8 November 2016
EMA/CVMP/737245/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Minutes of the 4-6 October 2016 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 interests were identified for the October 2016 meeting. In accordance with the Agency's policy and procedure on the handling of declarations of 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 Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

### iii. Declaration of contacts between members and companies with regard to points on the agenda

*Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.*

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

The minutes of the September 2016 meeting were adopted with no amendments.

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

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

## 1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

### 1.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs for **fluralaner** (EMEA/V/MRL/004380/FULL/0001) in chicken tissues and eggs. The Committee also agreed to extrapolate these MRLs to tissues and eggs of other poultry species. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU Reference Laboratory, two peer review reports and the summary of opinion for publication.

### 1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

### 1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in Salmonidae for a substance (EMEA/V/MRL/004481/FULL/0001), following discussion of the rapporteur's revised assessment report and two peer review reports.

### 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 majority (24 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **VarroMed** (EMEA/V/C/002723/0000), recommending the granting of a marketing authorisation. VarroMed is an antiparasitic product for in-hive use for the treatment of varroosis in honey bees. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. K. Baptiste, C. Ibrahim, W. Schlumbohm and B. Urbain signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.

- 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 the generic product **HALAGON** (EMEA/V/C/004201/0000), recommending the granting of a marketing authorisation. HALAGON is an antiparasitic (antiprotozoal) product for the reduction and prevention of diarrhoea due to infection with *Cryptosporidium parvum* in newborn calves. The

Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for the generic product **Cepedex** (EMEA/V/C/004376/0000), recommending the granting of a marketing authorisation. The product is a solution for injection containing dexmedetomidine hydrochloride for sedation and analgesia of dogs and cats. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

### 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 an extension application for **EQUIOXX** (EMEA/V/C/000142/X/0015), to add a new pharmaceutical form for horses. The Committee noted a peer review report and the comments received from CVMP members.
- 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 vaccine for sheep (EMEA/V/C/004185/0000). The Committee 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 musculo-skeletal disorder in horses (EMEA/V/C/004265/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview, including the list of questions, and agreed comments on the draft product information for an extension application for **Zactran** (EMEA/V/C/000129/X/0034), to add a new target species. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview, including the list of questions, and agreed comments on the draft product information for a new vaccine for pigs (EMEA/V/C/004276/0000). The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview, including the list of questions, and agreed comments on the draft product information for a new vaccine for pigs (EMEA/V/C/004364/0000). 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 was informed of the formal notification from Shernacre Enterprise Ltd of their decision to withdraw their application for a new marketing authorisation for **Somnena** (EMEA/V/C/004293/0000), an analgesic product for cats. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

- The Committee was informed of the corrections to the EPAR module scientific discussion for **ERAVAC** (EMEA/V/C/004239/0000).

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped worksharing type IB variation for **Virbagen Omega** and **CaniLeish** (EMEA/V/C/xxxxxx/WS/0929/G), recommending the variation of the marketing authorisations to implement quality changes. The Icelandic and Norwegian CVMP members 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 Eli Lilly and Company Ltd concerning a type II variation for **Trifexis** (EMEA/V/C/002635/II/0008), to add a new therapeutic indication. The adoption of the opinion is foreseen for the November 2016 CVMP meeting.
- The Committee adopted the list of outstanding issues to be addressed in writing for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0011), concerning changes in the SPC.

### 3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **COXEVAC** (EMEA/V/C/000155/II/0011), concerning quality changes.
- The Committee adopted the list of questions for a type II variation for **NEXGARD SPECTRA** (EMEA/V/C/003842/II/0008), to add new therapeutic indications.

### 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 agreed to the request from Zoetis for a 3-month extension to the clock-stop for the referral procedure for **Lincocin and its associated names** (EMEA/V/A/123), and adopted a revised timetable for the procedure.

