EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 June 2019
EMA/345458/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Minutes of the 21-22 May 2019 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 6.1 and 12.

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

The attendance list was completed and competing interests were identified for the May 2019 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.*

### iv. Adoption of the minutes of the previous meeting

The minutes of the April 2019 meeting were adopted with minor amendments, under section 3.1.

### 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 (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **EVICTO** (EMEA/V/C/004973/0000), recommending the granting of a marketing authorisation. EVICTO is a new generic product for cats and dogs for the treatment and prevention of infestation and/or diseases caused by different species of fleas, worms, lice and mites. 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 (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the product **NASYM** (EMEA/V/C/004897/0000), recommending the granting of a marketing authorisation. NASYM is a new vaccine for the active immunisation of cattle to reduce virus shedding and respiratory clinical signs caused by bovine respiratory syncytial virus infection. 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 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 for dogs (EMEA/V/C/004846/0000). The Committee agreed that an oral explanation would not be requested, 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 product for cattle, pigs and sheep (EMEA/V/C/005073/0000). 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 to postpone the oral explanation for a new product for cats.
- The Committee adopted the EPAR module scientific discussion for **Baycox Iron** (EMEA/V/C/004794/0000) concerning the granting of the initial marketing authorisation.

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Bravecto Plus** (EMEA/V/C/004440/II/0003), 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 noted the summary of opinion for publication.
- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II grouped variation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/II/0030/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 (30 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation for **Clomicalm** (EMEA/V/C/000039/II/0027), 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 (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **MiPet Easecto**, **Stronghold Plus** and **Simparica** (EMEA/V/C/xxxxxx/WS1611), 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 (27 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type IB grouped variation (subject to a worksharing procedure) for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS1569/0047/G) and nationally-authorised products, 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 (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II grouped variation for **Melovem** (EMEA/V/C/000152/II/0011/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 (27 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II variation for **CYTOPOINT** (EMEA/V/C/003939/II/0005), 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 (27 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation for **CLYNAV** (EMEA/V/C/002390/II/0007), 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 (27 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0011/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.

### 3.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from Prevtec Microbia GmbH concerning a type II variation for **Coliprotec F4/F18** (EMEA/V/C/004225/II/0005), to add a new therapeutic indication. The adoption of the opinion is foreseen for the June 2019 CVMP meeting.

### 3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Quadrisol** (EMEA/V/C/000032/II/0038) to introduce a new pharmacovigilance system.
- The Committee endorsed a list of questions for a type II variation for **Panacur AquaSol** (EMEA/V/C/002008/II/0017), 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

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique following responses to the list of outstanding issues for the Article 35 referral procedure for **veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep** (EMEA/V/A/130). The Committee also noted a peer review report and the comments made by CVMP members. The adoption of the CVMP opinion is foreseen for the June 2019 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

- 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 following document was circulated for information:***

- Veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep – Article 35 referral (EMEA/V/A/126) – questions and answers for publication.

## 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 **Versican Plus DHPPi/L4** (EMEA/V/C/00/REC/001-002).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Versican Plus DHPPi/L4R** (EMEA/V/C/00/REC/001-002).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Versican Plus DHPPi/L4** (EMEA/V/C/00/REC/015).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Versican Plus DHPPi/L4R** (EMEA/V/C/00/REC/012.2).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/REC/026.1).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ZOLVIX** (EMEA/V/C/000154/REC/006).

