7 November 2023
EMA/CVMP/510377/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 3-5 October 2023 meeting

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

Note on access to documents

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

i. Adoption of the Agenda

The Committee adopted the agenda with 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 3-5 October 2023

The attendance list was completed and competing interests were identified for the October 2023 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the September 2023 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

Information relating to briefing meetings taking place with applicants/marketing authorisation holders cannot be released at the present time as it is deemed to be commercially confidential.

1. Maximum residue limits

1.1. Opinions

- The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to poultry except turkey for **sodium salicylate** (EMEA/V/MRL/00340/EXTN/0004). The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted 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

- The Committee was informed of a correction of editorial nature to the adopted set of CVMP documents for **Ketoprofen** (EMEA/V/MRL/003652/EXTN/0004): the revised CVMP opinion including the EPMAR, the revised CVMP assessment report and the revised summary of opinion.

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Nobivac LoVo L4** (EMEA/V/C/005628/0000), recommending the granting of a marketing authorisation. The product is a new vaccine intended for the active immunisation of dogs against *Leptospira interrogans* serogroup Canicola serovar Canicola to reduce infection and urinary excretion, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni to reduce infection and urinary excretion*, L. interrogans* serogroup Australis serovar Bratislava to reduce infection and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Liangguang to reduce infection and urinary excretion. 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, the CVMP assessment report and the product information for **Senvelgo** (EMEA/V/C/005972/0000), recommending the granting of a marketing authorisation. The product is intended for the reduction of hyperglycaemia in cats with non-insulin-dependent diabetes mellitus. 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 (24 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Bovilis Cryptium** (EMEA/V/C/006045/0000), recommending the granting of a marketing authorisation. The product is a vaccine intended for the active immunisation of pregnant cows to raise antibodies in colostrum against glycoprotein Gp40 of *Cryptosporidium parvum*, intended for passive immunisation of calves to reduce clinical signs (i.e. diarrhoea) caused by *C. parvum*. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information, for a marketing authorisation application for a new product (EMEA/V/C/006143), for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted the comments received from a CVMP member.

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

- 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/0006254/0000), for dogs. 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 an extension to the clock-stop for a new product (EMEA/V/C/005993/0000), 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/006147/0000), for horses.

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

- There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (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 **Fortekor Plus** (EMEA/V/C/002804/VRA/0023/G), recommending the variation of the marketing authorisation to implement quality-related changes with the exception of the scope F.II.d.1.a (change in the specification parameters and/or limits of the finished product, outside the approved specifications limits range), which was refused. 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, the CVMP assessment report, and the product information, for a variation requiring assessment (subject to a worksharing procedure) for **Suiseng Diff/A** and other related nationally authorised product (EMEA/V/C/WS2395), recommending the variation of the marketing authorisation to add the associated use of the vaccine Suiseng Diff/A with the vaccine Suiseng Coli/C. 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 (25 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for CircoMax and for CircoMax Myco, for a variation requiring assessment (subject to a worksharing procedure) for **CircoMax and CircoMax Myco** (EMEA/V/C/WS2429), recommending the variation of the marketing authorisation to add intramuscular administration of CircoMax and CircoMax Myco, using needle-free devices. 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 (25 members present and eligible to vote) the CVMP opinion and the product information for a variation requiring assessment for **Porcilis PCV ID** (EMEA/V/C/003942/VRA/0008), recommending the variation of the marketing authorisation to extend the duration of immunity from 23 weeks to 26 weeks. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Clomicalm** (EMEA/V/C/000039/VRA/0041/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 (25 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 **Porcilis ColiClos/Porcilis PCV ID/Porcilis PCV/Porcilis PCV M Hyo/Porcilis Porcoli DF** (EMEA/V/C/WS2501), 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 **Suvaxyn CSF Marker** (EMEA/V/C/002757/VRA/0011), recommending the variation of the marketing authorisation to align the production information with version 9.0 of the QRD template and to implement editorial 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 **Tulinovet** (EMEA/V/C/005076/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.

3.1. Opinions under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

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

- There were no items for discussion.

