EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 January 2021
EMA/CVMP/36148/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 December 2020 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/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.
The CVMP welcomed Emer Cooke as new EMA Executive Director.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the December 2020 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 changes, omissions or errors to 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 of the 32 members eligible to vote attended the meeting. It was noted that 17 members were needed for an absolute majority.

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 November 2020 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Solensia** (EMEA/V/C/005719/0000), recommending the granting of a marketing authorisation. The product is indicated for the alleviation of pain associated with osteoarthritis in cats. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/005660/0000) for dogs. The Committee noted the comments received.
- The Committee adopted the updated scientific overview including the list of outstanding issues for an extension application for **Aivlosin** (EMEA/V/C/000083/X/0081) for pigs. The Committee noted two peer review reports and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions for a new generic product (EMEA/V/C/005597/0000) for cats, ferrets and dogs. The Committee noted a peer review report and the comments received from CVMP members.

- The Committee adopted the scientific overview including a list of questions for a new vaccine (EMEA/V/C/005596/0000) for pigs. The Committee noted two peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/005427/0000).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Mhyosphere PCV ID** (EMEA/V/C/005272/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **CircoMax Myco** (EMEA/V/C/005184/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Circovac** (EMEA/V/C/000114/II/0017/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP.
- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Innovax-ILT** (EMEA/V/C/003869/II/0006/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP.
- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Galliprant** (EMEA/V/C/004222/II/0014/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP.
- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Ubac** (EMEA/V/C/004595/II/0004), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues, to be addressed in writing, for a type II variation for **Simparica Trio** (EMEA/V/C/004846/II/0001) concerning quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II grouped variation for **Stelfonta** (EMEA/V/C/005018/II/0004/G) concerning quality-related changes.

- The Committee adopted a list of questions for a type II grouped variation (subject to a worksharing procedure) for **Versican Plus Pi/L4**, **Versican Plus Pi/L4R**, **Versican Plus L4**, **Versican Plus DHPPi/L4R** and **Versican Plus DHPPi/L4** (EMEA/V/C/xxxxxx/WS1928/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Versican Plus Pi/L4R**, **Versican Plus DHPPi/L4R** and other related nationally authorised products (EMEA/V/C/xxxxxx/WS1927) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation (subject to a worksharing procedure) for **Ingelvac CircoFlex** and other related nationally authorised products (EMEA/V/C/xxxxxx/WS1920/G) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the applicant for an extension to the clock-stop for a type II grouped variation for **VarroMed** (EMEA/V/C/002723/II/0003/G) concerning quality-related changes.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Innovax-ND-IBD** (EMEA/V/C/004422).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Zulvac BTV** (EMEA/V/C/004185).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Leucofeligen FeLV RCP** (EMEA/V/C/000143).

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee adopted by consensus (26 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the referral procedure for **Adjusol and its associated names** (EMEA/V/A/134), recommending the harmonisation of the product information for the concerned products. The Icelandic and Norwegian CVMP members agreed with recommendation of the CVMP.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **injectable veterinary medicinal products containing vitamin A for use in food producing species** (EMEA/V/A/141). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines** (EMEA/V/A/142). The Committee adopted a list of

outstanding issues for the marketing authorisation holders to address in writing. The Committee noted a peer review report and the comments made by CVMP members**.**

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Cytopoint** (EMEA/V/C/003939/REC/014.1).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 06.11.2020 – 10.12.2020:

Product	Period
Acticam (EMEA/V/C/000138)	09.12.2019 – 08.12.2020
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2019 – 20.11.2020
Broadline (EMEA/V/C/002700)	04.12.2019 – 03.12.2020
Contacera (EMEA/V/C/002612)	06.12.2019 – 05.12.2020
Draxxin (EMEA/V/C/000077)	11.11.2019 – 10.11.2020
Easotic (EMEA/V/C/000140)	20.11.2019 – 19.11.2020
Equip WNV (EMEA/V/C/000137)	21.11.2019 – 20.11.2020
Gumbohatch (EMEA/V/C/004967)	12.11.2019 – 11.11.2020
Imrestor (EMEA/V/C/002763)	09.12.2019 – 08.12.2020
Inflacam (EMEA/V/C/002497)	09.12.2019 – 08.12.2020
Masivet (EMEA/V/C/000128)	17.11.2019 – 16.11.2020
Meloxoral (EMEA/V/C/000151)	19.11.2019 – 18.11.2020
Mirataz (EMEA/V/C/004733)	10.12.2019 – 09.12.2020

Product	Period
Neptra (EMEA/V/C/004735)	10.12.2019 – 09.12.2020
Nobivac LeuFel (EMEA/V/C/004778)	06.11.2019 – 05.11.2020
Nobivac Myxo-RHD Plus (EMEA/V/C/004989)	19.11.2019 – 18.11.2020
Oxyglobin (EMEA/V/C/000045)	29.11.2019 – 28.11.2020
Panacur AquaSol (EMEA/V/C/002008)	09.12.2019 – 08.12.2020
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2019 – 15.11.2020
Porcilis PCV M Hyo (EMEA/V/C/003796)	07.11.2019 – 06.11.2020
Quadrisol (EMEA/V/C/000032)	04.12.2019 – 03.12.2020
Rabitec (EMEA/V/C/004387)	01.12.2019 – 30.11.2020
Simparica (EMEA/V/C/003991)	06.11.2019 – 05.11.2020
Stronghold (EMEA/V/C/000050)	25.11.2019 – 24.11.2020
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06.11.2019 – 05.11.2020
Vectra 3D (EMEA/V/C/002555)	04.12.2019 – 03.12.2020
Velactis (EMEA/V/C/003739)	09.12.2019 – 08.12.2020
Virbagen Omega (EMEA/V/C/000061)	06.11.2019 – 07.11.2020
Zycortal (EMEA/V/C/003782)	06.11.2019 – 05.11.2020

