16 January 2018
EMA/CVMP/30112/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 5–7 December 2017 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

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 the addition of a new item under section 12.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the December 2017 meeting. In accordance with the Agency's policy and procedure on the handling of competing 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 CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP 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.

No contacts were declared.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the November 2017 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

- 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 consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Suvaxyn Circo** (EMEA/V/C/004242/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of fattening pigs from 3 weeks against porcine circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues and faecal shedding. The Norwegian CVMP member 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 including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new antiparasitic product (EMEA/V/C/002836/0000). The Committee agreed to invite the applicant for an oral explanation, and noted a peer review report and the comments received from CVMP members.
- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new antiparasitic product (EMEA/V/C/004291/0000). The Committee agreed to invite the applicant for an oral explanation, and noted two peer review reports and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new fixed combination product (EMEA/V/C/004329/0000. 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 agreed to the request from the applicant for an extension to the clock-stop for a new product with a musculo-skeletal disorder indication (EMEA/V/C/002774/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Rabitec** (EMEA/V/C/004387/0000) 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 **ZACTRAN** (EMEA/V/C/000129/II/0036), recommending the variation of the marketing authorisation to add a new therapeutic indication. The Norwegian CVMP member 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 endorsed the rapporteur's assessment report for a grouped type II variation for **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993/II/0002/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member 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 endorsed the rapporteur's assessment report for a type II variation for **Easotic** (EMEA/V/C/000140/II/0012), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from Boehringer Ingelheim Vetmedica GmbH concerning a type II variation for **Metacam** (EMEA/V/C/000033/II/0127), to register an additional target species. The Committee also discussed the draft product information. The adoption of the opinion is foreseen for the February 2018 CVMP meeting.
- The Committee adopted a list of outstanding issues to be addressed in writing for a grouped type II variation for **Vaxxitek HVT +IBD** (EMEA/V/C/000065/WS1209/G), concerning quality changes.
- The Committee adopted a list of outstanding issues to be addressed in writing for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0007), concerning quality changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a grouped type II variation for **Pexion** (EMEA/V/C/002543/II/0011/G), to add a new therapeutic indication.
- The Committee adopted a list of questions for a type II variation for **Activyl Tick Plus** (EMEA/V/C/002234/II/0011), to change the conditions regarding supply and use.
- The Committee adopted a list of questions for a worksharing type II variation for **Naxcel** (EMEA/V/C/000079/WS1241/0034), concerning quality changes.
- The Committee adopted a list of questions for a worksharing type IB variation for **Vaxxitek HVT +IBD** (EMEA/V/C/000065/WS1242/0024), 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

- 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

- There were no items for discussion.

4.7 Other issues

- The Committee was informed of the updated questions and answers documents for Article 13, Article 33(4), Article 34 and Article 35 referrals, which will be published on the Agency website.

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 endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **NEXGARD SPECTRA** (EMEA/V/C/3842/REC/010).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 10.11.2017–07.12.2017:

Product	Period
Broadline (EMEA/V/C/002700)	04/12/2016 - 03/12/2017
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	05/11/2016 – 04/11/2017
Contacera (EMEA/V/C/002612)	06/12/2016 – 05/12/2017
DRAXXIN (EMEA/V/C/000077)	11/11/2016 - 10/11/2017
Easotic (EMEA/V/C/000140)	20/11/2016 - 19/11/2017
Equip WNV (EMEA/V/C/000137)	21/11/2016 - 20/11/2017
Halocur (EMEA/V/C/000040)	29/10/2016 – 28/10/2017
Masivet (EMEA/V/C/000128)	17/11/2016 - 16/11/2017
Meloxivet (EMEA/V/C/000124)	14/11/2016 - 13/11/2017
Meloxoral (EMEA/V/C/000151)	19/11/2016 - 18/11/2017
Oxyglobin (EMEA/V/C/000045)	21/11/2016 - 20/11/2017
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2016 - 15/11/2017
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2016 – 06/11/2017
Quadrisol (EMEA/V/C/000032)	04/12/2016 - 03/12/2017
Simparica (EMEA/V/C/003991)	06/11/2016 – 05/11/2017
Stronghold (EMEA/V/C/000050)	25/11/2016 - 24/11/2017
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06/11/2016 – 05/11/2017
Vectra 3D (EMEA/V/C/002555)	04/12/2016 – 03/12/2017
Virbagen Omega (EMEA/V/C/000061)	06/11/2016 – 05/11/2017
Zolvix (EMEA/V/C/000154)	04/11/2016 – 03/11/2017
Zycortal (EMEA/V/C/003782)	06/11/2016 – 05/11/2017

