



17 May 2016
EMA/CVMP/340807/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use Minutes of the 19-21 April 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 ongoing 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 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.



iv. Adoption of the minutes of the previous meeting

The minutes of the March 2016 meeting were adopted with minor 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 rapporteur's assessment of the responses to the list of outstanding issues including the co-rapporteur's critique for the extension of MRLs to bovine tissues and milk for a substance (EMA/V/MRL/003200/EXTN/0003). The adoption of the opinion is foreseen for the May 2016 meeting of the Committee.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by majority (27 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **CLYNAV** (EMA/V/C/002390/0000), recommending the granting of a marketing authorisation. The product is a plasmid DNA vaccine for intramuscular use for Atlantic salmon. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste and the Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.
- 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 **Sevocalm** (EMA/V/C/004199/0000), recommending the granting of a marketing authorisation. The product is an inhalation anaesthetic for the induction and maintenance of anaesthesia 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.

2.2 Oral explanations and lists of outstanding issues

- The Committee discussed the rapporteurs' joint assessment report of the remaining outstanding issues and the draft product information for an extension application for **Draxxin**

(EMEA/V/C/000077/X/0029), to add a new target species. The adoption of the opinion is foreseen for the May 2016 CVMP meeting.

- 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 product for psycholeptic use in dogs and cats (EMEA/V/C/004202/0000). The Committee discussed the draft product information and the rapporteurs' joint assessment of the responses to the list of questions, 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 antibacterial and anti-inflammatory product for use in cattle (EMEA/V/C/004099/0000). 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 **Poulvac E. coli** (EMEA/V/C/002007/X/0008/0000) concerning the extension of the marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Evalon** (EMEA/V/C/004013/0000) 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 **Aivlosin** (EMEA/V/C/000083/II/0064), recommending the variation of the marketing authorisation to change the withdrawal period for eggs and to include layers in the therapeutic indication, for the use of Aivlosin 625 mg/g Water Soluble Granules (WSG) to treat chickens with infections caused by *Mycoplasma gallisepticum*. 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a worksharing type II variation for **Versican Plus Pi/L4R** and **Versican Plus DHPPI/L4R** (EMEA/V/C/xxxxxx/WS/0785), recommending the variation of the marketing authorisations to extend the duration of immunity for the rabies component of Versican Plus DHPPI/L4R, Versican Plus Pi/L4R and the nationally authorised product Vanguard R to 3 years following the primary vaccination course. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Metacam** (EMEA/V/C/000033/II/0118/G), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **AFTOVAXPUR DOE** (EMA/V/C/002292/II/0005), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **Suvaxyn Circo+MH RTU** (EMA/V/C/003924/II/0002), concerning quality changes.
- The Committee adopted the list of questions for a grouped worksharing type IB variation for **Comfortis** and **Trifexis** (EMA/V/C/xxxxxx/WS/0906/G), concerning quality changes.
- The Committee adopted the list of questions for a type II variation for **Vectormune ND** (EMA/V/C/003829/II/0004), 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 heard an oral explanation from the marketing authorisation holders and discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** (EMA/V/A/095). The adoption of the opinion is foreseen for the May 2016 meeting of the Committee.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally** (EMA/V/A/111), concluding that the benefit-risk balance for the products concerned is negative as no benefit could be demonstrated for the use of colistin combination products over monotherapy and that no feasible risk mitigation measures could be identified to address the potential risk to human health. The Committee, therefore, recommended the withdrawal of the marketing authorisations for all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally to food producing species. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique on the marketing authorisation holders' responses to the list of outstanding issues and the revised rapporteur's assessment report for the referral procedure for **all veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** (EMA/V/A/110), and noted the comments made by CVMP members. The Committee agreed that no further outstanding issues remained. The adoption of the CVMP opinion is foreseen for the May 2016 meeting of the Committee.

