5 May 2015
EMA/294611/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 April 2015 meeting

Chair: A. Holm – Vice-chair: D. Murphy

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 interests were identified for the April 2015 meeting. In accordance with the Agency's revised policy and procedure on the handling of declarations of 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 Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee 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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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the March 2015 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 heard an oral explanation from the applicant and discussed the comments received from EFSA for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003923/FULL/0001). The adoption of the opinion is foreseen for the May 2015 meeting of the Committee.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

The Committee heard an oral explanation from the applicant and considered the arguments provided by the applicant for the re-examination of the CVMP opinion for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/003915/FULL/0001). The Committee discussed the rapporteurs' assessment report of the grounds for the re-examination, the revised EPMAR and noted the peer review report. The adoption of the final opinion is foreseen for the May 2015 meeting of the Committee.

1.5 Other issues

- The Committee received feedback from a virtual meeting with EFSA and ECHA representatives, in relation to the review under Article 11 of the MRLs established for **diflubenzuron** in *Salmonidae* and discussed the assessment carried out by the rapporteur.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Sileo** (EMEA/V/C/003764/0000), recommending the granting of a marketing authorisation. The product contains dexmedetomidine hydrochloride and is for the alleviation of acute anxiety and fear associated with noise in dogs. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Cerenia** (EMEA/V/C/000106/X/0023), recommending the extension of the marketing authorisation to include intravenous use as a new route of administration of Cerenia 10 mg/ml solution for injection for cats and dogs. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new cardiovascular product for dogs (EMEA/V/C/003836/0000). The Committee discussed the draft product information, and noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/003991/0000), an ectoparasiticide for dogs. The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee discussed the report from the ad hoc expert group meeting held on 7 April 2015, for the re-examination of the CVMP opinion adopted for a new cardiovascular product for cats (EMEA/V/C/003786/0000). The Committee discussed the rapporteur's assessment report and the co-rapporteur's critique. The adoption of the final opinion is foreseen for the May 2015 CVMP meeting.

2.5 Other issues

- The Committee endorsed the withdrawal EPAR following the formal notification from the applicant to withdraw their application for a new haematological product (solution for infusion) for dogs, **Oxapex** (EMEA/V/C/002794/0000), containing haemoglobin crosfumaril.
- The Committee endorsed the EPAR module 6 scientific discussion for **Suvaxyn CSF Marker** (EMEA/V/C/002757/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Metacam** (EMEA/V/C/000033/X/0107) concerning the extension of the marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **RHINISENG** (EMEA/V/C/000160/II/0004), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members 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 quality type II variation for **RESPIPORC FLU3** (EMEA/V/C/000153/II/0009), recommending the variation of the marketing

authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Gripovac 3** (EMEA/V/C/000157/II/0007), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members 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 quality grouped worksharing type IB variation for **Suvaxyn PCV, Equip WNV and Poulvac E.coli** (EMEA/V/C/xxxxxx/WS/0649/G), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues for a type II variation for **Poulvac E.coli** (EMEA/V/C/002007/II/0006), to add a new route of administration.

3.3 Lists of questions

- The Committee adopted the list of questions for a quality, grouped type II variation for **Aivlosin** (EMEA/V/C/000083/II/0062/G).

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

- The Committee heard an oral explanation from the applicant, Huvepharma N.V., and discussed the updated rapporteur's assessment report and the updated co-rapporteur's assessment report for the referral procedure for **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** (EMEA/V/A/108). The adoption of the opinion is foreseen for the May 2015 meeting of the Committee.

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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the procedure concerning the risk to the consumer resulting from the use of **lidocaine** in food producing species (EMEA/V/A/092) due to concerns relating particularly to new scientific data on the metabolite 2,6-xylidine. The Committee concluded that, with regard to the use of the substance in horses, existing regulatory provisions ensure that the risk to consumers is negligible. With regard to off-label use in cattle and pigs, the minimum cascade withdrawal periods ensure that the risk to consumers from potential exposure to residues in meat is negligible. In relation to residues that may occur in milk, the possibility that consumers could be exposed to lidocaine residues cannot be ruled out and consequently appropriate communication with veterinarians was recommended to ensure an adequate interval of time is allowed to elapse between administration of lidocaine and the taking of milk for human consumption. The Committee further concluded that, based on existing regulatory provisions, the use of xylazine in cattle and horses represents a negligible risk to consumer safety. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

4.7 Other issues

- There were no items for discussion.