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 **Ecoporc SHIGA** (EMEA/V/C/002588/R/0006), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017-31.07.2017 for **Canigen L4 and Nobivac L4** (EMEA/V/C/004079) with a recommendation for the MAH to submit a targeted PSUR on reports of death and death by euthanasia.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.07.2014-30.06.2017 for **LEUCOFELIGEN FeLV RCP** (EMEA/V/C/000143) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017-31.07.2017 for **Versican Plus DHPPi** (EMEA/V/C/003679) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2017-31.07.2017 for **Versican Plus Pi** (EMEA/V/C/003681) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
CORTAVANCE (EMEA/V/C/000110)	01.08.2014 - 31.07.2017
Gripovac 3 (EMEA/V/C/000157)	01.08.2014 - 31.07.2017
Innovax-ILT (EMEA/V/C/003869)	01.01.2017 - 31.07.2017
MELOXIDYL (EMEA/V/C/000115)	01.08.2014 - 31.07.2017
OSURNIA (EMEA/V/C/003753)	01.02.2017 - 31.07.2017
PIRSUE (EMEA/V/C/000054)	01.08.2014 - 31.07.2017
RESPIPORC FLU3 (EMEA/V/C/000153)	01.08.2014 - 31.07.2017
Sedadex (EMEA/V/C/004202)	13.02.2017 - 12.08.2017
Sileo (EMEA/V/C/003764)	01.01.2017 - 30.06.2017
Suvaxyn PCV (EMEA/V/C/000149)	01.08.2016 - 31.07.2017
UpCard (EMEA/V/C/003836)	01.02.2017 - 31.07.2017
ZACTRAN (EMEA/V/C/000129)	01.02.2017 - 31.07.2017

- The Committee endorsed the rapporteur's r for **Metacam** (EMEA/V/C/000072) with a recommendation to amend the product information.
- The Committee endorsed the rapporteur's proposal for **Improvac** (EMEA/V/C/000136) with a recommendation to amend the product information.
- 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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the EU comments on the following revised VICH guidelines on efficacy of anthelmintics, for the circulation to the expert working group:
  - VICH GL01 Rev. 1 - General Requirements;
  - VICH GL12 Rev. 1 - Bovines;
  - VICH GL13 Rev. 1 – Ovines;
  - VICH GL14 Rev. 1 - Caprines;
  - VICH GL15 Rev. 1 - Equines;
  - VICH GL16 Rev. 1 - Porcines;
  - VICH GL19 Rev. 1 - Canines;
  - VICH GL20 Rev. 1 - Felines;
  - VICH GL21 Rev. 1 – Poultry.
- The Committee endorsed the EU comments on the new draft VICH guideline on fixed combination products and the related discussion document. The comments will be forwarded to the expert working group.
- The Committee endorsed the EU comments on the draft training materials for the VICH guideline 52 on bioequivalence: blood level bioequivalence study. The comments will be circulated to the VICH Steering Committee.
- The Committee endorsed the EU comments on the draft (IV) annex to the VICH GL3(R) on stability studies for climatic zones III and IV and noted the compilation of comments on draft III. The EU comments will be forwarded to the expert working group.
- The Committee endorsed the updated draft guideline on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, revised following comments from the BQM EWG and the compilation of comments from the EWG with EU responses. The updated draft guideline and the compilation of comments will be forwarded to the expert working group.
- The Committee endorsed the draft VICH GL 57 - studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species, for sign-off by the VICH Steering Committee at step 3 of the VICH process.
- The Committee discussed the JMAFF proposal for advancing the work on extraneous viruses in veterinary vaccines and agreed to develop the EU comments on the document.
- The Committee discussed the JMAFF concept paper proposing development of a guideline on safety evaluation of biotechnology-derived/biological products and agreed to develop EU comments on the document.
- The Committee received a verbal report on the 35th VICH Steering Committee meeting and 9th Outreach Forum meeting held on 13–16 November 2017 in Tokyo, and noted the agendas of the meetings.

