10 February 2015
EMA/CVMP/96522/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 13-15 January 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 conflicts of interests

The attendance list was completed and conflicts of interests were identified for the January 2015 meeting. In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of 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 December 2014 meeting were adopted with no amendments.

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

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in bovine species for **sisapronil** (EMEA/V/MRL/003915/FULL/0001), and their extrapolation to caprine species. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the comments received from CVMP members and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee discussed the rapporteur's assessment report and a peer review report for the extension of MRLs to poultry for a substance (EMEA/V/MRL/003307/EXTN/0003), and agreed that there were no outstanding issues with regard to the evaluation and therefore no list of questions was prepared. The adoption of the opinion is foreseen for the February 2015 meeting of the Committee.

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 consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for **Lodipressin** (EMEA/V/C/003786/0000), recommending the refusal of the granting of a marketing authorisation. Lodipressin is a cardiovascular product proposed for the treatment of systemic arterial hypertension in 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Stronghold** (EMEA/V/C/000050/X/0051), recommending the extension of the marketing authorisation to

include a new strength for dogs and a new strength 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Coliprotec F4** (EMEA/V/C/003797/0000), recommending the granting of a marketing authorisation. The product is a new live bacterial vaccine for oral use against *Escherichia coli* in pigs. 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 anti-inflammatory product for horses (EMEA/V/C/003866/0000). 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 anti-inflammatory product for cattle (EMEA/V/C/002763/0000). The Committee noted two peer review reports 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 an extension application for **Zactran** (EMEA/V/C/000129/X/0027), to include a new food-producing target species. 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 an extension application for **Cerenia** (EMEA/V/C/000106/X/0023), to include a new route of administration for cats and dogs. The Committee noted a peer review report 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 agreed to the request from the applicant for an extension to the clock-stop for a new vaccine for Atlantic salmon (EMEA/V/C/002390/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **NEXGARD SPECTRA** (EMEA/V/C/003842/0000), concerning the granting of the initial 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 worksharing type II variation for **Purevax**

RCPCh, **Purevax RCP**, **Purevax RC**, **Purevax RCPCh FeLV** and **Purevax RCP FeLV** (EMEA/V/C/WS/0606), recommending the variation of the marketing authorisations to extend to 3 years the duration of immunity after revaccination, for the feline rhinotracheitis and feline calicivirus components. 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 a quality grouped type II variation for **Bluevac BTV8** (EMEA/V/C/000156/II/0004/G), recommending the variation of the marketing authorisation to increase the shelf life of the product from 1 year to 2 years. 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 worksharing type II variation for **ERYSENG PARVO** and nationally authorised product (EMEA/V/C/002762/WS/0618), recommending the variation of the marketing authorisations to amend the product information. 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 quality type II variation for **Acticam** (EMEA/V/C/000138/II/0014), 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 (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **Metacam** and **Novem** (EMEA/V/C/xxxxxx/WS/0661/G), recommending the variation of the marketing authorisations to register new manufacturing sites and delete an existing one. 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 **DRAXXIN** (EMEA/V/C/000077/II/0031), to add a new indication.
- The Committee adopted the list of questions for a quality grouped worksharing type II variation for **Poulvac E. coli**, **Suvaxyn PCV** and **Equip WNV** (EMEA/V/C/xxxxxx/WS/0649/G).
- The Committee adopted the list of questions for a worksharing type II variation for **Versican Plus DHPPi**, **Versican Plus DHPPi/L4R** and **Versican Plus DHPPi/L4** (EMEA/V/C/xxxxxx/WS/0620), to extend the duration of immunity.

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 agreed to the request from the applicant and MAHs for a further extension to the clock-stop for the referral procedure for **all veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** (EMEA/V/A/095) to allow for the completion of an ongoing study, and adopted a revised timetable.

