15 February 2022
EMA/CVMP/101771/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 18-19 January 2022 meeting

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

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

Due to the COVID-19 pandemic, the January 2022 CVMP meeting took 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 January 2022 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.

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the December 2021 meeting were adopted with no amendments.

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

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- The Committee discussed the rapporteurs' assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the extension of MRLs in chickens for a substance (EMEA/V/MRL/003652/EXTN/0004), and adopted a list of outstanding issues. The Committee noted peer review reports and the comments received from the CVMP members.

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

- There were no items for discussion.

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 an extension application for **Meloxoral** (EMEA/V/C/000151/X/0015), to add a new pharmaceutical form. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant for a further extension to the clock-stop for a new vaccine (EMEA/V/C/005538/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application for **VarroMed** (EMEA/V/C/002723/II/0003/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 application for **Credelio** (EMEA/V/C/004247/II/0019), recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of demodicosis (caused by *Demodex canis*) in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, and the product information and endorsed the rapporteur's assessment report, for a grouped type II variation application for **Evant** (EMEA/V/C/004902/II/0002/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a grouped type II variation application (subject to a worksharing procedure) for **Purevax RC, Purevax RCPCh, Purevax RCPCh FeLV,Purevax RC and Purevax RCP FeLV** (EMEA/V/C/xxxxxx/WS2166/G), recommending the variation of the marketing authorisation to implement quality-related changes. 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 application for **NexGard Spectra** (EMEA/V/C/003842/II/0031), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped type II variation application for **Gumbohatch** (EMEA/V/C/004967/II/0005/G), to reduce the minimum protective dose and make quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped type II variation application for **Bonqat** (EMEA/V/C/005489/II/0002/G), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped type II variation application for **Innovax-ND-ILT** (EMEA/V/C/005190/II/0003/G), concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

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 considered the notification from the Netherlands for a referral procedure for **veterinary medicinal products containing toltrazuril to be administered orally to chickens.** The referral concerns the appropriateness of current restriction periods before the onset of lay. The Committee agreed to start a referral procedure (EMEA/V/A/144) under Article 35 and appointed G. J. Schefferlie as rapporteur and S. Louet as co-rapporteur, and three CVMP members as peer reviewers for the procedure. The Committee adopted a list of questions and the timetable for the procedure.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 10.12.2021 – 20.01.2022:

Product	Period
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2021 – 08.01.2022
Bovela (EMEA/V/C/003703)	22.12.2020 – 21.12.2021
BTVPUR (EMEA/V/C/002231)	17.12.2020 – 16.12.2021
Cepedex (EMEA/V/C/004376)	13.12.2020 – 12.12.2021
Coliprotec F4/F18 (EMEA/V/C/004225)	09.01.2021 – 08.01.2022
Cortavance (EMEA/V/C/000110)	09.01.2021 – 08.01.2022
Galliprant (EMEA/V/C/004222)	09.01.2021 – 08.01.2022
Halagon (EMEA/V/C/004201)	13.12.2020 – 12.12.2021
Isemid (EMEA/V/C/004345)	09.01.2021 – 08.01.2022
Meloxidyl (EMEA/V/C/000115)	15.01.2021 – 14.01.2022
Metacam (EMEA/V/C/000033)	07.01.2021 – 06.01.2022
Mirataz (EMEA/V/C/004733)	10.12.2020 – 09.12.2021
Neptra (EMEA/V/C/004735)	10.12.2020 – 09.12.2021
NexGard Spectra (EMEA/V/C/000127)	15.01.2021 – 14.01.2022
Onsior (EMEA/V/C/000127)	16.12.2020 – 16.12.2021
Porcilis PCV (EMEA/V/C/000135)	12.01.2021 – 11.01.2022
Prac-tic (EMEA/V/C/000103)	18.12.2020 – 17.12.2021
Respiporc FLU3 (EMEA/V/C/000153)	14.01.2021 – 13.01.2022
Rheumocam (EMEA/V/C/005018)	10.01.2021 – 09.01.2022
SevoFlo (EMEA/V/C/005018)	11.12.2020 – 10.12.2021
Stelfonta (EMEA/V/C/005018)	15.01.2021 – 14.01.2022
Syvazul BTV (EMEA/V/C/004611)	09.01.2021 – 08.01.2022
Ypozane (EMEA/V/C/000112)	11.01.2021 – 10.01.2022
Zulvac 8 Ovis (EMEA/V/C/000147)	15.01.2021 – 14.01.2022

