7 September 2021
EMA/CVMP/500685/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 13-15 July 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 July 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 no competing interests were identified for the July 2021 CVMP 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.

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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 June 2021 CVMP meeting were adopted with a minor amendment.

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

- Further to a request from the European Commission, the Committee adopted by consensus (24 members present of those eligible to vote) the revised CVMP opinion including the EPMAR and the revised CVMP assessment report recommending the establishment of MRLs in poultry tissues for **bambermycin** (EMEA/V/MRL/004828/EXTN/0002). The Committee noted the report from the EU Reference Laboratory, the revised summary of the opinion for publication and the comments received from CVMP members.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- There were no items for discussion.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new vaccine (EMEA/V/C/005185/0000) for pigs. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/005597/0000) in cats, ferrets and dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

- The Committee adopted the updated scientific overview including the list of outstanding issues for an extension application for **Apoquel** (EMEA/V/C/002688/X/0019) to add a new pharmaceutical form. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- There were no items for discussion.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Bonqat** (EMEA/V/C/005489/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation (subject to a work-sharing procedure) for **Ingelvac CircoFLEX** (EMEA/V/C/xxxxxx/WS1921), recommending the variation of the marketing authorisation to change the product information to add the associated mixed use with other related nationally authorised products.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Suvaxyn CSF Marker** (EMEA/V/C/002757/II/0009), recommending the variation of the marketing authorisation to add a new therapeutic indication "*For active immunisation of breeding females to reduce transplacental infection caused by classical swine fever virus (CSFV)"*. 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 for **Apoquel** (EMEA/V/C/002688/II/0020), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 for **Ecoporc Shiga** (EMEA/V/C/002588/II/0013) recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 for **Librela** (EMEA/V/C/005180/II/0001), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 grouped variation for **Locatim** (EMEA/V/C/000041/II/0021/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 for **Nobilis**

Influenza H5N2 (EMEA/V/C/000118/II/0016), recommending the variation of the marketing authorisation to implement quality-related changes.

- 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 type II grouped variation for **Porcilis PCV** (EMEA/V/C/000135/II/0014/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 grouped variation for **Stelfonta** (EMEA/V/C/005018/II/0004/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- 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 grouped variation for **Vectormune ND** (EMEA/V/C/003829/II/0015/G), recommending the variation of the marketing authorisation to implement quality-related changes.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues to be addressed in writing for a type II variation for **Frontpro** (EMEA/V/C/005126/II/0010) to change the product information.
- The Committee adopted a list of outstanding issues to be addressed in writing for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0047) to add a new therapeutic indication.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/II/0013) to amend the product information.
- The Committee adopted a list of questions for a type II variation (subject to a work-sharing procedure) for **Nobivac L4** and other related products authorised by mutual recognition, decentralised and national procedures (EMEA/V/C/002010/WS2058/0012) to amend the product information.
- The Committee adopted a list of questions for a type II variation for **Credelio** (EMEA/V/C/004247/II/0018) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for an extension to the clock-stop for a type II grouped variation for **Neocolipor** (EMEA/V/C/000035/II/0018/G) concerning quality-related changes.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- There were no items for discussion.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- 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 adopted the rapporteur's assessment report on the data submitted in response to the Committee's quality-related recommendation for **CircoMax Myco** (EMEA/V/C/005184/REC/002.1.2.3.4).
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Letifend** (EMEA/V/C/003865/REC/014), which is now considered completed.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 16.06.2021 – 15.07.2021:

Product	Period
Aftovaxpur DOE (EMEA/V/C/002292)	15.07.2020 – 14.07.2021
Canigen L4 (EMEA/V/C/004079)	03.07.2020 – 02.07.2021
Circovac (EMEA/V/C/000114)	21.06.2020 – 20.06.2021
Clynav (EMEA/V/C/002390)	27.06.2020 – 26.06.2021
Convenia (EMEA/V/C/000098)	19.06.2020 – 18.06.2021
Equilis Prequenza (EMEA/V/C/000094)	08.07.2020 – 07.07.2021
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2020 – 07.07.2021
Equilis Te (EMEA/V/C/000093)	08.07.2020 – 07.07.2021
Equioxx (EMEA/V/C/000142)	25.06.2020 – 24.06.2021
Eryseng (EMEA/V/C/002761)	04.07.2020 – 03.07.2021

