4 December 2018
EMA/CVMP/745459/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 6-8 November 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 the addition of two new items under sections 2.5 and 5.6.

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

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

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 October 2018 meeting were adopted with no amendments.

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

- The Committee adopted the scientific overview including the list of questions for the establishment of MRLs in porcine species for a substance (EMEA/V/MRL/005009/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur. The Committee noted two peer review reports and the comments received from CVMP members.

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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Syvazul BTV** (EMEA/V/C/004611/0000), recommending the granting of a marketing authorisation. The product is a new multi-strain vaccine for the active immunisation of sheep to prevent viraemia and reduce clinical signs and lesions caused by bluetongue virus serotypes 1 and/or 8, and/or to reduce viraemia and clinical signs caused by bluetongue virus serotype 4; and for the active immunisation of cattle to prevent viraemia caused by bluetongue virus serotypes 1 and/or 8 and/or to reduce viraemia caused by bluetongue virus serotype 4. 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Isemid** (EMEA/V/C/004345/0000), recommending the granting of a marketing authorisation. Isemid is a new cardiovascular product intended for treatment of clinical signs related to congestive heart failure in dogs, including pulmonary oedema. 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

- There were no items for discussion.

2.3 Lists of questions

- There were no items for discussion.

2.4 Re-examination of CVMP opinions

- The Committee agreed to the request from the applicant for the re-examination, in accordance with Regulation (EC) No 726/2004, of the CVMP opinion adopted for **HorStem** (EMEA/V/C/004265/0000), a veterinary product intended for the treatment of ostheoathritis in horses, and appointed R. Breathnach as rapporteur and F. Hasslung Wikström as co-rapporteur, and peer reviewers for the procedure. The Committee agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). Members were invited to submit nominations for experts for the AHEG. The submission of the detailed grounds for the re-examination is foreseen by 3 January 2019. The adoption of the opinion is foreseen for the February 2019 meeting of the Committee.

2.5 Other issues

- The Committee was informed of the formal notification from OTR3 of their decision to withdraw the application for a new marketing authorisation for EQUITEND (EMEA/V/C/002774/0000), which was intended for use in non-food producing horses. More information about this application and the scientific assessment at the time of withdrawal will be made available in a public assessment report.

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 **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0009), recommending the variation of the marketing authorisation to change the onset of immunity for cattle and sheep. The Norwegian CVMP member 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 a list of questions for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0016), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee noted the request from the MAH for an extension to the clock-stop for a type II variation for **OSURNIA** (EMEA/V/C/003753/II/0008), concerning quality changes.

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

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the procedure concerning **veterinary medicinal products containing gentamicin for parenteral administration to horses** (EMEA/V/A/128), concluding that a maximum limit of 8 parts per million (ppm) histamine should be included in the specification for the active substance gentamicin which utilises fish peptone as a raw material. In addition, the Committee made recommendations to the European Directorate for the Quality of Medicines (EDQM), active substance manufacturers and marketing authorisation holders. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

4.7 Other issues

Information relating to certain topics discussed under section 4.7 at this meeting cannot be released at the present time as it is deemed to be confidential.

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

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Vaxxitek HVT + IBD** (EMEA/V/C/000065/REC/026).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 12.10.2018–08.11.2018:

Product	Period
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	05/11/2017 – 04/11/2018

Product	Period
Halocur (EMEA/V/C/000040)	29/10/2017 – 28/10/2018
Nobivac LeuFel (EMEA/V/C/004778)	06/11/2017 – 05/11/2018
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2017 – 06/11/2018
Simparica (EMEA/V/C/003991)	06/11/2017 – 05/11/2018
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06/11/2017 – 05/11/2018
Virbagen Omega (EMEA/V/C/000061)	06/11/2017 – 05/11/2018
ZOLVIX (EMEA/V/C/000154)	04/11/2017 – 03/11/2018
Zycortal (EMEA/V/C/003782)	06/11/2017 – 05/11/2018

