15 April 2019
EMA/CVMP/229277/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 19-21 March 2019 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 the addition of two new items under points 4.7 and 12.

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

The attendance list was completed and competing interests were identified for the March 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 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.

No contacts were declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the February 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

- 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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for the extension of MRLs in pigs for a substance.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Afoxolaner MERIAL** (EMA/V/C/005126/0000), recommending the granting of a marketing authorisation. The product is indicated for the treatment of flea and tick infestations, demodicosis and sarcoptic mange in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication. This is an informed consent application.
- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Baycox Iron** (EMEA/V/C/004794/0000), recommending the granting of a marketing authorisation. Baycox Iron is a new veterinary medicinal product for the concurrent prevention of clinical signs of coccidiosis (such as diarrhoea) in neonatal piglets on farms with a confirmed history of coccidiosis caused by *Cystoisospora suis,* and prevention of iron deficiency anaemia. 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 consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Innovax ND-IBD** (EMEA/V/C/004422/X/0001), recommending the extension of the marketing authorisation to add a new route of administration (*in ovo*) for chicken embryonated eggs. 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 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 (EMEA/V/C/004973/0000) for cats 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 scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine (EMEA/V/C/004897/0000) for cattle. The Committee agreed that an oral explanation would not be requested. The Committee noted three peer review reports 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

2.5 Other issues

- The Committee adopted the EPAR module scientific discussion for **Felisecto Plus** (EMEA/V/C/005093/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **Chanhold** (EMEA/V/C/004824/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0015), recommending the variation of the marketing authorisation to add a new target species. 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 (28 members in favour out of the 29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Vectra 3D** (EMEA/V/C/002555/II/0011), recommending the variation of the marketing authorisation to change the legal status from prescription-only to non-prescription veterinary medicine. M. Blixenkrone-Møller and the Norwegian CVMP member signed divergent positions not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.
- 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 type II variation for **ProZinc** (EMEA/V/C/002634/II/0016), recommending the variation of the marketing authorisation concerning 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 type II grouped variation for **CLYNAV** (EMEA/V/C/002390/II/0004/G), recommending the variation of the marketing authorisation concerning 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 type II grouped variation for **CYTOPOINT** (EMEA/V/C/003939/II/0003/G), recommending the variation of the marketing authorisation concerning 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 product information, and endorsed the rapporteur's assessment report for a type II variation for **MS-H Vaccine** (EMEA/V/C/00161/II/0013), recommending the variation of the marketing authorisation concerning 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 the product information, and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Simparica** and **MiPet Easecto** (EMEA/V/C/xxxxxx/WS1335), recommending the variation of the marketing authorisation to implement changes to the product information as the outcome of a PSUR assessment. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues to be addressed in writing and during an oral explanation for a type II variation for **Coliprotec F4/F18** (EMEA/V/C/ 004225/II/0005), to add a new therapeutic indication.

3.3 Lists of questions

- The Committee adopted a list of questions for a grouped type II variation for **Bravecto** (EMEA/V/C/002526/II/0033/G), to add new therapeutic indications.
- The Committee adopted a list of questions for a grouped type II variation for **Advocate** (EMEA/V/C/000076/II/0041/G), to add new therapeutic indications and to amend the product information.

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 paromomycin to be administered parenterally to pigs** (EMEA/V/A/129). 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 adoption of the CVMP opinion and assessment

report is foreseen for the July 2019 meeting of the Committee. The Committee noted three peer review reports 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

- There were no items for discussion.

