3 December 2019
EMA/CVMP/657101/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 5-7 November 2019 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).

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of four new items, a point under section 4.7, one under section 5.6 and two under section 7.7.

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

The attendance list was completed and competing interests were identified for the November 2019 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 of the 33 members eligible to vote 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the October 2019 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' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in bovine and porcine for a substance (EMEA/V/MRL/005072/FULL/0001) and adopted a list of outstanding issues. The Committee noted a peer review report and the comments received from 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

- The Committee adopted by majority (26 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 **Stelfonta** (EMEA/V/C/005018/0000) recommending the granting of a marketing authorisation. The product is a new product for the treatment of non-resectable, non-metastatic cutaneous and subcutaneous mast cell tumours in dogs. T-M. Muhonen and the Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation. 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 **Aservo EquiHaler** (EMEA/V/C/004991/0000) recommending the granting of a marketing authorisation. Aservo EquiHaler is a new product for the treatment of horses with clinical signs of severe equine asthma. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the scientific overview including a list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine (EMEA/V/C/005077/0000) for chickens. The Committee noted the comments received from CVMP members.

- The Committee adopted the scientific overview including a list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new generic product (EMEA/V/C/005073/0000) for cattle, pigs and sheep. The Committee noted one peer review report and the comments received from CVMP members.

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/005719/0000) for cats. The Committee noted three peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and comments on the draft product information for a marketing authorisation application for a new generic product (EMEA/V/C/005076/0000) for cattle, pigs and sheep. The Committee noted one 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 an extension of the clock-stop for a new product for dogs.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Gumbohatch** (EMEA/V/C/004967/0000) subsequent to the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Nobivac Myxo-RHD PLUS** (EMEA/V/C/004989/0000) subsequent to the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 for **Bravecto Plus** (EMEA/V/C/004440/II/0006) recommending the variation of the marketing authorisation to implement a modification of the approved therapeutic indication for the prevention of heartworm disease caused by *Dirofilaria immitis*, i.e. to extend the duration of prevention from 8 weeks to 12 weeks. 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 (28 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Poulvac E. Coli** (EMEA/V/C/002007/II/0016/G) recommending the variation of the marketing authorisation to implement quality 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 and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation (subject to a worksharing procedure) for **Vectormune ND** and nationally authorised products (EMEA/V/C/WS1597/G) recommending the variation of the marketing

authorisations to implement quality 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 and the product information and endorsed the rapporteur's assessment report for a type II grouped variation for **ProZinc** (EMEA/V/C/002634/II/0019/G) recommending the variation of the marketing authorisation to implement quality 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 and endorsed the rapporteur's assessment report for a type II grouped variation for **Exzolt** (EMEA/V/C/004344/II/0007/G) recommending the variation of the marketing authorisation to implement quality 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 for **Rabitec** (EMEA/V/C/004387/II/0002) to extend the duration of immunity.
- The Committee adopted a list of questions for a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0078) to add a new indication.
- The Committee adopted a list of questions for a type II variation for **Innovax-ND-IBD** (EMEA/V/C/004422/II/0003) to add a new indication.
- The Committee adopted a list of questions for a type II variation for **Evicto** (EMEA/V/C/004973/II/0001) concerning quality changes.

3.4 Re-examination of CVMP opinions

- The Committee adopted a list of questions to the ad hoc expert group (AHEG) and endorsed the list of AHEG members and the agenda of the AHEG meeting, for the re-examination of the CVMP opinion adopted in September 2019 for a type II variation application for **Velactis** (EMEA/V/C/003739/II/0004).

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Ketabel 100 mg/ml solution for injection and associated names** (EMEA/V/A/133). The Committee agreed that no outstanding issues remained and noted two peer review reports and the comments made by CVMP members. The adoption of the CVMP opinion is foreseen for the December 2019 meeting of the Committee.

4.2 Article 34 of Directive 2001/82/EC

- The Committee agreed to the request from Boehringer Ingelheim Santé Animale for an extension of the clock-stop for the referral procedure for **Ronaxan and its associated names** (EMEA/V/A/135) and adopted a revised timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing tylosin base (as single active substance) presented as solutions for injection for intramuscular use in pigs** (EMEA/V/A/131). The Committee also noted the comments received from the CVMP members. The adoption of the CVMP opinion is foreseen for the December 2019 meeting of the Committee.
- The Committee considered the notification from Belgium for a referral procedure for **veterinary medicinal products containing tiamulin hydrogen fumarate for pigs presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered**. The matter was referred to the Committee due to concerns relating to the efficacy of tiamulin for prevention or metaphylaxis of swine dysentery caused by *Brachyspira hyodysenteriae*. The Committee agreed to start a referral procedure (EMEA/V/A/137) under Article 35 and appointed B. Urbain as rapporteur and S. Louet as co-rapporteur 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

- The Committee considered the notification from the European Commission to the EMA of a procedure under Article 45 of Regulation (EC) No. 726/2004 for **Suvaxyn PRRS MLV** (porcine respiratory and reproductive syndrome virus vaccine (live)) (EU/2/17/215/001-003). The Committee agreed to start the procedure and appointed E. Werner as rapporteur and F. Klein as co-rapporteur for the procedure.