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

5.1 General issues

Information relating to certain topics discussed under section 5.1 at this meeting cannot be released at the present time as it is deemed to be confidential.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Improvac** (EMEA/V/C/000136/REC027).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 13.03.2015 – 10.04.2015:

Product	Period
Advocate (EMEA/V/C/000076)	02/04/2014 – 01/04/2015
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2014 – 16/03/2015
CaniLeish (EMEA/V/C/002232)	14/03/2014 – 13/03/2015
ClomicaIm (EMEA/V/C/000039)	01/04/2014 – 31/03/2015
ECOPORC SHIGA (EMEA/V/C/002588)	10/04/2014 – 09/04/2015

Product	Period
Eurican Herpes 205 (EMEA/V/C/000059)	26/03/2014 – 25/03/2015
Incurin (EMEA/V/C/000047)	24/03/2014 – 23/03/2015
Locatim (EMEA/V/C/000041)	29/03/2014 – 28/03/2015
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2014 – 05/04/2015
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14/03/2014 – 13/03/2015

5.4 Renewals

- The Committee adopted the list of outstanding issues for the renewal of **RHINISENG** (EMEA/V/C/000160/R/0003).
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Equilis Te** (EMEA/V/C/000093/R/0006), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members 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 the renewal of **Bovilis BTV8** (EMEA/V/C/000148/R/0007), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **COXEVAC** (EMEA/V/C/000155/R/0009), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2014 – 31.08.2014 for **Activyl** (EMEA/V/C/000163) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.2011 – 31.10.2014 for **Rabigen SAG2** (EMEA/V/C/000043) with a recommendation to amend the SPC.
- The Committee agreed to contact the marketing authorisation holder to request more information for **Vectra 3D** (EMEA/V/C/002255).
- The Committee was informed of the final study report for the post-authorisation safety study for **Nobivac Myxo-RHD**.

- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage for:

Product	Period
APOQUEL (EMEA/V/C/002688)	01.06.2014 – 30.11.2014
BTVPUR Alsap 2-4 (EMEA/V/C/000139)	01.06.2014 - 30.11.2014
Oncept IL-2 (EMEA/V/C/002562)	01.06.2014 – 30.11.2014
Palladia (EMEA/V/C/000150)	01.12.2013 – 30.11.2014
Panacur AquaSol (EMEA/V/C/002008)	01.06.2014 – 30.11.2014
Porcilis ColiClos (EMEA/V/C/002011)	01.07.2014 – 31.12.2014
Posatex (EMEA/V/C/000122)	01.01.2014 – 31.12.2014
PRILACTONE (EMEA/V/C/000105)	01.01.2012 – 31.12.2014
Vectra Felis (EMEA/V/C/002746)	01.06.2014 – 31.12.2014
Zuprevo (EMEA/V/C/002009)	01.06.2014 – 30.11.2014

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

5.6 Supervisions and sanctions

Information relating to supervisions 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

Information relating to certain topics discussed under section 6.1 at this meeting cannot be released at the present time as it is deemed to be confidential.

6.2 Codex Alimentarius

- The Committee was informed of the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) meeting to be held on 27 April – 1 May 2015 on matters of interest arising from FAO/WHO and from the 78th meeting of the Joint FAO/WHO expert committee on food additives (JECFA), and noted in particular the information provided on JECFA's work concerning the dietary exposure to veterinary drug residues and the draft priority list of veterinary drugs proposed for evaluation or re-evaluation by JECFA which includes diflubenzuron.

