5 December 2017
EMA/CVMP/809166/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 7-9 November 2017 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 November 2017 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.

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iv. Adoption of the minutes of the previous meeting

The minutes of the October 2017 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 (28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to fin fish for **eprinomectin** (EMEA/V/MRL/003141/EXTN/0004). Furthermore, the Committee agreed to extrapolate the established MRLs for eprinomectin in ruminants to horses and rabbits. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU Reference Laboratory, a peer review report, the comments received from CVMP members and the summary of opinion for publication.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in porcine species for **porcine prolactin** (EMEA/V/MRL/004113/FULL/0001). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted two peer review reports, the comments received from CVMP members and the summary of opinion for publication.

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

- The Committee adopted a list of outstanding issues for the modification of MRLs in *Salmonidae* for a substance (EMEA/V/MRL/003135/MODF/0003), following discussion of the rapporteur's assessment report and the EPMAR. The Committee noted a peer review report and the comments received from CVMP members.

1.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for an application for the extension of MRLs to eggs for a substance (EMEA/V/MRL/003517/EXTN/0003).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 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 **GALLIPRANT** (EMEA/V/C/004222/0000), recommending the granting of a marketing authorisation. GALLIPRANT is a new non-steroidal anti-inflammatory product for the treatment of pain

associated with mild to moderate osteoarthritis in dogs. 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

- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new antiparasitic product for cats (EMEA/V/C/004440/0000). The Committee agreed that an oral explanation would not be requested, and noted a peer review report and the comments received from CVMP members.

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 product for musculo-skeletal disorders in horses (EMEA/V/C/004727/0000). The Committee noted three 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 cardiovascular product for dogs (EMEA/V/C/004345/0000). The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant to provide an oral explanation for a new product acting on the nervous system (EMEA/V/C/004417/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Oxybee** (EMEA/V/C/004296/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Bovilis Blue-8** (EMEA/V/C/004776/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **MiPet Easecto** (EMEA/V/C/004732/0000) concerning the granting of the initial 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 worksharing type II variation for **Vectormune ND** and Cevac Transmune (authorised nationally via MRP) (EMEA/V/C/003829/WS1082(0006)), recommending the variation of the marketing authorisation to add concurrent use by subcutaneous and *in-ovo* use, in day-old broiler chickens and 18-day old embryonated broiler chicken eggs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 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 for **ERAVAC** (EMEA/V/C/004239/II/0002/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 (29 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped type II variation for **Exzolt** (EMEA/V/C/004344/II/0001/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 the list of questions for a grouped type II variation for **Zolvix** (EMEA/V/C/000154/II/0023/G), concerning quality changes.
- The Committee adopted the list of questions for a grouped type II variation for **ERAVAC** (EMEA/V/C/004239/II/0003/G), concerning changes in the product information.
- The Committee adopted the list of questions for a grouped worksharing type IB variation for **Ingelvac CircoFLEX** and **Ingelvac PCV FLEX** (EMEA/V/C/xxxxxx/WS1249/G), 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

- The Committee considered the request from the marketing authorisation holder, Elanco Animal Health, for a re-examination of the October 2017 CVMP opinion for **Girolan and its associated name Apralan** (EMEA/V/A/122), and appointed J. G. Beechinor as rapporteur and W. Schlumbohm as co-rapporteur for the re-examination procedure. The procedure will be initiated once the grounds for the re-examination are submitted.

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

Information relating to certain topics discussed under section 4.7 at this meeting cannot be released at the present time as it is deemed to be confidential.

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 recommendation for **CLYNAV** (EMEA/V/C/002390/REC/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 06.10.2017 – 09.11.2017:

Product	Period
Aivlosin (EMEA/V/C/000083)	09/09/2016 – 10/09/2017
APOQUEL (EMEA/V/C/002688)	12/09/2016 – 13/09/2017
Cerenia (EMEA/V/C/000106)	29/09/2016 – 30/09/2017
COXEVAC (EMEA/V/C/000155)	30/09/2016 – 01/10/2017
ERAVAC (EMEA/V/C/004239)	22/09/2016 – 23/09/2017
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2016 – 09/09/2017
Nobivac Bb (EMEA/V/C/000068)	10/09/2016 – 11/09/2017
Novaquin (EMEA/V/C/003866)	08/09/2016 – 09/09/2017
Palladia (EMEA/V/C/000150)	23/09/2016 – 24/09/2017
Previcox (EMEA/V/C/000082)	13/09/2016 – 14/09/2017
Recocam (EMEA/V/C/002247)	13/09/2016 – 14/09/2017
RHINISENG (EMEA/V/C/000160)	16/09/2016 – 17/09/2017
Trifexis (EMEA/V/C/002635)	19/09/2016 – 20/09/2017
Trocoxil (EMEA/V/C/000132)	09/09/2016 – 10/09/2017
Vectormune ND (EMEA/V/C/003829)	08/09/2016 – 09/09/2017

