



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 July 2020  
EMA/CVMP/452643/2020  
Committee for Medicinal Products for Veterinary Use (CVMP)

## Committee for Medicinal Products for Veterinary Use

### Minutes of the 16-18 June 2020 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

#### Note on access to documents

Some documents mentioned in the agenda or 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](#)).

The Committee agreed by consensus that, due to the COVID-19 pandemic, the June 2020 CVMP meeting takes place by means of remote participation and decision making.

#### 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 competing interests were identified for the June 2020 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 the presence of a quorum of members, *i.e.* 17 or more members of the 32 members eligible to vote were attending. 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 May 2020 meeting were adopted with no amendments.

### **v. Topics for rapporteurs' 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 (26 members attending of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report, recommending a 'no MRL required' maximum residue limit status for **bupivacaine** in bovine (EMA/V/MRL/005009/FULL/0002). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

### **1.2 Oral explanations and lists of outstanding issues**

- The Committee heard an oral explanation from the applicant and discussed the rapporteur's assessment of the responses to the list of outstanding issues including the co-rapporteur's critique for the extension of MRLs to porcine for a substance (EMA/V/MRL/003649/EXTN/0002). The adoption of the opinion is foreseen for the July 2020 meeting of the Committee.

### **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**

- There were no items for discussion.

### **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 product (EMA/V/C/005180/0000). The Committee noted three peer review reports and the comments received from CVMP members.

### 2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product (EMA/V/C/005354/0000) for dogs. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMA/V/C/005482/0000) for chickens. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for an extension application for **Aivlosin** (EMA/V/C/000083/X/0081), to add a new target species. 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

- There were no items for discussion.

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II grouped variation for **Bluevac BTV8** (EMA/V/C/000156/II/0010/G), recommending the variation of the marketing authorisation to convert the Bluevac BTV8 dossier into a multi-strain dossier and to add the strains BTV1 and BTV4 into the multi-strain dossier. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (27 members attending 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 **Stronghold Plus** and **Felisecto Plus** (EMA/V/C/xxxxxx/WS1828), recommending the variation of the marketing authorisations to amend translation errors in the product information identified in various languages. 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 adopted a list of outstanding issues and comments on the product information for a type II variation for **Nobilis IB Primo QX** (EMA/V/C/002802/II/0008) to amend the product information due to new data.
- The Committee adopted a second list of outstanding issues for a type II grouped variation for **UpCard** (EMA/V/C/003836/II/0005/G) to implement quality-related changes. The adoption of the opinion is foreseen for the July 2020 meeting of the Committee.

### 3.3 Lists of questions

- The Committee adopted a list of questions and comments on the product information for a type II variation for **Advocate** (EMA/V/C/000076/II/0043) to update the SPC.

- The Committee adopted a list of questions and comments on the product information for a type II variation for **Innovax-ND-IBD** (EMA/V/C/004422/II/0004), to extend the duration of immunity.
- The Committee adopted a list of questions for a type II variation for **Simparica Trio** (EMA/V/C/004846/II/0001) concerning quality-related 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 adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof** (EMA/V/A/136), recommending a two-day withdrawal period for cattle meat and offal to provide assurance of consumer safety. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique following the marketing authorisation holder's responses to the list of outstanding issues for the referral procedure for **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof** (EMA/V/A/138). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the July 2020 meeting of the Committee. The Committee noted the comments received from CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products** (EMA/V/A/140). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the November 2020 meeting of the Committee. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique following the marketing authorisation holder's responses to the list of outstanding issues for the referral procedure for **Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof** (EMA/V/A/132). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the July 2020 meeting of the Committee. The Committee noted two peer review reports and the comments received from CVMP members.

#### 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 Committee adopted by majority (25 members in favour out of the 27 members attending of those eligible to vote) a corrigendum of the CVMP opinion and the CVMP assessment report for the procedure under Article 45 of Regulation (EC) No 726/2004 of the European Parliament and of the Council concerning **Suvaxyn PRRS MLV** (EU/2/17/215/001-003). In the corrected opinion, a sentence was reinstated in the product information. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

N. C. Kyvsgaard and K. Baptiste signed a divergent position not supporting the CVMP recommendations.

### 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 endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Suvaxyn PRRS MLV** (EMA/V/C/004276/REC/012), which is now considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Fortekor Plus** (EMA/V/C/002804/REC/019), which is now considered fulfilled.

