10 March 2015
EMA/CVMP/163850/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Minutes of the 10-12 February 2015 meeting

Chair: A. Holm – Vice-chair: D. Murphy

**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 February 2014 meeting. In accordance with the Agency's revised 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.

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### 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.

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

The minutes of the January 2015 meeting were adopted with a minor amendment.

### 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 (30 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report, recommending the extension of MRLs to poultry for **diethylene glycol monoethyl ether** (EMEA/V/MRL/003307/EXTN/0003). Furthermore, and with reference to Article 5 of Regulation (EC) No 470/2009, the Committee agreed to extrapolate these MRLs to all food producing species. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted a peer review report, the comments received from CVMP members and the summary of opinion for publication.

### 1.2 Oral explanations and lists of outstanding issues

- The Committee discussed the rapporteurs' assessment of the responses to the list of questions and the rapporteurs' EPMAR for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003923/FULL/0001), and adopted a list of outstanding issues that should be addressed in an oral explanation. The adoption of the opinion is foreseen for the May 2015 meeting of the Committee.

### 1.3 Lists of questions

- There were no items for discussion.

### 1.4 Re-examination of CVMP opinions

- The Committee noted the request from the applicant for the re-examination, under Article 8(3) of Regulation (EC) No 470/2009, of the MRLs recommended in bovine species for **sisapronil** and appointed a rapporteur and a co-rapporteur for the procedure. The Committee agreed on the proposed timelines. The adoption of the opinion is foreseen for the May 2015 meeting of the Committee.

### 1.5 Other issues

- There were no items for discussion.

## 2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

### 2.1 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 **Metacam** (EMEA/V/C/000033/X/0107), recommending the extension of the marketing authorisation to include a new strength, 40 mg/ml solution for injection for cattle and horses. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

### 2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new psycholeptic product for dogs (EMEA/V/C/003764/0000). The Committee discussed the draft product information and noted two peer review reports and the comments received from CVMP members.

### 2.3 Lists of questions

- The Committee adopted the scientific overview and benefit-risk assessment, including the list of questions, and agreed comments on the draft product information for a new viral and bacterial vaccine for pigs (EMEA/V/C/003924/0000). The Committee noted two peer review reports and the comments received from CVMP members.

### 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 Lodipressin (EMEA/V/C/003786/0000), a cardiovascular product for cats, and appointed a rapporteur and a co-rapporteur for the procedure. The Committee agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG).

### 2.5 Other issues

- The Committee agreed to the request from the applicant for a 2 month extension to the clock-stop for a new corticosteroid product for dogs (EMEA/V/C/003782/0000).
- The Committee agreed to the request from the applicant for a 2 month extension to the clock-stop for a new cardiovascular product for dogs (EMEA/V/C/002804/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Bovela** (EMEA/V/C/003703/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **ZULVAC SBV** (EMEA/V/C/002781/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Stronghold** (EMEA/V/C/000050/X/0051/G) concerning the extension of the marketing authorisation.

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped type II variation for **Suvaxyn PCV** (EMEA/V/C/000149/II/0017/G), recommending the variation of the marketing authorisation. The Icelandic 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 the CVMP assessment report for a type II variation for **NexGard** (EMEA/V/C/002729/II/0001), recommending the variation of the marketing authorisation to change the SPC and the package leaflet. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Zuprevo** (EMEA/V/C/002009/II/0006/G), recommending the variation of the marketing authorisation to add a new therapeutic indication and to delete a precautionary statement. The Icelandic 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 the CVMP assessment report for a quality worksharing type IB variation for **Novem** and **Metacam** (EMEA/V/C/xxxxxx/WS/0667), recommending the variation of the marketing authorisations. The Icelandic 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 the list of questions for a type II variation for **Nobivac L4** (EMEA/V/C/002010/II/0003), to change the SPC and the package leaflet.

### 3.4 Re-examination of CVMP opinions

- There were no items for discussion.

### 3.5 Other issues

- The Committee refused the request from the MAH for an extension to the clock-stop for a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0031), to add a new indication.

## 4. REFERRALS AND RELATED PROCEDURES

### 4.1 Article 33 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report and the co-rapporteur's assessment report for the referral procedure for **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** (EMEA/V/A/108), and noted the request from the applicant to provide an oral explanation. The Committee considered that there are outstanding points where clarification is required, and adopted a list of outstanding issues for the applicant to address in writing and at an oral explanation, and a revised timetable for the procedure. The oral

explanation is scheduled for the April 2015 meeting of the Committee. The adoption of the CVMP opinion is foreseen for the May 2015 meeting of the Committee. The Committee noted four peer review reports and the comments made by CVMP members.

