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 ongoing 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.
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 osteoarthritis 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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTVPUR AlSap 2-4 (EMEA/V/C/000139)</td>
<td>05/11/2017 – 04/11/2018</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acticam</strong> (EMEA/V/C/000138)</td>
<td>01.07.2015 – 30.06.2018</td>
</tr>
<tr>
<td><strong>EQUIOXX</strong> (EMEA/V/C/000142)</td>
<td>01.01.2018 – 30.06.2018</td>
</tr>
<tr>
<td><strong>Fevaxyn Pentofel</strong> (EMEA/V/C/000030)</td>
<td>01.07.2017 – 30.06.2018</td>
</tr>
</tbody>
</table>
• 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.

<table>
<thead>
<tr>
<th>Country</th>
<th>CVMP Member</th>
<th>Outcome restriction following evaluation of e-DoI for the meeting</th>
<th>Topics on current agenda for which restriction applies</th>
</tr>
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<td>CHAIR</td>
<td>David Murphy</td>
<td>Full involvement</td>
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<tr>
<td>AT</td>
<td>Petra Falb</td>
<td>Full involvement</td>
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<tr>
<td>BG</td>
<td>Emil Kozhuharov</td>
<td>Full involvement</td>
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<tr>
<td>DE</td>
<td>Gesine Hahn</td>
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<tr>
<td>DK</td>
<td>Ellen-Margrethe Vestergaard</td>
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<tr>
<td>EE</td>
<td>Toomas Tiirats</td>
<td>Full involvement</td>
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<tr>
<td>ES</td>
<td>Cristina Muñoz Madero</td>
<td>Full involvement</td>
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<tr>
<td>FR</td>
<td>Jean-Claude Rouby</td>
<td>Full involvement</td>
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<tr>
<td>HR</td>
<td>Frane Božić</td>
<td>Involvement in discussions only and cannot act as rapporteur or peer reviewer for:</td>
<td>5.4 - Loxicom</td>
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<tr>
<td>HU</td>
<td>Gábor Kulcsár</td>
<td>Full involvement</td>
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<tr>
<td>IE</td>
<td>J. Gabriel Beechinor</td>
<td>Full involvement</td>
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<tr>
<td>IT</td>
<td>Paolo Pasquali</td>
<td>Full involvement</td>
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<tr>
<td>LV</td>
<td>Zanda Auce</td>
<td>Full involvement</td>
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<tr>
<td>NL</td>
<td>Peter Hekman</td>
<td>Full involvement</td>
<td></td>
</tr>
<tr>
<td>PL</td>
<td>Anna Wachnik-Święcicka</td>
<td>Involvement in discussions only and cannot act as rapporteur or peer reviewer for:</td>
<td>9 – One item</td>
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<tr>
<td>RO</td>
<td>Lollita Taban</td>
<td>Full involvement</td>
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<tr>
<td>SE</td>
<td>Frida Hasslung Wikström</td>
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<tr>
<td>SI</td>
<td>Katarina Straus</td>
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<tr>
<td>SK</td>
<td>Judita Hederová</td>
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<td>Helen Jukes</td>
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<td>Wilhelm Schlumbohm</td>
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<td>NO</td>
<td>Hanne Bergendahl</td>
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<th>Topics on current agenda for which restriction applies</th>
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<tbody>
<tr>
<td>BE</td>
<td>Frédéric Klein</td>
<td>Full involvement</td>
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<tr>
<td>CZ</td>
<td>Leona Nepejchalová</td>
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<td>DE</td>
<td>Esther Werner</td>
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<tr>
<td>EL</td>
<td>Angeliki Tsigouri</td>
<td>Full involvement</td>
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<tr>
<td>ES</td>
<td>Consuelo Rubio</td>
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<tr>
<td>FI</td>
<td>Katarina Kivilahti-Mantyla</td>
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<tr>
<td>FR</td>
<td>Sylvie Louet</td>
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<tr>
<td>IE</td>
<td>Mary O’Grady</td>
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<tr>
<td>NL</td>
<td>Jacqueline Poot</td>
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<tr>
<td>PT</td>
<td>Maria Azevedo Mendes</td>
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<tr>
<td>UK</td>
<td>Noemi Garcia del Blanco</td>
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<tr>
<td>NO</td>
<td>Tonje Hay</td>
<td>Full involvement</td>
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<tr>
<th>Country</th>
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<tr>
<td>AT</td>
<td>Barbara Zemann (remotely)</td>
<td>Full involvement</td>
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</tr>
<tr>
<td>DE</td>
<td>Uta Herbst</td>
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<tr>
<td>DE</td>
<td>Anke Finnah (remotely)</td>
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<tr>
<td>DK</td>
<td>Niels Christian Kyvsgaard (remotely)</td>
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<tr>
<td>ES</td>
<td>Mercedes Conradi (remotely)</td>
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<tr>
<td>ES</td>
<td>Sonia Gil (remotely)</td>
<td>Full involvement</td>
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<td>UK</td>
<td>Rory Cooney</td>
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<td>Ken Stapleton</td>
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<td>UK</td>
<td>Sam Fletcher (remotely)</td>
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<td>John Mitchell (remotely)</td>
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<tr>
<td>UK</td>
<td>Niall O’Brien (remotely)</td>
<td>Full involvement</td>
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* Experts were only evaluated against the topics they have been invited to talk about.

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<th>CVMP working parties and CMDv</th>
<th>Chair</th>
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<td>Jean-Claude Rouby</td>
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<td>CMDv</td>
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<td>Jason Weeks - remotely</td>
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<td>Cristina Muñoz</td>
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<td>Esther Werner</td>
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<td>J3Rs WG</td>
<td>Ellen-Margrethe Vestergaard</td>
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<td>Chair</td>
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<td>Els Dewaele - remotely</td>
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<td>QWP</td>
<td>Mary O'Grady (Vet vice chair) - remotely</td>
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<td>SWP-V</td>
<td>Stefan Scheid - remotely</td>
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**Observer from the European Commission**

Present

**Observers from Swissmedic**

Remotely

**European Medicines Agency support**

Meeting run with relevant support from the EMA staff