#### 5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 21.05.2020– 18.06.2020:

| Product                                   | Period                  |
|-------------------------------------------|-------------------------|
| <b>Dany's BienenWohl</b> (EMA/V/C/004667) | 14.06.2019 – 13.06.2020 |
| <b>Equilis West Nile</b> (EMA/V/C/002241) | 06.06.2019 – 05.06.2020 |
| <b>Leucogen</b> (EMA/V/C/000144)          | 17.06.2019 – 16.06.2020 |
| <b>MS-H Vaccine</b> (EMA/V/C/000161)      | 14.06.2019 – 13.06.2020 |
| <b>Nobilis IB 4-91</b> (EMA/V/C/000036)   | 09.06.2019 – 08.06.2020 |
| <b>Porcilis ColiClos</b> (EMA/V/C/002011) | 14.06.2019 – 13.06.2020 |
| <b>Porcilis Pesti</b> (EMA/V/C/000046)    | 09.06.2019 – 08.06.2020 |

| Product                                 | Period                  |
|-----------------------------------------|-------------------------|
| <b>Poulvac E. coli</b> (EMA/V/C/002007) | 15.06.2019 – 14.06.2020 |
| <b>Sileo</b> (EMA/V/C/003764)           | 10.06.2019 – 09.06.2020 |
| <b>Vectra Felis</b> (EMA/V/C/002746)    | 06.06.2019 – 05.06.2020 |

#### 5.4 Renewals

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Zycortal** (EMA/V/C/003782/R/0006) 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 attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Simparica** (EMA/V/C/003991/R/0018) 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 a list of outstanding issues for the renewal of the marketing authorisation for **Suvaxyn Circo + MH RTU** (EMA/V/C/003924/R/0015).

#### 5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.2016-31.10.2019 for **Purevax FeLV** (EMA/V/C/000056) with a recommendation to amend the SPC and the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.07.2018-30.12.2019 for **Vectra 3D** (EMA/V/C/002555) with a recommendation to amend the SPC and the package leaflet.
- The Committee endorsed the following rapporteur's assessment reports on PSURs, concluding that no changes to the product literature or other regulatory actions were required, for:

| Product                             | Period                |
|-------------------------------------|-----------------------|
| <b>Comfortis</b> (EMA/V/C/000056)   | 01.10.2016-30.09.2019 |
| <b>Credelio</b> (EMA/V/C/004247)    | 01.08.2019-31.01.2020 |
| <b>Innovax ILT</b> (EMA/V/C/003869) | 01.02.2019-31.01.2020 |
| <b>Masivet</b> (EMA/V/C/000128)     | 01.12.2016-30.11.2019 |
| <b>Melovem</b> (EMA/V/C/000152)     | 01.02.2017-31.01.2020 |
| <b>Nasym</b> (EMA/V/C/004897)       | 29.07.2019-31.01.2020 |
| <b>Osrnia</b> (EMA/V/C/003753)      | 01.02.2019-31.01.2020 |
| <b>ProZinc</b> (EMA/V/C/002634)     | 01.08.2017-31.01.2020 |
| <b>Sileo</b> (EMA/V/C/003764)       | 01.01.2019-31.12.2019 |
| <b>Ubac</b> (EMA/V/C/004595)        | 01.08.2019-31.01.2020 |

| Product                  | Period                |
|--------------------------|-----------------------|
| Zactran (EMA/V/C/000129) | 01.02.2019-31.01.2020 |

- 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.*

**The following documents were 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 nominated an EU expert to join the VICH Bioequivalence EWG.

### 6.2 Codex Alimentarius

- There were no items for discussion.

### 6.3 Other EU bodies and international organisations

- The Committee noted the call for members from the World Health Organisation to its Strategic and Technical Advisory Group for Antimicrobial Resistance (STAG-AMR). *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 cannot be released at the present time as it is deemed to be commercially confidential.*

### 7.1 Scientific Advice Working Party (SAWP-V)

- There were no items for discussion.

