused by strains of infectious bursal disease virus (IBDV) and to reduce viraemia and clinical signs of disease caused by avian reovirus, and reduction of egg drop and eggshell defects caused by egg drop syndrome virus. In the context of this marketing authorisation application, the Committee endorsed the first EMA certificates for vaccine antigen master files (VAMFs). 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, the CVMP assessment report and the product information for **Lotimax** (EMEA/V/C/006441/0000), recommending the granting of a marketing authorisation. The product is intended for the treatment of flea and tick infestations and demodicosis (caused by *Demodex canis*) in dogs. The Committee noted the summary of the opinion for publication.

2.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

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

- There were no items for discussion.

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/006300/0000) for cats. The Committee noted peer review reports and the comments received from CVMP members.

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

- There were no items for discussion.

2.6. Other issues under Regulation (EU) 2019/6

- The Committee agreed to the request from the applicant for a further extension to the clock-stop for a new product (EMEA/V/C/005902/0000) for dogs.

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/006247/0000) for sea bream.

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 grouped variations requiring assessment for **Aivlosin** (EMEA/V/C/000083/VRA/0094/G), recommending the variation of the marketing authorisation to add information to section 4.7 of the SPC and section 12 of the package leaflet on use during pregnancy, lactation or lay and to align the product information with version 9.0 of the QRD template.
- 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 **Purevax RCP FeLV** (EMEA/V/C/000089/VRA/0035), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Coliprotec F4/F18** (EMEA/V/C/004225/VRA/0011), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report, for grouped variations requiring assessment for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/VRA/0016/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 **Respiporc FluPan H1N1** (EMEA/V/C/003993/VRA/0017), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Tulaven** (EMEA/V/C/005153/VRA/0008), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Zulvac BTV** (EMEA/V/C/004185/VRA/0006), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to correct the name of the marketing authorisation holder (from Zoetis Belgium S.A. to Zoetis Belgium).
- 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 **Halocur** (EMEA/V/C/000040/VRA/0019), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to implement the ATCvet code change for halofuginone.

- 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 **Senvelgo** (EMEA/V/C/005972/VRA/0001), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 **Nobilis IB Primo QX** (EMEA/V/C/002802/VRA/0011), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Suiseng Diff/A** (EMEA/V/C/005596/VRA/0003), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Eurican Herpes 205** (EMEA/V/C/000059/VRA/0032), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Purevax RCP** (EMEA/V/C/000090/VRA/0035), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 **Bovela** (EMEA/V/C/003703/VRA/0026), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the CVMP assessment report for a variation requiring assessment for **Prevexxion RN+HVT+IBD** (EMEA/V/C/005057/VRA/0009), to add a new route of administration: *in ovo.*

3.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

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

- The Committee adopted a list of outstanding issues and agreed comments on the draft product information for a variation requiring assessment for **Rabitec** (EMEA/V/C/004387/VRA/0011), to add a new strength including a new target species, a new composition of the bait and new vaccine container.

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 **Virbagen Omega** (EMEA/V/C/000061/VRA/0011), to align the product information with version 9.0 of the QRD template.

- The Committee adopted a list of questions for grouped variations requiring assessment for **Tulissin** (EMEA/V/C/005073/VRA/0010/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 **Nobivac LoVo L4**, concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Simparica, Simparica Trio, Stronghold Plus, Felisecto Plus** (EMA/VRA/0000166127) concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **MS-H Vaccine** (EMEA/V/C/000161/VRA/0020), 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 **Porcilis AR-T DF** (EMEA/V/C/000055/VRA/0019), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for grouped variations requiring assessment for **Solensia** (EMEA/V/C/005179/VRA/0009/G), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Versican Plus DHPPi/L4R, Versican Plus Pi/L4R** (EMEA/V/C/WS2628), concerning quality-related changes.

3.5. Re-examination of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

- There were no items for discussion.

3.6. Other issues under Regulation (EU) 2019/6

- The Committee was informed of the formal notification from Zoetis Belgium SA of their decision to withdraw the application for a variation requiring assessment for **Apoquel** (EMEA/V/C/002688/VRA/0027), concerning quality-related changes.

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

- There were no items for discussion.

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

- There were no items for discussion.

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

- There were no items for discussion.

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

- There were no items for discussion.

4.5. 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.

- There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

Information relating to certain pharmacovigilance topics, and to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections

5.1. Pharmacovigilance under Regulation (EU) 2019/6

- There were no items for discussion.

5.2. Post-authorisation measures under Regulation (EU) 2019/6

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation for **Strangvac** (EMEA/V/C/005309/REC/006) which is now considered fulfilled.

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

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

- There were no items for discussion.

5.5 Other issues

- The Committee discussed the rapporteurs' assessment report on a quality defect procedure concerning **Kexxtone**.

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 5-6 March 2024, and noted the agenda of the meeting together with a summary record from the AWP meeting held on 28-29 November 2023.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 20-21 February 2024, and noted the agenda of the meeting together with the minutes of the meeting held on 10-11 October 2023.

