13 February 2018
EMA/CVMP/93469/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the January 2018 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 no modifications.

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

The attendance list was completed and competing interests were identified for the January 2018 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.

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 December 2018 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

- The Committee heard an oral explanation from a company and discussed the rapporteur's assessment of the responses to the list of outstanding issues including the co-rapporteur's critique for the modification of MRLs in *Salmonidae* for a substance (EMEA/V/MRL/003135/MODF/0003). The adoption of the opinion is foreseen for the February 2018 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

- The Committee agreed to the request from the applicant for a 7-month extension to the clock-stop for an application for the establishment of MRLs in rabbits for a substance (EMEA/V/MRL/004828/FULL/0001).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- There were no items for discussion.

2.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from the applicant concerning an application for a new product for musculo-skeletal disorders in dogs (EMEA/V/C/004375/0000). The Committee also discussed the draft product information and the rapporteurs' draft assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the February 2018 CVMP meeting.
- The Committee heard an oral explanation from the applicant concerning an application for a new product acting on the nervous system for dogs (EMEA/V/C/004417/0000). The Committee also discussed the draft product information and the rapporteurs' draft assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the February 2018 CVMP meeting.
- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for an extension application for

Semintra (EMEA/V/C/002436/X/0008), to add a new strength and a new indication. The Committee agreed that an oral explanation would not be requested.

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 antiparasitic product for cats and dogs (EMEA/V/C/004824/0000). 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 adopted the EPAR module 6 scientific discussion for **Galliprant** (EMEA/V/C/004222/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module 6 scientific discussion for **Suvaxyn Circo** (EMEA/V/C/004242/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Vectormune ND** (EMEA/V/C/003829/II/0007), recommending the variation of the marketing authorisation to add a new category of target species (layer chickens) and to clarify the existing indication against Marek's disease. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Panacur AquaSol** (EMEA/V/C/002008/II/0015), recommending the variation of the marketing authorisation to add a new therapeutic indication (*Capillaria* spp. *L5* and adult stages) in chickens and to modify the withdrawal period. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a grouped type II variation for **Advocate**, recommending the variation of the marketing authorisation to add new therapeutic indications (treatment of *Eucoleus aerophilus* (syn. *Capillaria aerophila*) in cats, treatment of *Eucoleus* (syn. *Capillaria*) *boehmi* in dogs, treatment of the eye worm *Thelazia callipaeda* in dog and implement changes to the product information. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a grouped type II variation for **Meloxidyl** (EMEA/V/C/000115/II/0023/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 (24 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Suvaxyn PCV** (EMEA/V/C/000149/II/0025), 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 (24 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a grouping of type IA and type IB variations, under a worksharing procedure, for **Procox** and the nationally-authorised Baycox oral solution and Baycox oral suspension (EMEA/V/C/002006/WS1244/0023/G), recommending the variation of the marketing authorisations 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 adopted a list of outstanding issues for a grouped type II variation for **Onsior** (EMEA/V/C/000127/II/0018/G) to add a new therapeutic indication and to modify the SPC.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0007) to modify the approved therapeutic indication.
- The Committee adopted a list of questions for a grouped type II variation for **Vectormune ND** (EMEA/V/C/003829/II/0009/G) 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

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the re-examination of the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122), and agreed that no outstanding issues remained. The adoption of the final CVMP opinion and assessment report is foreseen for the February 2018 meeting of the Committee. The Committee noted two peer review reports and the comments made by CVMP members.

4.3 Article 35 of Directive 2001/82/EC

- The Committee heard an oral explanation from Bayer Animal Health GmbH for the follow-up assessment of the referral procedure for **veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** (EMEA/V/A/089). The Committee adopted a further list of outstanding issues for the MAHs to address in writing. The adoption of the CVMP assessment report is foreseen for the February 2018 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

- The Committee discussed the rapporteur's assessment report and the co-rapporteur's assessment report for the referral procedure for **Seresto and its associated name Foresto** (EMEA/V/A/125). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the February 2018 CVMP meeting. The Committee noted two peer-review reports and the comments made by CVMP members.