### 7.2 Quality Working Party (QWP)

- The Committee adopted the guideline on water for pharmaceutical use and the overview of comments following the close of the public consultation. The new guideline will come into effect six months after publication on the EMA website.

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

- There were no items for discussion.

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

- The Committee discussed the reflection paper on 'Antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products' and noted the overview of comments received. The Committee gave a mandate to the ERAWP Chair in order for the ERAWP, together with the AWP, to review the comments received during the public consultation and update the document accordingly. *See also 7.6*
- The Committee appointed six new members of the ERAWP.

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

- There were no items for discussion.

## **7.6 Antimicrobials Working Party (AWP)**

- The Committee discussed the reflection paper on 'Antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products' and noted the overview of comments received. The Committee gave a mandate to the ERAWP Chair in order for the ERAWP, together with the AWP, to review the comments received during the public consultation and update the document accordingly. *See also 7.4*

## **7.7 Immunologicals Working Party (IWP)**

- The Committee adopted a questions and answers document on management of extraneous agents in immunological veterinary medicinal products.
- The Committee adopted a revised mandate, objectives and rules of procedure for the CVMP Immunologicals Working Party (IWP).

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

- There were no items for discussion.

## **7.9 Novel therapy groups and related issues**

- The Committee discussed a questions and answers document on stem cell-based products for veterinary use regarding a specific question on target animal safety. The adoption of the document is foreseen for the July 2020 meeting of the Committee.

## **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 document was circulated for information:***

- No documents.

## **8. OTHER SCIENTIFIC MATTERS**

### **8.1 MRL issues**

*Information on certain MRL related issues cannot be released at the present time as it is deemed to be commercially confidential*

- The Committee agreed to include **natural crystalline graphite** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients (EMA/CVMP/196776/2020).
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.44).

### **8.2 Environmental risk assessment**

- There were no items for discussion.

### **8.3 Antimicrobial resistance**

- The Committee adopted the CVMP strategy on antimicrobials 2021-2025 for 3 months' public consultation starting on 1 July 2020.
- The Committee noted the call for members from the World Health Organisation to its Strategic and Technical Advisory Group for Antimicrobial Resistance (STAG-AMR). *See also 6.3*
- The Committee noted the publication of the AMEG infographic translations ([link](#)).

### **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 be commercially confidential.*

- There were no items for discussion.

## **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 received a verbal report from the CMDv chair on the meetings held on 23 April and 19-20 May 2020 and noted the draft minutes of the 19-20 May 2020 meeting, as well as the draft agenda of the meeting held on 18-19 June 2020.

## **12. ORGANISATIONAL AND STRATEGIC MATTERS**

The Committee received a verbal report from the chair of the Strategic Planning (SPG) Group on the meeting held on 15 June 2020 and noted the agenda of the June meeting and the minutes of the meeting held on 20 April 2020.

## **13. LEGISLATION**

- The Committee adopted the scientific recommendations for implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products regarding the format of the data to be collected on antimicrobial medicinal products used in animals.
- The Committee received verbal report on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6.

#### **14. ANY OTHER BUSINESS**

- Upon the completion of the June 2020 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 June 2020 meeting