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 documents were circulated for information:

- Minutes of an informal preparatory meeting between EU experts and industry related to VICH guidelines on extraneous viruses;
- Status of active VICH guidelines and action plan of CVMP and working parties;
- Summary and conclusions from the 85th meeting of the Joint FAO/WHO Expert Committee on Food Additives held in October 2017 in Geneva.

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 5 December 2017, and noted the agenda of the meeting.
- The Committee adopted revised guidance for companies requesting scientific advice (EMA/CVMP/172329/2004).
- The Committee endorsed a survey on the impact of Innovation Task Force briefing meetings and scientific advice procedures on innovation support and development of new veterinary medicinal products.

7.2 Quality Working Party (QWP)

- The Committee adopted the guideline on chemistry of active substances for veterinary medicinal products (EMA/CVMP/QWP/707366/2017) and the overview of comments received (EMA/CVMP/QWP/502315/2017) during the public consultation.
- The Committee adopted questions and answers on in-use shelf life for solid dose forms in multidose containers.
- The Committee adopted guidance on the phased implementation of requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017) and the overview of comments received (EMA/CVMP/QWP/759110/2017) during the public consultation.

7.3 Safety Working Party (SWP-V)

- The Committee received verbal reports from the chair of the SWP-V on the meeting held on 20 September 2017 and on the training of assessors on genotoxicity testing held on 21 September 2017, as well as from the vice-chair of the SWP-V on the meeting held on 30 November – 1 December 2017. The Committee noted the agendas of the meetings and the agenda for the training event.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the chair of the ERAWP on the meeting held on 24 October 2017, and noted the agenda of the meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the vice-chair of the EWP-V on the meeting held on 28-29 November 2017, and noted the agenda of the meeting.
- The Committee agreed for EWP-V to continue working on the revision of the bioequivalence guideline following the comments received during the public consultation.
- The Committee adopted the concept paper on the revision of the guideline on the SPC for anthelmintics for a 3-month period of public consultation.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meetings held on 20-21 September 2017 and on 22-23 November 2017, and noted the agendas of the meetings.
- The Committee was informed of the comments received during the public consultation on the reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health, and agreed that the AWP could start on the revision of the paper taking the comments into account, and that the paper could also be considered by the AMEG.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 18-19 October 2017 as well as on the training of immunological assessors on quality of immunological veterinary medicinal products held on 19-20 October 2017, and noted the agenda of the meeting and the training programme.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 21-22 November 2017, and noted the agenda and draft minutes of the meeting.

7.9 Novel therapy groups and related issues

- The Committee adopted questions and answers on monoclonal antibodies for veterinary use: specific questions to be addressed by ADVENT (EMA/CVMP/ADVENT/307606/2017).

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- The Committee adopted a statement of the CVMP position on the ethical use of animals in the testing, development and manufacture of veterinary medicines.
- The Committee adopted the recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote reduction, refinement and replacement (3Rs) measures described in the European Pharmacopoeia.
- The Committee was informed of the extension of the mandate, objectives and rules of procedure for the joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (J3RsWG) (EMA/CHMP/CVMP/3Rs/442724/2012), and noted the JEG3Rs (J3RsWG) Annual Report 2017 (EMA/CHMP/CVMP/3Rs/502136/2017).

