18 April 2023
EMA/CVMP/188158/2023
Committee for Veterinary Medicinal Products (CVMP)

# Committee for Veterinary Medicinal Products

## Minutes of the 21-22 March 2023 meeting

Chair: G. J. Schefferlie – Vice-chair: F. Hasslung Wikström

**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/729522/2016).

### i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

### ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 21-23.03.2023

The attendance list was completed and competing interests were identified for the March 2023 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. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

### 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.*

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

No contacts were declared.

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

The minutes of the February 2022 meeting were adopted with no amendments.

### v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

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

# 1. Maximum residue limits

### 1.1. Opinions

- There were no items for discussion.

### 1.2. Oral explanations

- There were no items for discussion.

### 1.3. Lists of outstanding issues

- There were no items for discussion.

### 1.4. List of questions

- There were no items for discussion.

### 1.5. Re-examination of CVMP opinions on maximum residue limits

- There were no items for discussion.

### 1.6. Other issues

# 2. Marketing authorisations and extensions

### 2.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.1. Opinions under Regulation (EC) No 726/2004

- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Newflend ND H9** (EMEA/V/C/005860/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of one-day-old chicks or 18-day-old chicken embryonated eggs against Newcastle disease and H9 low pathogenic avian influenza. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

### 2.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.2. Oral explanations under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.3. List of outstanding issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.3. List of outstanding issues under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.4. List of questions under Regulation (EU) 2019/6

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/006128/0000), for dogs. 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 a new product (EMEA/V/C/006124/0000), for dogs. 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 a new vaccine (EMEA/V/C/005887/0000), 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 a new vaccine (EMEA/V/C/005628/0000), for dogs. The Committee noted a peer review report and the comments received from CVMP members.

### 2.4. List of questions under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.5. Re-examination of CVMP opinions under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.5. Re-examination of CVMP opinions under Regulation (EC) No 726/2004

- There were no items for discussion.

### 2.6. Other issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 2.6. Other issues under Regulation (EC) No 726/2004

- There were no items for discussion.

## 3. Variations to marketing authorisations

### 3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Porcilis PCV M Hyo** (EMEA/V/C/003796/VRA/0017), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Versican Plus Pi** (EMEA/V/C/003681/VRA/0013),

recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Versican Plus L4** (EMEA/V/C/003680/VRA/0012), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Versican Plus Pi/L4** (EMEA/V/C/003683/VRA/0015), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Bravecto** (EMEA/V/C/002526/VRA/0058), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Stronghold** (EMEA/V/C/000050/VRA/0059), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Suprelorin** (EMEA/V/C/000109/VRA/0038), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment (subject to a worksharing procedure) for **Leucofeligen FeLV/RCP** (EMEA/V/C/WS2398), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Kriptazen** (EMEA/V/C/004868/VRA/0007/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Innovax-ILT** (EMEA/V/C/003869/VRA/0010/G), recommending the variation of the marketing authorisation to align the product information with

version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Nexgard Combo** (EMEA/V/C/005094/VRA/0008), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Masivet** (EMEA/V/C/000128/VRA/0022), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Purevax Rabies** (EMEA/V/C/002003/VRA/0017), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Prevomax** (EMEA/V/C/04331/VRA/0014), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Nobilis Influenza H5N2** (EMEA/V/C/000118/VRA/0017), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Poulvac E. coli** (EMEA/V/C/002007/VRA/0020), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

