19 June 2018
EMA/CVMP/495564/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 19-21 June 2018 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

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).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the June 2018 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. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of May 2018 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 rapporteur's assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs for a substance (EMA/V/MRL/004856/FULL/0001) in chickens, and noted two peer review reports and the comments received from CVMP members. The adoption of the opinion is foreseen for the July 2018 meeting of the Committee.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Cortacare** (EMEA/V/C/004689/0000), recommending the granting of a marketing authorisation. The product is a cutaneous spray solution containing hydrocortisone aceponate, intended for symptomatic treatment of inflammatory and pruritic dermatoses in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by majority (18 members in favour out of the 27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Arti-Cell Forte** (EMEA/V/C/004727/0000), recommending the granting of a marketing authorisation. Arti-Cell Forte is a suspension for injection for horses, containing chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells, intended for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste, A. Battisti, F. Bozic, E. Kozhuharov, C. Muñoz, B. Urbain, J-C. Rouby, E-M. Vestergaard, and A. Wachnik-Święcicka, signed divergent positions not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication. The product has been classified as MUMS/limited markets.

- The Committee adopted by majority (26 members in favour out of the 27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for **Horse Allo 20** (EMEA/V/C/004222/0000), recommending the refusal of the granting of a marketing authorisation. Horse Allo 20 contains allogeneic mesenchymal stem cells from horse adipose tissue and was proposed for treatment of lameness associated with osteoarthritis in adult horses. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. C. Munoz signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication. The product has been classified as MUMS/limited markets. The Committee noted the summary of opinion for publication. The product has been classified as MUMS/limited markets.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for **LongRange** (EMEA/V/C/004291/0000), recommending the refusal of the granting of a marketing authorisation. LongRange is a new antiparasitic product containing eprinomectin for the treatment of certain specified parasites in cattle. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

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 the list of questions and agreed comments on the draft product information for a new antiprotozoal product (EMEA/V/C/004868/0000) for new-born calves. The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/004897/0000) for cattle. The Committee noted four 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 noted the request from the applicant for an extension to the clock-stop for **Inflacam** (EMEA/V/C/002497/X/0015), to add a new pharmaceutical form and strength for cats.

- The Committee noted the request from the applicant for an extension to the clock-stop for **Rheumocam** (EMEA/V/C/000121/X/0022), to add a new pharmaceutical form and strength for cats.

- The Committee endorsed the EPAR module 6 scientific discussion for **Credelio** (EMEA/V/C/004247/X/0001) concerning the granting of an extension to the marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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

for **BTVPUR** (EMEA/V/C/002231/II/0010), recommending the variation of the marketing authorisation to add a new serotype, BTV 2, for sheep and cattle. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a worksharing type II variation (EMEA/V/C/XXXXXX/WS1282) for **LEUCOFELIGEN FeLV/RCP**, **Nobivac LeuFel** and **LEUCOGEN**, recommending the granting of the variation to the marketing authorisation to modify the duration of immunity. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report, for a worksharing type IB variation for **Circovac** and **EQUIOXX** (EMEA/V/C/xxxxxx/WS1382), recommending the variation of the marketing authorisation to implement administrative 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 the list of questions for a type II variation for **Velactis** (EMEA/V/C/003739/II/0004) concerning target animal safety, and agreed to extend the clock stop following the request from the MAH. The Committee noted a peer review and the comments received from CVMP members.

- The Committee adopted a list of questions for a type II variation for **Econor** (EMEA/V/C/000042/II/0052) concerning changes in the SPC and package leaflet, and noted the comments received from CVMP members.

- The Committee adopted a list of questions for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0009) to change the onset of immunity for cattle and sheep, and noted the comments received from CVMP members.

- The Committee adopted a list of questions for a type II variation for **Clomicalm** (EMEA/V/C/000039/II/0027) concerning quality changes, and noted the comments received from CVMP members.

- The Committee adopted the list of questions for a type II variation for **OSURNIA** (EMEA/V/C/003753/II/0008) concerning quality changes, and noted the comments received from CVMP members.

- The Committee adopted the list of questions for a type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003753/II/0008) concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep** (EMEA/V/A/126). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted a peer review report and the comments made by CVMP members.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee discussed the rapporteur's assessment report including the critique from the co-rapporteur for the procedure **to consider the risk for the consumer resulting from the use of diethanolamine as an excipient in veterinary medicinal products for food producing species** (EMEA/V/A/127). The Committee noted two peer review reports. The opinion is foreseen to be adopted at the July 2018 CVMP meeting.