### 4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique on the marketing authorisation holders' responses to list of outstanding issues, and the revised rapporteur's assessment report with co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** (EMEA/V/A/117). The Committee noted the comments made by CVMP members and agreed that no outstanding issues remained. The

adoption of the CVMP opinion and assessment report is foreseen for the November 2016 meeting of the Committee.

- The Committee discussed the updated rapporteur's assessment report including the co-rapporteur's critique following marketing authorisation holders' responses to the list of outstanding issues for the referral procedure for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118). The Committee agreed to the request from aniMedica to provide an oral explanation and adopted a revised timetable for the procedure.

### 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

- There were no items for discussion.

## 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 condition for **EVALON** (EMEA/V/C/004013/ANX/001.1).

### 5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 09.09.2016 – 06.10.2016:

| Product | Period |
|---|---|
| **Aivlosin** (EMEA/V/C/000083) | 09/09/2015 – 08/09/2016 |
| **Trocoxil** (EMEA/V/C/000132) | 09/09/2015 – 08/09/2016 |
| **Nobivac Bb** (EMEA/V/C/000068) | 10/09/2015 – 09/09/2016 |
| **APOQUEL** (EMEA/V/C/002688) | 12/09/2015 – 10/09/2016 |
| **Previcox** (EMEA/V/C/000082) | 13/09/2015 – 12/09/2016 |
| **Recocam** (EMEA/V/C/002247) | 13/09/2015 – 12/09/2016 |
| **RHINISENG** (EMEA/V/C/000160) | 16/09/2015 – 15/09/2016 |
| **Trifexis** (EMEA/V/C/002635) | 19/09/2015 – 18/09/2016 |

| Product | Period |
|---|---|
| **Palladia** (EMEA/V/C/000150) | 23/09/2015 – 22/09/2016 |
| **Cerenia** (EMEA/V/C/000106) | 29/09/2015 – 28/09/2016 |
| **COXEVAC** (EMEA/V/C/000155) | 30/09/2015 – 29/09/2016 |
| **Recuvyra** (EMEA/V/C/002239) | 06/10/2015 – 05/10/2016 |

### 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 **Activyl Tick Plus** (EMEA/V/C/002234/R/0009), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **ZULVAC 1+8 Bovis** (EMEA/V/C/002473/R/0009), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members 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 01.06.2015 - 31.05.2016 for **CERTIFECT** (EMEA/V/C/002002) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.12.2015 – 31.05.2016 for **Porcilis PCV M Hyo** (EMEA/V/C/003796) with a recommendation to amend the SPC.
- The Committee adopted the following CVMP assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

| Product | Period |
|---|---|
| **Advocate** (EMEA/V/C/000076) | 01.05.2013 – 30.04.2016 |
| **APOQUEL** (EMEA/V/C/002688) | 01.12.2015 – 31.05.2016 |
| **BLUEVAC BTV8** (EMEA/V/C/000156) | 01.07.2015 – 30.06.2016 |
| **Comfortis** (EMEA/V/C/002233) | 01.04.2013 – 31.12.2015 |
| **EQUIP WNV** (EMEA/V/C/000137) | 01.12.2015 – 31.05.2016 |
| **MS-H Vaccine** (EMEA/V/C/000161) | 15.06.2015 – 14.06.2016 |
| **Naxcel** (EMEA/V/C/000079) | 01.06.2013 – 31.05.2016 |
| **RevitaCAM** (EMEA/V/C/002379) | 01.03.2016 – 26.05.2016 |
| **Simparica** (EMEA/V/C/003991) | 06.11.2015 – 31.05.2016 |
| **Suvaxyn Circo MH RTU** (EMEA/V/C/003924) | 06.11.2015 – 31.05.2016 |
| **Zycortal** (EMEA/V/C/003782) | 06.11.2015 – 31.05.2016 |

- 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 discussed the revised draft concept paper for a general guideline on pharmaceutical combination products.
- The Committee discussed the comments received/made from the VICH expert working group members on the EU proposal for a draft guideline on use of cell cultures for detection of extraneous viruses. The comments from the VICH EWP will be forwarded to the IWP for further consideration.
- The Committee endorsed the draft EU comments on topic 1 of the revision of the anthelmintics guidelines (i.e. VICH GLs 7, 12, 13, 14, 15, 16, 19, 20 and 21).