4.7 Other issues

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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 22.02.2019 – 21.03.2019:

Product	Period
Bovalto Ibraxion (EMEA/V/C/000051)	09.03.2018 – 08.03.2019
CaniLeish (EMEA/V/C/002232)	14.03.2018 – 13.03.2019
Coliprotec F4 (EMEA/V/C/003797)	16.03.2018 – 15.03.2019
Econor (EMEA/V/C/000042)	12.03.2018 – 11.03.2019
Equisolon (EMEA/V/C/002382)	12.03.2018 – 11.03.2019
Fungitraxx (EMEA/V/C/002722)	12.03.2018 – 11.03.2019
Novem (EMEA/V/C/000086)	02.03.2018 – 01.03.2019
Pexion (EMEA/V/C/002543)	25.02.2018 – 24.02.2019
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	29.02.2018 – 28.02.2019
ProteqFlu (EMEA/V/C/000073)	06.03.2018 – 05.03.2019
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2018 – 05.03.2019
Purevax RC (EMEA/V/C/000091)	23.02.2018 – 22.02.2019
Purevax RCP (EMEA/V/C/000090)	23.02.2018 – 22.02.2018

Product	Period
Purevax RCP FeLV (EMEA/V/C/000089)	23.02.2018 – 22.02.2018
Purevax RCPCh (EMEA/V/C/000088)	23.02.2018 – 22.02.2018
Purevax RCPCh FeLV (EMEA/V/C/000085)	23.02.2018 – 22.02.2018
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08.03.2018 – 07.03.2019
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14.03.2018 – 13.03.2019

5.4 Renewals

- The Committee adopted by consensus (31 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 **Versican Plus Pi/L4R** (EMEA/V/C/003682/R/0013), and recommended that a further 5-year renewal would be required based on pharmacovigilance grounds. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (31 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 **Suvaxyn PCV** (EMEA/V/C/000149/R/0028), 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 (29 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 **Nobilis IB Primo QX** (EMEA/V/C/002802/R/0006), 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 a list of outstanding issues for the renewal of the marketing authorisation for **OSURNIA** (EMEA/V/C/003753/R/0014).

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
CaniLeish (EMEA/V/C/002232)	01.10.2015-30.09.2018
Cimalgex (EMEA/V/C/000162)	01.09.2015-31.08.2018
EVALON (EMEA/V/C/004013)	01.05.2018-31.10.2018
Imrestor (EMEA/V/C/002763)	01.04.2018-30.09.2018
LETIFEND (EMEA/V/C/003865)	01.05.2018-31.10.2018
Procox (EMEA/V/C/002006)	01.11.2015-31.10.2018
Veraflox (EMEA/V/C/000159)	01.11.2015-31.10.2018

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee adopted VICH GL57 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species (EMA/CVMP/VICH/517152/2013), following the sign-off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process.
- The Committee adopted VICH GL36 (R2) on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI (EMA/CVMP/VICH/467/2003-Rev.2), following the sign-off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process.
- The Committee endorsed the draft EU comments relating to the revision of VICH GL16 on the efficacy of anthelmintics – specific recommendations for porcine – claims for *Ascaris suum*.
- The Committee endorsed the draft EU comments on the revised draft decision tree provided by the chair of the Safety EWG, relating to the revision of VICH GL23 on genotoxicity testing.
- The Committee endorsed draft 4 of the VICH guideline on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, for circulation to the VICH EWG along with the overview of comments received on draft 3.
- The Committee received an update following a teleconference of the VICH Expert Working Group for a general guideline on pharmaceutical combination products, held on 13 March 2019.
- The Committee received a verbal report on the 37th VICH Steering Committee, the 11th VICH Outreach Forum meeting and 6th VICH Conference, held between 24 February and 1 March in Cape Town, South Africa.

6.2 Codex Alimentarius

- The Committee received a verbal report on the 6th session of the Codex Ad Hoc intergovernmental task force on antimicrobial resistance, held on 10–14 December 2018 in Busan, Republic of Korea – *please see also 8.3*.

6.3 Other EU bodies and international organisations

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 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 March 2019, and noted the agenda of the meeting.
- The Committee was informed of the upcoming election of the chair of the SAWP-V for a 3-year term at the May 2019 CVMP meeting and noted the call for nominations circulated by the Secretariat.