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2021 – 31.07.2021 for **Stelfonta** (EMEA/V/C/005018) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.09.2020 – 31.08.2021 for **Suvaxyn Circo** (EMEA/V/C/004242) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product information or other regulatory actions were required for:

Product	Period
Cimalgex (EMEA/V/C/000162)	01.09.2018 – 31.08.2021
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	01.08.2018 – 31.07.2021
Ingelvac CircoFLEX (EMEA/V/C/000126)	01.09.2018 – 31.08.2021
Isemid (EMEA/V/C/004345)	01.02.2021 – 31.07.2021
NexGard / Frontpro (EMEA/V/C/002729) (EMEA/V/C/005126)	01.09.2018 – 31.08.2021
Solensia (EMEA/V/C/005179)	17.02.2021 – 31.08.2021
Stronghold Plus / Felisecto Plus (EMEA/V/C/004194) (EMEA/V/C/005093)	01.09.2020 – 31.08.2021
Syvazul BTV (EMEA/V/C/004611)	01.02.2021 – 31.07.2021

- The Committee received feedback from the EU Veterinary Pilot Signal Management Expert Group (P-SMEG) on its establishment and on the transition from PSURs to signal management.
- 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 document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee adopted the revised VICH guideline /GL18(R2) on impurities: residual solvents in new veterinary medicinal products, active substances and excipients, at step 4, for release in the EU following the sign-off by the VICH Steering Committee, for a 5-month period public consultation.

- The Committee endorsed the EU comments on the revised draft VICH guidelines on efficacy of anthelmintics:

  - VICH GL7 (general)
  - VICH GL12 (bovine)
  - VICH GL13 (ovine)
  - VICH GL14 (caprine)
  - VICH GL15 (equine)
  - VICH GL16 (porcine)
  - VICH GL19 (canine)
  - VICH GL20 (feline)
  - VICH GL21 (poultry)

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.
- Publication by the World Organisation for Animal Health (OIE) "Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species".

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)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 17 January 2022 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the revised guideline on quality of herbal medicinal products/traditional herbal medicinal products, and overview of comments, as well as the revised guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products, and overview of comments, following the close of the public consultation.
- The Committee adopted the concept paper for the revision of the guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water to develop an annex on the concomitant use of veterinary medicinal products and biocides for a 3-month period of public consultation. This concept paper has been developed to address the need to complement the guideline with information relating to the use of biocides in drinking water used to administer veterinary medicinal products.
- The Committee was informed of the upcoming election of the veterinary vice-chair of the QWP for 3-year term, renewable once, at the February 2022 CVMP meeting. A call for nominations was circulated by the Secretariat.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the draft guideline on determination of the need for an MRL evaluation for biological substances (EMA/CVMP/SWP/591282/2021), for a 3-month period of public consultation.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the overview of comments received during the public consultation of the concept paper on the development of a guideline on the environmental risk assessment of veterinary medicinal products intended to be used in aquaculture (EMA/CVMP/ERA/173026/2021) and gave ERAWP the mandate to develop the above-mentioned guideline.
- The Committee was informed of the upcoming election of the chair of the ERAWP for a 3-year term, renewable once, at the February 2022 CVMP meeting. A call for nominations was circulated by the Secretariat.