### 6.2 Codex Alimentarius

- There were no items for discussion.

### 6.3 Other EU bodies and international organisations

- The Committee deferred the verbal report from the 2nd EMA/JECFA liaison meeting held on 26 September 2016 to the November 2016 CVMP meeting.
- The Committee discussed the JECFA draft guidance document for the establishment of an acute reference dose (ARfD) for veterinary drug residues in food, which is published for consultation until 31 December 2016. The SWP-V will develop draft comments for discussion at its November meeting and endorsement at the December CVMP meeting.

***The following documents were circulated for information:***

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Presentation on “Managing resistance to anthelmintics” for the Regional Seminar for OIE National Focal Points for Veterinary Products (4th Cycle) held on 11-13 October 2016 in Budapest, Hungary.

## 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 4 October 2016, and noted the agenda of the meeting.
- The Committee elected unanimously Frida Hasslung Wikström as vice-chair of the SAWP-V for a 3-year term.

### 7.2 Quality Working Party (QWP)

- The Committee deferred the verbal report on the meeting held on 19–21 September 2016 to the November 2016 CVMP meeting.
- The Committee adopted the question and answer document on the deletion of a non-significant specification parameter.

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

- The Committee deferred the verbal report from the chair of the SWP-V on the meeting held on 22-23 September 2016 to the November 2016 CVMP meeting.
- The Committee was informed of the upcoming election of the chair of the SWP-V for a 3-year term at the December 2016 CVMP meeting. A call for nominations would be circulated by the Secretariat.

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

- The Committee appointed Ricardo Carapeto and Adam Lillicrap as new members of the ERAWP.

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

- The Committee deferred the verbal report from the chair of the EWP-V on the meeting held on 13-14 September 2016 to the November 2016 CVMP meeting.

### 7.6 Antimicrobials Working Party (AWP)

- The Committee deferred the verbal report from the chair of the AWP on the meeting held on 22-23 September 2016 to the November 2016 CVMP meeting.

### 7.7 Immunologicals Working Party (IWP)

- The Committee noted the upcoming election of the chair of the IWP for a 3-year term at the December 2016 CVMP meeting. A call for nominations would be circulated by the Secretariat.

### 7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee deferred the verbal report from the chair of the PhVWP-V on the meeting held on 27-28 September 2016, and on the PhVWP-V interested parties meeting to the November 2016 CVMP meeting.
- The Committee discussed the overview of comments received on the draft reflection paper on non-spontaneous adverse event reports (peer-reviewed literature, internet and social media) (EMA/CVMP/PhVWP/357539/2015), and agreed for the PhVWP-V to proceed with the revision of the reflection paper.
- The Committee noted the upcoming election of the chair of the PhVWP-V for a 3-year term at the December 2016 CVMP meeting. A call for nominations would be circulated by the Secretariat.

### 7.9 Novel therapy groups and related issues

### 7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- The Committee endorsed Klaus Cussler as veterinary speaker at the European Commission scientific conference on ‘Non-Animal Approaches - The Way Forward’, to be held on 6-7 December 2016 in Brussels.

### 7.11 Other working party and scientific group issues

The Committee discussed the draft work plans of the CVMP working parties and expert groups, foreseen to be adopted at the November 2016 meeting of the Committee.

- The SAWP-V draft work plan for 2017.
- The QWP draft work plan for 2017.
- The SWP-V draft work plan for 2017.
- The ERAWP draft work plan for 2017.
- The EWP-V draft work plan for 2017.
- The AWP draft work plan for 2017.
- The IWP draft work plan for 2017.
- The PhVWP-V draft work plan for 2017.
- The ADVENT draft work plan for 2017.
- The JEG 3Rs draft work plan for 2017.

