11 April 2022
EMA/CVMP/214973/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 15-16 March 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 15-16 March 2022

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

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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.

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the February 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

- 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 product (EMEA/V/C/005829/0000), in dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted peer review reports 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/005906/0000), for cattle. 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 an extension application for **Coxevac** (EMEA/V/C/000155/X/0015). The Committee noted 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

- There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment application for **Coliprotec F4/F18** (EMEA/V/C/004225/VRA/0010), 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 of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a type II variation application for **Advocate** (EMEA/V/C/000076/II/0046), recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of the lungworm *Troglostrongylus brevior* (adults) in cats. 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation application for **Cepedex** (EMEA/V/C/004376/II/0006), 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 (26 members present of those 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 **BTVPUR** (EMEA/V/C/002231/II/0025/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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application for **Porcilis ColiClos** (EMEA/V/C/002011/II/0013), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application (subject to a worksharing procedure) for **Inflacam** and **Rheumocam** (EMEA/V/C/WS2195), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a grouped type II variation application for **ProteqFlu-Te** (EMEA/V/C/000074/II/0032/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 (26 members present of those eligible to vote) the CVMP opinion, and the product information and endorsed the rapporteur's assessment report for a type II variation application for **Recocam** (EMEA/V/C/002247/II/0017), 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

- There were no items for discussion.

3.4. List of questions under Commission Regulation (EC) No 1234/2008

- The Committee adopted a list of questions and agreed comments on the draft product information, for a grouped type II variation application for **Bravecto** (EMEA/V/C/002526/II/0054/G), to add two new therapeutic indications. The Committee noted the comments received from CVMP members.
- The Committee adopted a list of questions for a type II variation application for **Prozinc** (EMEA/V/C/002634/II/0025), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information, for a type II variation application (subject to a worksharing procedure) for **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R** (EMEA/V/C/WS2184), 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.

3.5. 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

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

- There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

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

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.2021 - 30.09.2021 for **Mhyosphere PCV ID** (EMEA/V/C/005272) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product information or other regulatory actions were required for:

Product	Period
Clevor (EMEA/V/C/004417)	01.05.2021 – 31.10.2021
Cytopoint (EMEA/V/C/003939)	01.11.2020 – 31.10.2021
Forceris (EMEA/V/C/004329)	01.05.2021 – 31.10.2021
Leucogen & Nobivac LeuFel (EMEA/V/C/000144) (EMEA/V/C/004778)	01.11.2018 – 31.10.2021
Procox (EMEA/V/C/002006)	01.11.2018 – 31.10.2021
Veraflox (EMEA/V/C/000159)	01.11.2018 – 31.10.2021

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

- There were no items for discussion.

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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation for **CircoMax Myco** (EMEA/V/C/005184/REC/002).
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/REC/007) and **Suvaxyn Circo** (EMEA/V/C/004242/REC/015) which is now considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's condition for **Vectormune FP ILT + AE** (EMEA/V/C/005077/REC/007) which is now considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's condition for **MiPet Easecto** (EMEA/V/C/004732/REC/006) and **Simparica** (EMEA/V/C/003991/REC/014) which is now considered fulfilled.

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.

The following document was circulated for information:

- 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)

- There were no items for discussion.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 2-3 March 2022, and noted the agenda of the meeting, together with the minutes from the meeting held on 20 October 2021.
- The Committee adopted the reflection paper on the interpretation of Article 72 of Regulation (EU) 2019/6 (EMA/CVMP/ERA/245311/2021) and the overview of comments received (EMA/CVMP/ERA/56761/2022) following the close of the public consultation.

6.3. Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 22-23 February 2022, and noted the agenda of the meeting and the minutes from the meeting held on 19-20 October 2021.

6.4. Immunologicals Working Party (IWP)

- There were no items for discussion.

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 23 February 2022, and noted the agenda of the meeting.
- The Committee adopted the updated question and answer document on describing adverse events in the product information (SPC, labelling & packaging leaflet) (EMA/CVMP/150343/2016-Rev1).
- The Committee adopted a veterinary signal assessment report template to be used by MAHs to notify detected signals in the Union Pharmacovigilance database (EMA/464566/2021).

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 28 February – 2 March 2022 and noted the agenda of the meeting, together with the minutes of the QWP meeting held on 22 – 24 November 2021.
- The Committee elected Dr Marie-Hélène Sabinotto as veterinary vice-chair of the QWP for a 3-year term.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 14 March 2022, and noted the agenda of the meeting, along with the minutes of the meeting held on 14 February 2022.