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

- The Committee noted the question and answer document for publication for the Article 78 referral procedure for **Closamectin pour-on solution and associated names** (EMA/V/A/113).

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 a recommendation for **Fevaxyn Pentofel** (EMA/V/C/000030/REC/027).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 18.03.2016 – 21.04.2016:

Product	Period
Advocate (EMA/V/C/000076)	02/04/2015 – 01/04/2016
BLUEVAC BTV8 (EMA/V/C/000156)	14/04/2015 – 13/04/2016
Clomicalm (EMA/V/C/000039)	01/04/2015 – 31/03/2016
ECOPORC SHIGA (EMA/V/C/002588)	10/04/2015 – 09/04/2016
Eurican Herpes 205 (EMA/V/C/000059)	26/03/2015 – 25/03/2016
Incurin (EMA/V/C/000047)	24/03/2015 – 23/03/2016
Locatim (EMA/V/C/000041)	29/03/2015 – 28/03/2016
Neocolipor (EMA/V/C/000035)	14/04/2015 – 13/03/2016

Product	Period
Parvodus (EMEA/V/C/002740)	11/04/2015 – 10/04/2016
Procox (EMEA/V/C/002006)	20/04/2015 – 19/04/2016
Purevax FeLV (EMEA/V/C/000056)	13/04/2015 – 12/04/2016
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2015 – 05/04/2016
Veraflox (EMEA/V/C/000159)	12/04/2015 – 11/04/2016

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 **Nobivac Myxo-RHD** (EMEA/V/C/002004/R/0005), and recommended 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 (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 **Emdocam** (EMEA/V/C/002283/R/0007), and recommended 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 (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 **Nobilis Influenza H5N2** (EMEA/V/C/000118/R/0012), and recommended 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 endorsed the rapporteur's assessment report of the post-authorisation safety study (PASS) for **Trifexis** (EMEA/V/C/002635), and agreed to request further information from the MAH before a final conclusion could be drawn.
- The Committee was informed of an adverse event report involving a human death in the USA following accidental exposure to Micotil.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
APOQUEL (EMEA/V/C/002688)	01.06.2015 – 30.11.2015
Bovela (EMEA/V/C/003703)	01.07.2015 – 31.12.2015
BTVPUR AISap 1 (EMEA/V/C/002230)	01.01.2015 – 31.12.2015
BTVPUR AISap 1-8 (EMEA/V/C/002231)	01.01.2015 – 31.12.2015
Equilis Prequenza (EMEA/V/C/000094)	01.02.2015 – 31.01.2016
Equilis Prequenza Te (EMEA/V/C/000095)	01.02.2015 – 31.01.2016

Oxyglobin (EMA/V/C/000045)	30.11.2012 – 30.11.2015
Panacur AquaSol (EMA/V/C/002008)	01.07.2015 – 31.12.2015
Poulvac E. coli (EMA/V/C/002007)	01.01.2015 – 31.12.2015
SevoFlo (EMA/V/C/000072)	01.12.2012 – 30.11.2015
Sileo (EMA/V/C/003764)	10.06.2015 – 31.12.2015
UpCard (EMA/V/C/003836)	31.07.2015 – 31.01.2016
Versican Plus DHPPI/L4 (EMA/V/C/003678)	01.06.2015 – 30.11.2015
Zuprevo (EMA/V/C/002009)	01.12.2014 – 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 the participation of the CVMP vice-chair, D. Murphy, to represent the CVMP at the forthcoming VICH Steering Committee to be held on 20–23 June 2016.
- The Committee endorsed 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 for circulation to the VICH BQM EWG, 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, (2) a list of extraneous agents that need to be covered, for discussion at the VICH Steering Committee meeting.

6.2 Codex Alimentarius

Information relating to certain topics discussed under section 6.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

6.3 Other EU bodies and international organisations

- 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.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Externally organised projects and events of potential relevance to the safety assessment and assessment methodologies in general.