3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

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

- The Committee adopted a scientific overview and list of outstanding issues and agreed comments on the draft product information for a variation requiring assessment for **Bravecto** (EMEA/V/C/002526/VRA/0059), to add a new pharmaceutical form for dogs.

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 **Frontpro** (EMEA/V/C/005126/VRA/0014/G), to add a new therapeutic indication, to update SPC section 3.7 (reproductive safety) and to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Arti-Cell Forte** and **RenuTend** (EMEA/V/C/WS2512), 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 **Strangvac** (EMEA/V/C/005309/VRA/0006), to implement the outcome of the MAH's signal management process.

- The Committee adopted a list of questions for a variation requiring assessment for **Vectra 3D** (EMEA/V/C/002555/VRA/0024), 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 (EC) 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

- The Committee considered the request for clarification from the European Commission for **Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs** due to a lack of consensus between Member States in the CMDv review procedure on a variation requiring assessment. The Committee agreed to start a procedure (EMEA/V/A/149) under Article 54(8) of Regulation (EU) 2019/6 and appointed S. Louet as rapporteur and P. McNeill as co-rapporteur, and four CVMP members, as peer reviewers for the procedure. The Committee adopted the list of questions and the timetable for the procedure.

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

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.

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

- There were no items for discussion.

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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Solensia** (EMEA/V/C/005179/REC/004) which is considered fulfilled.

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

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

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

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 19-20 September 2023 and noted the agenda of the meeting, together with the summary record of the AWP meeting held on 23-24 May 2023.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the draft updated questions and answers document on the implementation of the CVMP guideline on environmental impact assessment for VMPs in support of VICH GLs 6 and 38. Adoption of the updated document is foreseen for the November 2023 meeting of the Committee.

- The Committee discussed the revised draft reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs (EMA/CVMP/ERA/31905/2021) and the overview of comments received following the close of the public consultation. Adoption of the document is foreseen for the November 2023 meeting of the Committee.

6.3. Efficacy Working Party (EWP-V)

- There were no items for discussion.

6.4. Immunologicals Working Party (IWP)

6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

- The Committee noted the agenda of the J3RsWP meeting held on 19 September 2023.
- The Committee noted an extension to the deadline regarding the call for nominations for the Batch Release Testing OEG (BRT OEG).

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee adopted the revised "Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy" (EMA/CVMP/NTWP/32862/2022) and the overview of comments received following the close of the public consultation.
- The Committee discussed the draft concept paper for the development of a guideline on the establishment of maximum residue limits for pharmacologically active materials in the nanoscale and on safety of nanomedicines for veterinary marketing authorisation applications. Adoption of the document is foreseen for the November 2023 meeting of the Committee.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The CVMP elected, by majority, A. Bottger as Vice-Chair of the PhVWP-V for a three-year mandate.
- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 26-27 September 2023 and noted the agenda of the meeting, together with a draft summary record of the PhVWP-V meeting held on 30 August 2023.
- The Committee received a verbal report from the PhVWP-V chair on the PhVWP-V Interested Parties meeting held on 27 September 2023, and noted the agenda of the meeting.
- The Committee adopted the guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD) for release for a one-month of public consultation.
- The Committee noted the draft agenda for the focus group for veterinarians or other healthcare professionals on facilitating pharmacovigilance reporting of medicinal products used in poultry to be held on 11 October 2023.

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 4-5 September 2023, and noted the agenda of the meeting, together with the minutes of the QWP meeting held on 26-28 June 2023.
- The Committee adopted the concept paper on a guideline on stability testing for variations for Veterinary Medicinal Products for release for two months of public consultation.

- The Committee adopted a joint (human and vet) guideline on development and manufacture of synthetic peptides for release for public consultation for release for six months of 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 2 October 2023, and noted the agenda of the meeting, together with the minutes of the SAWP-V meeting held on 1 September 2023.
- The Committee adopted the scientific advice report on a new veterinary medicinal product for horses.

6.10. Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

- The Committee adopted the Q&A on the use of X-ray sterilisation processes for Single Use Systems (SUS) used in pharmaceutical manufacturing (EMA/INS/GMP/397209/2023).

