13 June 2017
EMA/CVMP/376100/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 10-11 May 2017 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 no modifications.

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

The attendance list was completed and competing interests were identified for the May 2017 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the April 2017 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

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, including the EPMAR, and the CVMP assessment report recommending the establishment of MRLs in porcine species for **bromelain** (EMEA/V/MRL/004479/FULL/0001). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the comments received from CVMP members and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues, to be addressed in writing and at an oral explanation, for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004321/FULL/0001). The Committee noted two peer review reports.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

Information relating to certain topics discussed under section 1.4 at this meeting cannot be released at the present time as it is deemed to be confidential.

1.5 Other issues

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for the establishment of MRLs in Salmonidae for a substance (EMEA/V/MRL/004481/FULL/0001).
- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004333/FULL/0001).

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 scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new anti-inflammatory non-steroidal product for dogs (EMEA/V/C/004222/0000). The Committee agreed to invite the applicant for an oral explanation, and noted two peer review reports and the comments received from CVMP members.

- The Committee heard an oral explanation from the applicant concerning an application for a new antiparasitic product for chickens (EMEA/V/C/004344/0000). The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the June 2017 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 vaccine for chickens (EMEA/V/C/004422/0000). The Committee noted two peer review reports and the comments received from CVMP members. The adoption of the opinion is foreseen for the June 2017 CVMP meeting.

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 product for a musculo-skeletal disorder in horses (EMEA/V/C/004222/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview, including the list of questions, and agreed comments on the draft product information for a new antiparasitic product for cattle (EMEA/V/C/004291/0000). The Committee noted two peer review reports 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 EPAR module 6 scientific discussion for **Zeleris** (EMEA/V/C/004099/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Novem** (EMEA/V/C/000086/X/0018) concerning an extension of the marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Ingelvac PCV FLEX** (EMEA/V/C/004645/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Broadline** (EMEA/V/C/002700/II/0013), recommending the variation of the marketing authorisation to extend the indication with the addition of two cestodes and the cat liver fluke. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Activyl** (EMEA/V/C/000163/II/0011), recommending the variation of the marketing authorisation to change its legal status (from prescription only to non-prescription status). The Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type II variation for **Nobivac Bb** (EMEA/V/C/000068/WS1053/0015), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/WS1149/0020), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member 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 the list of questions for a type II variation for **Metacam** (EMEA/V/C/000033/II/0127), to register an additional non-food producing target species.
- The Committee adopted the list of questions for a type II variation for **Simparica** (EMEA/V/C/003991/II/0006), to add new indications.
- The Committee adopted the list of questions for a type II variation for **NEXGARD SPECTRA** (EMEA/V/C/003842/II/0011), concerning quality changes.
- The Committee adopted the list of questions for a worksharing type II variation for **Vectormune ND** (EMEA/V/C/003829/WS1082/0006), concerning changes in the SPC and package leaflet.
- The Committee adopted the list of questions for a worksharing type IB variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS1120), concerning quality changes.
- The Committee adopted the list of questions for a worksharing type IB variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS1142), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

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 adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and**

horses (EMEA/V/A/116), concluding that based on data from laboratory studies moxidectin fulfils the criteria for a PBT substance, and that the use of veterinary medicinal products containing the substance poses a risk to aquatic and sediment organisms and to dung fauna. The Committee agreed that these products are effective and an important therapeutic option in the treatment of internal and external parasites in cattle, sheep and horses, and recommended risk mitigation measures and warnings to be included in the product information in order to reduce and prevent as far as possible the identified risks for aquatic and sediment organisms and dung fauna. The Committee also agreed that a targeted sampling in the environment is necessary in order to obtain a better understanding of the actual environmental exposure, and consequently recommended conditions to the terms of the marketing authorisations. The Committee concluded that overall the benefit-risk balance for the products concerned by this referral is positive, subject to changes in the product information and conditions to the marketing authorisations. The Norwegian CVMP member 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

- 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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 13.04.2017 – 11.05.2017:

Product	Period
BLUEVAC BTV8 (EMEA/V/C/000156)	14/04/2016 – 13/04/2017
CERTIFECT (EMEA/V/C/002002)	06/05/2016 – 05/05/2017
Equilis StrepE (EMEA/V/C/000078)	07/05/2016 – 06/05/2017
Evalon (EMEA/V/C/004013)	18/04/2016 – 17/04/2017
Improvac (EMEA/V/C/000136)	11/05/2016 – 10/05/2017

