8 December 2020
EMA/CVMP/666630/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 3-5 November 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 the addition of a new item under point 6.1.

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

The attendance list was completed and competing interests were identified for the November 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 were present in the room. It was noted that 17 members were needed for an absolute majority.

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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 October 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

- The Committee discussed the rapporteur's assessment report to the list of questions and the rapporteur's draft EPMAR for the modification of MRLs in fin fish for a substance (EMEA/V/MLR/003802/MODF/0002) and adopted a list of outstanding issues that should be addressed in writing and at an oral explanation.

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

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 **NexGard Combo** (EMEA/V/C/005094/0000), containing esafoxolaner, eprinomectin and praziquantel, recommending the granting of a marketing authorisation. The product is a new spot-on solution for cats with, or at risk from, mixed infections by cestodes, nematodes and ectoparasites. 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 attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Enteroporc Coli** (EMEA/V/C/005148/0000), 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. 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/005719/0000) in cats. The Committee also discussed the draft assessment of the written responses. The adoption of the opinion is foreseen for the December 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/005354/0000) in dogs. The Committee noted two peer review reports and the comments received from CVMP members.
- 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/005325/0000) in dogs. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for an extension application for **Emdocam** (EMEA/V/C/002283/X/0012), to add a new strength and new target species. The Committee noted the comments received.
- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for an extension application for **Emdocam** (EMEA/V/C/002283/X/0013), to add a new strength and a new pharmaceutical form. The Committee noted the comments received.
- 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 vaccine (EMEA/V/C/005347/0000) for chickens. 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 and agreed comments on the draft product information for a new vaccine (EMEA/V/C/005185/0000) for pigs. 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 and agreed comments on the draft product information for a new product (EMEA/V/C/005464/0000) for cats. The Committee noted a 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 endorsed the European public assessment report (EPAR) 'scientific discussion' for **Ovugel (**EMEA/V/C/005219/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (29 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Advocate** (EMEA/V/C/000076/II/0043), recommending the variation of the marketing

authorisation to update section 4.7 of the SPC as regards the use of the product during pregnancy and lactation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (29 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Clynav** (EMEA/V/C/002390/II/0011), 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.
- The Committee adopted by consensus (29 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 **Sevohale** (EMEA/V/C/004199/II/0006/G), 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.
- The Committee adopted by consensus (29 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 (subject to a worksharing procedure) for **Equilis Prequenza** and **Equilis Prequenza Te** (EMEA/V/C/xxxxxx/WS1836), 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.
- The Committee adopted by consensus (29 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Respiporc FLU3, Ecoporc Shiga, Respiporc FLUpan H1N1** and **Rabitec** (EMEA/V/C/xxxxxx/WS1887), 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 for a type II variation for **Suvaxyn CSF Marker** (EMEA/V/C/002757/II/0008) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Gumbohatch** (EMEA/V/C/004967/II/0004) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Melosus** (EMEA/V/C/002001/II/0012) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Meloxoral** (EMEA/V/C/000151/II/0011) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- No items.

3.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Nobilis IB Primo QX** (EMEA/V/C/002802/0000) concerning the granting of the initial marketing authorisation.

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Cytopoint** (EMEA/V/C/003939/0000) concerning the granting of the initial 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

- The Committee discussed the revised rapporteur's assessment report including co-rapporteur's critique following MAHs' responses to the list of outstanding issues and the comments on the product information for the referral procedure for **Adjusol and its associated names** (EMEA/V/A/134). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the December 2020 meeting of the Committee. The Committee noted two peer review reports and the comments made by CVMP members**.**

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Valbazen oral suspension and associated names, including its generic/hybrid products** which contain 100 mg or 200 mg albendazole per ml (EMEA/V/A/140). The Committee recommended that the withdrawal periods for milk, meat and offal derived from treated cattle should be amended to ensure consumer safety. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

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

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 recommendations for **Versican Plus DHPPi/L4R**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi**, **Versican Plus Pi**, **Versican Plus Pi/L4R** and **Versican Plus Pi/L4** (EMEA/V/C/002759/REC/016.1, EMEA/V/C/003678/REC/016.1, EMEA/V/C/003679/REC/011.1, EMEA/V/C/003681/REC/011.1, EMEA/V/C/003682/REC/013.1, EMEA/V/C/003683/REC/012.1).

- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendations for **Gumbohatch** (EMEA/V/C/004967/REC/007).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 8 October 2020 – 5 November 2020.

Product	Period
Halocur (EMEA/V/C/000040)	29.10.2019 – 28.10.2020
Zolvix (EMEA/V/C/000154)	04.11.2019 – 03.11.2020

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
Bovilis Blue-8 (EMEA/V/C/004776)	01.07.2019-30.06.2020
Bravecto (EMEA/V/C/002526)	01.03.2019-29.02.2020
Bravecto Plus (EMEA/V/C/004440)	01.06.2019-30.11.2019
Bravecto Plus (EMEA/V/C/004440)	01.12.2019-31.05.2020
Mirataz (EMEA/V/C/004733)	10.12.2019-30.06.2020
Vectra 3D (EMEA/V/C/002555)	01.01.2020-30.06.2020

- 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.