### 3.1. Opinions under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

### 3.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

### 3.3. List of outstanding issues under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

### 3.4. List of questions under Regulation (EU) 2019/6

- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Naxcel** (EMEA/V/C/000079/VRA/0043), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Cytopoint** (EMEA/V/C/003939/VRA/0016), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Tessie** (EMEA/V/C/005427/VRA/0001), to amend the product information in relation to interactions with other medicinal products.
- The Committee adopted a list of questions and agreed comments on the draft product information, for a grouped variation requiring assessment for **NexGard Combo** (EMEA/V/C/005094/VRA/0007/G), to add two new therapeutic indications and to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/VRA/0044), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **MiPet Easecto** (EMEA/V/C/004732/VRA/0012), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Simparica** (EMEA/V/C/003991/VRA/0023) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Canigen L4** (EMEA/V/C/004079/VRA/0011), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Nobivac L4** (EMEA/V/C/002010/VRA/0014), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a Rapporteur's Assessment report including a list of questions for a grouped variation requiring assessment for **Forceris** (EMEA/V/C/004329/VRA/0006/G), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Porcilis ColiClos** (EMEA/V/C/002011/VRA/0015), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/VRA/0012), concerning quality-related changes.

### 3.4. List of questions under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

### 3.5. Re-examination of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

- There were no items for discussion.

### 3.5. Re-examination of CVMP opinions on variations under Regulation (EC) 726/2004

- There were no items for discussion.

### 3.6. Other issues under Regulation (EU) 2019/6

- The Committee was informed of the formal notification from MSD Animal Health Innovation GmbH of their decision to withdraw the application for a grouped variation requiring assessment for **Halocur** (EMEA/V/C/000040/VRA/0018/G), to implement quality-related changes.
- The Committee was informed of the formal notification from MSD Animal Health Innovation GmbH of their decision to withdraw the application for a variation requiring assessment for **Bravecto** (EMEA/V/C/002526/VRA/0057), to implement quality-related changes.

### 3.6. Other issues under Commission Regulation (EC) 1234/2008

- There were no items for discussion.

## 4. Referrals and related procedures

### 4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

- There were no items for discussion.

### 4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

- There were no items for discussion.

### 4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

- There were no items for discussion.

### 4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.7. Other issues

*Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential.*

### 4.7.1. Referrals under Regulation (EU) 2019/6

- The Committee noted the question and answer document for publication on the review of veterinary medicines containing N-methyl pyrrolidone as an excipient regarding the outcome of an Article 82 referral procedure (EMEA/V/A/146).

### 4.7.2. Referrals under Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the follow-up assessment of the referral procedure for **veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses** (EMEA/V/A/116). The Committee adopted the list of questions for the marketing authorisation holders and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the September 2023 meeting of the Committee. The Committee noted peer review reports and the comments made by CVMP members.

## 5. Post-authorisation issues for marketing authorisations

*Information relating to certain pharmacovigilance topics, and to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections*

### 5.1. Pharmacovigilance under Regulation (EU) 2019/6

- The Committee adopted a recommendation proposing amendments to the product information for **Galliprant** (EMEA/V/C/004222) as an outcome of signal detection activities.
- The Committee discussed an updated proposal for the signal management approach by P-SMEG.

### 5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

- There were no items for discussion.

### 5.2. Post-authorisation measures under Regulation (EU) 2019/6

- There were no items for discussion.

### 5.2. Post-authorisation measures under Regulation (EC) No 726/2004

- There were no items for discussion.

### 5.3. Inspections and controls under Regulation (EU) 2019/6

### 5.3. Supervision and sanctions under Regulation (EC) No 726/2004

- The Committee adopted the list of veterinary products to be tested in the Sampling and Testing Programme 2024.

### 5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

- There were no items for discussion.

## 6. Working parties

*Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.*

### 6.1. Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 14- 15 March 2023 and noted the agenda of the meeting.

### 6.2. Environmental Risk Assessment Working Party (ERAWP)

### 6.3. Efficacy Working Party (EWP-V)

- There were no items for discussion.

### 6.4. Immunologicals Working Party (IWP)

- The Committee endorsed the appointment of Dr Daniela Loos and Dr Judith Romberg as new members of the Immunologicals Working Party (IWP).

### 6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (3RsWP)

- The Committee noted the minutes from the 3RsWP meeting held on 23 November 2022.

### 6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee received a verbal report from the NTWP chair on the meeting held on 23 February 2023 and noted the agenda and the draft minutes of the meeting.

### 6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 22 February 2023.
- The Committee adopted the revised question and answer document on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL)) (EMA/CVMP/150343/2016-Rev. 3).