Product	Period
Eryseng Parvo (EMEA/V/C/002762)	08.07.2020 – 07.07.2021
HorStem (EMEA/V/C/004265)	19.06.2020 – 18.06.2021
Innovax-ILT (EMEA/V/C/003869)	03.07.2020 – 02.07.2021
Leucofeligen FeLV/RCP (EMEA/V/C/000143)	25.06.2020 – 24.06.2021
Melovem (EMEA/V/C/000152)	07.07.2020 – 06.07.2021
Posatex (EMEA/V/C/000122)	23.06.2020 – 22.06.2021
Prevomax (EMEA/V/C/004331)	19.06.2020 – 18.06.2021
ProZinc (EMEA/V/C/002634)	12.07.2020 – 11.07.2021
Reconcile (EMEA/V/C/000133)	08.07.2020 – 07.07.2021
Sevohale (EMEA/V/C/004199)	21.06.2020 – 20.06.2021
Suprelorin (EMEA/V/C/000109)	10.07.2020 – 09.07.2021
Versican Plus DHPPi (EMEA/V/C/003679)	04.07.2020 – 03.07.2021
Versican Plus Pi (EMEA/V/C/003681)	04.07.2020 – 03.07.2021

5.4 Renewals

- 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 the renewal of the marketing authorisation for **Halagon** (EMEA/V/C/004201/R/0006), and recommended that the authorisation should now be indefinite.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted a recommendation for changes to the SPC section 4.6 'Adverse reactions (frequency and seriousness)' and the corresponding section of the package leaflet for **Advocate** based on the outcome of signal detection activities.
- The Committee adopted a recommendation for changes to the SPC section 4.6 'Adverse reactions (frequency and seriousness)' for **Kriptazen** based on the outcome of signal detection activities.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.07.2020-31.12.2020 for **Vectra 3D** (EMEA/V/C/002555) with a recommendation to amend section 4.5 'Special precautions for use' and section 4.9 'Amounts to be administered and administration route' of the SPC and the corresponding sections of the package leaflet.
- 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
Acticam (EMEA/V/C/000138) (WD)	01.07.2018-22.03.2021
Bravecto Plus (EMEA/V/C/004440)	01.06.2020-30.11.2020
Chanhold (EMEA/V/C/004824)	17.04.2019-31.01.2021

Product	Period
Evant (EMEA/V/C/004902)	01.09.2020-28.02.2021
Exzolt (EMEA/V/C/004344)	01.03.2020-28.02.2021
Innovax ND-IBD (EMEA/V/C/004422)	01.03.2020-28.02.2021
Suvaxyn PRRS MLV (EMEA/V/C/004276)	01.03.2020-28.02.2021
Vepured (EMEA/V/C/004364)	01.03.2020-28.02.2021

- 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.

- 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 EU comments on the draft VICH guideline on target animal safety evaluation for veterinary monoclonal antibody products.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- 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 12 July 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted a guideline on manufacture of the veterinary finished dosage form (EMA/CVMP/QWP/798401/2015) and the overview of comments received during the public consultation (EMA/CVMP/QWP/485008/2019). The guideline will come into effect 6 months after publication but not before 28 January 2022.

7.3 Safety Working Party (SWP-V)

- The Committee adopted a concept paper on the development of a guideline on determination of the need for an MRL evaluation for biological substances (EMA/CVMP/SWP/207500/2021) for a 2-month period of public consultation.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee noted the minutes from the ERAWP meeting held on 4 March 2021 as well as the agenda of the meeting held on 30 June-1 July.
- The Committee adopted a 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) for a 3-month period of public consultation.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 22-23 June 2021 and noted the agenda of the meeting and the minutes from the meeting held on 23-24 March 2021.
- The Committee adopted a draft revised guideline on the summary of product characteristics for antiparasitic veterinary medicinal products (EMA/CVMP/EWP/170208/2005) for a 2-month period of public consultation.
- The Committee adopted revised efficacy guidelines aligned with the terminology and definitions provided by Regulation (EU) 2019/6 on: conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/EWP/16/2000); demonstration of palatability of veterinary medicinal products (EMA/CVMP/EWP/206024/2011); statistical principles for clinical trials for veterinary medicinal products (pharmaceuticals) (EMA/CVMP/EWP/81976/2010); conduct of efficacy studies for non-steroidal anti-inflammatory drugs (EMA/CVMP/EWP/1061/2001); demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish (EMA/CVMP/EWP/459868/2008); dossier requirements for anticancer medicinal products for dogs and cats (EMA/CVMP/28510/2008); veterinary medicinal products controlling *Varroa destructor* parasitosis in bees (EMA/CVMP/EWP/459883/2008); testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats (EMA/CVMP/EWP/5/2000); pharmaceutical fixed combination products (EMA/CVMP/83804/2005); specific efficacy requirements for ectoparasiticides in cattle (EMA/CVMP/625/2003); and specific efficacy requirements for ectoparasiticides in sheep (EMA/CVMP/411/2001).