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

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

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

5.1 General issues

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 endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Econor** (EMEA/V/C/000042/REC/038).
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Clynav** (EMEA/V/C/002390/REC/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 8.12.2017 – 18.01.2018:

Product	Period
Acticam (EMEA/V/C/000138)	09/12/2016 – 08/12/2017
Activyl Tick Plus (EMEA/V/C/002234)	09/01/2017 – 08/01/2018
Bovela (EMEA/V/C/003703)	22/12/2016 – 21/12/2017
BTVPUR (EMEA/V/C/002231)	17/12/2016 – 16/12/2017
BTVPUR AlSap 1 (EMEA/V/C/002230)	17/12/2016 – 16/12/2017
Cepedex (EMEA/V/C/004376)	13/12/2016 – 12/12/2017
Coliprotec F4/F18 (EMEA/V/C/004225)	09/01/2017 - 08/01/2018
CORTAVANCE (EMEA/V/C/000110)	09/01/2017 – 08/01/2018
Gripovac 3 (EMEA/V/C/000157)	14/01/2017 – 13/01/2018

Product	Period
Halagon (EMEA/V/C/004201)	13/12/2016 - 12/12/2017
Imrestor (EMEA/V/C/002763)	09/12/2016 – 08/12/2017
Inflacam (EMEA/V/C/002497)	09/12/2016 – 08/12/2017
MELOXIDYL (EMEA/V/C/000115)	15/01/2017 – 14/01/2018
Metacam (EMEA/V/C/000033)	07/01/2017 – 06/01/2018
NEXGARD SPECTRA (EMEA/V/C/003842)	15/01/2017 – 14/01/2018
Onsior (EMEA/V/C/000127)	16/12/2016 – 15/12/2017
Panacur AquaSol (EMEA/V/C/002008)	09/12/2016 – 08/12/2017
Porcilis PCV (EMEA/V/C/000135)	12/01/2017 – 11/01/2018
Prac-tic (EMEA/V/C/000103)	18/12/2016 – 17/12/2017
RESPIPORC FLU3 (EMEA/V/C/000153)	14/01/2017 – 13/01/2018
Rheumocam (EMEA/V/C/000121)	10/01/2017 – 09/01/2018
SevoFlo (EMEA/V/C/000072)	11/12/2016 – 10/12/2017
Ypozane (EMEA/V/C/000112)	11/01/2017 – 10/01/2018
ZULVAC 8 Bovis (EMEA/V/C/000145)	15/01/2017 – 14/01/2018
ZULVAC 8 Ovis (EMEA/V/C/000147)	15/01/2017 – 14/01/2018

5.4 Renewals

- The Committee adopted by consensus (24 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 **Equilis West Nile** (EMEA/V/C/002241/R/0005), and recommended that a further renewal would be required. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 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 **Oncept IL-2** (EMEA/V/C/002562/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 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
Coliprotec F4/F18 (EMEA/V/C/004225)	09.01.2017 - 21.07.2017
Kexxtone (EMEA/V/C/002235)	01.08.2016 - 31.07.2017
NEXGARD SPECTRA (EMEA/V/C/003842)	01.02.2017 - 31.07.2017

Porcilis PCV ID (EMEA/V/C/003942)	01.03.2017-31.08.2017
ProZinc (EMEA/V/C/002634)	01.08.2016 - 31.07.2017
Semintra (EMEA/V/C/002436)	01.03.2017 - 31.08.2017
Stronghold Plus (EMEA/V/C/004194)	09.02.2017 - 31.08.2017
Vectra 3D (EMEA/V/C/002555)	01.07.2016-30.06.2017

- 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 adopted the draft VICH GL57 on 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 (EMA/CVMP/VICH/517152/2013), for release for a 5-month public consultation period in the EU at step 4 of the VICH process.
- The Committee discussed the EU comments on the revised concept paper proposing the development of a VICH guideline on safety evaluation of biotechnology-derived/biological products, which are foreseen to be endorsed at the February 2018 CVMP meeting.
- The Committee discussed the EU comments on the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) proposal for advancing the work on extraneous viruses in veterinary vaccines, which are foreseen to be endorsed at the February 2018 CVMP meeting.
- The Committee endorsed the revised draft VICH GL56 on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for circulation to the VICH EWG at step 4 of the VICH process.
- The Committee discussed the draft concept paper for a VICH guideline providing guidance on the establishment and running of a basic pharmacovigilance system and referred the topic to the CVMP Pharmacovigilance Working Party for development of draft EU comments.
- The Committee endorsed the EU comments on the draft concept paper for the revision of the VICH GL22 on studies to evaluate the safety of residues of veterinary drugs in human food: reproduction testing. The comments will be fed back to the VICH Safety Expert Working Group.
- The Committee noted the report on the 35th VICH Steering Committee meeting held on 13-16 November 2017 in Tokyo.