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 rapporteur's assessment report including the critique from the co-rapporteur for the procedure for **lidocaine** (EMEA/V/A/092). The Committee adopted a revised timetable, with adoption of the scientific opinion currently scheduled for the March 2015 CVMP meeting.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHOIRSATION 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 two recommendations for **Purevax Rabies** (EMEA/V/C/002003/REC001-002).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 12 December 2014 – 15 January 2015:

Product	Period
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2014 – 08.01.2015

Product	Period
BTVPUR AlSap 1 (EMEA/V/C/002230)	17.12.2013 – 16.12.2014
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	17.12.2013 – 16.12.2014
CORTAVANCE (EMEA/V/C/000110)	09.01.2014 – 08.01.2015
Gripovac 3 (EMEA/V/C/000157)	14.01.2014 – 13.01.2015
MELOXIDYL (EMEA/V/C/000115)	15.01.2014 – 14.01.2015
Metacam (EMEA/V/C/000033)	07.01.2014 – 06.01.2015
Onsior (EMEA/V/C/000127)	16.12.2013 – 15.12.2014
Porcilis PCV (EMEA/V/C/000135)	12.01.2014 – 11.01.2015
Prac-Tic (EMEA/V/C/000103)	18.12.2013 – 17.12.2014
ProMeris (EMEA/V/C/000107)	19.12.2013 – 18.12.2014
ProMeris Duo (EMEA/V/C/000108)	19.12.2013 – 18.12.2014
RESPIPORC FLU3 (EMEA/V/C/000153)	14.01.2014 – 13.01.2015
Rheumocam (EMEA/V/C/000121)	10.01.2014 – 09.01.2015
TruScient (EMEA/V/C/002000)	14.12.2013 – 13.12.2014
Ypozane (EMEA/V/C/000112)	11.01.2014 – 10.01.2015
ZULVAC 8 Bovis (EMEA/V/C/000145)	15.01.2014 – 14.01.2015
ZULVAC 8 Ovis (EMEA/V/C/000147)	15.01.2014 – 14.01.2015

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the draft CVMP assessment report of the PSUR for the period 01.09.2013 – 31.08.2014 for **Cimalgex** (EMEA/V/C/000162) and agreed a list of questions to be addressed by the MAH.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.03.2014 – 31.08.2014 for **Pexion** (EMEA/V/C/002543) with a recommendation to amend section 4.4 of the SPC, special warnings.
- 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
Bovilis BTV8 (EMEA/V/C/000148)	01.04.2014 – 30.09.2014
Bravecto (EMEA/V/C/002526)	11.02.2014 – 31.08.2014
Equisolon (EMEA/V/C/002382)	12.03.2014 – 12.09.2014

Kexxtone (EMEA/V/C/002235)	01.02.2014 – 31.07.2014
RevitaCAM (EMEA/V/C/002379)	01.03.2014 – 31.08.2014
Suvaxyn PCV (EMEA/V/C/000149)	01.02.2014 – 31.07.2014
ZULVAC 1 Bovis (EMEA/V/C/000145)	01.03.2014 – 31.08.2014
ZULVAC 1 Ovis (EMEA/V/C/000147)	01.03.2014 – 31.08.2014

- 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 Committee adopted the 2015 EMA GMP re-inspection programme.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products (EMA/CVMP/497281/2006).

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the EU comments on the revised draft VICH guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species – residue depletion in fish groups.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

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 13 January 2015, 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 3–5 December 2014.

7.3 Safety Working Party (SWP-V)

- The Committee endorsed the nomination of B. Zemann and U. Wolfinger as SWP-V representatives on the JEG-3Rs.
- The Committee discussed the work undertaken in relation to the note for guidance on the approach towards harmonisation of withdrawal periods – comparing approaches for dealing with results below the limit of quantification. The SWP-V will discuss the topic further at its February meeting.
- The Committee adopted the guideline on risk characterisation and assessment of MRLs for biocides used in animal husbandry (EMA/CVMP/90250/2010) and the overview of comments received (EMA/CVMP/SWP/33896/2013). The new guideline will come into effect in August 2015.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the secretariat on the Commission Workshop on the 'Assessment of Persistent, Bioaccumulative and Toxic (PBT) substances in different EU legislations'.