5.4 Renewals

- The Committee adopted by consensus the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Parvoduk** (EMEA/V/C/002740/R/0006). The Committee concluded that a further 5-year renewal would be required, based on pharmacovigilance grounds (limited post-marketing safety information). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Loxicom** (EMEA/V/C/000141/R/0031), 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 of 01.12.2017 – 31.05.2018 for **Simparica and MiPet Easecto** (EMEA/V/C003991) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period of 01.01.2018 – 31.05.2018 for **Zycortal** (EMEA/V/C003782) with a recommendation to amend the product information.
- The Committee endorsed the proposal for streamlining of PSURs and signal detection which will bring the signal detection activity for each product just prior to the PSUR data lock point allowing for potential input or questions to the MAH arising from the signal detection prior to the preparation of the PSUR.
- The Committee endorsed the following rapporteurs' assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Acticam (EMEA/V/C/000138)	01.07.2015 – 30.06.2018
EQUIOXX (EMEA/V/C/000142)	01.01.2018 – 30.06.2018
Fevaxyn Pentofel (EMEA/V/C/000030)	01.07.2017 – 30.06.2018

Halagon (EMEA/V/C/004201)	01.01.2018 – 30.06.2018
Rabitec (EMEA/V/C/004387)	01.12.2017 – 30.06.2018
Trifexis (EMEA/V/C/002635)	05.01.2018 – 04.07.2018
Velactis (EMEA/V/C/003739)	01.01.2018 – 30.06.2018
Versican Plus DHPPi L4 (EMEA/V/C003678)	01.06.2017 – 31.05.2018
Versican Plus DHPPi L4R	01.06.2017 – 31.05.2018

- 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 comments on the draft training slides on VICH GL10, GL11, GL18, GL45 and GL51, and on the VICH TABST guidelines GL50(R) and GL55.
- The Committee endorsed the proposal for the revision of VICH GL36 on the general approach to establish a microbiological ADI, limited to a change in the value for the volume of the human colon in the formula for the calculation of the microbiological ADI. The position will be communicated to the VICH Steering Committee.
- The Committee discussed the draft VICH GL57 on marker residue depletion studies to establish product withdrawal periods in aquatic species, revised with responses to comments received during the public consultation. Endorsement of EU comments on the document is foreseen for the December 2018 meeting of the Committee.

6.2 Codex Alimentarius

- The Committee noted the proposed draft guideline on integrated surveillance of antimicrobial resistance (CX/AMR 18/6/6), the proposed draft revision of the code of practice to minimize and contain foodborne antimicrobial resistance (CXC 61-2005, CX/AMR 18/6/5) and the EC request for comments. – *see also 8.3*

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 SAWP-V chair on the meeting held on 7 November 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted a draft reflection paper on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/153641/2018) for release for public consultation until 31 August 2019. The Committee also adopted a revision to the planned phased implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products (EMA/CVMP/QWP/631010/2017-Rev.1).
- The Committee adopted a question and answer on the requirements for selection and justification of starting materials for the manufacture of chemical active substances in veterinary medicinal products for publication.
- The Committee adopted the revised guideline on the active substance master file procedure (EMEA/CVMP/134/02-Rev.4).
- The Committee discussed the revised guideline on the conduct of bioequivalence studies for veterinary medicinal products and the overview of comments received from stakeholders following the close of the public consultation. The adoption of the guideline is foreseen for the December 2018 meeting of the Committee. – *see also 7.5*
- The Committee discussed the guideline on the sterilisation of the medicinal product, active substance, excipient and primary container. The adoption of the guideline is foreseen for the December 2018 meeting of the Committee.

7.3 Safety Working Party (SWP-V)

- The Committee discussed the revised guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market. The guideline is foreseen to be adopted for release for public consultation at the December 2018 CVMP meeting.
- The Committee discussed the draft guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products, which is foreseen to be adopted at the December 2018 CVMP meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products (EMA/CVMP/ERA/632109/2014) for release for public consultation until 31 August 2019. – *see also 7.6*

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 18-19 September, and noted the agenda and the draft minutes of the meeting.
- The Committee discussed the revised guideline on the conduct of bioequivalence studies for veterinary medicinal products and the overview of comments received from stakeholders following the close of the public consultation. The adoption of the guideline is foreseen for the December 2018 meeting of the Committee. – *see also 7.2*

- The Committee discussed a new question and answer on the CVMP guideline on veterinary medicinal products controlling varroa destructor parasitosis in bees, which is foreseen to be adopted at the December 2018 CVMP meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 18-19 September 2018, and noted the agenda and draft minutes of the meeting.
- The Committee adopted a reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products (EMA/CVMP/ERA/632109/2014) for release for public consultation until 31 August 2019. – *see also 7.4*
- The Committee adopted a reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union (EMA/CVMP/AWP/237294/2017) and the overview of comments received following the close of the public consultation (EMA/CVMP/AWP/30098/2018).
- The Committee received a verbal update on the focus group meeting on the guideline "Assessment of the risk for public health for antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product" held on 19 September 2018, and noted the agenda and minutes of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 25 September, and noted the agenda of the meeting.
- The Committee discussed the revised guideline, the overview of comments received following the close of the public consultation and the revised question and answer document on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot-and-mouth disease. The guideline is foreseen to be adopted at the December 2018 CVMP meeting.
- The Committee discussed the draft guideline on production and control of allergen products for use in animals, which is foreseen to be adopted for release for public consultation at the December 2018.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 25-26 September 2018, and noted the agenda and the draft minutes of the meeting. The chair also reported on the PhVWP-V interested parties meeting held on 26 September 2018.