### 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 discussed the rapporteur's assessment report for the procedure concerning **the potential risk for the consumer resulting from the use of lidocaine in food producing species** (EMEA/V/A/092). The Committee noted the comments received from the co-rapporteur. The Committee discussed the proposals for responses to the questions posed by the Netherlands. The adoption of the CVMP opinion and assessment report is foreseen for the March 2015 meeting of the Committee.

### 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 relating to certain topics discussed under section 5.1 at this meeting cannot be released at the present time as it is deemed to be confidential.*

### 5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition and a recommendation for **Porcilis ColiClos** (EMEA/V/C/002011/ANX002, REC012).

### 5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 16/01/2015 – 12/02/2015:

| Product | Period |
|---|---|
| **Bravecto** (EMEA/V/C/002526) | 11/02/2014 – 10/02/2015 |
| **Comfortis** (EMEA/V/C/002233) | 11/02/2014 – 10/02/2015 |

| Product | Period |
|---|---|
| **Dicural** (EMEA/VC/000031) | 16/01/2014 – 15/01/2015 |
| **Fevaxyn Pentofel** (EMEA/V/C/000030) | 05/02/2014 – 04/02/2015 |
| **Hiprabovis IBR Marker Live** (EMEA/V/C/000158) | 27/01/2014 – 26/01/2015 |
| **Ingelvac CircoFLEX** (EMEA/V/C/000126) | 13/02/2014 – 12/02/2015 |
| **Kexxtone** (EMEA/V/C/002235) | 28/01/2014 – 27/01/2015 |
| **Loxicom** (EMEA/V/C/000141) | 10/02/2014 – 09/02/2015 |
| **NexGard** (EMEA/V/C/002729) | 11/02/2014 – 10/02/2015 |
| **Nobilis OR inac** (EMEA/V/C/000062) | 24/01/2014 – 23/01/2015 |
| **PIRSUE** (EMEA/V/C/000054) | 29/01/2014 – 28/01/2015 |
| **STARTVAC** (EMEA/V/C/000130) | 11/02/2014 – 10/02/2015 |
| **Slentrol** (EMEA/V/C/000116) – MA withdrawn | 13/04/2014 – 15/01/2015 |
| **TruScient** (EMEA/V/C/002000) – MA withdrawn | 14/12/2014 – 15/01/2015 |

### 5.4 Renewals

- There were no items for discussion.

### 5.5 Pharmacovigilance – PSURs and SARs

- The Committee was informed of the progress update report for the post-authorisation study for **Trifexis** (EMEA/V/C/002635).
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage for:

| Product | Period |
|---|---|
| **Aivlosin** (EMEA/V/C/000083) | 01.04.2014 – 30.09.2014 |
| **CaniLeish** (EMEA/V/C/002232) | 01.10.2013 – 30.09.2014 |
| **Comfortis** (EMEA/V/C/002233) | 01.04.2014 – 30.09.2014 |
| **Econor** (EMEA/V/C/000042) | 01.04.2014 – 30.09.2014 |
| **Meloxidolor** (EMEA/V/C/002590) | 22.04.2014 – 22.10.2014 |
| **Previcox** (EMEA/V/C/000082) | 01.10.2011 – 30.09.2014 |
| **ProteqFlu** (EMEA/V/C/000073) | 01.04.2013 – 30.09.2014 |
| **ProteqFlu-Te** (EMEA/V/C/000074) | 01.04.2013 – 30.09.2014 |
| **Recocam** (EMEA/V/C/002247) | 01.04.2014 – 30.09.2014 |
| **ZULVAC 1+8 Bovis** (EMEA/V/C/002473) | 01.04.2014 – 30.09.2014 |

| | |
|---|---|
| **ZULVAC 1+8 Ovis** (EMEA/V/C/002251) | 01.04.2014 – 30.09.2014 |

- The Committee endorsed the list of products and calendar for signal detection analysis.

### 5.6 Supervisions and sanctions

*Information relating to supervisions and sanctions will not be published as it would be undermining the purpose of such inspections.*

