8 April 2015
EMA/CVMP/234214/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 10-12 March 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 March 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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iv. Adoption of the minutes of the previous meeting

The minutes of the February 2015 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 discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/003988/FULL/0001) and adopted a list of outstanding issues that should be addressed in writing.

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

- The Committee discussed the revised EPMAR following the rapporteur's assessment of the responses to the list of questions in relation to the review under Article 11 of the MRL for **diflubenzuron** in *Salmonidae* (EMEA/V/MRL/003135/MODF/0003), and also discussed two peer review reports, and the comments received from CVMP members, ECHA and EFSA. The Committee will discuss the topic further at its April 2015 meeting.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Rheumocam** (EMEA/V/C/000121/X/0015), recommending the extension of the marketing authorisation to include a new strength (330 mg) and a new pharmaceutical form (granules in sachet) for horses. 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 hormonal product for cattle (EMEA/V/C/002590/0000). The Committee agreed to invite the applicant for an oral explanation in September 2015. The Committee discussed the draft product

information and noted two peer review reports and the comments received from CVMP members.

- 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 viral vaccine for chickens (EMEA/V/C/003869/0000). The Committee agreed that an oral explanation will not be necessary. 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/004079/0000), a bacterial vaccine for dogs. The Committee noted the comments received from CVMP members.
- 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 **Bravecto** (EMEA/V/C/002526/X/0005), to add a new pharmaceutical form. The Committee noted a peer review report and the comments received from CVMP members.
- 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 bacterial vaccine (EMEA/V/C/003685/0000) 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 adopted the list of questions to the ad hoc expert group (AHEG) and endorsed the list of AHEG members, the agenda of the AHEG meeting, the list of documents to be sent to the AHEG members and the 60-day timetable for the re-examination of the negative CVMP opinion adopted for a cardiovascular product for cats, **Lodipressin** (EMEA/V/C/003786/0000).

2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **Coliprotec F4** (EMEA/V/C/003797/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **COXEVAC** (EMEA/V/C/000155/S/0007) concerning the annual reassessment of the 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 and the CVMP assessment report for a type II variation for **BROADLINE** (EMEA/V/C/002700/II/0001), recommending the variation of the marketing authorisation to add new indications: treatment of infestations with feline lungworms (L3, L4, immature adults and adults of *Aelurostrongylus abstrusus*); treatment of notoedric mange (*Notoedres cati*). 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 and the CVMP assessment report for a worksharing type II variation for **Nobilis IB 4-91** (EMEA/V/C/000036/WS/0607(0019)), recommending the variation of the marketing authorisation to add a claim for the mixed-use of Nobilis IB 4-91 and Nobilis IB Ma5. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type II variation for **Versican Plus DHPPi**, **Versican Plus DHPPi/L4R** and **Versican Plus DHPPi/L4** (EMEA/V/C/00xxxx/WS/0620), recommending the variation of the marketing authorisations to extend to 3 years the duration of immunity for CDV (canine distemper virus), CPV (canine parovirus), CAV-1 (canine adenovirus) and CAV-2. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0034), recommending the variation of the marketing authorisation to change the withdrawal periods for cattle and pigs affecting all authorised Draxxin presentations, following the revision of MRLs for tulathromycin. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

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 quality grouped type II variation for **COXEVAC** (EMEA/V/C/000155/II/0008/G).

- The Committee adopted the list of questions for a quality worksharing type IB variation for **the BTVPUR AlSap range** (EMEA/V/C/xxxxxx/WS/0669).

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to the revised request from the MAH for an extension to the clock-stop for up to 6 months for a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0031), to add a new indication.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- The Committee discussed the rapporteur's and the co-rapporteur's assessment reports for the referral procedure for **Coglapix vakcina A.U.V. suspension for injection for pigs** (EMEA/V/A/109), and noted the request from the marketing authorisation holder to provide an oral explanation. The Committee considered that there are outstanding points where clarification is required, and adopted a list of outstanding issues for the marketing authorisation holder to address in writing and at an oral explanation and a revised timetable

for the procedure. The oral explanation is scheduled for the May 2015 meeting and the adoption of the CVMP opinion is foreseen for the June 2015 meeting of the Committee. The Committee noted four peer review reports and the comments made by CVMP members.