7.9 Novel therapy groups and related issues

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

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following document was circulated for information:

- Draft minutes of the ADVENT meeting held on 13 September 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 endorsed the revised templates for the MRL scientific overview and list of questions and the MRL assessment report.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee discussed the draft scientific advice by the Antimicrobial Advice Ad Hoc Expert Group (AMEG) on the categorisation of antimicrobials and the preliminary risk profiling for new antimicrobials and noted the feedback on the AMEG meeting held on 22 October 2018. The scientific advice, which will also be presented to CHMP for discussion, is foreseen to be adopted at the December 2018 CVMP meeting.
- The Committee received a verbal report on the 8th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 30 European countries in 2016.
- The Committee received a verbal report on the "Focus group meeting on dose optimisation of established veterinary antibiotics in the context of summary of product characteristics harmonisation" held on 12 October 2018, and noted the agenda and minutes of the meeting.
- The Committee noted the proposed draft guideline on integrated surveillance of antimicrobial resistance (CX/AMR 18/6/6), the proposed draft revision of the code of practice to minimize and contain foodborne antimicrobial resistance (CXC 61-2005, CX/AMR 18/6/5) and the EC request for comments. – *see also 6.2*

8.4 Pharmacovigilance

- The Committee noted the United States Food and Drug Administration alert (link) to veterinarians and pet owners about potential neurologic adverse reactions in dogs and cats receiving flea and tick treatment from the isoxazoline class of drugs and fact sheet (link) for pet owners and veterinarians.

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.

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.

- The Committee agreed to the transfer of all co-rapporteurships and peer review responsibilities from Brigitte Hauser to Ines Lindner and to Petra Falb.

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 11-12 October 2018 as well as the draft agenda of the meeting to be held on 8-9 November 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from K. Kivilahti-Mantyla on the CVMP presidency meeting held on 25-26 October 2018 in Helsinki, Finland.
- The Committee discussed the draft CVMP work plan for 2019, which is foreseen to be adopted at the December CVMP meeting.
- The Committee noted the nominations received for the appointment of CVMP co-opted members. The election of the co-opted members will take place at the December CVMP meeting.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 7 November 2018, and noted the agenda of the meeting and the minutes of the meeting held on 12 September 2018.
- The Committee received an update on Brexit operational preparedness.
- The Committee received an update on the EMA Regulatory Science Strategy 2020-2025 and noted the draft agenda of the public consultation veterinary stakeholder's workshop, to be held on 6 December at the EMA premises in London.
- The Committee received an update on the knowledge sharing package to support UK product portfolio transfer.
- The Committee deferred an update on the European Medicines Agency relocation to a future meeting of the Committee.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the November 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 November 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**	
AT	Petra Falb	Full involvement	
BG	Emil Kozhuharov	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	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 5.4 - Loxicom
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 9 – One item
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	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	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio	Full involvement	
FI	Katariina Kivilahti-Mantyla	Full involvement	
FR	Sylvie Louet	Full involvement	
IE	Mary O'Grady	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Maria Azevedo Mendes	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.			
AT	Barbara Zemann *(remotely)*	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Anke Finnah *(remotely)*	Full involvement	
DK	Niels Christian Kyvsgaard *(remotely)*	Full involvement	
ES	Mercedes Conradi *(remotely)*	Full involvement	
ES	Sonia Gil *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
UK	Rory Cooney	Full involvement	
UK	Ken Stapleton	Full involvement	
UK	Sam Fletcher *(remotely)*	Full involvement	
UK	John Mitchell *(remotely)*	Full involvement	
UK	Niall O'Brien *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	---
ERAWP	Jason Weeks - *remotely*
EWP-V	Cristina Muñoz
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard

CVMP working parties and CMDv	Chair
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	Rory Breathnach
SWP-V	Stefan Scheid - *remotely*

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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