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted a draft reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6 (EMA/CVMP/AWP/387275/2020) for a 3-month period of public consultation. This reflection paper has been developed to establish an understanding of the term 'prophylaxis' as defined in Article 4(16) of the above-mentioned Regulation and to develop high level principles to guide the implementation of the restrictions on prophylactic use as required by the provisions of Article 107(3) of Regulation (EU) 2019/6.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted a draft reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6 (EMA/CVMP/AWP/387275/2020) for a 3-month period of public consultation. This reflection paper has been developed to establish an understanding of the term 'prophylaxis' as defined in Article 4(16) of the above-mentioned Regulation and to develop high level principles to guide the implementation of the restrictions on prophylactic use as required by the provisions of Article 107(3) of Regulation (EU) 2019/6.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted a revised guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines (EMA/CVMP/IWP/105506/2007 - Rev.2) and the overview of comments received (EMA/CVMP/IWP/532516/2021) following the close of the public consultation. The guideline has been amended to align with the provisions for multi-strain dossiers in Regulation (EU) 2019/6, which extends the multi-strain approach to viral diseases, in addition to avian influenza, bluetongue and foot-and-mouth disease, and to bacterial diseases requiring a need for rapid or frequent change in the strains included in the final product. The main aim of the guideline is to address the use of a multi-strain dossier for inactivated vaccines against antigenically variable viruses or bacteria and to provide information on criteria for eligibility to use the multi-strain approach and on data to be included in a multi-strain dossier. The revised guideline will come into effect on 28 January 2022.
- The Committee adopted a new guideline on data requirements for vaccine antigen master files (EMA/CVMP/IWP/258755/2021) and the overview of comments received (EMA/CVMP/IWP/544053/2021) following the close of the public consultation. The comments received during the consultation procedure were taken into account when finalising the guideline. This guideline has been developed to address the data to be included in a VAMF for veterinary vaccines. The new guideline will come into effect on 28 January 2022.

- The Committee adopted a new guideline on data requirements for vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/283631/2021) and the overview of comments received (EMA/CVMP/IWP/618280/2021) following the close of the public consultation. The comments received during the consultation procedure were taken into account when finalising the guideline. This guideline has been developed to address the type of data to be included in vPTMF and also the data requirements for subsequent dossier submissions for marketing authorisations based on a vPTMF after its first evaluation and certification. The new guideline will come into effect on 28 January 2022.
- The Committee adopted the draft guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances (EMA/CVMP/IWP/251947/2021) and the overview of comments (EMA/CVMP/IWP/618299/2021) received following the close of the public consultation. The comments received during the consultation procedure were taken into account when finalising the guideline. This guideline has been developed to define the minimum data requirements for applications in exceptional circumstances for all relevant parts of the dossier to support applications for authorisation of IVMPs under Article 25 of Regulation (EU) 2019/6. The new guideline will come into effect on 28 January 2022.
- The Committee adopted a new guideline on clinical trials with immunological veterinary medicinal products (IVMPs) (EMA/CVMP/IWP/260956/2021), and the overview of comments (EMA/CVMP/IWP/618327/2021) received following the close of the public consultation. The comments received during the consultation procedure were taken into account when finalising the guideline. This guideline has been developed to advise on how to perform clinical trials (also called field trials) with IVMPs and to address the requirements of the Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council regarding clinical trials for IVMPs. The guideline will come into effect on 28 January 2022.
- The Committee adopted a draft revised guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010) for a 2-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion*. See agenda point 7.11*

7.9 Novel therapy groups and related issues

- The Committee adopted a draft concept paper on quality, safety and efficacy of bacteriophages as veterinary medicines (EMA/CVMP/NTWP/438290/2021) for a 3-month period of public consultation.
- The Committee adopted a draft concept paper on the development and data requirements of potency tests for cell-based therapy products and the relation to clinical efficacy (EMA/CVMP/NTWP/470741/2021) for a 3-month period of public consultation.