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 25–26 November 2014, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and the overview of comments received, following the close of the public consultation.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 18-19 November 2014, and noted the agenda of the meeting.
- The Committee adopted the reflection paper on the risk of antimicrobial resistance transfer from companion animals (EMA/CVMP/AWP/401740/2013) and the overview of comments received (EMA/CVMP/89283/2014), following the close of the public consultation.
- The Committee discussed the guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals, which is foreseen to be adopted at the February meeting of the Committee.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the draft revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (BVDV) (EMA/CVMP/IWP/205351/2006) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

- The Committee elected J.-C. Rouby as chair of the Ad Hoc Expert Group on Novel Veterinary Therapies (ADVENT) for a two-year mandate period.
- The Committee discussed the draft ADVENT work plan 2015 including the topic list and topic priorities.

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:

- Minutes of the SAWP-V meeting held on 9 December 2014;
- Table of decisions of the 73rd Joint CHMP/CVMP QWP meeting held on 3–5 December 2014 and draft agenda of the 74th QWP Joint CHMP/CVMP QWP meeting to be held on 3–5 February 2015;
- Draft minutes of the ERAWP meeting held on 21-22 October 2014;
- Draft minutes of the EWP-V meeting held on 25-26 November 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 **alcohol, C9-11, ethoxylated substances** 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, and adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.25).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee was informed of the ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals.

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 agenda of the meeting held on 15-16 January 2015 and the draft minutes of the meeting held on 11-12 December 2014.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee endorsed the revised PIQ/QRD process concerning the review of the product information, for implementation of earlier availability of PIQ and QRD comments from the Agency on the product information in the first two phases of the assessment of an initial marketing authorisation application or extension application procedure.
- The Committee discussed the CVMP work plan.
- The Committee discussed the guidance on the principles to prepare CVMP assessment reports.
- The Committee discussed the CVMP implementation of multinational assessment teams.
- The Committee noted the table of actions following the December 2014 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the January 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 January 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 - Metacam-Novem WS (EMEA/V/C/xxxxxx/WS/0661/G) • 5.5 - Pexion
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
EL	Ioannis Malemis	Full involvement	
FI	Irmeli Happonen	Full involvement	
HR	Ljiljana Markuš-Cizelj	Involvement in discussions only and cannot act as rapporteur for:	• 1.3 - EMEA/V/MRL/003307/EXTN/ 0003 • 2.3 - EMEA/V/C/002763/0000 • 4.3 - Altrenogest (EMEA/V/A/095) • 5.5 - Bovilis BTV8, Bravecto • 5.6 - Re-inspection programme • 10. - one item
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Involvement in discussions only and cannot act as rapporteur for:	• 2.3 - Zactran (EMEA/V/C/000129/X/0027) • 2.5 - NexGard Spectra (EMEA/V/C/003842/0000) • 3.1 - Purevax WS (EMEA/V/C/xxxxxx/WS/0606) • 5.2 - Purevax Rabies (EMEA/V/C/002003/REC001-002) • 5.5 - CIMALGEX • 5.6 - one item • 5.6 - Re-inspection programme
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	
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	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	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 3.1 - Metacam-Novem WS (EMEA/V/C/xxxxxx/WS/0661/G)
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.			
DE	Stefan Scheid *(remotely)*	Full involvement	
DK	Nanna Aaby Kruse	Full involvement	
FR	Elisabeth Bégon *(remotely)*	Full involvement	
FR	Damien Bouchard *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
FR	Sylvie Louet	Full involvement	
LU	Jean-Louis Robert *(remotely)*	Full involvement	
PT	Berta Braz *(remotely)*	Full involvement	
SE	Fredrik Hultén *(remotely)*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Peter Borriello	Full involvement	
UK	Sharon Reynolds	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	--
ERAWP	Boris Kolar
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	--
QWP	Jean-Louis Robert *(remotely)*; Piet-Hein Overhaus *(Vet vice chair - 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