| Country      | CVMP Member                | Outcome restriction following evaluation of e-DoI for the meeting                                        | Topics on current agenda for which restriction applies |
|--------------|----------------------------|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <b>CHAIR</b> | <b>David Murphy</b>        | <b>Full involvement</b>                                                                                  |                                                        |
| AT           | Petra Falb                 | Full involvement                                                                                         |                                                        |
| BE           | Bruno Urbain               | Full involvement                                                                                         |                                                        |
| BG           | Svetoslav Branchev         | Full involvement                                                                                         |                                                        |
| CY           | Hristodoulos Pipis         | Full involvement                                                                                         |                                                        |
| DE           | Esther Werner              | Full involvement                                                                                         |                                                        |
| DK           | Niels Christian Kyvsgaard  | Full involvement                                                                                         |                                                        |
| EE           | Toomas Tiirats             | Full involvement                                                                                         |                                                        |
| ES           | Cristina Muñoz Madero      | Full involvement                                                                                         |                                                        |
| FI           | Tita-Maria Muhonen         | Full involvement                                                                                         |                                                        |
| FR           | Sylvie Louet               | Full involvement                                                                                         |                                                        |
| HR           | Frane Božić                | Involvement in discussions only and cannot act as rapporteur or peer reviewer for <b>Genera Research</b> | <b>4.3 – Betamox LA</b>                                |
| HU           | Gábor Kulcsár              | Full involvement                                                                                         |                                                        |
| IE           | J. Gabriel Beechinor       | Full involvement                                                                                         |                                                        |
| IT           | Paolo Pasquali             | Full involvement                                                                                         |                                                        |
| LU           | Marc Schmit                | Full involvement                                                                                         |                                                        |
| LV           | Zanda Auce                 | Full involvement                                                                                         |                                                        |
| NL           | Peter Hekman               | Full involvement                                                                                         |                                                        |
| PL           | Anna Wachnik-Świąćicka     | Involvement in discussions only and cannot act as rapporteur or peer reviewer for <b>Bayer</b>           | <b>3.3 – Advocate</b>                                  |
| PT           | João Pedro Duarte da Silva | Full involvement                                                                                         |                                                        |
| RO           | Lollita Taban              | Full involvement                                                                                         |                                                        |
| SE           | Frida Hasslung Wikström    | Full involvement                                                                                         |                                                        |
| SI           | Katarina Straus            | Full involvement                                                                                         |                                                        |
| SK           | Judita Hederová            | Full involvement                                                                                         |                                                        |
| Co-opted     | Keith Baptiste             | Full involvement                                                                                         |                                                        |
| Co-opted     | Rory Breathnach            | Full involvement                                                                                         |                                                        |
| Co-opted     | G. Johan Schefferlie       | Full involvement                                                                                         |                                                        |
| Co-opted     | Mary O’Grady               | Full involvement                                                                                         |                                                        |
| Co-opted     | Ricardo Carapeto García    | Full involvement                                                                                         |                                                        |
| IS           | Peter Zsolt Fekete         | 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 |
|---------|-----------------------------|-------------------------------------------------------------------|--------------------------------------------------------|
| AT      | Manuela Leitner             | Full involvement                                                  |                                                        |
| BE      | Frédéric Klein              | Full involvement                                                  |                                                        |
| CZ      | Leona Nepejchalová          | Full involvement                                                  |                                                        |
| DE      | Andrea Golombiewski         | Full involvement                                                  |                                                        |
| DK      | Merete Blixenkrone-Møller   | Full involvement                                                  |                                                        |
| EL      | Spyridon Farlopoulos        | Full involvement                                                  |                                                        |
| FI      | Katariina Kivilahti-Mantyla | Full involvement                                                  |                                                        |
| FR      | Christine Miras             | Full involvement                                                  |                                                        |
| IE      | Paul McNeill                | Full involvement                                                  |                                                        |
| NL      | Jacqueline Poot             | Full involvement                                                  |                                                        |
| SE      | Carina Bergman              | Full involvement                                                  |                                                        |
| SK      | Eva Chobotová               | Full involvement                                                  |                                                        |
| NO      | Annelin Aksdal Bjelland     | 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. |                       |                                                                       |                                                        |
| CZ                                                                                     | Dana Halová           | Full involvement                                                      |                                                        |
| Cz                                                                                     | Dana Studená          | Full involvement                                                      |                                                        |
| CZ                                                                                     | Eva Pomezná           | Full involvement                                                      |                                                        |
| CZ                                                                                     | Vilma Dosedlová       | Full involvement                                                      |                                                        |
| CZ                                                                                     | Zdenka Mašková        | Full involvement                                                      |                                                        |
| DE                                                                                     | Anke Finnah           | Full involvement                                                      |                                                        |
| DE                                                                                     | Ingun Lemke           | Full involvement                                                      |                                                        |
| DE                                                                                     | Kathrin Dietze        | Full involvement                                                      |                                                        |
| DE                                                                                     | Kathrin Schmidt       | Full involvement                                                      |                                                        |
| DE                                                                                     | Nikola Lange          | Full involvement                                                      |                                                        |
| DE                                                                                     | Roswitha Merkel       | Full involvement                                                      |                                                        |
| DE                                                                                     | Sandra Bertulat       | Full involvement                                                      |                                                        |
| DE                                                                                     | Sarah Bolda           | Full involvement                                                      |                                                        |
| DE                                                                                     | Uta Herbst            | Full involvement                                                      |                                                        |
| DE                                                                                     | Werner Terhalle       | Full involvement                                                      |                                                        |
| DK                                                                                     | Malene Nissen         | Full involvement                                                      |                                                        |
| ES                                                                                     | Carles Cristòfol Adel | Full involvement                                                      |                                                        |
| ES                                                                                     | Cristina Villegas     | Full involvement                                                      |                                                        |
| ES                                                                                     | Gema Cortés Ruiz      | Full involvement                                                      |                                                        |
| ES                                                                                     | Jezabel Domenech      | Full involvement                                                      |                                                        |
| ES                                                                                     | Luis Agote Casado     | Full involvement                                                      |                                                        |
| ES                                                                                     | Rosa Donoso           | Full involvement                                                      |                                                        |
| ES                                                                                     | Rosario Bullido       | Full involvement                                                      |                                                        |
| ES                                                                                     | Sonia Gil Morales     | Full involvement                                                      |                                                        |