6.10. Safety Working Party (SWP-V)

- The Committee adopted the residues guidelines on determination of withdrawal periods for edible tissues (EMA/CVMP/SWP/735325/2012), determination of withdrawal periods for milk (EMA/CVMP/SWP/735418/2012), and injection site residues (EMA/CVMP/SWP/185470/2004) to align with the new definition for withdrawal periods provided in Regulation (EU) 2019/6, and the overview of comments received following the close of the public consultation (EMA/CVMP/SWP/10857/2022), (EMA/CVMP/SWP/10941/2022), and (EMA/CVMP/SWP/11010/2022). The guidelines will come into effect on 1 August 2022.

6.11. Other working party and scientific group issues

- There were no items for discussion.

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 commercially confidential.

7.1. MRL issues

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

- The Committee discussed the draft procedural advice for veterinary vaccine antigen master file (VAMF) certification (EMA/127488/2021), and the overview of comments received during the 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

- The Committee endorsed the revised VICH guidelines on efficacy of anthelmintics, for sign-off at the VICH Expert Working Group level (step 2 of the VICH process);

  - VICH GL07(R) - Anthelmintics - General requirements
  - VICH GL12(R) - Anthelmintics – Bovines
  - VICH GL13(R) - Anthelmintics – Ovines
  - VICH GL14(R) – Anthelmintics – Caprines
  - VICH GL15(R) - Anthelmintics – Equines
  - VICH GL16(R) - Anthelmintics – Porcines
  - VICH GL19(R) - Anthelmintics – Canines
  - VICH GL20(R) - Anthelmintics – Felines
  - VICH GL21(R) - Anthelmintics – Chickens

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- The Committee discussed the development of a harmonised approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides in food of animal origin, and noted a draft report of the working group.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.
- Draft revised EFSA guidance on the use of the Benchmark Dose approach in risk assessment, for public consultation until 11 April 2022 (link)

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 received a verbal report from the chair of the Veterinary Domain (VetD) on the meeting held on 10 March 2022, and noted the agenda of the March meeting and the minutes of the meeting held on 13 January 2022.

11. CMDv

- The Committee noted the minutes of the CMDv meeting held on 17-18 February 2022 as well as the draft agenda of the meeting to be held on 17-18 March 2022, the minutes of the CMDv-Interested Parties meeting held on 21 January 2022 (link), and the draft agenda of the CMDv-Interested Parties meeting to be held on 18 March 2022.

12. Legislation

- The Committee adopted a concept paper on the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6 on the classification of a veterinary medicinal product (EMA/CVMP/65618/2022), for a 1-month period of public consultation.
- The Committee adopted a guideline on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species (EMA/CVMP/345236/2020) and the overview of comments received (EMA/CVMP/148042/2021) following the close of public consultation.

- The Committee endorsed the revision of the CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products (EMEA/CVMP/248499/2007), which will be done in consideration of the comments received during the public consultation on the related concept paper.
- The Committee received a verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6)).

13. Any other business

13.1. Meeting highlights

- Upon the completion of the March 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 March 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	
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	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	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	
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	
FI	Tita-Maria Muhonen	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Kim Boerkamp	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SE	Carina Bergman	Full involvement	
SK	Eva Chobotová	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.			
DE	Regina Wolf	Full involvement	
FR	Nathalie Bridoux	Full involvement	
NL	Erik den Hertog	Full involvement	
CZ	Ludek Blaha	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Nikola Lange	Full involvement	
SE	Mats Welin	Full involvement	
BE	Sandy Vermout	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Tommi Nurminen	Full involvement	
FI	Jukka Pakkanen	Full involvement	
FI	Stella Attia	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
ES	Sonia Gil Morales	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
ES	Susana Casado Hernandez	Full involvement	
ES	Carlos Ballesteros Vicente	Full involvement	
ES	Rosario Bullido Gomez-Heras	Full involvement	
ES	Rosa Donoso Carrero	Full involvement	
ES	Maria Jose Ferrer Montesa	Full involvement	
ES	Alberto de Prado Lopez	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Wilmar Igl	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Sonja Haase	Full involvement	
DE	Anja Pfalzgraff	Full involvement	
DE	Jana Fischer	Full involvement	
DE	Sarah Adler-Flindt	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	Svenja Rieke	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Uta Herbst	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	
IE	Susan Reid	Full involvement	
IE	Tatyana Devine	Full involvement	
IE	Sarah Buckley	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 - *remotely*
QWP	Mary O'Grady *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman - *remotely*

Observers from Swissmedic	
Present	

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