The following document was circulated for information:

- Referrals tracking table.

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 concerning a recommendation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/REC/026).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 11.10.2019-7.11.2019:

Product	Period
Halocur (EMEA/V/C/000040)	29.10.2018 – 28.10.2019
Nobivac LeuFel (EMEA/V/C/004778)	06.11.2018 – 05.11.2019
Porcilis PCV M Hyo (EMEA/V/C/003796)	07.11.2018 – 06.11.2019
Simparica (EMEA/V/C/003991)	06.11.2018 – 05.11.2019
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06.11.2018 – 05.11.2019
Virbagen Omega (EMEA/V/C/000061)	06.11.2018 – 05.11.2019
Zolvix (EMEA/V/C/000154)	04.11.2018 – 03.11.2019
Zycortal (EMEA/V/C/003782)	06.11.2018 – 05.11.2019

5.4 Renewals

- 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 the renewal of the marketing authorisation for **Coliprotec F4** (EMEA/V/C/003797/R/0005) and recommended that the authorisation should now be indefinite. 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Zulvac SBV** (EMEA/V/C/002781/R/0007) 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 adopted the CVMP assessment report of the PSUR for the period 01.06.2018-31.05.2019 for **Simparica** and **MiPet Easecto** (EMEA/V/C/003991) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.2018-30.04.2019 for **Letifend** (EMEA/V/C/003865) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2018-31.01.2019 for **Osurnia** (EMEA/V/C/003753) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.06.2018-31.05.2019 for **Zycortal** (EMEA/V/C/003782) with a recommendation to amend the product information.
- The Committee endorsed the following rapporteurs' assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Bluevac BTV8 (EMEA/V/C/000156)	01.07.2018-30.06.2019
Bovela (EMEA/V/C/003703)	01.07.2018-30.06.2019

Bovilis Blue8 (EMEA/V/C/004776)	01.07.2018-30.06.2019
Bravecto Plus (EMEA/V/C/004440)	01.12.2018-31.05.2019
Clynav (EMEA/V/C/002390)	01.01.2019-30.06.2019
Halagon (EMEA/V/C/004201)	01.01.19.2030.06.2019
Inflacam (EMEA/V/C/002497)	01.07.2016-30.06.2019
Porcilis PCV (EMEA/V/C/000135)	13.07.2016-12.07.2019
Respiporc FluPan H1N1 (EMEA/V/C/003993)	01.12.2018-31.05.2019
SevoFlo (EMEA/V/C/000072)	01.12.2018-31.05.2019
Velactis (EMEA/V/C/003739)	01.07.2018-30.06.2019

- 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:

- No items.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the revised draft VICH GL58 on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV, for sign-off by the Expert Working Group at step 5 of the VICH process.
- The Committee adopted the draft VICH GL59 on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use for release for public consultation in the EU at step 4 of the VICH process.
- The Committee noted the draft agenda for the VICH Steering Committee meeting scheduled to take place on 18–21 November 2019 in Tokyo, Japan and the VICH Outreach Forum meeting to take place on 19-20 November, and noted the progress reports from the VICH quality expert working group (EWG) , the ESI - Pharmacovigilance EWG, the biologicals quality monitoring EWG, the metabolism and residue kinetics EWG, the safety EWG, the anthelmintics EWG and the combination products EWG.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

Information relating to certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be commercially confidential.

The following document was circulated for information:

- VICH status of guidelines (EMA/CVMP/28625/2005).

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 5 November 2019 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

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 8 October 2019.

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 commercially confidential

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee deferred the verbal report on the 9th European Surveillance of Veterinary Antimicrobial Consumption report on sales of veterinary antimicrobial agents in 31 European countries in 2017 to the December 2019 CVMP meeting.

8.4 Pharmacovigilance

- The Committee discussed the draft responses to the questions raised at the Bravecto petition hand over, and endorsed the response to the questions received with the petition (link).

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

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 concept paper for the revision of scientific guidelines on MUMS/limited markets for veterinary medicinal products (EMA/CVMP/538961/2019) in order to take into account the provisions on limited markets in Regulation 2019/6, for release for a 2-month period of public consultation.

