10 September 2019
EMA/CVMP/498139/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 16-18 July 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 no modifications.

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

The attendance list was completed and competing interests were identified for the July 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 member eligible to vote were present in the room. It was noted that 17 members were needed for an absolute majority.

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

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

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the June 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 establishment of MRLs in pigs for a new substance (EMEA/V/MRL/005009/FULL/0001).
- The Committee agreed to the request from the applicant for an extension to the clock-stop for the establishment of MRLs in cattle and pigs for a new substance (EMEA/V/MRL/005072/FULL/0001).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 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 **Simparica Trio** (EMEA/V/C/004846/0000), recommending the granting of a marketing authorisation. The product is a new antiparasitic for dogs containing sarolaner, moxidectin and pyrantel for the treatment of flea and tick infestations, gastrointestinal roundworm and hookworm infections, and for the prevention of heartworm disease and angiostrongylosis. The Committee noted the summary of the CVMP 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 product (EMEA/V/C/004735/0000) for dogs. The Committee agreed that an oral explanation would

not be requested. The Committee noted two peer review reports 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 product (EMEA/V/C/005018/0000) for dogs. The Committee agreed to invite the applicant for an oral explanation in October 2019. The Committee noted two peer review reports 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/004989/0000) for rabbits. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new product for dogs (EMEA/V/C/005132/0000). 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 generic product for cattle, pigs and sheep (EMEA/V/C/005199/0000). The Committee noted a peer review report 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 generic product for cattle, pigs and sheep (EMEA/V/C/005153/0000. 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 adopted the public assessment report for **Evicto** (EMEA/V/C/004973/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the public assessment report for **Nasym** (EMEA/V/C/004897/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the public assessment report for **HorStem** (EMEA/V/C/004265/0000) 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 type II variation for **Nexgard Spectra** (EMEA/V/C/003842/II/0019), recommending the variation of the marketing authorisation to add a new therapeutic indication. The Committee noted the summary of opinion for publication.

- 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 **Nexgard Spectra** and **NexGard** for a type II variation (subject to a worksharing procedure) (EMEA/V/C/xxxxxx/WS1559), recommending the variation of the marketing authorisation to add a new therapeutic indication. The Committee noted the summary of opinion for publication.
- 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 **Broadline** (EMEA/V/C/002700/II/0024), recommending the variation of the marketing authorisation to add a new therapeutic indication. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **MS-H Vaccine** (EMEA/V/C/000161/II/0014/G), recommending the variation of the marketing authorisation to implement quality changes.

3.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from Ceva Sante Animale SA concerning a type II variation for **Velactis** (EMEA/V/C/003739/II/0004), in relation to the submission of data with the aim to fulfil the conditions for lifting the suspension of the marketing authorisation and introducing changes to the product information. The adoption of the opinion is foreseen for the September 2019 CVMP meeting.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **Vectormune ND** and nationally authorised products (EMEA/V/C/xxxxxx/WS1597) concerning quality changes.
- The Committee adopted a list of questions for a type II grouped variation for **Poulvac E. coli** (EMEA/V/C/002007/II/0016/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

- The Committee considered the notification from the Reference Member State, France, for a referral for **Ketamine 100 mg/ml solution for injection** due to concerns expressed by Germany regarding the appropriateness of the withdrawal period when this veterinary medicinal product is administered via the intramuscular route to cattle, pigs, sheep and goats. The Committee agreed to start a referral procedure (EMEA/V/A/133) under Article 33(4), and appointed G. Hahn as rapporteur and S. Louet as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable for the procedure.