***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 draft VICH guideline GL53 on electronic exchange of documents: electronic file formats, from the VICH Expert Working Group on Electronic File Formats (EFF), for sign-off by the VICH Steering Committee at step 6 of the VICH procedure, for implementation at step 7.
- The Committee endorsed the draft EU comments on topics 5 (new indications) and 6 (Faecal Egg Count Reduction Tests) of the VICH Task Force on the revision of anthelmintic guidelines.
- The Committee supported the proposal for the continuation of the work by the VICH ESI Expert Working Group on the maintenance of pharmacovigilance guidelines by the Expert Working Group chair and to address the prioritization and organization of the maintenance of the lists under VICH GL30 on pharmacovigilance: controlled list of terms.
- The Committee noted the meeting documents for the VICH Steering Committee meeting to be held on 23-26 February 2015 in Washington DC, USA.
- The Committee adopted the revised VICH guideline GL48(R) on studies to evaluate the metabolism and residues kinetics of veterinary drugs in food-producing animals: market residue depletion studies to establish product withdrawal periods, for publication and implementation.
- The Committee adopted the revised VICH guideline GL49(R) on studies to evaluate the metabolism and residues kinetics of veterinary drugs in food-producing animals: validation of analytical methods used in residue depletion studies, for publication and implementation.

### 6.2 Codex Alimentarius

- There were no items for discussion.

### 6.3 Other EU bodies and international organisations

- The Committee noted a request from the European Commission to EFSA for a risk assessment on the presence of malachite green in food of animal origin.

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

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Preliminary opinion on Synthetic Biology II. Risk assessment methodologies and safety aspects from the European Commission scientific committees SCHER, SCENIHR and SCCS.

## 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 10 February 2015, and noted the agenda of the meeting.

### 7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 3–5 February 2015.
- The Committee adopted the question and answer document on plastic containers for eye drops.
- The Committee was informed of the final QWP work programme for 2015.

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

- There were no items for discussion.

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

- The Committee received a verbal report from the chair of the ERAWP on the meeting held on 27-28 January 2015, and noted the agenda and the minutes of the meeting.
- The Committee received a verbal report on the Cefic-LRI sponsored workshop on recent scientific developments in bioaccumulation research, held at the ECHA in Helsinki-Finland, on 24 September 2014.

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

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 3-4 February 2015.
- The Committee adopted the revised draft guideline on the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/261180/2012), for a 3-month period of public consultation. The Committee also adopted the overview of comments received during the first public consultation (EMA/CVMP/EWP/737951/2013).

### 7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the draft guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (EMA/CVMP/AWP/706422/2013), for a 6-month period of public consultation.
- The Committee received a verbal report from the chair of the AWP on the meeting held on 20-21 January 2015, and noted the agenda of the meeting.

### 7.7 Immunologicals Working Party (IWP)

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

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 27-28 January 2015, and noted the agenda of the meeting.
- The Committee endorsed the veterinary pharmacovigilance 2014 - public bulletin (EMA/CVMP/793263/2014).

### 7.9 Novel therapy groups and related issues

- The Committee received a verbal report from the chair of the ADVENT on the meeting held on 15 January 2015, and noted the draft minutes of the meeting.

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

- There were no items for discussion.

### 7.11 Other working party and scientific group issues

- The Committee adopted the revised mandates, objectives and rules of procedure to reflect the new EMA policy on handling of declarations of interests for:
  - SAWP-V (EMA/CVMP/SAWP/676117/2010-rev.4);
  - SWP-V (EMA/CVMP/SWP/131613/2004-rev.4);
  - ERAWP (EMA/CVMP/ERA/705470/2009-rev.2);
  - EWP-V (EMA/CVMP/EWP/208686/2004-rev.2);
  - AWP (EMA/CVMP/AWP/749774/2012-rev.2);
  - IWP (EMA/CVMP/IWP/208689/2004-rev.2);
  - PhVWP-V (EMA/CVMP/PhVWP/133883/2004-rev.4);
  - JEG 3Rs (EMA/CHMP/CVMP/JEG-3Rs/442724/2012-rev.1);
  - ADVENT (EMA/CVMP/ADVENT/630299/2014-rev.1).

## 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 include **polyethylene glycol-8 beeswax** and **octadecenoyloxyethyl–heptadecenyl-hydroxyethylimidazolinium chloride (DOTIM)** as new entries in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients and adopted a revised list (EMA/CVMP/519714/2009-Rev. 26). This decision followed the Committee's review of requests submitted in accordance with the relevant CVMP guidance.

### 8.2 Environmental risk assessment

*Information on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential.*

### 8.3 Antimicrobial resistance

- There were no items for discussion.

### 8.4 Pharmacovigilance

- There were no items for discussion.

### 8.5 Other issues

- There were no items for discussion.

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

- WHO draft global action plan on antimicrobial resistance;
- ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals. Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report, as published on 30 January 2015.

## 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 from I. Happonen to M. Nevalainen, and the transfer of co-rapporteurship of one product from K. Lehmann to M. Nevalainen.

### 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 received a verbal report from the chair of CMDv on the meeting held on 15-16 January 2015 and noted the draft minutes of the meeting, and also noted the draft agenda of the meeting held on 12-13 February 2015.