***The following documents were circulated for information:***

- Draft agenda of the IWP meeting held on 19-20 October 2016;
- Training programme of IWP assessors training 'Efficacy of immunological veterinary medicinal products: Focus on challenge studies, duration of immunity and influence of maternally derived antibodies' held on 20-21 October 2016.

## 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

- There were no items for discussion.

### 8.3 Antimicrobial resistance

- The Committee adopted the revised CVMP strategy on antimicrobials 2016-2020 (EMA/CVMP/209189/2015) and the response to the comments received following the close of the public consultation (EMA/CVMP/185871/2016).
- The Committee endorsed the draft terms of reference for the CVMP/MAHs pilot project on the harmonisation of SPCs related to authorised "old" veterinary antibiotics.
- The Committee received a verbal report on the Reduction of the Need for Antimicrobials in Food Producing Animals (RONAFA) meeting held on 20 September 2016, and discussed the draft joint EMA/EFSA scientific opinion of the RONAFA Advisory Group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU.

- The Committee noted the presentation from K. Baptiste on the update on the European Agencies reports on antimicrobial resistance at the Regional Seminar for OIE National Focal Points for Veterinary Products, held on 11-13 October 2016 in Budapest, Hungary.

### 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.

***The following documents were circulated for information:***

- FAO Action Plan on Antimicrobial resistance 2016-2020;
- Drug Resistant Infections - A threat of our economic future - World Bank Sept 2016;
- 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) meeting held on 9 September 2016, draft minutes;
- Hermes EOS roundtable on Bee Welfare, 11 October 2016, London-UK (http://uksif.org/events/hermes-eos-roundtable-on-bee-welfare/).

## 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.*

- The Committee endorsed the analysis of the industry's recommendations adopted by the CVMP ad hoc group on veterinary vaccine availability (CADVVA), and was informed a redacted version of the document will be published on the EMA website, and that one of the priorities listed in the document relates to a workshop to discuss efficacy field trials, planned to take place in 2017. The Committee also endorsed the minutes of the CADVVA meeting held on 25 August 2016 and noted the draft minutes from CADVVA meeting held on 22 September 2016.

## 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 reviewer responsibilities from C. Friis to E.-M. Vestergaard.

### 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 deferred the verbal report from the chair of CMDv on the meetings held on 14-15 July 2016 and on 8-9 September 2016 to the November 2016 CVMP meeting, and noted the

draft minutes of the September meeting as well as the draft agenda of the meeting held on 6-7 October 2016.

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee re-elected Rory Breathnach and Wilhelm Schlumbohm as co-opted members for a further 3-year mandate to respectively complement its expertise in large and small animal clinical practice and in the quality of pharmaceuticals. The Committee elected Gerrit Johan Schefferlie as a co-opted member with specific expertise in residue metabolism, pharmacokinetics and MRL assessment for a 3-year mandate.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 5 October 2016, and noted the agenda of the meeting and the minutes of the meeting held on 12 July 2016.
- The Committee received a verbal update on the EMA eSubmission Gateway, the use of which will be mandatory for all veterinary submissions from 1 January 2017. Plans for a common repository for veterinary submissions in the centralised procedure will be presented at the November 2016 CVMP meeting.
- The Committee deferred the report to the revision of the dossier submission requirements for submission of marketing authorisation and MRL applications to the EMA and to members of the CVMP to the November 2016 CVMP meeting.
- The Committee noted the CVMP meeting dates for 2017.

## 13. LEGISLATION

- There were no items for discussion.