7.11 Other working party and scientific group issues

- The Committee adopted the work plans for 2018 for the CVMP working parties: SAWP-V (EMA/CVMP/SAWP/574285/2017), QWP (EMA/CHMP/CVMP/QWP/504882/2017), SWP-V (EMA/CVMP/SWP/278493/2017), ERAWP (EMA/CVMP/ERA/289769/2017), EWP-V (EMA/CVMP/EWP/222886/2017), AWP (EMA/CVMP/AWP/484533/2017), IWP (EMA/CVMP/IWP/347865/2017), PhVWP-V (EMA/CVMP/PhVWP/384293/2017), ADVENT (EMA/CVMP/ADVENT/573725/2017) and the J3RsWG (EMA/CHMP/CVMP/3Rs/479556/2017).

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 3 October 2017;
- Minutes of the AWP meeting held on 20-21 September 2017;
- Draft minutes of the IWP meeting held on 18-19 October 2017;
- Draft agenda of the ADVENT meeting to be held on 7 December 2017.

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.

- There were no items for discussion.

8.2 Environmental risk assessment

- The Committee discussed the European Commission public consultation on pharmaceuticals in the environment.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the progress of the pilot project on dose optimisation in the context of SPC harmonisation of established veterinary antibiotics (PPHOVA) and on the second meeting held on 10 November 2017, and noted the draft minutes of the meeting.

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.

- The Committee was informed of the revised incident management plan for medicines for veterinary use (EMA/711053/2010-Rev.2).

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 adopted the final QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP) (EMA/776723/2017).
- The Committee adopted the procedural guidance on Quick Response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures (EMA/364980/2017).

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a report from the chair of CMDv on the meeting held on 9-10 November 2017, and noted the draft minutes of the meeting as well as the draft agenda of the meeting to be held on 7-8 December 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the public CVMP work plan for 2018 (EMA/CVMP/254946/2017).
- The Committee received a presentation on the user manual for CxMP/WP/SAG members and experts representing CxMP or EMA at external meetings.
- The Committee received a verbal report on the EMA working group on operational preparedness for veterinary medicines.
- The Committee noted the announcement of the presidency CVMP meeting to be held during the Bulgarian presidency on 7-8 May 2018 in Madrid, Spain.

13. LEGISLATION

- The Committee noted the ongoing 4-week consultation on the draft Commission regulation on the methodological principles for the risk assessment and risk management recommendations for the Maximum Residue Limits.

14. ANY OTHER BUSINESS

- Upon the completion of the December 2017 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 December 2017 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Gesine Hahn	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	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LV	Zanda Auce	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 5.4 – 1 item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Katarina Straus	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	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	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
AT	Petra Falb	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Noemi Garcia del Blanco	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	Els Dewaele	Full involvement	
BE	Sandy Vermout - *remotely*	Full involvement	
DE	Anke Finnah - *remotely*	Full involvement	
DE	Silke Hickmann - *remotely*	Full involvement	
DE	Nadine Matzmohr	Full involvement	
DE	Svenja Rieke - *remotely*	Full involvement	
DE	Stefan Scheid - *remotely*	Full involvement	
DE	Gunther Speichert - *remotely*	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Ines Vogel - *remotely*	Full involvement	
DK	Christian Friis - *remotely*	Full involvement	
DK	John Jensen - *remotely*	Full involvement	
ES	Ricardo Carapeto García - *remotely*	Full involvement	
ES	Mercedes Conradi Monner - *remotely*	Full involvement	
ES	Sonia Gil Morales - *remotely*	Full involvement	
ES	Rocío Fernández Granda - *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
ES	Amparo López Rivera - *remotely*	Full involvement	
ES	Javier Pozo - *remotely*	Full involvement	
FR	Nathalie Bridoux - *remotely*	Full involvement	
IE	Mary O'Grady - *remotely*	Full involvement	
SE	Helena Back - *remotely*	Full involvement	
UK	John Mitchell - *remotely*	Full involvement	
UK	Jean-Paul Schmidt	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero
IWP	Esther Werner
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(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