5.4 Renewals

- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Evalon** (EMEA/V/C/004013/R/0003), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP.
- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Letifend** (EMEA/V/C/003865/R/0023), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 10.12.2019-30.06.2020 for **Neptra** (EMEA/V/C/004735) with a recommendation to amend the section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2020-30.06.2020 for **Vectra Felis** (EMEA/V/C/002746) with a recommendation to amend the section 4.5 `Special precautions for use' and the section 4.10 'Overdose (symptoms, emergency procedures, antidotes)', and the corresponding sections of the package leaflet.

- The Committee endorsed the following rapporteurs' assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Bovela (EMEA/V/C/003703)	01.07.2019-30.06.2020
Cortavance (EMEA/V/C/000110)	01.08.2017-31.07.2020
Ecoporc Shiga (EMEA/V/C/002588)	01.08.2017-31.07.2020
Gripovac 3 (EMEA/V/C/000157)	01.08.2017-31.07.2020
Isemid (EMEA/V/C/004345)	01.02.2020-31.07.2020
Meloxidyl (EMEA/V/C/000115)	01.08.2017-31.07.2020
Nasym (EMEA/V/C004897)	01.02.2020-31.07.2020
ProZinc (EMEA/V/C/002634)	01.02.2020-31.07.2020
Syvazul BTV (EMEA/V/C/004611)	01.02.2020-31.07.2020
Ubac (EMEA/V/C/004595)	01.02.2020-31.07.2020
Velactis (EMEA/V/C/003739)	01.07.2019-30.06.2020

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

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

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee adopted VICH GL59 on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, following the sign-off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process.
- The Committee heard a verbal report on the VICH Steering Committee meeting held on 16-19 November 2020 and the VICH Outreach Forum meeting held on 17 November 2020.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 cannot be released at the present time as it is deemed to be commercially confidential.

7.1 Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 7 December 2020 and noted the agenda of the meeting.
- The Committee adopted the SAWP-V work plan for 2021.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 12 November 2020 and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee elected B. Kolar as vice-chair of the ERAWP for a 3-year term.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 30 November – 1 December 2020 and noted the agenda of the meeting.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 24-25 November 2020 and noted the agenda of the meeting.
- The Committee adopted the PhVWP-V work plan for 2021.

7.9 Novel therapy groups and related issues

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

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following document were circulated for information:

- Minutes of the SAWP-V meeting held on 29 October 2020.

8. OTHER SCIENTIFIC MATTERS

8.1 MRL issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be commercially confidential

- The Committee agreed to revise the current entry limit for **propylene carbonate** in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 and adopted a revised list (EMA/CVMP/519714/2009–Rev.48).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted a reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation (EMA/CVMP/849775/2017)

L. Nepejchalová did not support the aforementioned reflection paper, expressing concerns in line with comments provided by ÚSKVBL during the public consultation process.

- The Committee discussed the draft CVMP strategy on antimicrobials for 2021-2025 following public consultation**.**

8.4 Pharmacovigilance

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee noted the draft minutes of the 5-6 November 2020 meeting and draft agenda of the meeting held on 3-4 December 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the CVMP draft work plan for 2021.
- The Committee endorsed the minutes of the CVMP presidency meeting held virtually on 20 October 2020.
- The Committee noted the newly published European medicines agencies network strategy to 2025.

13. LEGISLATION

- The Committee received a verbal report on progress of the expert group concerning provision of scientific recommendations for an implementing act to Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans.
- The Committee received a verbal report on progress of the expert group concerning provision of scientific recommendations for an 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)).

14. ANY OTHER BUSINESS

- Upon the completion of the December 2020 CVMP meeting, the draft meeting highlights were circulated for members to provide any 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 December 2020 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 Branchev	Involvement in discussions only and cannot act as rapporteur or peer reviewer for the company KRKA:	**4.3** Art. 35 Vitamin A injectables
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	Tita-Maria Muhonen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for the company Bayer:	**5.5** Neptra **5.6** One item **8.1** One item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
IS	Peter Zsolt Fekete	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	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	Full involvement	
RO	Gabriela Tuchila	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.			
CZ	Dana Halová	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Zdenka Malanová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Franziska Schulz	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Sandra Schack	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Werner Terhalle	Full involvement	
DE	Yasemin Süzer	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Martin Oleksiewicz	Full involvement	
ES	Amparo López Rivera	Full involvement	
ES	Carlos Ballesteros	Full involvement	
ES	Javier Martinez	Full involvement	
ES	Jesus Alberto Sanchez	Full involvement	
ES	Luis Agote Casado	Full involvement	
ES	Rocio Fernandez	Full involvement	
ES	Rosa Donoso	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
ES	Rosario Bullido	Full involvement	
ES	Susana Casado	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Gerard Moulin	Full involvement	
FR	Nathalie Bridoux	Full involvement	
FR	Pascal Sanders	Full involvement	
IE	Rhona McHugh	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Susan Reid	Full involvement	
NL	Peter Hekman	Full involvement	
SE	Fredrik Hultén	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Jenny Larsson	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
AWP	---
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(Vet vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Stefan Scheid

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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