11 September 2018
EMA/CVMP/455551/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 17-19 July 2018 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

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 section 12.

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

The attendance list was completed and competing interests were identified for the July 2018 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. 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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iv. Adoption of the minutes of the previous meeting

The minutes of the June 2018 meeting were adopted with minor amendments to provide clarifications under section 2.1.

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

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs for **ovotransferrin** (EMEA/V/MRL/004856/FULL/0001) in chicken tissues and eggs, and agreed to extrapolate these to tissues of other poultry species. The Committee noted the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the establishment of MRLs for a substance in horses (EMEA/V/MRL/005010/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. The Committee noted three peer review reports and the comments received.

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

- There were no items for discussion.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new generic antiparasitic product for cats and dogs (EMEA/V/C/004824/0000). The Committee agreed that an oral explanation would not be requested. 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 a marketing authorisation application for a new cardiovascular product for dogs (EMEA/V/C/004345/0000). The Committee agreed that an oral explanation would not be requested. 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 the list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/004858/0000) for pigs. The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee agreed to the request from the applicant for the re-examination, in accordance with Regulation (EC) No 726/2004, of the CVMP opinion adopted at the June 2018 meeting for **Horse Allo 20** (EMEA/V/C/004222/0000), and appointed a rapporteur and a co-rapporteur for the procedure. The Committee also agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). The adoption of the opinion is foreseen for the October 2018 meeting of the Committee.

- The Committee discussed the request from the applicant for the re-examination, in accordance with Regulation (EC) No 726/2004, of the CVMP opinion adopted at the June 2018 meeting for **LongRange** (EMEA/V/C/004291/0000), and appointed a rapporteur and a co-rapporteur for the procedure. The Committee agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). The adoption of the opinion is foreseen for the October 2018 meeting of the Committee.

2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **UBAC** (EMEA/V/C/004595/0000) concerning the granting of the initial marketing authorisation.

- The Committee endorsed the withdrawal EPAR module scientific discussion for **HopGuard Gold** (EMEA/V/C/002836/0000).

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 worksharing type IB variation for **Inflacam and Rheumocam** (EMEA/V/C/xxxxxx/WS1301), recommending the granting of the variation to the marketing authorisation to implement quality changes.

- 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 grouped type II variation for **Palladia** (EMEA/V/C/000150/II/0012/G), recommending the granting of the variation to the marketing authorisation to implement quality changes.

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 worksharing type IB variation for **Versican Plus DHPPi** and for **Versican Plus Pi** (EMEA/V/C/xxxxxx/WS1397), concerning quality changes.

- The Committee adopted a list of questions for a worksharing type IB variation for **Versican Plus DHPPi L4R**, **Versican Plus DHPPi L4**, **Versican Plus L4**, **Versican Plus Pi L4R** and **Versican Plus Pi L4** (EMEA/V/C/xxxxxx/WS1398), concerning quality 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 MAH for a extension to the clock-stop for a type II variation for **Clomicalm** (EMEA/V/C/000039/II/0027) concerning quality changes.

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

- There were no items for discussion.

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

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the procedure concerning **diethanolamine** (EMEA/V/A/127). The Committee concluded that, on the basis of the information available, it is not possible to rule out a risk for consumers of food produced from animals treated with veterinary medicinal products containing diethanolamine, thus confirming that the substance is not appropriate for inclusion in the list of substances considered as not falling within the scope of Regulation 470/2009 (the 'out of scope' list). In order to allow further consideration of the risk to consumer safety associated with the use of diethanolamine in veterinary medicinal products for food-producing animals, an application for the establishment of MRLs would be needed.

- The Committee discussed the rapporteur's assessment report, including the critique from the co-rapporteur for the procedure for **veterinary medicinal products containing gentamicin for parenteral administration to horses** (EMEA/V/A/128), and adopted a list of outstanding issues and a revised timetable of the procedure. The Committee noted two peer review reports and the comments received from CVMP members.