4.2 Article 34 of Directive 2001/82/EC

- The Committee considered the notification from the European Commission for a referral for **Adjusol and its associated names** due to divergent decisions reached by Member States resulting in differences in the product information. The Committee agreed to start a referral procedure (EMEA/V/A/134) under Article 34 and appointed C. Muñoz Madero as rapporteur and S. Louet as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing paromomycin to be administrated parenterally to pigs** (EMEA/V/A/129), concluding that the benefit-risk balance for the concerned veterinary medicinal products is negative, as there were inadequate data to support efficacy of these veterinary medicinal products for the proposed indications at the recommended treatment dose, and that this deficiency poses a risk of ineffective treatment and antimicrobial resistance development. Accordingly, the Committee recommended the suspension of the marketing authorisations for the concerned veterinary medicinal products.

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

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 21.06.2019 – 16.07.2019:

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15.07.2018 – 14.07.2019
Canigen L4 (EMEA/V/C/004079)	03.07.2018 – 02.07.2019
Circovac (EMEA/V/C/000114)	21.06.2018 – 20.06.2019
CLYNAV (EMEA/V/C/002390)	27.06.2018 – 26.06.2019

Product	Period
Equilis Prequenza (EMEA/V/C/000094)	08.07.2018 – 07.07.2019
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2018 – 07.07.2019
Equilis Te (EMEA/V/C/000093)	08.07.2018 – 07.07.2019
EQUIOXX (EMEA/V/C/000142)	25.06.2018 – 24.06.2019
ERYSENG (EMEA/V/C/002761)	04.07.2018 – 03.07.2019
ERYSENG PARVO (EMEA/V/C/002762)	08.07.2018 – 07.07.2019
Innovax-ILT (EMEA/V/C/003869)	03.07.2018 – 02.07.2019
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25.06.2018 – 24.06.2019
Melovem (EMEA/V/C/000152)	07.07.2018 – 06.07.2019
Nobivac L4 (EMEA/V/C/002010)	16.07.2018 – 15.07.2019
Posatex (EMEA/V/C/000122)	23.06.2018 – 22.06.2019
ProZinc (EMEA/V/C/002634)	12.07.2018 – 11.07.2019
Reconcile (EMEA/V/C/000133)	08.07.2018 – 07.07.2019
Sevohale (EMEA/V/C/004199)	21.06.2018 – 20.06.2019
Suprelorin (EMEA/V/C/000109)	10.07.2018 – 09.07.2019
Versican Plus DHPPi (EMEA/V/C/003679)	04.07.2018 – 03.07.2019
Versican Plus Pi (EMEA/V/C/003681)	04.07.2018 – 03.07.2019

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 **Porcilis PCV M Hyo** (EMEA/V/C/003796/R/0012), and recommended that the authorisation should now be indefinite.
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Bovela** (EMEA/V/C/003703/R/0014).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2018-31.12.2018 for **Broadline** (EMEA/V/C/002700) with a recommendation to amend the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.08.2018-31.01.2019 for **Credelio** (EMEA/V/C/004247) 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 **Suprelorin** (EMEA/V/C/000109) with a recommendation to amend the product information.
- 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
CEPEDEX (EMEA/V/C/004376)	13.12.2016-28.02.2019
Coliprotec F4/F18 (EMEA/V/C/004225)	01.08.2018-31.01.2019
Dexdomitor (EMEA/V/C/000070)	01.03.2016-28.02.2019
Emdocam (EMEA/V/C/002283)	01.03.2016-28.02.2019
Innovax ND IBD (EMEA/V/C/004422)	01.09.2018-28.02.2019
Melosus (EMEA/V/C/002001)	01.03.2016-28.02.2019
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.03.2018-28.02.2019
Porcilis PCV ID (EMEA/V/C/003942)	01.03.2018-28.02.2019
Proteq West Nile (EMEA/V/C/002005)	01.03.2016-28.02.2019
Sedadex (EMEA/V/C/004202)	13.08.2018-12.02.2019
Semintra (EMEA/V/C/002436)	01.09.2018-28.02.2019
Stronghold Plus (EMEA/V/C/004194)	01.09.2018-28.02.2019
Suvaxyn Circo (EMEA/V/C/004242)	01.09.2018-28.02.2019
Suvaxyn PRRS MLV (EMEA/V/C/004276)	01.09.2018-28.02.2019
UpCard (EMEA/V/C/003836)	01.09.2018-28.02.2019
VEPURED (EMEA/V/C/004363)	01.09.2018-28.02.2019

- 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:

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

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the VICH GL59 for the harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, for sign-off by the VICH Steering Committee at step 3 of the VICH process.
- The Committee endorsed the draft EU comments on the draft training slides on VICH GL57 on marker residue depletion studies to establish product withdrawal periods in aquatic species.