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 concerning a condition for **CYTOPOINT** (EMEA/V/C/003939/ANX/001).
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Fevaxyn Pentofel** (EMEA/V/C/000030/REC/028).
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Onsior** (EMEA/V/C/000127/REC/006.1).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 26.05.2018–21.06.2018:

Product	Period
Circovac (EMEA/V/C/000114)	21.06.2017 – 20.06.2018
Convenia (EMEA/V/C/000098)	19.06.2017 – 18.06.2018
Equilis West Nile (EMEA/V/C/002241)	06.06.2017 – 05.06.2018
LEUCOGEN (EMEA/V/C/000144)	17.06.2017 – 16.06.2018
MS-H Vaccine (EMEA/V/C/000161)	14.06.2017 – 13.06.2018
Nobilis IB 4-91 (EMEA/V/C/000036)	09.06.2017 – 08.06.2018
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2017 – 13.06.2018
Porcilis Pesti (EMEA/V/C/000046)	09.06.2017 – 08.06.2018
Poulvac E. coli (EMEA/V/C/002007)	15.06.2017 – 14.06.2018
Prevomax (EMEA/V/C/004331)	19.06.2017 – 18.06.2018
Sevohale (EMEA/V/C/004199)	21.06.2017 – 20.06.2018
Sileo (EMEA/V/C/003764)	10.06.2017 – 09.06.2018
Spironolactone Ceva (EMEA/V/C/000105)	20.06.2017 – 19.06.2018
Vectra Felis (EMEA/V/C/002746)	06.06.2017 – 05.06.2018

5.4 Renewals

- The Committee adopted by consensus (26 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 **Vectra 3D** (EMEA/V/C/002555/R/0009), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Credelio (EMEA/V/C/004247)	01.08.17-31.01.18
DRAXXIN (EMEA/V/C/000077)	01.06.17-30.11.17
Exzolt (EMEA/V/C/004344)	18.08.17-28.02.18
Innovax NB-IBD (EMEA/V/C/004422)	22.08.17-28.02.18
Porcilis PCV ID (EMEA/V/C/003942)	01.09.17-28.02.18

Sileo (EMEA/V/C/003764)	01.07.17-31.12.17
Stronghold (EMEA/V/C/000050)	01.02.15-31.01.18
Trifexis (EMEA/V/C/002635)	05.07.17-04.01.18
ZULVAC 8 Bovis (EMEA/V/C/000145)	01.02.17-31.01.18
ZULVAC 8 Ovis (EMEA/V/C/000147)	01.02.17-31.01.18

- 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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the draft EU comments in relation to the FDA questions on the use of geometric versus arithmetic means for the calculation of efficacy and the scarcity of naturally infected dogs as part of the revision of the VICH anthelmintic guidelines (7, 12-16, and 19-21).
- The Committee endorsed the draft EU comments on the first draft of the new VICH guideline on fixed combination products.
- The Committee endorsed the draft VICH GL58 on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV for sign off at step 4 by the VICH Steering Committee.
- The Committee endorsed the draft VICH GL56 on study design recommendations for residues in honey for establishing MRLs and withdrawal periods for sign off at step 7 by the VICH Steering Committee.
- The Committee discussed the proposal for the formation of a VICH taskforce to consider the scope of a possible guideline on medicated premixes, and the comments provided. The Committee expressed a number of reservations about the scope of any future guideline but did not object to the formation of a taskforce. The Committee's position will be communicated to the VICH Steering Committee.
- The Committee discussed the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) response to EU comments on the proposal for advancing the extraneous agents topic, and agreed that its position remained unchanged and that it did not support the activity as proposed. The Committee's position will be communicated to the VICH Steering Committee.
- The Committee discussed the JMAFF response to EU comments on the draft concept paper for development of a guideline on safety evaluation of biotechnology-derived/biological products. The Committee noted the revised timelines provided and highlighted that at this time it is not able to commit to timelines for development of a guideline. The Committee's position will be communicated to the VICH Steering Committee.
- The Committee noted the draft agenda of the 36th VICH Steering Committee meeting and the draft agenda of the 10th VICH Outreach Forum meeting, both to be held between 25-28 of June 2018 in Bruges, Belgium. The Committee also noted the following Expert Working Group (EWG) progress reports: for quality EWG, electronic standards implementation EWG,

biologicals quality monitoring EWG, metabolism and residues kinetics EWG, safety EWG, combination products EWG, anthelmintics EWG and progress on individual topics.

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 report of VICH guidelines and externally organised projects and events.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 19 June 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report on the QWP-V meeting held on 5-7 June 2018, and noted the agenda of the meeting.

7.3 Safety Working Party (SWP-V)

- The Committee was informed of the upcoming election of the vice-chair of the SWP-V for a three year mandate and noted the call for nominations.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 29-30 May 2018, and noted the agenda.
- The Committee agreed for EWP-V to consider the revision of the CVMP guideline on the conduct of pharmacokinetic studies in target animal species following the close of the public consultation based on the comments received.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 29-30 May 2018, and noted the draft minutes and agenda of the meeting.
- The Committee adopted a revised reflection paper on the use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health and the overview of comments received, following the close of the public consultation.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the draft revised guideline on the use of adjuvanted veterinary vaccines (EMA/CVMP/IWP/315887/2017) for release for a 6-month period of public consultation.
- The Committee noted the agenda and draft minutes from the Joint EDQM 15V/EMA meeting held on 12 April 2018 in Strasbourg, in relation to the guidance on implementation of extraneous agent (EA) testing.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 29-30 May 2018, and noted the agenda of the meeting.
- The Committee adopted the revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/10418/2009), following the yearly review and update. Implementation of the VeDDRA list in EudraVigilance Veterinary is provisionally scheduled for 1 October 2018. The Committee also adopted the revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.11).
- The Committee adopted a revised question and answer document on adverse event reporting.
- The Committee adopted a revised question and answer document on preparation, management and assessment of periodic safety update reports (PSURs).