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 endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/REC/009).
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Prac-tic** (EMEA/V/C/000103/REC/024).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 22.06.2018 – 19.07.2018:

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2017 – 14/07/2018
Canigen L4 (EMEA/V/C/004079)	03/07/2017 – 02/07/2018
CLYNAV (EMEA/V/C/002390)	27/06/2017 – 26/06/2018
Equilis Prequenza (EMEA/V/C/000094)	08/07/2017 – 07/07/2018
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2017 – 07/07/2018
Equilis Te (EMEA/V/C/000093)	08/07/2017 – 07/07/2018
EQUIOXX (EMEA/V/C/000142)	25/06/2017 – 24/06/2018
ERYSENG (EMEA/V/C/002761)	04/07/2017 – 03/07/2018
ERYSENG PARVO (EMEA/V/C/002762)	08/07/2017 – 07/07/2018
Innovax-ILT (EMEA/V/C/003869)	03/07/2017 – 02/07/2018
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25/06/2017 – 24/06/2018
Melovem (EMEA/V/C/000152)	07/07/2017 – 06/07/2018
Nobivac L4 (EMEA/V/C/002010)	16/07/2017 – 15/07/2018
Posatex (EMEA/V/C/000122)	23/06/2017 – 22/06/2018
ProZinc (EMEA/V/C/002634)	12/07/2017 – 11/07/2018
Reconcile (EMEA/V/C/000133)	08/07/2017 – 07/07/2018
Suprelorin (EMEA/V/C/000109)	10/07/2017 – 09/07/2018
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2017 – 03/07/2018
Versican Plus Pi (EMEA/V/C/003681)	04/07/2017 – 03/07/2018

5.4 Renewals

- 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 the renewal of the marketing authorisation for **Broadline** (EMEA/V/C/2700/R/0020), and recommended that the authorisation should now be indefinite.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.17-31.01.18 for **ERYSENG** (EMEA/V/C/002761) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.17-31.01.18 for **ERYSENG PARVO** (EMEA/V/C/002762) 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 literature or other regulatory actions were required for:

Product	Period
Canigen L4 (EMEA/V/C/004079) / **Nobivac L4** (EMEA/V/C/002010)	01.08.17-31.01.18
Coliprotec F4/F18 (EMEA/V/C/004225)	01.08.17-31.01.18
Equilis Te (EMEA/V/C/000093)	01.02.15-31.01.18
Imrestor (EMEA/V/C/00273)	01.04.17-30.09.17
Purevax RCP (EMEA/V/C/000090)	01.03.15-28.02.18
Purevax RCPCh (EMEA/V/C/000088)	01.03.15-28.02.18
Sedadex (EMEA/V/C/004202)	13.08.17-12.02.18
Stronghold Plus (EMEA/V/C/004194)	01.09.17-28.02.18
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24.08.17-28.02.18
UpCard (EMEA/V/C/003836)	01.08.17-31.01.18
Ypozane (EMEA/V/C/000112)	01.02.15-31.01.18
ZACTRAN (EMEA/V/C/000129)	01.08.17-31.01.18

- 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 the VICH GL56 on design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, following the sign-off by the VICH Steering Committee for implementation in the EU at step 7 of the VICH process.
- The Committee adopted the VICH GL 58 on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV, for release for a 5-month consultation period at step 4 of the VICH process.
- The Committee received a verbal report on the 36th VICH Steering Committee meeting held on 25-26 and 28 June 2018, and on the 10th VICH Outreach Forum meeting held on 26-27 June in Bruges, Belgium.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

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

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

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

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 17 July 2018, and noted the agenda.

7.2 Quality Working Party (QWP)

- The Committee adopted a question and answer on the control of content of active substance in a veterinary medicinal product where there can be batch to batch variability in potency of the active substance.
- The Committee adopted the guideline on water for pharmaceutical use (EMA/CHMP/CVMP/QWP/383481/2018) for a 6-month period of public consultation.
- The Committee adopted the draft revision of the guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005) for a 3-month period of public consultation.
- The Committee adopted the draft revised guideline on specifications of herbal medicinal products (EMA/HMPC/162241/2005) for a 3-month period of public consultation.

7.3 Safety Working Party (SWP-V)

- The Committee was informed that no nominations were received for the election of a SWP-V vice-chair and noted that a further call for nominations will be considered if necessary.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the reflection paper on antimicrobial resistance in the environment, which is foreseen to be adopted at the September CVMP meeting. – *see also 7.6*

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted a new draft guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector-borne diseases in dogs and cats for a 12-month period of public consultation.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted a draft revised guideline on the assessment of the risk to public health from antimicrobial resistance in food-producing animals for release for a second period of public consultation for 3 months, and noted the overview of comments received following the first public consultation.

- The Committee discussed the reflection paper on antimicrobial resistance in the environment, which is foreseen to be adopted at the September CVMP meeting. – *see also 7.4*
- The Committee discussed the reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the EU, which is foreseen to be adopted at the September 2018 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 10 July 2018, and noted the agenda of the meeting.

