18 January 2022
EMA/CVMP/31894/2022
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 7-9 December 2021 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 December 2021 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 December 2021 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 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 November 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

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to poultry eggs for **toltrazuril** (EMEA/V/MRL/003363/EXTN/0004). The Norwegian CVMP member 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

- There were no items for discussion.

1.3 Lists of questions

- The Committee discussed the need for a list of questions for the extension of MRLs to fin fish for a substance, (EMEA/V/MRL/003477/EXTN/0004), and adopted a list of questions. The Committee noted a peer review report and the comments received from CVMP members.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 (EMEA/V/C/005579/0000) in dogs. The Committee noted the peer review reports.

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 marketing authorisation application for a new product, (EMEA/V/C/005577/0000) for pigs. The Committee noted 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 (EMEA/V/C/005860/0000) for chickens. The Committee noted 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

- The Committee was informed of the revised product information in relation to the marketing authorisation application for the generic product **Imoxat** (EMEA/V/C/005597/0000) containing imidacloprid and moxidectin for the treatment and/or prevention of mixed parasitic infections in cats, ferrets and dogs.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **CircoMax** (EMEA/V/C/005185/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Suiseng Diff/A** (EMEA/V/C/005596/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Imoxat** (EMEA/V/C/005597/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Zenalpha** (EMEA/V/C/005465/0000) concerning the granting of the initial marketing authorisation.

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, the CVMP assessment report and the product information for a type II variation application for **Improvac** (EMEA/V/C/000136/II/0036), recommending the variation of the marketing authorisation to change the indication by adding the suppression of oestrus in female pigs and subsequent changes to the product information. 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 (27 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 **Bravecto** (EMEA/V/C/002526/II/0051), recommending the variation of the marketing authorisation to add a new therapeutic indication for Bravecto chewable tablets for the reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for up to 12 weeks 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 endorsed the rapporteur's assessment report, for a type II variation application (subject to a worksharing procedure) for **Meloxidyl** and **Zeleris** (EMEA/V/C/xxxxxx/WS2038), 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 IB variation application (subject to a worksharing procedure) for **Simparica, Felisecto Plus, Simparica Trio, MiPet Easecto** and **Stronghold Plus** (EMEA/V/C/xxxxxx/WS2073/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 type IB variation application (subject to a worksharing procedure) for **Vaxxitek HVT+IBD** (EMEA/V/C/xxxxxx/WS2149), 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 type II variation application for **Bravecto** (EMEA/V/C/002526/II/0053), 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 for **Neocolipor** (EMEA/V/C/000035/II/0018/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 for **Cytopoint** (EMEA/V/C/003939/II/0014/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 (27 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 **Mhyosphere PCV ID** (EMEA/V/C/005272/II/0001/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, for a type IB variation application (subject to a worksharing procedure) for **Forceris** (EMEA/V/C/004329/WS2097/0003), 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, and agreed comments on the draft product information, for a type II variation application for **Advocate** (EMEA/V/C/000076/II/0046), concerning the addition of a new therapeutic indication.
- The Committee adopted a list of questions, for a type II variation application for **Porcilis ColiClos** (EMEA/V/C/0002011/II/0013), concerning quality-related changes.
- The Committee adopted a list of questions, for a type II variation application for **Suprelorin** (EMEA/V/C/000109/II/0003), 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 **BTVPUR** (EMEA/V/C/002231/II/0025/G), concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Poulvac E. coli** (EMEA/V/C/002007/II/0018) concerning the variation of the marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/II/0013) concerning the variation of the marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Apoquel** (EMEA/V/C/002688/X/0019) concerning the extension of the marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **NexGard Combo** (EMEA/V/C/005094/II/0002/G) concerning the variation of the marketing authorisation.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- There were no items for discussion.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- 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

- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Versican Plus DHPPi/L4R, Versican Plus Pi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4** (EMEA/V/C/002759/REC/017, EMEA/V/C/003682/REC/014, EMEA/V/C/003678/REC/017, EMEA/V/C/003680/REC/012, EMEA/V/C/003683/REC/013), which is now considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Poulvac E. coli** (EMEA/V/C/002007/REC/016, EMEA/V/C/002007/REC/017), which is now considered fulfilled.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 06.11.2021 – 09.12.2021:

Product	Period
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2020 – 20.11.2021
Broadline (EMEA/V/C/002700)	04.12.2020 – 03.12.2021
CircoMax Myco (EMEA/V/C/005184)	09.12.2020 – 08.12.2021
Contacera (EMEA/V/C/002612)	06.12.2020 – 05.12.2021
Draxxin (EMEA/V/C/000077)	11.11.2020 – 10.11.2021
Easotic (EMEA/V/C/000140)	20.11.2020 – 19.11.2021
Enteroporc Coli AC (EMEA/V/C/005149)	09.12.2020 – 08.12.2021
Equip WNV (EMEA/V/C/000137)	21.11.2020 – 20.11.2021
Gumbohatch (EMEA/V/C/004967)	12.11.2020 – 11.11.2021
Imrestor (EMEA/V/C/002763)	09.12.2020 – 08.12.2021
Inflacam (EMEA/V/C/002497)	09.12.2020 – 08.12.2021
Librela (EMEA/V/C/005180)	10.11.2020 – 09.11.2021
Masivet (EMEA/V/C/000128)	17.11.2020 – 18.11.2021
Meloxoral (EMEA/V/C/000151)	19.11.2020 – 18.11.2021
Nobivac DP Plus (EMEA/V/C/005251)	09.12.2020 – 08.12.2021
Nobivac LeuFel (EMEA/V/C/004778)	06.11.2020 – 05.11.2021

Product	Period
Nobivac Myxo-RHD Plus (EMEA/V/C/004989)	19.11.2020 – 18.11.2021
OvuGel (EMEA/V/C/005219)	10.11.2020 – 09.11.2021
Oxyglobin (EMEA/V/C/000045)	29.11.2020 – 28.11.2021
Panacur AquaSol (EMEA/V/C/002008)	09.12.2020 – 08.12.2021
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2020 – 15.11.2021
Porcilis PCV M Hyo (EMEA/V/C/003796)	07.11.2020 – 06.11.2021
Quadrisol (EMEA/V/C/000032)	04.12.2020 – 03.12.2021
Rabitec (EMEA/V/C/004387)	01.12.2020 – 30.11.2021
Rexxolide (EMEA/V/C/005384)	03.12.2020 – 02.12.2021
Simparica (EMEA/V/C/003991)	06.11.2020 – 05.11.2021
Stronghold (EMEA/V/C/000050)	25.11.2020 – 24.11.2021
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06.11.2020 – 05.11.2021
Vectormune FP ILT (EMEA/V/C/005482)	09.12.2020 – 08.12.2021
Vectra 3D (EMEA/V/C/002555)	04.12.2020 – 03.12.2021
Virbagen Omega (EMEA/V/C/000061)	06.11.2021 – 05.11.2021
Zycortal (EMEA/V/C/003782)	06.11.2020 – 05.11.2021

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 01.07.2018 – 30.06.2021 for **Fevaxyn Pentofel** (EMEA/V/C/000030) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2021 – 30.06.2021 for **Vectra 3D** (EMEA/V/C/002555) 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
Bovela (EMEA/V/C/003703)	01.07.2020 – 30.06.2021
Coliprotec F4/F18 (EMEA/V/C/004225)	01.08.2020 – 31.07.2021
CircoMax Myco (EMEA/V/C/005184)	09.12.2020 – 30.06.2021
Nasym (EMEA/V/C/004897)	01.02.2021 – 31.07.2021
Neptra (EMEA/V/C/004735)	01.01.2021 – 30.06.2021
NexGard Combo (EMEA/V/C/005094)	06.01.2021 – 31.07.2021
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	01.08.2018 – 31.07.2021
Prevexxion RN+HVT+IBD (EMEA/V/C/005057)	01.02.2021 – 31.07.2021
Profender (EMEA/V/C/000097)	01.08.2018 – 30.07.2021
Reconcile (EMEA/V/C/000133)	01.08.2018 – 31.07.2021
VarroMed (EMEA/V/C/002723)	03.08.2020 – 02.08.2021

- 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 endorsed the draft VICH guideline GL18 (R2) on impurities: residual solvents in new veterinary medicinal products, active substances and excipients for sign-off by the VICH Steering Committee at step 3 of the VICH process, after which it will be released for a 6-month public consultation at step 4.
- The Committee endorsed the concept paper proposing development of a VICH guideline to parallel ICH Q8 (R2) on Pharmaceutical Development.
- The Committee received a report from virtual meetings of the Safety EWG held on 8 and 9 November to discuss the ongoing revisions of GL22 on reproduction studies and GL23 on genotoxicity testing.
- The Committee received a verbal report on the VICH Steering Committee meeting held on 15, 17 and 18 November 2021, and the VICH Outreach Forum (VOF) meeting held on 16 November 2021.