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 discussed the draft CVMP assessment report for the procedure for **lidocaine** (EMEA/V/A/092). The CVMP opinion and assessment report are scheduled for adoption at the April 2015 CVMP meeting.

4.7 Other issues

- There were no items for discussion.

The following documents were circulated for information:

- Veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses - Article 35 referral (EMEA/V/A/104) – Background information for publication.
- Veterinary medicinal products containing colistin to be administered orally - Article 35 referral (EMEA/V/A/106) – Background information for publication.

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

5.1 General issues

Information on certain topics discussed under section 5.1 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 recommendation REC-012.1 for **Equilis Te** (EMEA/V/C/000093).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 13.02.2015 – 12.03.2015:

Product	Period
Activyl (EMEA/V/C/000163)	18/02/2014 – 17/02/2015
Cimalgex (EMEA/V/C/000162)	18/02/2014 – 17/02/2015
Econor (EMEA/V/C/000042)	12/03/2014 – 11/03/2015
Equisolon (EMEA/V/C)/002382	12/03/2014 – 11/03/2015
Fungitraxx (EMEA/V/C/002722)	12/03/2014 – 11/03/2015
Ibraxion (EMEA/V/C/000051	09/03/2014 – 08/03/2015
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2014 – 12/02/2015
Melosus (EMEA/V/C/002001)	21/02/2014 – 20/02/2015
Novem (EMEA/V/C/000086)	02/03/2014 – 01/03/2015
Pexion (EMEA/V/C/002543)	25/02/2014 – 24/02/2015
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	28/02/2014 – 27/02/2015
ProteqFlu (EMEA/V/C/000073)	06/03/2014 – 05/03/2015
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2014 – 05/03/2015
Purevax Rabies (EMEA/V/C/002003)	18/02/2014 – 17/02/2015
Purevax RC (EMEA/V/C/000091)	23/02/2014 – 22/02/2015
Purevax RCCh (EMEA/V/C/000092)	23/02/2014 – 22/02/2015
Purevax RCP (EMEA/V/C/000090)	23/02/2014 – 22/02/2015
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2014 – 22/02/2015
Purevax RCPCh (EMEA/V/C/000088)	23/02/2014 – 22/02/2015
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2014 – 22/02/2015
RevitaCAM (EMEA/V/C/002379)	23/02/2014 – 22/02/2015
Semintra (EMEA/V/C/002436)	13/02/2014 – 12/02/2015
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08/03/2014 – 07/03/2015

5.4 Renewals

- The Committee adopted the list of outstanding issues for the renewal of **Equilis Te** (EMEA/V/C/000093/R/0006).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.09.2013 – 31.08.2014 for **Cimalgex** (EMEA/V/C/000162/PSU/008) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.10.2011 – 30.09.2014 for **Eurican Herpes 205** (EMEA/V/C/000059/PSU/018) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2014 – 31.08.2014 for **NexGard** (EMEA/V/C/002729/PSU/002) with a recommendation to amend the SPC.
- 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
Procox (EMEA/V/C/002006/PSU/007)	01.11.2013 – 31.10.2014
Recuvyra (EMEA/V/C/002239/PSU/011)	01.05.2014 – 31.10.2014
Veraflox (EMEA/V/C/000159/PSU/013)	01.11.2013 – 30.10.2014

- 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

- The Committee endorsed the revised draft VICH guideline on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods. The document will be circulated to the VICH expert working group.
- The Committee adopted the VICH guideline GL54 on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for release for public consultation in the EU at step 4 of the VICH process.
- The Committee adopted the VICH guideline GL53 on electronic exchange of documents: electronic file formats, following the sign off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process.
- The Committee received a verbal report on the 31st VICH Steering Committee meeting and 5th VICH Outreach Forum held on 23-26 February 2015, in Washington DC, USA.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee was informed of the EFSA's public consultation on conclusions and recommendations of the EFSA/WHO expert working group on the threshold of toxicological concern approach (http://www.efsa.europa.eu/en/consultations/call/150212.htm).