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

- The Committee adopted the review and update of EMA guidelines to implement best practices with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (EMA/CHMP/CVMP/3Rs/677407/2015) and the overview of comments received during the public consultation (EMA/CHMP/CVMP/3Rs/731086/2016). The document was also adopted by CHMP/ORGAM and will be published on the Agency's website following the June CHMP meeting.
- The Committee adopted the reflection paper on the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/3Rs/164002/2016), and the overview of comments received during the public consultation (EMA/CHMP/CVMP/3Rs/731924/2016).

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 17 April 2018.
- Minutes of the QWP meeting held on 27 February-1 March 2018.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be 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 development of the scientific advice prepared by the Antimicrobial Advice Ad Hoc Expert Group.
- The Committee noted the public consultation on the discussion papers informing the AMR report of the Interagency Coordination Group to the UN Secretary-General.

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 contain commercially confidential information.

- The Committee received an update following the preparatory meeting of the CVMP ad hoc regulatory expert group on RD114 held on 24 May 2018, and noted the meeting agenda.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

10. PROCEDURAL AND REGULATORY MATTERS

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

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

10.2 Regulatory matters

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

- The Committee noted the updated dossier requirements for submission of MA and MRL applications to the EMA and to members of the CVMP (EMA/466102/2007) following the mandatory use of the Common Repository, effective from 1st June 2018.

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

- The Committee noted the draft minutes of the meeting held on 24-25 May as well as the draft agenda of the meeting held on 21-22 June 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the secretariat on the Strategic Planning Group meeting held on 20 June 2018, and noted the agenda of the June meeting and the minutes of the meeting held on 18 April 2018.
- The Committee continued its discussion relating to the review of CVMP roles. Following the initial discussion at the May 2018 CVMP meeting, further discussions explored the responsibility of rapporteurs and their assessment teams focusing on the need for additional guidance, the timing of secretariat engagement during the assessment and the interaction between rapporteurs and scientific leads. It was agreed that further guidance on the above topics would be useful.
- The Committee deferred the discussion on the draft CVMP work plan for 2019 to the July 2018 meeting.
- The Committee noted the draft minutes of the CVMP informal presidency meeting held on 7-8 May 2018 in Madrid, Spain. Comments from CVMP members that participated in the informal presidency meeting were requested. Recommendations arising from the informal presidency meeting will be brought back to a future CVMP meeting for discussion/endorsement.

13. LEGISLATION

- The Committee noted Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009

14. ANY OTHER BUSINESS

- Upon the completion of the June 2018 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the June 2018 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	Brigitte Hauser	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 5.5 Sileo • 10.1 – one item
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Wilhelm Schlumbohm	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
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
FR	Sylvie Louet	Full involvement	
IT	Antonio Battisti	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SI	Maja Turk	Full involvement	
SK	Eva Chobotová	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Noemi Garcia del Blanco	Full involvement	
NO	Tonje Høy	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	Sonja Beken	Full involvement	
DE	Christine Schwarz	Full involvement	
DE	Maren Friederichs *(remotely)*	Full involvement	
DE	Stephan Steuber *(remotely)*	Full involvement	
DE	Anke Finnah *(remotely)*	Full involvement	
DE	Svenja Rieke *(remotely)*	Full involvement	
DE	Stefan Scheid *(remotely)*	Full involvement	
DE	Sabine Klee *(remotely)*	Full involvement	
DE	Nadine Matzmohr *(remotely)*	Full involvement	
DE	Uta Herbst *(remotely)*	Full involvement	
DK	Anne Malene Nissen	Full involvement	
DK	Niels Christian Kyvsgaard *(remotely)*	Full involvement	
ES	Javier Alonso Naveda *(remotely)*	Full involvement	
ES	Sonia Gil Morales *(remotely)*	Full involvement	
ES	Javier Martínez de Velasco *(remotely)*	Full involvement	
ES	Carlos Ballesteros Vicente *(remotely)*	Full involvement	
ES	Rosario Bullido *(remotely)*	Full involvement	
FI	Kristina Lehmann (remotely)	Full involvement	
FI	Jukka Pakkanen (remotely)	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Benoit Courty *(remotely)*	Full involvement	
FR	Jean-Christophe Faucon *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
SE	Denise Laskowski	Full involvement	
SE	Andreea Barbu *(remotely)*	Full involvement	
SE	Fredrik Hultén *(remotely)*	Full involvement	
SE	Helena Back *(remotely)*	Full involvement	
UK	Samuel Fletcher *(remotely)*	Full involvement	

Country	CVMP Expert	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Gillian Clarke *(remotely)*	Full involvement	
UK	Sharon Reynolds *(remotely)*	Full involvement	
UK	Claire Stratford *(remotely)*	Full involvement	
UK	John Mitchell*(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	---
ERAWP	---
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady
SAWP-V	Rory Breathnach
SWP-V	Stefan Scheid – *remotely*

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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