19 April 2016
EMA/CVMP/283054/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 15-17 March 2016 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 March 2016 meeting. In accordance with the Agency's 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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iv. Adoption of the minutes of the previous meeting

The minutes of the February 2016 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the extension of MRLs to ovine species for a substance (EMEA/V/MRL/003158/EXTN/0003), following discussion of the rapporteur's assessment report and a peer review report.
- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004333/FULL/0001), following discussion of the rapporteur's revised assessment report and two peer review reports.

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 heard an oral explanation from the applicant concerning an application for a new vaccine for Atlantic salmon (EMEA/V/C/002390/0000). The Committee endorsed the report from the 2nd ad hoc expert group (AHEG) meeting, and noted the updated scientific overview and benefit-risk assessment and the draft product information. An opinion is foreseen for the April 2016 CVMP meeting.
- The Committee heard an oral explanation from Zoetis concerning an extension application for **DRAXXIN** (EMEA/V/C/000077/X/00029), to add a new target species. The Committee also noted the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The Committee adopted a list of remaining outstanding issues to be addressed in writing by the applicant.
- 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 anaesthetic product for dogs (EMEA/V/C/004199/0000). The Committee agreed that an oral explanation

would not be requested. 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 an extension application for **Metacam** (EMEA/V/C/000033/X/00119), to add a new route of administration for the 40 mg/ml solution for injection in cattle. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee heard an oral explanation from Intervet International B.V. and discussed the report from the AHEG meeting held on 14 March 2016 concerning the re-examination of the CVMP opinion adopted for an extension application for **Bravecto** (EMEA/V/C/002526/X/0005), to add a new pharmaceutical form (spot-on solution) for dogs and a new target species (cats) for this spot-on formulation. The Committee adopted by majority (19 members in favour out of the 29 members present of those eligible to vote) the final CVMP opinion, the CVMP assessment report for the re-examination of the CVMP opinion and the product information, recommending the extension of the marketing authorisation. Z. Auce, M. Azevedo-Mendes, K. Baptiste, C. Friis, L. Markuš-Cizelj, M. Nevalainen, J.-C. Rouby, G. J. Schefferlie, M. Schmit and M. Tollis signed a divergent position not supporting the aforementioned recommendation. The Icelandic and Norwegian CVMP members also signed the divergent position. The Committee noted the summary of opinion for publication.

2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **ZACTRAN** (EMEA/V/C/000129/X/0027) concerning the extension of the marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Profender** (EMEA/V/C/000097/II/0032), recommending the variation of the marketing authorisation to add therapeutic indications for the spot-on solution for cats. 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0006), recommending the variation of the marketing authorisation to change the vaccination schedule to as early as 2 weeks of age for all target species. 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 to be addressed in writing for a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0064) concerning safety and efficacy changes.

- The Committee adopted the list of outstanding issues to be addressed in writing for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0005) concerning quality changes.

3.3 Lists of questions

- There were no items for discussion.

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 adopted by majority (26 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **CattleMarker IBR Inactivated emulsion for injection for cattle** (EMEA/V/A/115), recommending the granting of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. C. Ibrahim and H. Jukes signed a divergent position not supporting the aforementioned recommendation.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally** (EMEA/V/A/111). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the April 2016 meeting of the Committee. The Committee noted a peer review report and the comments made by CVMP members.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

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 adopted the rapporteur's assessment report on the data submitted concerning three conditions for **ZULVAC SBV** (EMEA/V/C/002781).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 19.02.2016 – 17.03.2016:

Product	Period
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2015 – 16/03/2016
CaniLeish (EMEA/V/C/002232)	14/03/2015 – 13/03/2016
Coliprotec F4 (EMEA/V/C/003797)	16/03/2015 – 15/03/2016
Econor (EMEA/V/C/000042)	12/03/2015 – 11/03/2016
Equisolon (EMEA/V/C/002382)	12/03/2015 – 11/03/2016
Fungitraxx (EMEA/V/C/002722)	12/03/2015 – 11/03/2016
Ibraxion (EMEA/V/C/000051)	09/03/2015 – 08/03/2016
Melosus (EMEA/V/C/002001)	21/02/2015 – 20/02/2016
Novem (EMEA/V/C/000086)	02/03/2015 – 01/03/2016
Pexion (EMEA/V/C/002543)	25/02/2015 – 24/02/2016
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	28/02/2015 – 29/02/2016
ProteqFlu (EMEA/V/C/000073)	06/03/2015 – 05/03/2016
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2015 – 05/03/2016
Purevax RC (EMEA/V/C/000091)	23/02/2015 – 22/02/2016
Purevax RCP (EMEA/V/C/000090)	23/02/2015 – 22/02/2016
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2015 – 22/02/2016
Purevax RCPCh (EMEA/V/C/000088)	23/02/2015 – 22/02/2016
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2015 – 22/02/2016
RevitaCAM (EMEA/V/C/002379)	23/02/2015 – 22/02/2016
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08/03/2015 – 07/03/2016
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14/03/2015 – 13/03/2016

5.4 Renewals

- 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 the renewal of the marketing authorisation for **Proteq West Nile** (EMEA/V/C/002005/R/0007), and recommended that the authorisation should now be indefinite. The Icelandic 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **MS-H Vaccine** (EMEA/V/C/000161/R/0009), and recommended that the authorisation should now be indefinite. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- 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
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	01.06.2015 – 30.11.2015
CERTIFECT (EMEA/V/C/002002)	01.06.2015 – 31.10.2015
Dicural (EMEA/V/C/000031)	01.05.2015 – 28.10.2015
Equip WNV (EMEA/V/C/000137)	01.06.2015 – 30.11.2015
Meloxidolor (EMEA/V/C/002590)	23.04.2015 – 22.11.2015
Oncept IL-2 (EMEA/V/C/002562)	01.06.2015 – 30.11.2015
Parvoduk (EMEA/V/C/002740)	31.05.2015 – 31.10.2015
Pexion (EMEA/V/C/002543)	01.03.2015 – 31.08.2015
Porcilis ColiClos (EMEA/V/C/002011)	01.01.2015 – 31.12.2015
Porcilis PCV M Hyo (EMEA/V/C/003796)	01.01.2015 – 31.12.2015
Procox (EMEA/V/C/002006)	01.11.2015 – 31.10.2015
ProteqFlu (EMEA/V/C/000073)	01.04.2015 – 30.09.2015
ProteqFlu-Te (EMEA/V/C/000074)	01.04.2015 – 30.09.2015
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	01.06.2015 – 30.11.2015
Virbagen Omega (EMEA/V/C/000061)	01.12.2015 – 30.11.2015

- 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 an updated version of the draft VICH guideline on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for circulation to the VICH EWG.

- The Committee discussed the proposal on the draft VICH guideline on the use of cell cultures for the detection of extraneous agents in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines, and the draft concept paper for two VICH guidelines: (1) general principles for detection of extraneous agents in veterinary vaccines and defining the testing of seeds and materials of animal origin, and (2) a list of extraneous agents that need to be covered.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee received an update on the draft EFSA opinion on reference points for action for malachite green.
- The Committee discussed the draft guidance document of the EFSA Panel on Plant protection products and their residues with regard to the establishment of the residue definition for dietary risk assessment, released for public consultation until 5 May 2016.

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 chair of the SAWP-V on the meeting held on 15 March 2016, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee elected Mary O'Grady as veterinary vice-chair of the QWP for a 3-year term.
- The Committee adopted the question and answer document on active pharmaceutical ingredient (API)-excipient mixtures.
- The Committee was informed of the revised note for guidance on limitations to the use of ethylene oxide in the manufacture of medicinal products EMEA/CVMP/271/01-Rev.1, which is now applicable only to veterinary medicinal products.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 3-4 March 2016, and noted the agenda of the meeting.
- The Committee endorsed the proposal for a training event on the safety of residues in the marketing authorisation procedure for veterinary medicinal products.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the reflection paper on poorly extractable and/or non-radiolabelled substances (EMA/CVMP/ERA/349254/2014) and the overview of comments received (EMA/CVMP/ERA/603511/2015).
- The Committee received a verbal report from the vice-chair of the ERAWP on the meeting held on 2-3 February 2016, and noted the agenda and the draft minutes of the meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 23-24 February 2016, and noted the agenda of the meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 23-24 February 2016, and noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Draft minutes of the SAWP meeting held on 16 February 2016;
- Agenda of the QWP meeting held on 1–3 March 2016;
- Final minutes of the QWP meeting held on 1–3 December 2015;
- Draft minutes of the EWP meeting held on 23-24 February 2016;
- CVMP activities regarding antimicrobials;
- Draft minutes of the AWP meeting held on 23-24 February 2016;
- Draft agenda of the PhVWP-V meeting to be held on 22-23 March 2016.