### 5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 17.04.2019 – 23.05.2019:

| Product | Period |
|---|---|
| **Bravecto Plus** (EMEA/V/C/004440) | 08.05.2018 – 07.05.2019 |
| **Credelio** (EMEA/V/C/004247) | 25.04.2018 – 24.04.2019 |
| **CYTOPOINT** (EMEA/V/C/003939) | 25.04.2018 – 24.04.2019 |
| **Equilis StrepE** (EMEA/V/C/000078) | 07.05.2018 – 06.05.2019 |
| **Evalon** (EMEA/V/C/004013) | 18.04.2018 – 17.04.2019 |
| **Improvac** (EMEA/V/C/000136) | 11.05.2018 – 10.05.2019 |
| **LETIFEND** (EMEA/V/C/003865) | 20.04.2018 – 19.04.2019 |
| **Meloxidolor** (EMEA/V/C/002590) | 22.04.2018 – 21.04.2019 |
| **Naxcel** (EMEA/V/C/000079) | 19.05.2018 – 18.05.2019 |
| **Oncept IL-2** (EMEA/V/C/002562) | 03.05.2018 – 02.05.2019 |
| **Procox** (EMEA/V/C/002006) | 20.04.2018 – 19.04.2019 |
| **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993) | 17.05.2018 – 16.05.2019 |
| **Versican Plus DHPPi/L4** (EMEA/V/C/003678) | 07.05.2018 – 06.05.2019 |
| **Versican Plus DHPPi/L4R** (EMEA/V/C/002759) | 07.05.2018 – 06.05.2019 |
| **Zeleris** (EMEA/V/C/004099) | 15.05.2018 – 14.05.2019 |
| **Zulvac BTV** (EMEA/V/C/004185) | 25.04.2018 – 24.04.2019 |
| **Zuprevo** (EMEA/V/C/002009) | 06.05.2018 – 05.05.2019 |

### 5.4 Renewals

- There were no items for discussion.

### 5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.06.2018-20.11.2018 for **DRAXXIN** (EMEA/V/C/000077) with a recommendation to amend the product information.
- 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 |
|---|---|
| **Canigen L4 & Nobivac L4** (EMEA/V/C/004079) | 15.07.2012-31.12.2017 |
| **CLYNAV** (EMEA/V/C/002390) | 01.07.2018-31.12.2018 |
| **HALAGON** (EMEA/V/C/004201) | 01.07.2018-31.12.2018 |
| **Locatim** (EMEA/V/C/000041) | 01.01.2016-31.12.2018 |
| **Poulvac E. coli** (EMEA/V/C/002007) | 01.01.2018-31.12.2018 |
| **Sileo** (EMEA/V/C/003764) | 01.01.2018-31.12.2018 |

| | |
|---|---|
| **Vectra Felis** (EMEA/V/C/002746) | 01.01.2017-31.12.2018 |
| **ZUPREVO** (EMEA/V/C/002009) | 01.12.2015-30.11.2018 |

- 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.*

- There were no items for discussion.

***The following document was circulated for information:***

- Status report on PSURs for centrally authorised veterinary medicinal products.

## 6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

### 6.1 VICH

- The Committee endorsed the EU comments on the draft concept paper for a revision of VICH GL22 on reproduction testing to include the extended one generation reproduction toxicity study.
- The Committee endorsed the EU comments on the draft training slides on VICH pharmacovigilance guidelines.
- The Committee considered the VICH Anthelmintics GLs revision topic summary document prepared by the FDA (topic lead), where proposed changes for the revision of the guidelines and their outcome are listed. A number of the topics highlighted as still pending were discussed and an EU position was agreed. Further issues requiring discussion and agreement will be brought to the June CVMP meeting.
- The Committee endorsed the VICH GL59 on harmonisation of criteria to waive laboratory animal batch safety testing (LABST) for vaccines for veterinary use for sign off at step 2.
- The Committee agreed that a new expert, possibly to be supported by an adviser, should be nominated to represent the EU at the Bioequivalence Expert Working Group and noted that a call for nominations will be circulated shortly. The nominations received will be further discussed at the June 2019 CVMP meeting.

### 6.2 Codex Alimentarius

- There were no items for discussion.

### 6.3 Other EU bodies and international organisations

- The Committee discussed the EFSA request to nominate an expert representing the Agency to contribute to the European Commission mandate for an EFSA scientific opinion as regards specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, and agreed for D. Bouchard to represent CVMP as an expert. – *see also 8.3*.

***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 21 May 2019, and noted the agenda of the meeting. The SAWP-V chair presented a summary report on the reflections on the functioning of SAWP-V.
- The Committee elected F. Hasslung Wikström as the new chair of the SAWP-V for a 3-year term.

### 7.2 Quality Working Party (QWP)

- There were no items for discussion.

### 7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

### 7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

### 7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

### 7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

### 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

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

- There were no items for discussion.

### 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 15 April 2019;
- Draft agenda for PhVWP-V to be held on 28-29 May 2019.