7.2 Quality Working Party (QWP)

- The Committee adopted questions and answers on the use of peptone in the manufacture of active substances via fermentation process, which were adopted by the CHMP at their February meeting and will be published on the Agency's website.

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)

- There were no items for discussion.

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

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 19 February 2018*;*
- Draft agenda for the PhVWP-V meeting to take place on 26-27 March 2019;
- Draft minutes of the ADVENT meeting held on 29 January 2019;
- ITF briefing meeting minutes from the meeting held with Eco Animal Health on 12 December 2018;

- ITF briefing meeting minutes from the meeting held with Orion Pharma on 28 August 2018;
- ITF briefing meeting minutes from the meeting held with PrimeBEE on 4 October 2018;
- ITF briefing meeting minutes from the meeting held with Panion Animal Health AB on 5 June 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

- The Committee received an update on the communication from the European Commission on an EU Strategic approach to pharmaceuticals in the environment (link). The report identifies six areas for action for the Commission with a view to reduce overall emissions of pharmaceuticals into the environment.

8.3 Antimicrobial resistance

- The Committee noted the report of the 6th session of the Codex Ad Hoc intergovernmental task force on antimicrobial resistance, held on 10–14 December 2018 in Busan, Republic of Korea – *please see also 6.3.*

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.

- 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.

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 minutes of the meeting held on 21-22 February 2019 and the draft agenda of the meeting held on 21-22 March 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft agenda of the upcoming informal CVMP/CMDv Presidency meeting, to be held on 6-8 May 2019 at Lake Balaton, Hungary, under the Romanian Presidency of the Council of the European Union. The agenda will be brought for discussion and adoption at the April 2019 CVMP meeting.

13. LEGISLATION

- The Committee was informed of the outcome of the written procedure for endorsement of the mandates for the expert groups for provision of scientific advice on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products concerning: revision of Annex II - Biologicals and novel therapies expert group; Revision of Annex I - Non-biologicals expert group; collection of data on antimicrobials; criteria to designate antimicrobials reserved for human use; list of variations not requiring assessment; Good pharmacovigilance practice - AEs/signal management; Good pharmacovigilance practice – inspections; Good pharmacovigilance practice - Communication; Pharmacovigilance system master file.
- The Committee received verbal reports from the expert group leaders on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the March 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 March 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	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Gesine Hahn	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	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	
MT	Stephen Spiteri	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 2.1 – Baycox Iron • 3.3 – Advocate • 5.5 – Procox and Veraflox
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	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	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	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
EL	Angeliki Tsigouri	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Cristina Gonçalves Santos	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SI	Maja Turk	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.			
BE	Michel Goret *(remotely)*	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Daniela Loos	Full involvement	
DE	Kathrin Schmidt *(remotely)*	Full involvement	
DE	Nikola Lange *(remotely)*	Full involvement	
DE	Uta Herbst *(remotely)*	Full involvement	
DE	Sabine Kalweit *(remotely)*	Full involvement	
DK	Niels Christian Kyvsgaard		
FI	Jukka Pakkanen *(remotely)*	Full involvement	
FI	Kristina Lehmann *(remotely)*	Full involvement	
FI	Jonna Kumpulainen *(remotely)*	Full involvement	
FI	Martti Nevalainen *(remotely)*	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
FR	Gérard Moulin *(remotely)*	Full involvement	
IE	Sarah Buckley *(remotely)*	Full involvement	
IE	Paul McNeill *(remotely)*	Full involvement	
NL	Kim Boerkamp	Full involvement	
NL	Anita Bottger *(remotely)*	Full involvement	
NO	Kari Grave *(remotely)*	Full involvement	
PL	Anita Piwowarczyk	Full involvement	
PL	Marcin Glanda *(remotely)*	Full involvement	
UK	Sharon Reynolds *(remotely)*	Full involvement	
UK	Stephen Spencer *(remotely)*	Full involvement	
UK	John Mitchell *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Christine Schwarz - *remotely*
CMDv	Laetitia Le Letty - *remotely*
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
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