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 EU comments on the 'critical questions' identified in the draft concept paper for development of VICH guidelines on *in vitro* dissolution testing and biowaivers for *in vivo* blood bioequivalence determination.
- The Committee indicated its support for the concept paper proposing development of VICH guidelines to parallel ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System) but noted that further reflection is required on the issue of whether the guidance would cover only pharmaceuticals or whether it would also be relevant for immunologicals and other biologicals.

- The Committee endorsed the draft VICH GL59 on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, for sign-off by the VICH Steering Committee at step 6 of the VICH process.
- The Committee endorsed the nomination of an adviser to support the EU expert in the work to develop a VICH guideline on Good Manufacturing Practice for Active Pharmaceutical Ingredients.
- The Committee noted the draft agenda for VICH Steering Committee meeting scheduled to be held on 16-19 November 2020 and for VICH Outreach Forum meeting to be held on 17 November 2020, and the progress reports from the VICH expert working groups on anthelmintics, bioequivalence, biologicals, combination products, metabolism and residue kinetics, pharmacovigilance, quality and safety.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following document(s) was/were 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 29 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)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 15-16 October 2020 and noted the agenda of the meeting. The Committee also noted the minutes from the meetings held on 30-31 January 2018 and on 15-16 October 2020.
- The Committee adopted the ERAWP work plan 2020.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 13-14 October 2020 and noted the agenda and minutes of the meeting.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

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 document was circulated for information:

- Minutes of the SAWP-V meeting held on 5 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 modify the entry for **propylene carbonate** on 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.47).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee endorsed the draft concept paper for the development of a guideline on reporting antimicrobial sales and use data in line with the requirements of Article 57 of Regulation (EU) 2019/6. The draft concept paper will be published for public consultation in November 2020 after its adoption by the ESVAC network. The Committee gave a mandate to the ESVAC denominator and indicators review *Ad Hoc* Expert Group to continue the initiative for the development of a guideline.
- The Committee discussed the revised reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation and the overview of comments received by stakeholders during the public consultation.
- The Committee noted the verbal report on the 10th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 31 European countries in 2018 (link).

8.4 Pharmacovigilance

- There were no items for discussion.

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. 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.

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.

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

- The Committee received a verbal report from the chair of CMDv on the meetings held on 10-11 September and 8-9 October 2020. The Committee noted the draft minutes of the October meeting as well as the draft agenda of the meeting held on 5-6 November 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 29 October 2020 and noted the agenda of the meeting and the minutes of the meeting held on 7 September 2020.
- The Committee discussed the CVMP draft work plan for 2021.
- The Committee received a verbal report from D. Murphy, E. Werner and A. Golombiewski on the CVMP Presidency meeting held virtually on 20 October 2020.

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 November 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 November 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 Valentinov Branchev	Full involvement	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Falopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Sylvie Louet	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	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	2.3 – One item 3.1 – Advocate
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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
HR	Hrvoje Pavasovic	Full involvement	
HU	Melinda Nemes-Terenyi	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Kim Boerkamp	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	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	Eva Pomezná	Full involvement	
CZ	Vilma Smítalová		
DE	Anke Finnah		
DE	Christina Bredtmann		
DE	Christine Schwarz		
DE	Christopher Janich		
DE	Franziska Schulz		
DE	Jan Brosda		
DE	Judith Romberg		
DE	Kathrin Schmidt		
DE	Nikola Lange		
DE	Roswitha Merkel		
DE	Sarah Adler-Flindt		
DE	Silke Hickmann		
DE	Stefan Scheid		
DE	Svenja Rieke		
DE	Stephan Steuber		
DE	Werner Terhalle		
DK	Anja Silke Christensen		
DK	Henrik Duelund Pedersen		
DK	Susanne Havn Aamand		
DK	Trine Jensen		
ES	Aránzazu González-Canga		
ES	Jesús Sánchez Rodriguez		
ES	Luis Agote Casado		

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
ES	María Domínguez Nicolás		
ES	María José González Fernández		
FI	Jonna Kumpulainen		
FI	Jukka Pakkanen		
FI	Minna Leppänen		
FI	Pertti Pellinen		
FR	Anne Sagnier		
FR	Caroline Guittré		
FR	Damien Bouchard		
FR	Florence Pillet		
FR	Gérard Moulin		
FR	Laetitia Le Letty		
FR	Martine Rederau		
FR	Meg-Anne Moriceau		
IE	Aideen Brownen		
IE	Sarah Buckley		
NL	Erik den Hertog		
NL	Peter Hekman		
NO	Hans Kristian Østensen		
SE	Hanna Bremer		
SE	Jenny Larsson		
SE	Malin Öhlund		

CVMP working parties and CMDv	Chair
ADVENT	---
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	---
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