3 November 2020
EMA/CVMP/584892/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 6-7 October 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).

Due to the COVID-19 pandemic, the October 2020 CVMP meeting took place by means of remote participation and associated rules relating to decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of two new items: under point 3.5 regarding a request from the MAH for a extension to the clock-stop period for a type II variation for **Cortavance**, and under point 13 regarding a verbal update from the EC on the status of the implementation of Regulation (EU) 2019/6.

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

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

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the September 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **CircoMax Myco** (EMEA/V/C/005184/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of pigs against porcine circovirus type 2 and *Mycoplasma hyopneumoniae*. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Enteroporc Coli AC** (EMEA/V/C/005149/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of pregnant gilts and sows to provide passive protection to piglets against porcine neonatal diarrhoea caused by *Escherichia coli* strains expressing the fimbrial adhesins F4ab, F4ac, F5 and F6 and enteric disease caused by toxins of *Clostridium perfringens* types A and C. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Rexxolide** (EMEA/V/C/005384/0000), containing tulathromycin, recommending the granting of a marketing authorisation. The product is indicated for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Nobivac DP Plus** (EMEA/V/C/005251/0000), recommending the granting of a marketing authorisation. The product is a new live recombinant viral vaccine for the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Vectormune FP ILT** (EMEA/V/C/005482/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of chickens from 8 weeks of age in order to reduce the skin lesions due to fowlpox and to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis. The Icelandic and Norwegian CVMP members agreed with the above-mentioned 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 heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/005094/0000). The Committee also discussed the scientific overview and list of outstanding issues, the comments on the draft product information and the draft CVMP assessment report. The adoption of the opinion is foreseen for the November 2020 CVMP meeting.
- 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/005427/0000) for dogs. The Committee noted a peer review report and the comments received from other CVMP members.

2.3 Lists of questions

- 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/005489/0000) for cats. The Committee noted three peer review reports and the comments received from other CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product for dogs (EMEA/V/C/005465/0000). The Committee noted two peer review reports and the comments received from other 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 vaccine (EMEA/V/C/005301/0000).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Tulinovet** (EMEA/V/C/005076) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Increxxa** (EMEA/V/C/005305) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 for **Innovax-ND-IBD** (EMEA/V/C/004422/II/0004), recommending the variation of the marketing authorisation to extend the duration of immunity for the protection against Newcastle disease and infectious bursal disease from 8 weeks to 60 weeks. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion for a grouped type II variation application for **Arti-Cell Forte** (EMEA/V/C/004422/II/0004), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted a list of questions and comments on product information for a type II variation (subject to a worksharing procedure) for **Vectormune ND** (EMEA/V/C/003829/WS1892) and other related nationally authorised products concerning quality-related changes.
- The Committee adopted a list of questions and comments on product information for a type II variation for **Eravac** (EMEA/V/C/004239/II/0006) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **VarroMed** (EMEA/V/C/002723/II/0003/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **VarroMed** (EMEA/V/C/002723/II/0004/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Cytopoint** (EMEA/V/C/003939/II/0011/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 the request from the MAH for an extension to the clock-stop period for a type II variation for **Cortavance** (EMEA/V/C/000110/II/0015), concerning the addition of a new therapeutic indication.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Bluevac BTV** (EMEA/V/C/000156) concerning type II variation to the marketing authorisation.

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

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique following the marketing authorisation holders' responses to the list of outstanding issues for the referral procedure for **Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products** (EMEA/V/A/140). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the November 2020 meeting of the Committee. The Committee noted a peer review report and the comments received from 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.

The following documents were circulated for information:

- Referrals tracking table;
- Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof – Article 35 referral (EMEA/V/A/132) – Questions and answers for publication;
- Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof – Article 35 referral (EMEA/V/A/138) – Questions and answers for publication.

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 endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Nobivac Myxo-RHD Plus** (EMEA/V/C/004989/REC/001), which is now considered completed.
- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Purevax RC**, **Purevax RCP** and **Purevax RCPCh** (EMEA/V/C/000091/REC/022, EMEA/V/C/000090/REC/022 and EMEA/V/C/000088/REC/024), which is now considered completed.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 09.09.2020 – 08.10.2020:

Product	Period
Apoquel (EMEA/V/C/002688)	12.09.2019 – 11.09.2020
Cerenia (EMEA/V/C/000106)	29.09.2019 – 28.09.2020
Coxevac (EMEA/V/C/000155)	30.09.2019 – 29.09.2020
Eravac (EMEA/V/C/004239)	22.09.2019 – 21.09.2020
Palladia (EMEA/V/C/000150)	23.09.2019 – 22.09.2020
Previcox (EMEA/V/C/000082)	13.09.2019 – 12.09.2020
Recocam (EMEA/V/C/002247)	13.09.2019 – 12.09.2020
Rhiniseng (EMEA/V/C/000160)	16.09.2019 – 15.09.2020
Simparica Trio (EMEA/V/C/004846)	17.09.2019 – 16.09.2020