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 documents were circulated for information:

- Minutes of the SAWP-V meeting held on 19 June 2018
- Agenda of the ADVENT core group meeting held on 10 July 2018
- Minutes of the ADVENT core group meeting held on 15 February 2018

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

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

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted the reflection paper on the pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation for a 6-month period of public consultation.

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 contain commercially confidential information.

- There were no items for discussion.

The following documents were circulated for information:

- Draft agenda and draft minutes of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) Adobe Connect meeting held on 27 June 2018.
- Final summary report of the joint FAO/WHO "Expert meeting on foodborne AMR: Role of environment, crops and biocides" held, in collaboration with OIE, on 11-15 June 2018 in Rome to provide scientific advice to the inter-governmental Task Force on AMR of the Codex Alimentarius

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 CMDv chair on the meetings held on April, May and June 2018, and noted the draft minutes of the 21-22 June meeting as well as the draft agenda of the meeting held on 19-20 July 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft CVMP work plan for 2019 presented by the chair and its general areas of activity. The members were asked to review the draft CVMP work plan for 2019 and provide any comments to the chair and secretariat for discussion at the September CVMP meeting.
- The Committee discussed the recommendations arising from the CVMP session of the informal presidency meeting held on 7-8 May 2018 in Madrid, Spain, which are foreseen to be endorsed by CVMP at their September meeting.
- The Committee discussed CVMP roles and responsibilities, and the conclusions presented by D. Murphy from the outcome of discussion at the May-June 2018 CVMP meetings on the CVMP roles review and points for consideration. It was agreed that the CVMP chair together with the secretariat will identify any revisions that can be made to the guidance on appointment and responsibilities of the rapporteurs and present these to CVMP at the September meeting.
- The Committee discussed the draft agenda of the upcoming informal Presidency CVMP/CMDv meeting (to be held during the Austrian presidency) on 25-26 October 2018 in Helsinki, Finland.
- The Committee noted an update regarding the relocation of EMA.
- The Committee was informed of the implementation of EMA Business Continuity Phase 3.

- The Committee was informed of the potential issues or procedures requiring CVMP decision via written procedure during August 2018.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the July 2018 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 July 2018 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**	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou-Patsia	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	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:	**3.3** Versican Plus DHPPi and Versican Plus Pi **3.3** Versican Plus DHPPi L4R, Versican Plus DHPPi L4, Versican Plus L4, Versican Plus Pi L4R and Versican Plus Pi L4 **10.1** One item
FR	Jean-Claude Rouby	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	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Petra Falb	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
FR	Sylvie Louet	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
IE	Mary O'Grady	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Maja Turk	Full involvement	
UK	Noemi Garcia del Blanco	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 Vernerova *(remotely)*	Full involvement	
CZ	Eva Pomezná *(remotely)*	Full involvement	
DE	Uta Herbst *(remotely)*	Full involvement	
DE	Sabine Kalweit *(remotely)*	Full involvement	
DE	Stephan Steuber *(remotely)*	Full involvement	
DE	Maren Friederichs *(remotely)*	Full involvement	
DE	Daniela Loos *(remotely)*	Full involvement	
DE	Inke Reimer *(remotely)*	Full involvement	
DE	Luela Fröhlich *(remotely)*	Full involvement	
DE	Klaus Cussler *(remotely)*	Full involvement	
DE	Yasemin Suzer *(remotely)*	Full involvement	
DE	Karin Duchow *(remotely)*	Full involvement	
DE	Ingun Lemke *(remotely)*	Full involvement	
DK	Anja Silke Christensen *(remotely)*	Full involvement	
DK	Malene Nissen *(remotely)*	Full involvement	
ES	Raúl Belmar *(remotely)*	Full involvement	
ES	Rocío Fernández *(remotely)*	Full involvement	
ES	Héctor Duran *(remotely)*	Full involvement	
FR	Elisabeth Begon *(remotely)*	Full involvement	
FR	Damien Bouchard *(remotely)*	Full involvement	
SE	Jennie Sandberg	Full involvement	
SE	Malin Öhlund	Full involvement	
UK	Gillian Clarke *(remotely)*	Full involvement	
UK	Ruth Pearson *(remotely)*	Full involvement	
UK	John Mitchell *(remotely)*	Full involvement	
UK	Jean-Paul Schmidt	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Michael Stephens	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Muñoz Madero
IWP	---
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady
SAWP-V	Rory Breathnach
SWP-V	---

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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