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties (EMA/CVMP/28625/2005);
- Provisional agenda for the 22nd meeting of the Joint FAO/WHO Food Standards Programme Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) to be held between 27 April – 1 May 2015 in San Jose, Costa Rica.

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 10 March 2015, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

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 19-20 February 2015, and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the reflection paper on poorly extractable and/or non-radiolabelled substances (EMA/CVMP/ERAWP/349254/2014) for release for a 6-month period of public consultation.

7.5 Efficacy Working Party (EWP-V)

- The Committee endorsed that the EWP-V should start work on drafting the new guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases (VBD), following the public consultation on the concept paper.
- The Committee adopted the revised guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats (EMA/CVMP/EWP/290132/2013-Rev.3-draft 10) for release for a 6-month period of public consultation.

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the reflection paper on promotion of pharmacovigilance reporting (EMA/CVMP/PhVWP/390033/2014).
- The Committee discussed the recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products and requested the PhVWP-V to consider the next steps for revision of the basic recommendation on surveillance of EVVet data.
- The Committee was informed of the draft minutes of the meeting held on 27-28 January 2015.

7.9 Novel therapy groups and related issues

- The Committee adopted the ADVENT work plan for 2015 (EMA/CVMP/ADVENT/630656/2014).

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

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

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

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

8.3 Antimicrobial resistance

- The Committee received a verbal report on the ESVAC annual network meeting held on 3-4 March 2015.
- The Committee was informed of the principles on the assignment of defined daily dose for animals (DDDA) and defined course dose for animals (DCDA). The principles will be published shortly for consultation on the EMA website.

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:

- Progress report on the action plan against the rising threats from antimicrobial resistance (Commission staff working document) http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_amr_progress_report_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.

- The Committee discussed the timing for the appointment of the rapporteurs and agreed to take note of notifications for intent to submit a marketing authorisation application also when submitted late, in time for a third mailing, for appointment of rapporteurs only at a next meeting to allow for establishment of multinational assessor teams. The implication is that appointments of rapporteurs would take place 6 months in advance of intended submission.

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

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the break-out session on the CVMP implementation of multinational assessment teams.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 11 March 2015, and noted the agenda of the meeting and the minutes of the meeting held on 10 December 2014.
- The Committee was informed of the CVMP Interested Parties' meeting to be held on 6 May 2015, and noted the draft minutes of the previous meeting, held on 7 May 2014.
- The Committee noted the programme of the EMA/IFAH-Europe Info Day 2014, to be held on 13-14 March 2014.

- The Committee noted the table of actions following the February 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the March 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 March 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	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• 2.2 EMEA/V/C/003869/0000 • 2.3 Bravecto (EMEA/V/C/002526/X/0005) • 2.3 EMEA/V/C/004079/0000 • 3.1 Nobilis IB4-91 (EMEA/V/C/000036/WS/0607) • 5.2 Equilis Te (EMEA/V/C/000093/REC012.1) • 5.4 Equilis Te (EMEA/V/C/000093/R/0006)
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:	• 3.1 Broadline (EMEA/V/C/002700/II/0001) • 3.3 BTVPUR AlSap range (EMEA/V/C/xxxxxx/WS/0669) • 5.2 Equilis Te (EMEA/V/C/000093/REC012.1) • 5.4 Equilis Te (EMEA/V/C/000093/R/0006) • 5.5 CIMALGEX, Eurican Herpes 205, NexGard
LV	Zanda Auce	Full involvement	
NL	Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
IS	Jóhann Lenharðsson	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	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 5.5 Procox, Veraflox
SE	Frida Hasslung Wikström	Full involvement	
SK	Eva Chobotová	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.			
DE	Gerd Maack *(remotely)*	Full involvement	
DE	Stephan Steuber *(remotely)*	Full involvement	
ES	Noemi Garcia del Blanco	Full involvement	
ES	Javier Martínez de Velasco	Full involvement	
FR	Michael Holzhauser-Alberti *(remotely)*	Full involvement	
FR	Sylvie Louet	Full involvement	
FR	Christine Miras	Full involvement	
UK	Noel Joseph	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Boris Kolar
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	--
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Not present	

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