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report on the discussions in respect to the CVMP implementation of multinational assessment teams from the HMA meeting held on 3-5 February 2015 in Latvia. The Committee adopted the revised document on appointment and

responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products.

- The Committee discussed the format and timing of future CVMP Interested Parties' meetings, following the responses to the CVMP Interested Parties' Survey.
- The Committee discussed the procedure and timelines for CVMP comments on the EMA-HMA Road Map 2016-2020, and agreed that it would be necessary for the CVMP members to comment in writing prior to the Management Board meeting on 18-19 March 2015.
- The Committee was informed of the draft programme of the EMA/IFAH-Europe Info Day 2015 to be held on 12-13 March 2015 at the EMA.
- The Committee was informed of the CVMP Presidency meeting and joint CVMP/CMDv Presidency meetings to be held on 21-22 September 2015 in Luxembourg.
- The Committee noted the table of actions following the January 2015 CVMP meeting.

## 13. LEGISLATION

- There were no items for discussion.

## 14. ANY OTHER BUSINESS

- The Committee noted the call for new members of the ATCvet Working Group.
- Upon the completion of the February 2015 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 February 2015 meeting

| Country | CVMP Member | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| **CHAIR** | **Anja Holm** | **Full involvement** | |
| AT | Barbara Zemann | Cannot act as rapporteur or peer reviewer for: | • 2.1 - Metacam (EMEA/V/C/000033/X/0107)<br>• 3.1 - Novem-Metacam (EMEA/V/C/xxxxxx/WS/0667) |
| 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 | |
| FI | Martti Nevalainen | Full involvement | |
| HU | Gábor Kulcsár | Full involvement | |
| IE | David Murphy (vice-chair) | Full involvement | |
| IT | Maria Tollis | Full involvement | |
| LU | Marc Schmit | No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for: | • 3.1 - NexGard (EMEA/V/C/002729/II/0001)<br>• 5.5 - Econor, Previcox, ProteqFlu, ProteqFlu-Te<br>• 5.6 - one item<br>• 7.1 - one item |
| LV | Zanda Auce | Full involvement | |
| PL | Ewa Augustynowicz | Full involvement | |
| PT | João Pedro Duarte da Silva | Full involvement | |
| RO | Lollita Taban | Full involvement | |
| SE | Eva Lander Persson | Full involvement | |
| SI | Stane Srčič | 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 | Christian Friis | Full involvement | |
| Co-opted | Boris Kolar | Full involvement | |
| Co-opted | Wilhelm Schlumbohm | Full involvement | |
| 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 | |
| EL | Angeliki Tsigouri | Full involvement | |
| ES | Consuelo Rubio Montejano | Full involvement | |
| FR | Jean-Claude Rouby | Full involvement | |
| HR | Frane Božić | Full involvement | |
| NL | Peter Hekman | Full involvement | |
| PL | Anna Wachnik-Święcicka | Cannot act as rapporteur or peer reviewer for: | • 3.1 - Novem-Metacam (EMEA/V/C/xxxxxx/WS/0667)<br>• 7.1 – one item |
| SE | Frida Hasslung Wikström | Full involvement | |
| UK | Anna-Maria Brady | 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. | | | |
| FR | Hélène Amar | Full involvement | |
| FR | Nathalie Bridoux *(remotely)* | Full involvement | |
| FR | Jean-Christophe Faucon *(remotely)* | Full involvement | |
| FR | Alan Fauconnier *(remotely)* | Full involvement | |
| FR | Michael Holzhauser-Alberti *(remotely)* | Full involvement | |
| FR | Anne-Marie Jacques | Full involvement | |
| NL | Caroline Moermond *(remotely)* | Full involvement | |
| NL | Willie Peijnenburg *(remotely)* | Full involvement | |
| NL | Peter van Vlaardingen *(remotely)* | Full involvement | |
| SE | Fredrik Hultén *(remotely)* | Full involvement | |
| UK | Niall O'Brian | Full involvement | |
| UK | Kenneth Stapleton | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| AWP | Helen Jukes |
| CMDv | Gavin Hall |

| CVMP working parties and CMDv | Chair |
|---|---|
| ERAWP | Boris Kolar |
| EWP-V | Gesine Hahn |
| IWP | Esther Werner |
| PhVWP-V | Peter Ekström *(remotely)* |
| QWP | Piet-Hein Overhaus *(Vet vice chair - remotely)* |
| SAWP-V | Rory Breathnach |
| SWP-V | Eva Lander Persson |

| Observer from the European Commission | |
|---|---|
| Present | |

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