6.2 Codex Alimentarius

- The Committee discussed the request from the European Commission to provide comments on circular letter CL 2017/85/OCS-RVDF and the proposed draft MRLs for veterinary drugs.

6.3 Other EU bodies and international organisations

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 16 January 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report on the QWP meeting held on 28–30 November 2017, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on manufacture of the finished dosage form, which is foreseen to be adopted at the February 2018 CVMP meeting for release for public consultation.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the concept paper for the revision of the guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market for a one month period of public consultation.
- The Committee discussed the revised draft guideline on user safety of topically administered veterinary medicinal products, which is foreseen to be adopted at the February 2018 CVMP meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted an updated question and answer document on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH GL6 (Phase I) and GL38 (Phase II).

7.5 Efficacy Working Party (EWP-V)

- The Committee discussed the revised guideline on the SPC for antimicrobial products, which is foreseen to be adopted shortly for release for public consultation - s*ee also point 7.6.*

7.6 Antimicrobials Working Party (AWP)

- The Committee discussed the revised guideline on the SPC for antimicrobial products, which is foreseen to be adopted shortly for release for public consultation - *see also point 7.5.*

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

- The Committee received a verbal report from the J3RsWG chair on the PARERE ESTAF (Preliminary Assessment of Regulatory Relevance network and the ECVAM Stakeholder Forum) workshop held on 28-29 November 2017, and noted the presentation and the summary of the meeting.

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 5 December 2017.
- Draft minutes of the EWP-V meeting held on 28–29 November 2017.
- Draft agenda of the PhVWP-V meeting to be held on 23-24 January 2018.

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 remove **diethanolamine** from the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 and adopted a revised list (EMA/CVMP/519714/2009-Rev.37). This decision was taken by the Committee in light of information on potential genotoxicity and carcinogenicity.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the first meeting of the Antimicrobial Advice Ad Hoc Expert Group (AMEG), and noted the draft minutes of the meeting as well as the agenda of the meeting held on 14 December 2017.
- The Committee received a verbal report on the second OIE Annual report on antimicrobial agents intended for use in animals (link)

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 7-8 December 2017 and the draft agenda of the meeting held on 18-19 January 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

Information relating to certain topics discussed under section 12 at this meeting cannot be released at the present time as it is deemed to be confidential.

13. LEGISLATION

Information relating to certain topics discussed under section 13 at this meeting cannot be released at the present time as it is deemed to be confidential.

14. ANY OTHER BUSINESS

- Upon the completion of the January 2018 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 2018 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	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Bayer**	• 3.1 Advocate, Procox • 4.3 Enrofloxacin oral • 4.5 Seresto • 7.1 One item • 10.2 One item
SE	Eva Lander Persson	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	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Sylvie Louet	Full involvement	
HU	Tibor Soós	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
RO	Simona Sturzu	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.			
DE	Anke Finnah	Full involvement	
DE	Luela Fröhlich - *remotely*	Full involvement	
DE	Uta Herbst - *remotely*	Full involvement	
DE	Kristin Schallschmidt - *remotely*	Full involvement	
DE	Stefan Scheid - *remotely*	Full involvement	
DE	Stephan Steuber - *remotely*	Full involvement	
DE	Wiebke Weiher - *remotely*	Full involvement	
Fi	Martti Nevalainen -*remotely*	Full involvement	
FR	Florence Pillet - *remotely*	Full involvement	
IE	Mary O'Grady - *remotely*	Full involvement	
NL	Kim Boerkamp - *remotely*	Full involvement	
NL	Anita Bottger - *remotely*	Full involvement	
NL	Sandra ten Voorde - *remotely*	Full involvement	
PL	Ewa Augustynowicz - *remotely*	Full involvement	
PL	Marcin Glanda - *remotely*	Full involvement	
UK	Georgina Blanc	Full involvement	
UK	Gillian Clarke - *remotely*	Full involvement	
UK	Miguel Escribano - *remotely*	Full involvement	
UK	Samuel Fletcher - *remotely*	Full involvement	
UK	John Mitchell	Full involvement	
UK	Niall O'Brien - *remotely*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero
IWP	Esther Werner
PhVWP-V	Els Dewaele - *remotely*
QWP *(Vet vice chair)*	Mary O'Grady - *remotely*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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