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 noted the draft minutes of the October 2019 meeting as well as the draft agenda of the meeting held on 7-8 November 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee re-appointed G. J. Schefferlie and R. Breathnach as co-opted members to complement its expertise in MRLs/residues and in general clinical veterinary practice, respectively, for a further 3-year mandate. The Committee also appointed M. O'Grady as a co-opted member to complement its expertise in quality pharmaceuticals assessment for a 3-year mandate.
- The Committee endorsed the report on the conclusions and recommendations and the draft minutes of the informal CVMP/CMDv presidency meeting held during the Finnish Presidency on 25-27 September 2019 in Porvoo, Finland.
- The Committee discussed the draft CVMP work plan for 2020 which is foreseen to be adopted at the December 2019 CVMP meeting.

- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 6 November 2019 and noted the agenda of the meeting and the minutes of the meeting held on 9 October 2019.
- The Committee deferred the update on the Agency's relocation to the December 2019 CVMP meeting.

13. LEGISLATION

- The Committee endorsed additional information to the advice on the list of variations not requiring assessment with regard to the pharmacovigilance variations.
- The Committee adopted the mandates for the expert groups to deliver the scientific advices on implementing and delegated acts on the list of antimicrobials reserved for the treatment of certain infections in humans, on the format of the data to be collected on antimicrobial medicinal products used in animals, and on veterinary medicinal products used for oral administration.
- The Committee received verbal reports from the expert group leaders on work progress concerning the provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.
- The Committee noted the final report on the criteria for the designation of antimicrobials to be reserved for treatment of certain infections in human.

14. ANY OTHER BUSINESS

- Upon the completion of the November 2019 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 November 2019 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	
DE	Gesine Hahn	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Angeliki Tsigouri	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:	• 9. One item • 10.1 One item
FR	Jean-Claude Rouby	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	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 8.1 One item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SK	Judita Hederová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Ricardo Carapeto	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
BE	Frédéric Klein	Full involvement	
BG	Svetoslav Branchev	Full involvement	
CZ	Leona Nepejchalová	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
UK	Rory Cooney	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
* Experts were only evaluated against the topics they have been invited to talk about.			
AT	Jan Joseph - *remotely*	Full involvement	
AT	Roland Reimann - *remotely*	Full involvement	
BE	Bruno Urbain - *remotely*	Full involvement	
BE	Michel Goret - *remotely*	Full involvement	
BE	Koenraad Brusselsman	Full involvement	
CZ	Dana Halová - *remotely*	Full involvement	
CZ	Dana Studená - *remotely*	Full involvement	
CZ	Eva Pomezná - *remotely*	Full involvement	
CZ	Jakub Stejkora - *remotely*	Full involvement	
CZ	Lucie Pokludová - *remotely*	Full involvement	
CZ	Zdenka Mašková - *remotely*	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Anke Finnah - *remotely*	Full involvement	
DE	Christian Kühne - *remotely*	Full involvement	
DE	Kathrin Schmidt - *remotely*	Full involvement	
DE	Sarah Adler-Flindt - *remotely*	Full involvement	
DE	Thilo Nölke - *remotely*	Full involvement	
DE	Uta Herbst - *remotely*	Full involvement	
DK	Anja Silke Christensen - *remotely*	Full involvement	
DK	Malene Nissen - *remotely*	Full involvement	
DK	Mette Madsen - *remotely*	Full involvement	
ES	Maria Dominguez Nicolas - *remotely*	Full involvement	
ES	Mercedes Ureña Montilla - *remotely*	Full involvement	
ES	Raul Belmar Liberato - *remotely*	Full involvement	
ES	Rocio Fernandez Granda – *remotely*	Full involvement	
ES	Rosario Bullido - *remotely*	Full involvement	
ES	Susana Casado Hernandez - *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
FR	Carole Cousin - *remotely*	Full involvement	
FR	Gerard Moulin - *remotely*	Full involvement	
FR	Khadija Selouaoui - *remotely*	Full involvement	
IE	Paul McNeill- *remotely*	Full involvement	
IE	Sarah Buckley- *remotely*	Full involvement	
IE	Susan Reid- *remotely*	Full involvement	
NL	Anita Bottger - *remotely*	Full involvement	
NL	Kim Boerkamp	Full involvement	
NO	Annelin Bjelland – *remotely*	Full involvement	
NO	Hans Kristian Østensen – *remotely*	Full involvement	
NL	Sandra ten Voorde	Full involvement	
SE	Catarina Eriksson - *remotely*	Full involvement	
SE	Jenny Larsson - *remotely*	Full involvement	
UK	Miguel Escribano	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	---
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele – *remotely*
QWP	---
SAWP-V	Frida Hasslung Wikström
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