6.4. Immunologicals Working Party (IWP)

6.5. 3Rs Working Party (3RsWP)

- The Committee noted the "Batch Release Testing" Operational Expert Group (BRT OEG) kick-off meeting agenda.
- The Committee noted that the 3RsWP will hold its second annual stakeholder meeting on 20-21 March 2024.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee re-elected J. Poot as a Chair of the NTWP for a further 3-year mandate.
- The Committee re-elected S. Casado as a Vice-chair of the NTWP for a further 3-year mandate.
- The Committee received a verbal report from the NTWP chair on the meeting held on 28 February 2024, and noted the agenda of the meeting.
- The Committee endorsed the survey on novel therapies to be circulated to stakeholders that aims to map the development or intentions of development of novel therapies/innovative veterinary medicinal products (VMP) as well as the main hurdles for the development and authorisation of these products. The survey will be available for a period of 3 months.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 21 February 2024, and noted the agenda and draft summary record of the February 2024 PhVWP-V meeting.

6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the QWP meeting held on 12-13 February 2024 and noted the agenda of the meeting; minutes of the QWP meeting held on 15-16 January 2024 were noted.
- The Committee adopted the final feedback from EMA to the EC's request to evaluate the feasibility of alternatives to replace titanium dioxide (TiO2) in medicinal products and its possible impact on the availability of medicines.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 8 March 2024, and noted the agenda of the meeting and final minutes of the SAWP-V meeting held on 9 February 2024.

6.10. Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

- The Committee received a verbal report by the co-chairs of the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group on the meeting held on 22

February 2024, together with the summary record from the ESUAvet meeting held on 1 December 2023.

- The Committee discussed the ESUAvet Working Group's draft Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations.
- The Committee discussed the draft mandate, objectives and rules of procedure for the Working Parties, Operational Expert Groups and Drafting Groups. The adoption of the document is expected for the April meeting of the Committee.

7. Other scientific matters

Information relating to certain topics 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

7.4. Pharmacovigilance

- There were no items for discussion.

7.5. Vaccine antigen master file (VAMF) certification

- There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

7.7. Other issues

8. Co-operation with other EU or International bodies

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

8.1. VICH

- The Committee endorsed the EU comments on the draft 5 of VICH guideline GL81(R1) on Stability testing for medicated premixes.
- The Committee endorsed the EU comments on version 3.1 of the draft VICH guideline on target animal safety of monoclonal antibody products.
- The Committee endorsed a revised draft VICH guideline GL23 (R) on genotoxicity testing.
- The Committee adopted the revised VICH guideline GL 61 on pharmaceutical development for public consultation.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- There were no items for discussion.

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

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

9.3. Regulatory matters

10. Organisational and strategic matters

- The Committee endorsed the draft agenda of the CVMP / CMDv Informal meeting under the Belgian Presidency, Ghent, 10–11 April 2024.

11. CMDv

- The Committee noted the draft agenda of the meeting to be held on 14-15 March 2024; the minutes of the CMDv meeting held on 15-16 February 2024 together with minutes of the CMDv Interested Parties meeting held on 19 January 2024.

12. Legislation

- The Committee received a verbal report on the progress made by the expert group developing a scientific advice under Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances that are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months.
- The Committee received a verbal report from the expert group for the scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with Article 114(1).

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the March 2024 CVMP meeting, the draft meeting highlights were 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 March 2024 meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the participant attended remotely. Additional experts participated in (part of) the meeting, remotely.

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Els Dewaele	Full involvement	
BG	Krasimir Zlatkov	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	Paul McNeill	Full involvement	
IT	Fulvio Marsilio	Full involvement	
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 (Vice-Chair)	Full involvement	
SI	Katarina Straus*	Full involvement	
SK	Eva Chobotová*	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
Co-opted	Carina Bergman	Full involvement	
NO	Hanne Bergendahl*	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Manuela Leitner*	Full involvement	
BE	Frédéric Klein*	Full involvement	
DE	Esther Werner*	Full involvement	
DK	Merete Blixenkrone-Møller*	Full involvement	
FI	Kristina Lehmann*	Full involvement	
FR	Christine Miras	Full involvement	
LU	Caroline Coner	Full involvement	
SE	Hanna Bremer	Full involvement	
SK	Katarína Massányiová	Full involvement	
NO	Knud Sveen Torjesen*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were evaluated against the topics they have been invited to talk about.			
DE	Katja Kaulich	Full involvement	
DK	Theis Moeslund Jensen	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Kirsten Brolin Thomsen	Full involvement	
DK	Malene Nissen	Full involvement	
IE	Emily Hams	Full involvement	
AT	Elvira Zimre-Grabensteiner	Full involvement	
AT	Harald Weninger	Full involvement	
DE	Dusan Palic	Full involvement	
FI	Jukka Pakkanen	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Marta Martin Juárez	Full involvement	
ES	Rocio Fernández Granda	Full involvement	
IE	Alma Moffett	Full involvement	
FR	Laurent Fabry	Full involvement	
FR	Guillaume Grach	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
FR	Anne Sagnier	Full involvement	
DE	Kerstin Cramer	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Christina Bredtmann	Full involvement	
DE	Antje Gerofke	Full involvement	
DE	Juliane Bauch	Full involvement	
IE	Sarah Hanley	Full involvement	
SE	Malin Öhlund	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Eva Pomezná	Full involvement	
CZ	Dana Halová	Full involvement	
CZ	Martina Rejtharová	Full involvement	
CZ	Jaroslav Maxa	Full involvement	
DE	Daniela Loos	Full involvement	
ES	Luis González Rivas	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
DE	Norbert Moller	Full involvement	
DE	Kathrin Schirmann	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
ESUAVet WG	Sara Sacristan *(ESUAVet WG CVMP co-chair)*
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner*
PhVWP-V	James Mount*
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

European Medicines Agency support
Meeting run with support from the relevant EMA staff