6.2 Codex Alimentarius

- The Committee received a verbal report on the Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR) meeting held in October and the meeting of the Codex Alimentarius Commission held in November 2021.

6.3 Other EU bodies and international organisations

- The Committee received an update on the European Commission actions on titanium dioxide.
- The Committee received a status report of the enlarged Working Group on development of a common approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides in food of animal origin and annex.

The following documents were 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)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 6 December 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP veterinary vice-chair on the meeting held on 22-23 November and noted the agenda of the meeting.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 18 November 2021 and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

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

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the revised guideline on the summary of product characteristics for antiparasitic veterinary medicinal products (EMA/CVMP/EWP/170208/2005) and the overview of comments received following the close of the public consultation. The revised guideline will come into effect in July 2022.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 23-24 November 2021, and noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 17-18 November and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 16-17 November, and noted the agenda of the meeting.

7.9 Novel therapy and Technologies Working Party (NTWP)

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

The Committee discussed the draft work plans of the CVMP working parties, foreseen to be adopted at the January 2022 meeting of the Committee.

- The SAWP-V draft work plan for 2022.
- The SWP-V draft work plan for 2022.
- The ERAWP draft work plan for 2022.
- The EWP-V draft work plan for 2022.
- The AWP draft work plan for 2022.
- The IWP draft work plan for 2022.
- The PhVWP-V draft work plan for 2022.

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 27 October 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

- There were no items for discussion.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee received feedback on the eleventh ESVAC report: Sales of veterinary antimicrobial agents in 31 European countries in 2019 and 2020. Trends from 2010 to 2020 (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

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 Regulation (EU) 2019/6

Information relating to limited market classifications and confirmation of eligibility for authorisation according to Regulation (EU) 2019/6 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 (veterinary)

- The Committee received a verbal report from the chair of CMDv on the meetings held on 7-8 October and 4-5 November 2021, and noted the draft agenda of the meeting due to be held on 9-10 December 2021 and the minutes of the meeting held on 4-5 November 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Veterinary Domain (VetD) on the meeting held on 25 November 2021, and noted the agenda of the meeting and the minutes of the meetings held on 3 September 2021 and 25 October 2021.
- The Committee adopted the rules on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer.
- The Committee adopted the CVMP work plan for 2022.
- The Committee re-appointed Dr. K. Baptiste as CVMP co-opted member to complement its expertise in antimicrobial resistance for a further 3-year mandate. The Committee also re-appointed Dr. R. Carapeto García as CVMP co-opted member to complement its expertise in environmental risk assessment for a further 3-year mandate.
- The feedback on the annual report on the Veterinary Big Data initiative was postponed to the January 2022 meeting of the Committee.

13. LEGISLATION

14. ANY OTHER BUSINESS

- Upon the completion of the December 2021 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 December 2021 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	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	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	Lollita Taban	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	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	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
HU	Melinda Nemes-Terenyi	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Carina Bergman	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	María José Ferrer Montesa	Full involvement	
ES	Carlos Ballesteros Vicente	Full involvement	
FR	Damien Bouchard	Full involvement	
IT	Luca Busani	Full involvement	
DE	Sandra Bertulat	Full involvement	
BE	Koenraad Brusselmans	Full involvement	
FR	Gérard Moulin	Full involvement	
FR	Caroline Guittré	Full involvement	
ES	Rosario Bullido	Full involvement	
DE	Anke Finnah	Full involvement	
BE	Sandy Vermout	Full involvement	
DE	Stefan Scheid	Full involvement	
IE	Gavin Ryan	Full involvement	
IE	Sarah Buckley	Full involvement	
DE	Daniela Loos	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Thilo Nölke	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Silke Hickmann	Full involvement	
DK	Mikkel Kjelkvist Calum	Full involvement	
DK	Yen Ngoc Pham	Full involvement	
DK	Mette T. Madsen	Full involvement	
DE	Anja Pfalzgraff	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García

CVMP working parties and CMDv	Chair
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