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 19 April 2016, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 1–3 March 2016.
- The Committee adopted the draft reflection paper on the dissolution specification for generic oral immediate release products for a 3-month period of public consultation.

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee agreed technical corrections in the guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL 38 (EMA/CVMP/ERA/418282/2005- Corr.), to address an omission in equation 49 and to include additional clarification on the PEC (Predicted Environmental Concentration) formulas to avoid mistakes in calculations.
- The Committee elected Jason Weeks as chair of the ERAWP and re-elected Silke Hickmann as vice-chair of the ERAWP, for 3-year terms.

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the revised reflection paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013) and the overview of comments received (EMA/CVMP/EWP/464714/2014) for a 3-month period of public consultation.
- The Committee adopted the concept paper (EMA/CVMP/EWP/707453/2015) for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2 /2007) for a 3-month period of public consultation.

7.6 Antimicrobials Working Party (AWP)

- The Committee was informed of the election of the vice-chair of the AWP for a 3-year term at the May 2016 CVMP meeting. A call for nominations had been circulated by the Secretariat.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the concept paper on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use (EMA/CVMP/IWP/867401/2015) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP Pharmacovigilance Working Party (EMA/CVMP/PhVWP/133883/2004-Rev.5). The revised mandate will also be submitted to the Heads of Medicines Agencies (HMA) – Veterinary for

endorsement. The publication of the revised mandate will take place following the endorsement by the HMA – Veterinary.

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 22-23 March 2016, and noted the agenda and 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 vice-chair of the JEG-3Rs on the meeting held on 30 March 2016.
- The Committee adopted the reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/JEG-3Rs/164002/2016) for a 6-month period of public consultation.

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 15 March 2016;
- Draft minutes of the IWP meeting held on 11-12 October 2016;
- Draft minutes of the ADVENT check point meeting held on 17 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.

- The Committee agreed to include **tris(nonylphenyl)phosphite** 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.34).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee endorsed H. Jukes to represent the CVMP at the 4th International Conference on Responsible Use of Antibiotics in Animals, to be held on 26-28 September 2016, in The Hague, the Netherlands.

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.

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 noted the draft minutes of the meeting held on 17 March 2016 as well as the draft agenda of the meeting held on 21-22 April 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee endorsed the draft agenda of the CVMP Interested parties meeting held on 20 April 2016.
- The Committee discussed the draft agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held on 26-28 June 2016 in Utrecht, the Netherlands.
- The Committee received an introductory presentation on the Veterinary Change programme aiming to review the operation of the procedures run by the Veterinary Division of the EMA. The Committee noted the call for volunteers from CVMP to participate in an informal advisory group.
- The Committee received feedback from the CVMP chair on the Scientific Co-ordination Board meeting held on 18 March 2016, and noted the agenda of the meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the April 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 April 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:	<ul style="list-style-type: none"> • 3.1 Metacam (EMEA/V/C/000033/II/0118/G) • 5.5 PSUR for Bovela • 7.1 one item
BE	Bruno Urbain	Full involvement	
BG	Emil Kozuharov	Full involvement	
CZ	Jiří Bureš	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	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
HU	Gábor Kulcsár	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-Świącicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	
FR	Sylvie Louet	Full involvement	
UK	Anna-Maria Brady	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.			
BE	Sandy Vermout (<i>remotely</i>)	Full involvement	
BE	Wendy Wuyts (<i>remotely</i>)	Full involvement	
DE	Gerd Maack	Full involvement	
DE	Jens Schonfeld (<i>remotely</i>)	Full involvement	
ES	Mercedes Conradi Moner (<i>remotely</i>)	Full involvement	
NL	Sandra ten Voorde (<i>remotely</i>)	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	
UK	Stephen Spencer	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	--
ERAWP	Silke Hickmann (<i>vice-chair</i>)
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström (<i>remotely</i>)
QWP	Mary O'Grady (<i>Vet vice-chair</i>)
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