5.4 Renewals

- 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 the renewal of the

marketing authorisation for **Semintra** (EMEA/V/C/002436/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 adopted the CVMP assessment report on the PSUR for the period 01.07.2016 – 30.06.2017 for **Bluevac BTV8** (EMEA/V/C/000156) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report on the PSUR for the period 11.02.2014 – 28.02.2017 for **NexGard** (EMEA/V/C/002729) with a recommendation to amend the product information.
- The Committee endorsed the rapporteur's assessment report on the PSUR for the period 01.07.2016 – 30.06.2017 for **Vectra 3D** (EMEA/V/C/002555) with a list of questions to be addressed by the MAH.
- 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
Leucogen (EMEA/V/C/000144)	01.07.2014 – 30.06.2017
Poulvac E. Coli (EMEA/V/C/002007)	01.01.2017 - 30.06.2017
Trifexis (EMEA/V/C/002635)	05.01.2017 – 04.07.2017
Velactis (EMEA/V/C/003739)	01.01.2017 – 30.06.2017

- 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 joint statement of EU regulators and industry on the further development of VICH guidance on extraneous viruses.
- The Committee discussed the updated draft of the document on 'Definition of Biologics', prepared by the Japanese Ministry of Agriculture, Farming and Fisheries (JMAFF), and agreed that previously provided comments remained valid and that further written comments would not be necessary.
- The Committee noted the draft agenda and the meeting documents of the 35th VICH Steering Committee meeting to be held on 13-16 November 2017 in Tokyo, Japan.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The chair of the CVMP provided the Committee his presentation to be given at the HMA meeting to be held on 29-30 November in Tallinn, Estonia.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Externally organised projects and events for CVMP to note.

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 chair of the SAWP-V on the meeting held on 7 November 2017, and noted the agenda of the meeting.
- The Committee discussed the updated guidance for companies requesting scientific advice, which is foreseen to be adopted at the December 2017 CVMP meeting.

7.2 Quality Working Party (QWP)

- The Committee discussed the guideline on chemistry of active substances for veterinary medicinal products and the overview of comments on the draft guideline received during the public consultation, which are foreseen to be adopted at the December 2017 CVMP meeting.
- The Committee discussed the questions and answers document on in-use shelf life for solid dose forms in multidose containers, which is foreseen to be adopted at the December 2017 CVMP meeting.

7.3 Safety Working Party (SWP-V)

- The verbal report from the chair of the SWP-V on the meeting held on 20 September 2017 and on the training of assessors on genotoxicity testing held on 21 September 2017 was deferred to the December 2017 CVMP meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The verbal report from the chair of the ERAWP on the meeting held on 24 October 2017 was deferred to the December 2017 CVMP meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the draft revised guideline on conduct of pharmacokinetic studies in target animals (EMA/CVMP/EWP/133/1999-Rev.1) for a 6-month period of public consultation.
- The Committee discussed the concept paper for the revision of the guideline on the SPC for anthelmintics, which is foreseen to be adopted at the December 2017 CVMP meeting.

7.6 Antimicrobials Working Party (AWP)

- The verbal report from the chair of the AWP on the meeting held on 20-21 September 2017 was deferred to the December 2017 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- The verbal report from the chair of the IWP on the meeting held on 18-19 October 2017 and on the training of immunological assessors on quality of IVMPs held on 19-20 October 2017 was deferred to the December 2017 CVMP meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the revised questions and answers document on preparation, management and assessment of periodic safety update reports (PSURs) (EMA/CVMP/PhVWP/126661/2009-Rev.4).
- The Committee adopted the revised questions and answers document on adverse event reporting (EMA/CVMP/PhVWP/145186/2013-Rev.2).

7.9 Novel therapy groups and related issues

- The Committee adopted the questions and answers document to address the topic of tumorigenicity for the development of stem cell-based products for veterinary use (EMA/CVMP/ADVENT/791465/2016).

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

- The Committee adopted the guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs (EMA/CHMP/CVMP/3Rs/94436/2014), and the overview of comments received during the public consultation (EMA/CHMP/CVMP/3Rs/83712/2017).