| Country | CVMP Expert*          | Outcome restriction following evaluation of the e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---------|-----------------------|-----------------------------------------------------------------------|--------------------------------------------------------|
| ES      | Susana Casado         | Full involvement                                                      |                                                        |
| ES      | Teresa Gómez Martínez | Full involvement                                                      |                                                        |
| FR      | Damien Bouchard       | Full involvement                                                      |                                                        |
| FR      | Anne-Marie Jacques    | Full involvement                                                      |                                                        |
| FR      | Mathilde Harvey       | Full involvement                                                      |                                                        |
| FI      | Kristina Lehmann      | Full involvement                                                      |                                                        |
| FI      | Minna Leppänen        | Full involvement                                                      |                                                        |
| IE      | Aideen Browne         | Full involvement                                                      |                                                        |
| NL      | Anita Bottger         | Full involvement                                                      |                                                        |
| NO      | Kari Grave            | Full involvement                                                      |                                                        |
| PT      | Luisa Vieira Peixe    | Full involvement                                                      |                                                        |
| SE      | Fredrik Hultén        | Full involvement                                                      |                                                        |
| SE      | Hanna Bremer          | Full involvement                                                      |                                                        |
| SE      | Jennie Sandberg       | Full involvement                                                      |                                                        |
| SE      | Jenny Larsson         | Full involvement                                                      |                                                        |
| SE      | Malin Öhlund          | Full involvement                                                      |                                                        |
| SE      | Mats Jernberg         | Full involvement                                                      |                                                        |
| SE      | Stefan Nilsson        | Full involvement                                                      |                                                        |
| SE      | Wilmar Igl            | Full involvement                                                      |                                                        |

| CVMP working parties and CMDv | Chair                                         |
|-------------------------------|-----------------------------------------------|
| ADVENT                        | ---                                           |
| AWP                           | Christine Schwarz                             |
| CMDv                          | Laetitia Le Letty                             |
| ERAWP                         | Ricardo Carapeto García                       |
| EWP-V                         | Cristina Muñoz Madero                         |
| IWP                           | Esther Werner                                 |
| J3Rs WG                       | ---                                           |
| PhVWP-V                       | Els Dewaele                                   |
| QWP                           | Mary O'Grady ( <i>Veterinary vice chair</i> ) |
| SAWP-V                        | Frida Hasslung Wikström                       |
| SWP-V                         | Stefan Scheid                                 |

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

| Observers from Swissmedic |  |
|---------------------------|--|
| Remotely                  |  |

### ***European Medicines Agency support***

Meeting run with relevant support from the EMA staff