### 6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 6-8 March 2023, and noted the agenda of the meeting, together with the minutes of the QWP meeting held on 21-23 November 2022 (EMA/897603/2022).
- The Committee adopted the guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water - Annex on compatibility studies between veterinary medicinal products and biocidal products for a 3-month period of public consultation.

### 6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 20 March 2023, and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting held on 10 February 2023.
- The Committee adopted the scientific advice report on a veterinary medicinal product for lactating cows.
- The Committee adopted the scientific advice report on a veterinary medicinal product for salmon.
- The Committee adopted the scientific advice report on a veterinary medicinal product for dogs.
- The Committee adopted the scientific advice report on a veterinary medicinal product for horses.

### 6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

### 6.11. Other working party and scientific group issues

- The Committee noted the Quality Innovation Group (QIG) work plan for 2023.

## 7. Other scientific matters

*Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential.*

### 7.1. MRL issues

- There were no items for discussion.

### 7.2. Environmental risk assessment

- There were no items for discussion.

### 7.3. Antimicrobial resistance

- There were no items for discussion.

### 7.4. Pharmacovigilance

- There were no items for discussion.

### 7.5. Vaccine antigen master file (VAMF) certification

- There were no items for discussion.

### 7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

### 7.7. Other issues

- There were no items for discussion.

## 8. Co-operation with other EU or International bodies

*Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.*

### 8.1. VICH

- The Committee noted the request to nominate an adviser to support the review of VICH GL47 on laboratory animal comparative metabolism studies.
- The Committee endorsed the draft concept paper for the preparation of a VICH guideline on technical requirements for *in vitro* methods for batch potency tests in veterinary immunologicals.
- The Committee endorsed the final VICH guideline /GL18(R2) on Impurities: Residual solvents in new VMPs, active substances and excipients, from the VICH EWG, for sign-off by the VICH Steering Committee at step 6 of the VICH process.

### 8.2. Codex Alimentarius

- There were no items for discussion.

### 8.3. Other EU bodies and international organisations

- There were no items for discussion.

# 9. Procedural and regulatory matters

*Information on certain topics relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.*

### 9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

- The Committee considered the request for limited market classification for the veterinary medicinal product in cats and dogs. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered the request for limited market classification for the veterinary medicinal product in dogs. The Committee classified the product as not intended for a limited market and not eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

### 9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

### 9.3. Regulatory matters

# 10. Organisational and strategic matters

- There were no items for discussion.

# 11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 19-20 January 2023 and 16 February 2023, and noted the draft minutes of the meeting held on 16 February 2023, the minutes of the CMDv-Interested Parties meeting held on 20 January 2023 (EMA/CMDv/64847/2023, link); as well as the draft agenda of the meeting to be held on 23-24 March 2023 and the draft agenda of the CMDv-Interested Parties meeting to be held on 24 March 2023.

# 12. Legislation

- The Committee received a verbal update on the work progress of the expert group concerning the provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6)).
- The Committee received a verbal report on the work progress of the expert group concerning the provision of scientific advice on the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months (Article 115(5) of Regulation (EU) 2019/6). A survey to the stakeholders regarding the current list of substances essential for the treatment of *Equidae* is to be launched in April 2023.
- The Committee agreed that the work on the draft reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (EMA/CVMP/64911/2021) should resume, following the close of the public consultation, during which comments were received.

# 13. Any other business

## 13.1. Meeting highlights

- Upon the completion of the March 2023 CVMP meeting, the draft news highlights was circulated for members to provide 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 March 2023 meeting