## 14. ANY OTHER BUSINESS

- Upon the completion of the October 2016 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 October 2016 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 | Barbara Zemann | Cannot act as rapporteur or peer reviewer for: | • 9. one item |
| BE | Bruno Urbain | Full involvement | |
| BG | Emil Kozhuharov | Full involvement | |
| CY | Alia Michaelidou | Full involvement | |
| CZ | Jiří Bureš | Full involvement | |
| DE | Cornelia Ibrahim | 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 | Ljiljana Markuš-Cizelj | Full involvement | |
| HU | Gábor Kulcsár | Full involvement | |
| IE | J. Gabriel Beechinor | Full involvement | |
| LV | Zanda Auce | Full involvement | |
| NL | Peter Hekman | Full involvement | |
| PT | João Pedro Duarte da Silva | Full involvement | |
| RO | Lollita Taban | Full involvement | |
| SE | Eva Lander Persson | Full involvement | |
| SI | Stane Srčič | Cannot act as rapporteur or peer reviewer for: | • 4.3 Gentamicin (EMEA/V/A/117) |
| UK | Helen Jukes | Full involvement | |
| Co-opted | Keith Baptiste | Full involvement | |
| Co-opted | Rory Breathnach | Full involvement | |
| Co-opted | Christian Friis | Full involvement | |
| Co-opted | Wilhelm Schlumbohm | Full involvement | |
| Co-opted | Jason Weeks | No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for: | • 1.3 EMEA/V/MRL/004481/FULL/0001 |
| IS | Jóhann Lenharðsson | Full involvement | |

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| BE | Frédéric Klein | Full involvement | |
| DE | Esther Werner | Full involvement | |
| ES | Consuelo Rubio Montejano | Cannot act as rapporteur or peer reviewer for: | • 1.1 Fluralaner (EMEA/V/MRL/004380/FULL/0001)<br>• 3.2 Bravecto (EMEA/V/C/002526/II/0011)<br>• 5.4 Activyl Tick Plus (EMEA/V/C/002234/R/0009)<br>• 5.5 Porcilis PCV M Hyo |
| FR | Sylvie Louet | Full involvement | |
| NL | G. Johan Schefferlie | Full involvement | |
| PL | Ewa Augustynowicz | Full involvement | |
| SE | Frida Hasslung Wikström | Full involvement | |
| SK | Eva Chobotová | 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 | Petra Falb - *remotely* | Full involvement | |
| AT | Martin Spruth - *remotely* | Full involvement | |
| CZ | Radka Smitalova - *remotely* | Full involvement | |
| DE | Karin Duchow - *remotely* | Full involvement | |
| DE | Anke Finnah - *remotely* | Full involvement | |
| DE | Ingun Lemke - *remotely* | Full involvement | |
| DE | Stefan Scheid - *remotely* | Full involvement | |
| DE | Yasemin Süzer - *remotely* | Full involvement | |
| ES | Ricardo Carapeto García - *remotely* | Full involvement | |
| ES | Mercedes Conradi Moner - *remotely* | Full involvement | |
| ES | Sonia Gil Morales - *remotely* | Full involvement | |
| ES | María Amparo Haro Castuera - *remotely* | Full involvement | |
| ES | Javier Martínez de Velasco - *remotely* | Full involvement | |
| ES | María C. Porrero Calonge - *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 |
|---|---|---|---|
| FR | Jean-Christophe Faucon - *remotely* | Full involvement | |
| FR | Florence Pillet- *remotely* | Full involvement | |
| UK | Sam Fletcher - *remotely* | Full involvement | |
| UK | Rutendo Manyarara - *remotely* | Full involvement | |
| UK | Niall O'Brien - *remotely* | Full involvement | |
| UK | Javier Pozo - *remotely* | Full involvement | |
| UK | Jean-Paul Schmidt- *remotely* | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| ADVENT | Jean-Claude Rouby |
| AWP | Helen Jukes |
| CMDv | -- |
| ERAWP | Jason Weeks |
| EWP-V | Gesine Hahn |
| IWP | Esther Werner |
| PhVWP-V | -- |
| QWP | -- |
| 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 |