- The Committee appointed a CVMP expert and an adviser to the VICH Expert Working Group on bioequivalence.

6.2 Codex Alimentarius

- The Committee noted and endorsed the EU comments regarding the revision of the Codex Code of Practice to minimise the development of antimicrobial resistance by the Codex Task Force on Antimicrobial Resistance electronic Working Group on AMR surveillance.

6.3 Other EU bodies and international organisations

- The Committee appointed a CVMP member to participate in the "Pain in Animals Workshop 2019" to be held on 2-3 October 2019 in Bethesda, Maryland, USA.

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 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 16 July 2019 and noted the agenda of the meeting.
- The Committee elected S. Louet as the new vice-chair of the SAWP-V for a 3-year term.
- The Committee appointed L. Nepejchalová as a new SAWP-V member.

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)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The verbal report from the PhVWP-V chair on the meeting held on 9-10 July 2019 was deferred to the next meeting.

7.9 Novel therapy groups and related issues

- The Committee postponed the discussion.

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

- The Committee postponed the discussion.

7.11 Other working party and scientific group issues

- The Committee postponed the discussion.

The following document(s) was/were circulated for information:

- No items circulated.

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.

- The Committee agreed to amend the list of substances not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009–Rev.40) and to add **DEAE-dextran hydrochloride** to the entry of **DEAE-dextran**.

8.2 Environmental risk assessment

- The Committee postponed the discussion.

8.3 Antimicrobial resistance

- The Committee heard an update on the work on the revised reflection paper on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation and noted the updated overview of comments received from stakeholders during the public consultation.

8.4 Pharmacovigilance

- The Committee postponed the discussion on the response from the marketing authorisation holder concerning the use of gloves with Bravecto Spot on / Bravecto Plus.

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.

- The Committee agreed to the transfer of all (co-)rapporteurships and peer reviewer responsibilities from I. Malemis to S. Farlopoulos.

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 heard a verbal report from the chair of CMDv on the meetings held in April, May and June and noted the draft minutes of the meeting held on 20-21 June 2019 as well as the draft agenda of the meeting to be held on 18-19 July 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft agenda for the upcoming informal presidency CVMP/CMDv meeting to be held in Finland on 25-27 September 2019, under the Finnish Presidency of the Council of the European Union. The finalisation of the agenda is foreseen for the September 2019 CVMP meeting.
- The Committee endorsed the conclusions and recommendations arising from the informal presidency meeting held on 6-8 May 2019 in Hungary, under the Romanian Presidency of the Council of the European Union.
- The Committee noted the list of provisions in new veterinary legislation with impact on CVMP work and potentially requiring action. The discussion of this item is foreseen for the September 2019 CVMP meeting.
- The Committee was informed of the potential issues or procedures requiring CVMP decision via written procedure during August 2019.
- The Committee received an update on impact of committee's and working parties during the relocation to the new EMA building at the end of 2019 and noted that the meetings of the Committee and the Scientific Advice Working Party will not be affected.

13. LEGISLATION

- The Committee adopted the scientific recommendation on the list of variations not requiring assessment relating to the implementing acts under Article 60(1) of Regulation (EU) 2019/6 on veterinary medicinal products.
- The Committee adopted the scientific recommendations on the revision of Annex II of Regulation 2019/6 on veterinary medicinal products.