6.3 Other EU bodies and international organisations

- The Committee received a verbal report from D. Mackay on the draft outcome of the Joint European Medicines Agency (EMA)/Heads of Medicines Agencies (HMA) workshop on requirements for the authorisation of veterinary vaccines in the European Union (EU), held on

25 March 2015. The Committee was informed that a report on the outcome of the joint workshop will be published.

- The Committee was informed of the ECHA/EFSA topical scientific workshop on soil risk assessment to be held on 7-8 October 2015 in Helsinki, Finland.
- The Committee was informed of the draft programme of the EFSA's scientific conference on 'Shaping the future of food safety together' to be held on 14-16 October 2015 in Milan, Italy.

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 J.-C. Rouby, who chaired the SAWP-V meeting held on 8 April 2015, 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)

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 26-27 March 2015, and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products (EMA/CVMP/PhVWP/901279/2011) and the overview of comments received (EMA/CVMP/PhVWP/459562/2014). Following its adoption by HMA-V in May 2015, the final recommendation will then be published.
- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 24-25 March 2015, and noted the agenda and the draft minutes of the meeting.

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- The Committee received a verbal report from the chair of the JEG-3Rs on the meeting held on 3 March 2015, and noted the agenda of the meeting.
- The Committee adopted the note on the removal of the target animal batch safety test (TABST) from Ph. Eur. monographs (EMA/CVMP/IWP/107173/2015).
- The Committee was informed of the comments received on the concept paper on a guideline on transferring methods validated in collaborative trials to a product/lab specific context.
- The Committee was informed of the comments received on the draft guideline on regulatory acceptance of 3Rs testing approaches.

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 10 March 2015;
- Final minutes of the IWP meeting held on 30 September - 1 October 2014.

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.

- The Committee agreed to include **bis(2,6-diisopropylphenyl)carbodiimide** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- The Committee agreed to include **polyvinyl chloride homopolymer** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- The Committee agreed to include **pine wood flour** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- 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.27).

8.2 Environmental risk assessment

Information relating to certain topics discussed under section 8.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

8.3 Antimicrobial resistance

- The Committee discussed the request from the European Commission for developing a joint scientific opinion of the EFSA and EMA, relating to the measures to reduce the need to use antimicrobial agents in animal husbandry in the EU and the resulting impacts on food safety.

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 document was circulated for information:

- WHO Sixty-Eighth World Health Assembly -Draft global action plan on antimicrobial resistance - (http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf).

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 meeting held on 12-13 March 2015, and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 9-10 April 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft agenda of the CVMP Interested Parties' meeting to be held on 6 May 2015.
- The Committee noted the table of actions following the March 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the April 2015 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 April 2015 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 3.1 Suvaxyn PCV, Equip WNV, Poulvac E.coli (EMEA/V/C/xxxxxx/WS/0649/G)
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• 5.4 Bovilis BTV8 (EMEA/V/C/000148/R/0007) • 5.4 Equilis Te (EMEA/V/C/000093/R/0006) • 5.5 Activyl, Panacur AquaSol, Porcilis ColiClos, Posatex, Zuprevo
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• 2.2 EMEA/V/C/003836 • 3.1 Gripovac 3 (EMEA/V/C/000157/II/0007) • 5.4 Equilis Te (EMEA/V/C/000093/R/0006) • 5.5 BTVPUR AlSap 2-4, Oncept IL2 • 7.1 one item • 10.1 one item • 10.2 one item
LV	Zanda Auce	Full involvement	
NL	Johan Schefferlie	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Rory Breathnach	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
Co-opted	Christian Friis	Full involvement	
Co-opted	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
IS	Jóhann Lenharðsson	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
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
NO	Tonje Høy	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.			
ES	Noemi Garcia del Blanco	Full involvement	
FR	Helene Amar-Deguerville	Full involvement	
FR	Jean-Christophe Faucon *(remotely)*	Full involvement	
FR	Michael Holzhauser-Alberti *(remotely)*	Full involvement	
NL	Willie Peijnenburg *(remotely)*	Full involvement	
UK	John Mitchell	Full involvement	
UK	Niall O'Brian	Full involvement	
UK	Kenneth Stapleton	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Boris Kolar

CVMP working parties and CMDv	Chair
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

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