## 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

*Information relating to certain topics discussed under section 8.2 at this meeting cannot be released at the present time as it is deemed to be confidential.*

### 8.3 Antimicrobial resistance

- The Committee discussed the EFSA request to nominate an expert representing the Agency to contribute to the European Commission mandate for an EFSA scientific opinion as regards specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed, and agreed for D. Bouchard to represent CVMP as an expert. – *see also 6.3*.

### 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.*

## 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 16-17 April 2019 as well as the draft agenda of the meeting held on 23-24 May 2019.

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee re-elected D. Murphy as the chair of the Committee for Medicinal Products for Veterinary Use (CVMP) for a final 3-year term.

- The Committee received a brief verbal report from the CVMP chair on the CVMP presidency meeting held on 6-8 May 2019 at Lake Balaton, Hungary, highlighting the meeting report.
- The Committee noted the invitation to the CVMP/CMDv informal presidency meeting to be held on 25-27 September 2019 in Haikko Manor, Finland, under the Finnish presidency.
- The Committee noted the upcoming discussion on the status of the CVMP work plan for 2019 at the June 2019 CVMP meeting.

## 13. LEGISLATION

- The Committee received verbal reports from the expert group leaders on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.

## 14. ANY OTHER BUSINESS

- Upon the completion of the May 2019 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 May 2019 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 | |
| BE | Bruno Urbain | Full involvement | |
| DE | Gesine Hahn | Full involvement | |
| DK | Niels Christian Kyvsgaard | Full involvement | |
| EE | Toomas Tiirats | Full involvement | |
| ES | Cristina Muñoz Madero | Full involvement | |
| FI | Tita-Maria Muhonen | **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 for: | • 5.5 Sileo |
| FR | Jean-Claude Rouby | Full involvement | |
| HR | Frane Božić | Full involvement | |
| HU | Gábor Kulcsár | Full involvement | |
| IE | J. Gabriel Beechinor | Full involvement | |
| IT | Paolo Pasquali | Full involvement | |
| LT | Snieguolė Trumpickaitė Dzekčiorienė | Full involvement | |
| LU | Marc Schmit | Full involvement | |
| LV | Zanda Auce | Full involvement | |
| PL | Anna Wachnik-Święcicka | Full involvement | |
| PT | João Pedro Duarte da Silva | Full involvement | |
| RO | Lollita Taban | Full involvement | |
| SE | Frida Hasslung Wikström | 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 | Ricardo Carapeto | 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 | |
| BG | Svetoslav Branchev | Full involvement | |
| CZ | Leona Nepejchalová | Full involvement | |
| DE | Esther Werner | Full involvement | |
| EL | Angeliki Tsigouri | Full involvement | |
| FR | Sylvie Louet | Full involvement | |
| NL | Jacqueline Poot | Full involvement | |
| PL | Ewa Augustynowicz | Full involvement | |
| SI | Maja Turk | Full involvement | |
| UK | Rory Cooney | 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 | Beate Gasser – *remotely* | Full involvement | |
| DE | Andrea Golombiewski | Full involvement | |
| DE | Anke Finnah – *remotely* | Full involvement | |
| ES | Carlos Ballesteros Vicente – *remotely* | Full involvement | |
| ES | Maria Dominguez Nicolas – *remotely* | Full involvement | |
| ES | Patricia Vera Luque – *remotely* | Full involvement | |
| ES | Raul Belmar Liberato – *remotely* | Full involvement | |
| ES | Susana Casado Hernandez – *remotely* | Full involvement | |
| FI | Kristina Lehmann – *remotely* | Full involvement | |
| FI | Martti Nevalainen – *remotely* | Full involvement | |
| FR | Gerard Moulin – *remotely* | Full involvement | |
| IE | Sara Buckley – *remotely* | Full involvement | |
| NL | Peter Hekman – *remotely* | Full involvement | |
| NO | Kari Grave – *remotely* | Full involvement | |
| PL | Anita Piwowarczyk | Full involvement | |
| UK | Sharon Reynolds – *remotely* | Full involvement | |
| UK | Stephen Spencer – *remotely* | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| ADVENT | Jean-Claude Rouby |
| AWP | Christine Schwarz |
| CMDv | --- |
| ERAWP | Ricardo Carapeto García |
| EWP-V | Cristina Muñoz Madero |
| IWP | Esther Werner |
| J3Rs WG | --- |
| PhVWP-V | Els Dewaele - *remotely* |
| QWP | --- |
| 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 |