7.11 Other working party and scientific group issues

- The Committee discussed the draft work plans for 2018 of the following CVMP working parties: SAWP-V, QWP, SWP-V, ERAWP-V, EWP-V, AWP, IWP, PhVWP-V, ADVENT and J3RsWG. The draft work plans are foreseen to be adopted at the December 2017 CVMP meeting.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 3 October 2017;
- Draft minutes of the EWP-V meeting held on 12-13 September 2017;
- Final minutes of the IWP meeting held on 21-22 June 2017;
- Overview of comments received on the revised guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/EWP/016/00-Rev.3);
- Overview of comments received on the 'Reflection paper (EMA/CVMP/AWP/721118/2014) on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health';
- Minutes of the ADVENT meeting held on 7 September 2017.

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.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the 7th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 30 European countries in 2015.
- The Committee appointed H. Jukes, K. Baptiste and C. Munoz as CVMP representatives for the Antimicrobial Advice Ad hoc Expert Group (AMEG), following a call for nominations. The new AMEG will consist of 11 experts representing CVMP/AWP, ECDC, EFSA and JIACRA.

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 endorsed the revised incident management plan for medicines for veterinary use.

The following documents were circulated for information:

- WHO: Call for data on foodborne antimicrobial resistance. Deadline: 31.12.2017 http://www.who.int/foodsafety/DATA_Foodborne_AMR.pdf?ua=1;
- WHO: Call for experts on foodborne antimicrobial resistance. Deadline: 31.12.2017 http://www.who.int/foodsafety/Call_for_experts_oct2017.pdf;
- Publication of Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals (EMA/CVMP/AWP/549799/2017), press release link;
- WHO guidelines on use of medically important antimicrobials in food-producing animals 2017 http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia_guidelines/en/.

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 endorsed for publication the final report of the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, held on 22-23 June 2017 (EMA/405642/2017).

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 endorsed the procedural advice to applicants / marketing authorisation holders on the re-examination of CVMP opinions (EMA/CVMP/321528/2017).

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

- The Committee noted the draft minutes of the meeting held on 5-6 October 2017 as well as the draft agenda of the meeting held on 9-10 November 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft CVMP work plan for 2018, which is foreseen to be adopted at the December 2017 CVMP meeting.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the *ad hoc* meeting held on 8 November 2017, and noted the agenda of the meeting and the minutes of the meeting held on 4 October 2017.
- The Committee received an update on the release of the Common Repository for veterinary submissions in the centralised procedure. The release of the system is planned for 21 November 2017. The EMA proposes that the mandatory use of the system by all NCAs will commence on 1 May 2018, following a transition period.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the November 2017 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.
- The Committee noted the date of the CVMP Christmas party (6 December 2017).

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the November 2017 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	
CY	Alia Michaelidou	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 8.1 - one item
IE	J. Gabriel Beechinor	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	Joao Pedro Duarte da Silva		
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	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	Jason Weeks	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	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
HU	Tibor Soós	Full involvement	
LT	Laimis Jodkonis	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Maja Turk	Full involvement	
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
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Sandy Vermout - *remotely*	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Sabine Kalweit – *remotely*	Full involvement	
DE	Birgit Kegel – *remotely*	Full involvement	
DE	Nikola Lange – *remotely*	Full involvement	
DE	Stefan Scheid – *remotely*	Full involvement	
DK	Niels Christian Kyvsgaard - *remotely*	Full involvement	
ES	Raúl Belmar Liberato – *remotely*	Full involvement	
ES	Mercedes Conradi Monner – *remotely*	Full involvement	
ES	María José Ferrer Montesa - *remotely*	Full involvement	
ES	Alberto de Prado López – *remotely*	Full involvement	
FR	Florence Pillet – *remotely*	Full involvement	
IE	Mary O'Grady - *remotely*	Full involvement	
NL	Kim Boerkamp	Full involvement	
NO	Tora Gauslaa – *remotely*	Full involvement	
SE	Helena Back	Full involvement	
SE	Andreea Barbu – *remotely*	Full involvement	
SE	Catarina Eriksson - *remotely*	Full involvement	
SE	Susanne Stenlund – *remotely*	Full involvement	
UK	Niall O'Brien – *remotely*	Full involvement	
UK	Noemi Garcia del Bianco - *remotely*	Full involvement	
UK	John Mitchell – *remotely*	Full involvement	
UK	Ruth Pearson – *remotely*	Full involvement	
UK	Jean-Paul Schmidt – *remotely*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	--
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero
IWP	Esther Werner
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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