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

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

Product	Period
Baycox Iron (EMEA/V/C/004794)	01.12.2019-31.05.2020
Bluevac BTV8 (EMEA/V/C/000156)	01.07.2019-30.06.2020
Nobivac Myxo RHD Plus (EMEA/V/C/004989)	19.11.2019-31.05.2020
Respiporc FLUPan H1N1 (EMEA/V/C/003993)	01.12.2019-31.05.2020
Simparica and **MiPet Easecto** (EMEA/V/C/003991) (EMEA/V/C/004732)	01.06.2019-31.05.2020
Zycortal (EMEA/V/C/003782)	01.06.2019-31.05.2020

- 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.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the VICH concept paper on the development of further guidance around medicated premixes for sign-off by the VICH Steering Committee.
- The Committee endorsed the VICH concept paper proposing development of guidance on good manufacturing practice for active pharmaceutical ingredients for sign-off by the VICH Steering Committee.
- The Committee endorsed the revised draft VICH GL59 "Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use" for sign-off by the EWG at step 5 of the VICH process.
- The Committee noted the draft agendas for the VICH Steering Committee meeting scheduled to held on 16-19 November 2020 and for the VICH Outreach Forum meeting scheduled to take place on 17 November 2020.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following document was circulated for information:

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

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 5 October 2020 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- The Committee endorsed the recommendation of the selection committee and appointed a new panel of members under the revised mandate, objectives and rules of procedure for the SWP-V.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- The Committee re-elected C. Muñoz Madero as EWP-V chair for a 3-year mandate. The Committee also endorsed the recommendation of the selection committee and appointed a new panel of members under the revised mandate, objectives and rules of procedure for the EWP-V.

7.6 Antimicrobials Working Party (AWP)

- The Committee elected D. Bouchard as AWP vice-chair for a 3-year mandate.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 22-23 September 2020 and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee re-elected E. Dewaele as PhVWP-V chair for a 3-year mandate.
- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 22-23 September 2020 and noted the agenda of the meeting.
- The Committee received a verbal report from the PhVWP-V Interested Parties meeting held on 23 September 2020 and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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 documents were circulated for information:

- Minutes of the SAWP-V meeting held on 7 September 2020;
- Minutes of QWP meeting held on 4-6 May 2020;
- Agenda of QWP meeting held on 16-18 September 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 include **dipropylene glycol, 1,2-benzisothiazol-3(2H)-one** and **polydimethylsiloxane, hydroxy-terminated** as new entries in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev. 46).

8.2 Environmental risk assessment

- The Committee noted the resolution on a strategic approach to pharmaceuticals in the environment adopted by European Parliament on 17 September 2020 (link).

8.3 Antimicrobial resistance

- The Committee noted the comments received during the public consultation of the draft CVMP strategy on antimicrobials for 2021-2025 and endorsed the approach for further development of the strategy. CVMP expects to discuss the proposed revisions at its November meeting and to adopt the revised strategy at the December 2020 meeting of the Committee.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

- 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. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee agreed to the transfer of all co-rapporteurships from I. Lindner to M. Leitner.

10.2 Regulatory matters

- There were no items for discussion.

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

- The Committee noted the draft minutes of the 10-11 September 2020 meeting and the draft agenda of the meeting held on 8-9 October 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

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 work 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 October 2020 CVMP meeting, the draft press release was 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 October 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	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	Tita-Maria Muhonen	Involvement in discussions only and cannot act as rapporteur or peer reviewer for Orion Corporation	2.2 – one item 2.3 – one item
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	
LU	Marc Schmit	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	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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	
NL	Kim Boerkamp	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	Zdenka Mašková	Full involvement	
DE	Katja Kaulich	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Werner Terhalle	Full involvement	
DE	Wiebke Weiher	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Hassan Kassem	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DK	Anne Malene Nissen	Full involvement	
DK	Mette T. Madsen	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
DK	Trine Jensen	Full involvement	
ES	Carlos Ballesteros	Full involvement	
ES	Raúl Belmar Liberato	Full involvement	
ES	Rosario Bullido	Full involvement	
FR	Anne Sagnier	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Gérard Moulin	Full involvement	
FR	Hicham Ait Lbacha	Full involvement	
FR	Khadija Selouaoui	Full involvement	
FR	Mathilde Harvey	Full involvement	
FR	Meg-Anne Moriceau	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Nathalie Bridoux	Full involvement	
IE	Aideen Brownen	Full involvement	
IE	Bairbre Sharkey	Full involvement	
IE	Sarah Hanley	Full involvement	
NL	Piet-Hein Overhaus	Full involvement	
NL	Sandra ten Voorde	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Lennart Åkerblom	Full involvement	
SE	Malin Öhlund	Full involvement	
SI	Luka Kosec	Full involvement	
SI	Mojca Ogriz	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
AWP	Christine Schwarz
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