- The Committee adopted the report on specific requirements for collection of data for antimicrobials used in animals relating to the delegated acts under Article 57(3) of Regulation (EU) 2019/6 on veterinary medicinal products.
- The Committee received verbal reports on the work progress of the relevant expert groups concerning the provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6 on veterinary medicinal products on criteria to designate antimicrobials for human use, on signal detection and adverse events, on pharmacovigilance inspections, and on pharmacovigilance system master files and on pharmacovigilance communication.
- The Committee noted the second package of requests from the European Commission to the Agency regarding Regulation (EU) 2019/6 on a list of antimicrobials reserved for the treatment of certain infections in humans; the format of the data to be collected on antimicrobial medicinal products used in animals; and rules for veterinary medicinal products for oral administration.

14. ANY OTHER BUSINESS

- The draft press release for the July 2019 CVMP meeting was circulated to members upon completion of the meeting, with comments to be provided within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the July 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	Angelikin 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
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	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:	• 2.2 – 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	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Ricardo Carapeto	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	
DE	Esther Werner	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Sylvie Louet	Full involvement	
HU	Melinda Nemes-Terenyi	Full involvement	
NL	Jacqueline Poot	Full involvement	
UK	Rory Cooney	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	Beate Gasser	Full involvement	
BE	Michel Goret – *remotely*	Full involvement	
BE	Sandra De Boever – *remotely*	Full involvement	
BE	Sandy Vermout – *remotely*	Full involvement	
CZ	Dana Studená – *remotely*	Full involvement	
CZ	Eva Vernerová – *remotely*	Full involvement	
CZ	Sandy Vermout – *remotely*	Full involvement	
CZ	Jakub Stejkora – *remotely*	Full involvement	
CZ	Josef Suchy – *remotely*	Full involvement	
CZ	Petra Kubová – *remotely*	Full involvement	
CZ	Vilma Dosedlová – *remotely*	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Daniela Loos – *remotely*	Full involvement	
DE	Kathrin Schirmann	Full involvement	
DE	Rolf Beckmann – *remotely*	Full involvement	
DE	Sabine Kalweit – *remotely*	Full involvement	
DE	Sabine Klee	Full involvement	
DE	Svenja Rieke – *remotely*	Full involvement	
DK	Lotte Dahl	Full involvement	
ES	Belén Gutiérrez Soriano – *remotely*	Full involvement	
ES	Hector Duran – *remotely*	Full involvement	
ES	Jesús Alberto Sánchez Rodríguez – *remotely*	Full involvement	
ES	Luis Agote Casado – *remotely*	Full involvement	
ES	Maria Jose Ferrer – *remotely*	Full involvement	
ES	Raul Belmar Liberato – *remotely*	Full involvement	
ES	Rocío fernández Granda – *remotely*	Full involvement	
ES	Roda Donoso Carrero – *remotely*	Full involvement	
DK	Lotte Dahl	Full involvement	
FI	Ann Marie Tötterman – *remotely*	Full involvement	
FI	Jokka Kumpulainen – *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
FI	Pertti Pellinen – *remotely*	Full involvement	
FI	Tiina Hakonen – *remotely*	Full involvement	
FR	Florence Pillet – *remotely*	Full involvement	
FR	Khadija Selouaoui	Full involvement	
FR	Laetitia Le Letty	Full involvement	
FR	Marie-Hélene Sabinotto – *remotely*	Full involvement	
FR	Meg-Anne Moriceau – *remotely*	Full involvement	
IE	Paul McNeill – *remotely*	Full involvement	
IE	Rory Breathnach – *remotely*	Full involvement	
NL	Kim Boerkamp	Full involvement	
NL	Piet-Hein Overhaus	Full involvement	
PL	Marcin Glanda – *remotely*	Full involvement	
SE	Jenny Larsson	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady - *remotely*
SAWP-V	Frida Hasslung Wikström
SWP-V	----

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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