Product	Period
LETIFEND (EMEA/V/C/003865)	20/04/2016 – 19/04/2017
Meloxidolor (EMEA/V/C/002590)	22/04/2016 – 21/04/2017
Neocolipor (EMEA/V/C/000035)	14/04/2016 – 13/03/2017
Oncept IL-2 (EMEA/V/C/002562)	03/05/2016 – 02/05/2017
Procox (EMEA/V/C/002006)	20/04/2016 – 19/04/2017
Purevax FeLV (EMEA/V/C/000056)	13/04/2016 – 12/04/2017
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2016 – 06/05/2017
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2016 – 06/05/2017
Zuprevo (EMEA/V/C/002009)	06/05/2016 – 05/05/2017

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.06.2016 – 30.11.2016 for **Simparica** (EMEA/V/C/003991) with a recommendation to amend the SPC in order to include gastrointestinal and neurological adverse reactions.
- The Committee adopted the following CVMP assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
BTVPUR (EMEA/V/C/002231)	01.01.2016 – 31.12.2016
BTVPUR AlSap 1 (EMEA/V/C/002230)	01.01.2016 – 31.12.2016
Cardalis (EMEA/V/C/002524)	01.02.2016 – 31.01.2017
Convenia (EMEA/V/C/000098)	01.01.2014 – 31.12.2016
Equilis Prequenza (EMEA/V/C/000094)	01.02.2016 – 31.01.2017
Equilis Prequenza Te (EMEA/V/C/000095)	01.02.2016 – 31.01.2017
Eryseng (EMEA/V/C/002761)	01.08.2016 – 31.01.2017
Eryseng Parvo (EMEA/V/C/002762)	01.08.2016 – 31.01.2017
Innovax ILT (EMEA/V/C/003869)	01.08.2016 – 31.01.2017
Onsior (EMEA/V/C/000127)	01.01.2014 – 31.12.2016
Porcilis ColiClos (EMEA/V/C/002011)	01.01.2016 – 31.12.2016
Poulvac E. coli (EMEA/V/C/002007)	01.07.2016 – 31.12.2016
Sileo (EMEA/V/C/003764)	01.07.2016 – 31.12.2016
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	01.01.2014 – 31.12.2016

Trifexis (EMEA/V/C/002635)	05.01.2016 – 04.01.2017
UpCard (EMEA/V/C/003836)	01.08.2016 – 31.01.2017
Velactis (EMEA/V/C/003739)	01.07.2016 – 31.12.2016
Zulvac 8 Bovis (EMEA/V/C/000145)	01.08.2016 – 31.01.2017
Zulvac 8 Ovis (EMEA/V/C/000147)	01.08.2016 – 31.01.2017

- 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 final draft VICH GL50 on harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use and the final draft VICH GL55 on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use, for sign-off by the VICH Steering Committee at step 6 of the VICH process.
- The Committee endorsed the EU comments on the preliminary concept paper for a guideline for safety evaluation of biotechnology-derived/biological products.
- The Committee agreed that the appointment of a new expert for the VICH Electronic Standards Implementation Expert Working Group will take place by election at the June 2017 CVMP meeting.
- The Committee appointed an adviser with expertise in analytical methods to support the work of the VICH Metabolism and Residues Kinetics Expert Working Group.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee was informed of the attendance of L. Vesterager Borge at the 2017 Global Animal Health Workshop to be held in June 2017 in Nairobi, Kenya.

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 vice-chair of the SAWP-V on the meeting held on 10 May 2017, and noted the agenda of the meeting.
- The Committee appointed Anke Finnah as new member of the SAWP-V.

7.2 Quality Working Party (QWP)

- The Committee was informed of the upcoming election of the chair of the QWP for a 3-year term at the June 2017 QWP meeting, and noted the call for nominations.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee was informed of the invitation to the CVMP and ERAWP members to the workshop on higher tier testing of veterinary medicinal products in dung fauna, to be held on 21 June 2017.

7.5 Efficacy Working Party (EWP-V)

- The Committee elected Nathalie Bridoux as vice-chair of the EWP-V for a 3-year term.