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 discussed the feedback on the 1st meeting of the EFSA BIOCONTAM–BIOHAZ Working Group held on 22 February 2016, concerning the request for a scientific opinion on the risk for the development of antimicrobial resistance due to feeding of calves with milk.
- The Committee discussed the proposal for future collaboration between the EMA and the Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST). The Committee was informed of the next VetCAST meeting, which is scheduled to take place on 11 April 2016 in Amsterdam, the Netherlands.
- The Committee received an update on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety). It was agreed for CVMP members to send any information they have, to be utilised for the RONAFA opinion, on national training programmes for veterinarians and farmers relating to the responsible use of antimicrobials.
- The Committee received a verbal report on the Antimicrobial Advice ad hoc expert group (AMEG) meeting held on 26 February 2016 to address the update the document on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health.

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.

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 6th Annual Report on Veterinary MUMS/limited market, which will be published once endorsed by Management Board at their March 2016 meeting.
- The Committee adopted the terms of reference for the CVMP ad hoc group on veterinary vaccine availability, and agreed for F. Hasslung Wikström to become a member of the group.

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 21-22 January 2016 and 18-19 February 2016, and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 17-18 March 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft agenda of the CVMP Interested Parties' meeting to be held on 20 April 2016 (EMA/CVMP/47072/2016), and agreed the agenda topics and speakers.
- The Committee endorsed the inclusion of International Veterinary Regenerative Medicine Society (IVRMS) in the CVMP Interested parties group, following a request from IVRMS.
- The Committee discussed the request from the FVE Aquaculture coalition for a satellite meeting with the CVMP in June 2016, and agreed that no separate meeting would be held but that the coalition could present their topics at the CVMP Interested Parties' meeting in April 2016.
- The Committee noted the programme of the EMA/IFAH-Europe Info Day to be held on 17-18 March 2016.
- The Committee received a verbal report from the chair of the CVMP Strategic Planning Group on the meeting held on 16 March 2016, and noted the agenda of the meeting and the minutes of the meeting held on 9 December 2015.
- The Committee received a verbal report from the HMA/EMA Task Force on adherence to timetables and the forthcoming meeting with industry to be held on 21 April 2016.
- The Committee noted an announcement regarding the mandatory use of the eSubmissions Gateway/Web Client for centralised veterinary applications to the European Medicines Agency from 1 January 2017.
- The Committee noted the table of actions following the February 2016 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the March 2016 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 March 2016 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:	• 2.3 Metacam (EMEA/V/C/000033/X/0119) • 5.5 PSUR for Pexion
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	
FI	Martti Nevalainen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	G. Johan Schefferlie	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 3.1 Profender (EMEA/V/C/000097/II/0032) • 5.5 PSUR for Procox
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Christian Friis	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	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
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio Montejano	Cannot act as rapporteur or peer reviewer for:	• 2.4 Bravecto (EMEA/V/C/002526/X/0005) • 4.3 Colistin (EMEA/V/A/111) • 5.5 PSURs for Porcilis ColiClos, Porcilis PCV M-Hyo • 8.5 one item • 10.1 one item
FR	Sylvie Louet	Full involvement	
HU	Tibor Soós	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	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.			
EU	Leonard Levy	Full involvement	
BE	Els Dewaele *(remotely)*	Full involvement	
DE	Klaus Cussler *(remotely)*	Full involvement	
DE	Ingun Lemke *(remotely)*	Full involvement	
FR	Laure Baduel	Full involvement	
SE	Helena Back	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	
UK	John Mitchell	Full involvement	
UK	Steve Spencer	Full involvement	
UK	Ralph Woodland	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Silke Hickman – *vice-chair*
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	--
QWP	--
SAWP-V	Rory Breathnach

CVMP working parties and CMDv	Chair
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

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