| Country | CVMP Member | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| **CHAIR** | **G. Johan Schefferlie** | **Full involvement** | |
| AT | Petra Falb | Full involvement | |
| BE | Bruno Urbain | Full involvement | |
| CZ | Leona Nepejchalová | Full involvement | |
| DE | Esther Werner | Full involvement | |
| DK | Niels Christian Kyvsgaard | Full involvement | |
| EE | Toomas Tiirats | Full involvement | |
| EL | Spyridon Farlopoulos | Full involvement | |
| FI | Minna Leppänen | Full involvement | |
| FR | Sylvie Louet | Full involvement | |
| HU | Gábor Kulcsár | Full involvement | |
| IE | Paul McNeill | Full involvement | |
| IT | Paolo Pasquali | Full involvement | |
| NL | Jacqueline Poot | Full involvement | |
| PL | Anna Wachnik-Święcicka | Full involvement | |
| PT | João Pedro Duarte da Silva | Full involvement | |
| RO | Gabriela Tuchila | Full involvement | |
| SE | Frida Hasslung Wikström | Full involvement | |
| SI | Katarina Straus | Full involvement | |
| SK | Eva Chobotová | Full involvement | |
| Co-opted | Keith Baptiste | Full involvement | |
| Co-opted | Rory Breathnach | Full involvement | |
| Co-opted | Mary O'Grady | Full involvement | |
| Co-opted | Ricardo Carapeto García | Full involvement | |
| Co-opted | Carina Bergman | 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 | |
| BG | Nadya Ognyanova Vladimirova | Full involvement | |
| DE | Andrea Golombiewski | Full involvement | |
| DK | Merete Blixenkrone-Møller | Full involvement | |
| ES | Consuelo Rubio Montejano | Full involvement | |
| FR | Christine Miras | Full involvement | |
| HR | Hrvoje Pasavovic | Full involvement | |

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| LV | Santa Ansonska | Full involvement | |
| NL | Kim Boerkamp | Full involvement | |
| SK | Katarína Massányiová | 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. | | | |
| DE | Roswitha Merkel | Full involvement | |
| DE | Kathrin Schmidt | Full involvement | |
| CZ | Eva Pomezná | Full involvement | |
| ES | Beatriz Corcho Corral | Full involvement | |
| ES | Mercedes Ureña Montilla | Full involvement | |
| IE | Sarah Hanley | Full involvement | |
| IE | Sarah Buckley | Full involvement | |
| ES | María Amparo Haro Castuera | Full involvement | |
| FR | Benoit Courty | Full involvement | |
| FR | Jean-Christophe Faucon | Full involvement | |
| DK | John Jensen | Full involvement | |
| DK | Gunther Speichert | Full involvement | |
| DK | Susanne Schmitz | Full involvement | |
| DK | Ina Ebert | Full involvement | |
| FR | Mathilde Harvey | Full involvement | |
| FR | Anne Sagnier | Full involvement | |
| FR | Walid Oumessad | Full involvement | |
| ES | Raul Belmar Liberato | Full involvement | |
| DE | Christina Bredtmann | Full involvement | |
| DE | Wiebke Weiher | Full involvement | |
| DE | Anke Finnah | Full involvement | |
| BE | Els Dewaele | Full involvement | |
| DK | Emilie Pouplier | Full involvement | |
| ES | Marta Martin Juárez | Full involvement | |
| DE | Kathrin Schirmann | Full involvement | |
| FR | Laetitia Le Letty | Full involvement | |
| FR | Anne-Marie Jacques | Full involvement | |
| FR | Pascale Macours | Full involvement | |
| CZ | Dana Halová | Full involvement | |
| CZ | Lucie Pokludová | Full involvement | |
| ES | Susana Casado | Full involvement | |
| DE | Christine Schwarz | Full involvement | |
| FR | Marie-Hélène Sabinotto | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| NTWP | Jacqueline Poot |
| AWP | Christine Schwarz |
| CMDv | Laetitia Le Letty |
| ERAWP | Ricardo Carapeto García |
| EWP-V | Cristina Muñoz Madero |
| IWP | Esther Werner |
| J3Rs WP | --- |
| PhVWP-V | Els Dewaele |
| QWP | Marie-Hélène Sabinotto *(veterinary vice chair)* |
| SAWP-V | Frida Hasslung Wikström |
| SWP-V | Carina Bergman |

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

| Observers from Swissmedic | |
|---|---|
| Present | |

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