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

- The Committee adopted the guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022) and overview of comments received (EMA/CVMP/229549/2023) following the close of the public consultation.
- The Committee noted the request from WOAH for contact details for national/regional organisations involved in research on and funding of research on AMR.

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 endorsed the recommendations proposed by the CVMP ad-hoc group on nitrosamines.

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 comment on the scope of discussions on the revisions of VICH GL23 on genotoxicity testing, for submission to the VICH Safety EWG.
- The Committee endorsed the draft concept paper for the revision of VICH GL34 following the revision of Ph. Eur. Chapter 2.6.7. Mycoplasmas.
- The Committee noted the draft agenda of the 42nd VICH Steering Committee meeting that will take place in Tokyo from 14-16 November 2023.
- The Committee adopted the draft VICH GL60 Good Manufacturing Practice for active ingredients used in VMPs for release for six months of public consultation in the EU following the sign-off by the VICH Steering Committee (EMA/CVMP/196216/2021).

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

9. Procedural and regulatory matters

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

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

- The Committee considered the request for limited market classification for the veterinary medicinal product for freely moving large zoo animals. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered the request for limited market classification for the veterinary medicinal product for horses. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

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

- The Committee agreed to the transfer of all (co-)rapporteurships responsibilities from Paolo Pasquali to Fulvio Marsilio, the new CVMP member from Italy.

9.3. Regulatory matters

10. Organisational and strategic matters

- The Committee received an update on IRIS for core Regulatory Procedures.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 13-14 July 2023 and 7-8 September 2023 and noted the minutes of the meeting held on 7-8 September 2023 as well as the draft agenda of the meeting to be held on 5-6 October 2023. The Committee also noted the minutes of the CMDv-Interested Parties meeting held on 16 June 2023 (link) and the draft agenda of the CMDv-Interested Parties meeting to be held on 6 October 2023.

12. Legislation

- The Committee received a verbal report from the Chair of the expert group for the scientific advice on Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months.
- The Committee received a verbal report from the Chair of the expert group for the scientific advice on Article 93(2) of Regulation (EU) 2019/6 as regards the GMP for veterinary medicinal products and active substances used as starting materials. The document is foreseen for adoption by CVMP at the December 2023 meeting of the Committee.
- The Committee received a verbal report from the secretariat of the expert group for the scientific advice on 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 under article 114(1). The Committee was also informed that D. Palic will chair this expert group.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the October 2023 CVMP meeting, the draft news 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 October 2023 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
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	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Eva Chobotová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
Co-opted	Carina Bergman	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Christine Miras	Full involvement	
LU	Caroline Coner	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Hanna Bremer	Full involvement	
NO	Knud 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 only evaluated against the topics they have been invited to talk about.			
SE	James Mount	Full involvement	
DE	Svenja Rieke	Full involvement	
ES	Susana Casado	Full involvement	
FR	Grégory Verdier	Full involvement	
NL	Alejandro Montón Silva	Full involvement	
DE	Dušan Palic	Full involvement	
ES	Irene de la Casa	Full involvement	
AT	Haru Kroneis	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Jana Fluksová	Full involvement	
CZ	Jitka Chumchalová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Radka Smítalová	Full involvement	
DK	Kira Rosenkilde Underbjerg	Full involvement	
DE	Gunther Speichert	Full involvement	
DE	Jens Schönfeld	Full involvement	
DE	Silke Hickmann	Full involvement	
DE	Anke Finnah	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Carlos Ballesteros Vicente	Full involvement	
ES	Cristina Ballesteros Tercero	Full involvement	
ES	Verónica Devesa García	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
FR	Anne Sagnier	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Benoit Courty	Full involvement	
FR	Béatrice Leroux	Full involvement	
FR	Mariette Saléry	Full involvement	
PL	Anna Zadrożna	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
IE	Sarah Hanley	Full involvement	
IE	Rhona McHugh	Full involvement	
IE	Bryan Deane	Full involvement	
IE	Sarah Beesley	Full involvement	
IE	Gavin Ryan	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	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