7.6 Antimicrobials Working Party (AWP)

- The Committee deferred the election of the vice-chair of the AWP to the June 2017 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 chair of the PhVWP-V on the meeting held on 21-22 March 2017, and noted the agenda and the draft minutes of the meeting.
- The Committee adopted the reflection paper on non-spontaneous adverse event reports (peer-reviewed literature, internet and social media) (EMA/CVMP/PhVWP/357539/2015) and the overview of comments received (EMA/CVMP/PhVWP/615063/2016).

7.9 Novel therapy groups and related issues

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

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 14 April 2017;
- Draft agenda for the 83rd Joint CHMP/CVMP QWP meeting to be held on 22-24 May 2017;
- Draft agenda for the Joint CHMP/CVMP QWP Interested Parties meeting to be held on 23 May 2017;
- Draft agenda for the EWP-V meeting to be held on 30-31 May 2017;
- Draft agenda of the Pharmacovigilance Working Party meeting to be held on 16-17 May 2017;
- Draft minutes of the ADVENT meeting held on 16 February 2017;
- Draft agenda of the ADVENT meeting to be held on 15 May 2017 (via Adobe).

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.

- There were no items for discussion.

8.2 Environmental risk assessment

- The Committee adopted the revised reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances (EMA/CVMP/448211/2015), and the overview of comments received during the public consultation (EMA/CVMP/401418/2016).

8.3 Antimicrobial resistance

- The Committee deferred the verbal report on the pilot project on dose optimization in the context of SPC harmonization of established veterinary antibiotics and on the 2nd meeting held on 29 March 2017 to the June 2017 CVMP meeting.
- The Committee deferred the information on the Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) workshop to be held on 12-15 September 2017 in France to the June 2017 CVMP meeting.

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:

- WHO revised list of Critically Important Antimicrobials http://who.int/foodsafety/areas_work/antimicrobial-resistance/cia/en/;
- WHO Highest Priority Critically Important Antimicrobials http://who.int/foodsafety/cia/en/.

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.

- The Committee endorsed the draft agenda, the draft list of experts and the revised concept note for the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU.

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 (co-)rapporteurship from G. J. Schefferlie to J. Poot.

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.

- The Committee adopted the change of selected terms in the target species list (EUTCT) to plural in English language only.

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

- The Committee noted the draft minutes of the meeting held on 11-12 April 2017 as well as the draft agenda of the meeting held on 11-12 May 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the CVMP operation and procedures: practical guidance document for CVMP members.
- The Committee noted the presentation from the CVMP chair on the SciCoBo meeting held on 24 April 2017, and noted the agenda of the meeting.
- The Committee received a verbal report from the EMA on the impact of the triggering of Article 50 of the Lisbon Treaty by the UK.
- The Committee was informed of the CVMP chair's report to the HMA-v meeting on 11 May 2017.
- The Committee noted the press release on 'EMA and heads of national competent authorities discuss consequences of Brexit. Key principles and working methodology established'.
- The Committee noted the invitation to the informal CVMP/CMDv meeting to be held on 26-27 June 2017 in Rotterdam, the Netherlands, and the draft agenda of the meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the May 2017 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.
- The Committee noted the EFSA call for experts to renew its Scientific Panels and Scientific Committee (news story).

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the May 2017 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	Brigitte Hauser	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
LU	Marc Schmit	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	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	
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
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	
IE	Mary O'Grady	Full involvement	
IT	Antonio Battisti	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SI	Maja Turk	Full involvement	
SK	Eva Chobotová	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.			
BE	Sandy Vermout - remotely		
CZ	Dana Studena - remotely		
DE	Ina Ebert - remotely		
DE	Anke Finnah - remotely		
DE	Andrea Golombiewski		
DE	Wolfgang Koch - remotely		
DE	Svenja Rieke - remotely		
DE	Susanne Schmitz - remotely		
DE	Stephan Steuber		
DK	Anne Engelbrecht Thomsen - remotely		
DK	Lotte Gam Kristensen - remotely		
DK	Niels Christian Kyvsgaard - remotely		
ES	Sonia Gil Morales	Full involvement	
ES	Javier Martinez de Velasco		
NL	René van Herwijnen - remotely		
SE	Helena Back		
SE	Andreea Barbu - remotely		
SE	Jonas Tallkvist - remotely		
UK	Claire Stratford - remotely		

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	--
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero

CVMP working parties and CMDv	Chair
IWP	Esther Werner
PhVWP-V	Lisbet Vesterager Borge - *remotely*
QWP	Mary O'Grady *(Vet vice chair)*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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