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted a revised guideline on data requirements for adjuvants in vaccines for veterinary use (EMA/CVMP/IWP/315887/2017) and the overview of comments received during the public consultation (EMA/CVMP/IWP/30398/2019). The new guideline will come into effect on 28 January 2022.
- The Committee adopted a draft guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances (EMA/CVMP/IWP/299554/2021) for a 3-month period of public consultation.
- The Committee adopted a draft guideline on data requirements for vaccine platform technology master files (vPTMF) (EMA/CVMP/IWP/283631/2021) for a 3-month period of public consultation.
- The Committee adopted a draft guideline on clinical trials with immunological veterinary medicinal products (IVMPs) (EMA/CVMP/IWP/260956/2021) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a report from the PhVWP-V chair on the meeting held on 6-7 July 2021 and noted the agenda and draft summary record (EMA/CVMP/PhVWP/365813/2021) of the meeting.

7.9 Novel Therapies & Technologies Working Party (NTWP)

- The Committee appointed experts for the operational expert group on cell therapies and for the operational expert group on bacteriophages.

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

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 14 June 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

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted a reflection paper on promoting the authorisation of alternatives to antimicrobial veterinary medicinal products in the EU (EMA/CVMP/143258/2021) and the overview of comments received (EMA/200935/2021) following the close of the public consultation – *see also point 9.*
- The Committee noted the JIACRA III report - Third joint inter-agency report on integrated analysis of antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA (link).

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee adopted a reflection paper on promoting the authorisation of alternatives to antimicrobial veterinary medicinal products in the EU (EMA/CVMP/143258/2021) and the overview of comments received (EMA/200935/2021) following the close of the public consultation. – *see also point 8.3.*

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a report from the chair of CMDv on the meetings held on 11-12 May and 17-18 June 2021, and noted the draft agenda of the meeting held on 15-16 July 2021 as well as the minutes of the meeting held on 17-18 June 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee was informed of the potential issues or procedures requiring CVMP decision via written procedure during August 2021.

13. LEGISLATION

- The Committee adopted the English version of the revised QRD product information template v.9. The translated versions will be published in October 2021. QRD template v.9 reflects the requirements of Regulation (EU) 2019/6 for the summary of product characteristics and packaging, as well as taking into account the outcome of the public consultation.
- The Committee adopted a reflection paper on eligibility criteria for limited markets (EMA/CVMP/235292/2020) and the overview of comments received during the public consultation (EMA/147858/2021).
- The Committee adopted a guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/345237/2020) following the close of the public consultation.
- The Committee adopted a guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/52665/2020) following the close of the public consultation.

- The Committee adopted a guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/59531/2020) following the close of the public consultation.
- The Committee adopted a procedural form for requests to CVMP for classification of a veterinary medicinal product intended for a limited market according to Article 4(29) and for eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/272194/2021).
- The Committee received a verbal report on work progress concerning provision of scientific recommendations on implementing acts required by Regulation (EU) 2019/6 and in line with the mandates received from the European Commission.
- The Committee noted the publication of the European Commission Notice and the EMA questions and answers on marketing authorisations for veterinary medicinal products for which the expiry of the 5-year period of validity falls on or after the date of entry into application of Regulation (EU) 2019/6.

14. ANY OTHER BUSINESS

- Upon the completion of the July 2021 CVMP meeting the draft news highlights were 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 July 2021 CVMP 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	
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	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	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	
SK	Judita Hederová	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	

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	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Kim Boerkamp	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Sandy Vermout	Full involvement	
DE	Birgit Kegel	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Nadine Matzmohr	Full involvement	
DE	Sarah Bolda	Full involvement	
DE	Silke Hickmann	Full involvement	
DE	Stefan Scheid	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Wiebke Weiher	Full involvement	
DK	Helle Mulvad	Full involvement	
DK	John Jensen	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
ES	Rocio Fernandez	Full involvement	
ES	Rosario Bullido	Full involvement	
FR	Gérard Moulin	Full involvement	
FR	Laetitia Le Letty	Full involvement	
IE	Sarah Hanley	Full involvement	
PT	Luísa Vieira Peixe	Full involvement	
* Experts were only evaluated against the topics they have been invited to talk about.			

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 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