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

7.11 Other working party and scientific group issues

- The Committee adopted the work plans for 2022 for the following CVMP working parties: SAWP-V (EMA/CVMP/SAWP/605699/2021), SWP-V (EMA/CVMP/SWP/586313/2021), ERAWP (EMA/CVMP/ERA/602113/2021), EWP-V (EMA/CVMP/EWP/526164/2021), AWP (EMA/CVMP/AWP/605507/2021), IWP (EMA/CVMP/IWP/612767/2021), and PhVWP-V (EMA/CVMP/PhVWP/365246/2021).

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 6 December 2021.

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 alcohols, C11-14 iso, C13 rich (CAS No: 68526-86-3), neodecanoic acid, zinc salt (CAS No: 27253-29-8), and phosphorous acid, tris(iso-tridecyl) ester (CAS No: 77745-66-5) as new entries in the list of substances considered as not falling within the scope of Regulation (EC) 470/2009 under the heading of excipients.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 – Rev. 50 (EMA/CVMP/519714/2009).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- There were no items for discussion.

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.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

9.1 MUMS/limited markets classifications

Information relating to MUMS/limited markets classifications cannot be released at the present time as it is deemed to be commercially confidential

- There were no items for discussion.

9.2 Limited market classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of the Regulation (EU) 2019/6

Information relating to limited market classifications and confirmation of eligibility for authorisation according to Regulation 2019 (EU) 2019/6 cannot be released at the present time as it is deemed to be commercially confidential

- The Committee discussed a draft concept paper on scientific guidelines for limited market products deemed not eligible for authorisation under Article 23 of Regulation 2019/6 (EMA/CVMP/435071/2021), together with the overview of comments received during the consultation of the draft concept paper. It was noted that the work on drafting the guidelines is progressing at the individual working parties concerned (EWP, IWP, QWP and SWP).

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.

- There were no items for discussion.

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 agenda of the CMDv meeting to be held on 20-21 January 2022, the minutes of the meeting held on 09-10 December 2021, the minutes of the CMDv-Interested Parties meeting held on 08 October 2021, and the draft agenda of the CMDv-Interested Parties meeting to be held on 21 January 2022.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Veterinary Domain on the meeting held on 13 January 2022, and noted the agenda of the meeting, together with the minutes of the meeting held on 25 November 2021.
- The Committee noted the Annual report on Veterinary Big Data initiative.

13. LEGISLATION

- The Committee adopted a question and answer document on GLP/GCP requirements for pre-clinical studies submitted in support of a marketing authorisation application for a veterinary medicinal product (EMA/CVMP/565615/2021).
- The Committee adopted a CVMP Agenda template in accordance with Regulation (EU) 2019/6.
- The Committee adopted a new scientific overview and list of questions template for biological veterinary medicinal products other than immunologicals, and co-rapporteur assessment report template for initial marketing authorisation applications for biological veterinary medicinal products other than immunologicals.

- The Committee received a verbal update on work progress for the scientific recommendations on the implementing act to Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans.
- The Committee received a verbal update on work progress of the expert group concerning provision of scientific recommendations on the 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)).

14. ANY OTHER BUSINESS

- Upon the completion of the January 2022 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 January 2022 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Svetoslav Valentinov Branchev	Full involvement	
CZ	Leona Nepejchalová	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	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	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	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie **VICE CHAIR**	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	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	
DE	Andrea Golombiewski	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	3.3 One item
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Kim Boerkamp	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.			
ES	Susana Casado	Full involvement	
DE	Anja Pfalzgraff	Full involvement	
DE	Anke Finnah	Full involvement	
FR	Gerard Moulin	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Celine Simoneit	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
FR	Nathalie Bridoux	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Caroline Guittré	Full involvement	
ES	Rosario Bullido	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Maren Osmers	Full involvement	
DE	Andrea Orthmann	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Silke Hickmann	Full involvement	
DE	Wiebke Weiher	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Uta Herbst	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Anne Sagnier	Full involvement	
FR	Anne Marie Jacques	Full involvement	
CZ	Eva Pomezna	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Zdenka Mašková	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(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 relevant support from the EMA staff