6 November 2018
EMA/CVMP/680007/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 9-11 October 2018 meeting

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

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of a new item under point 5.6.

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

The attendance list was completed and competing interests were identified for the October 2018 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

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

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

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iv. Adoption of the minutes of the previous meeting

The minutes of the September 2018 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- 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

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted (14 members in favour out of the 29 members present of those eligible to vote) a negative CVMP opinion for **HorStem** (EMEA/V/C/004265/0000), recommending the refusal of a marketing authorisation. In accordance with the CVMP Rules of procedure (EMEA/CVMP/422/04), in the event of no absolute majority position in favour of granting a marketing authorisation, the Committee opinion is deemed negative. HorStem is a stem-cell based veterinary medicinal product intended for the treatment of ostheoathritis in horses. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
  Z. Auce, M. Azevedo Mendes, J. G. Beechinor, E. Chobotová, G. Hahn, I. Malemis, T.-M. Muhonen, C. Muñoz, L. Nepejchalová, M. Schmit, W. Schlumbohm, S. Sturzu, T. Tiirats, M. Turk, and A. Wachnik-Święcicka signed a divergent position not supporting the aforementioned recommendation.

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 product (EMEA/V/C/004868/0000) for calves. The Committee agreed that an oral explanation would not be requested, and noted two peer review reports and the comments received from CVMP members.
- 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 vaccine (EMEA/V/C/004902/0000) for chicks. The Committee agreed that

an oral explanation would not be requested, and noted the comments received from CVMP members.

- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for an extension application for **Zulvac BTV Ovis** (EMEA/V/C/004185/X/0001). The Committee agreed that an oral explanation would not be requested, and noted one peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the revised scientific overview including the list of questions and agreed comments on the draft product information for an extension application for **Innovax-ND-IBD** (EMEA/V/C/004422/X/0001), to add a new route of administration. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee was informed of the applicant's, Centauri Biotech SL, notification to withdraw its application for the product **Horse Allo 20** (EMEA/V/C/004222/0000), which was proposed for the treatment of lameness associated with osteoarthritis in horses and was undergoing a re-examination procedure. As a consequence, there was no oral explanation and the negative CVMP opinion adopted by majority at the June 2018 meeting becomes the final CVMP opinion. An AHEG had been convened at the request of the applicant to provide advice on the grounds for re-examination and met on 4-5 October 2018. The Committee heard the feedback from the chair of the ad hoc expert group (AHEG) on the conclusions of their review.

- The Committee heard an oral explanation from the applicant concerning the re-examination of the CVMP negative opinion adopted for the product **LONGRANGE** (EMEA/V/C/004291/0000), a proposed antiparasitic product containing eprinomectin for the treatment of, and the prevention of reinfections with, certain specified parasites in cattle. The Committee adopted by consensus (28 members present of those eligible to vote) the final CVMP opinion and the final CVMP assessment report recommending the refusal of the granting of a marketing authorisation. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new antiparasitic product (EMEA/V/C/004824/0000) for cats and dogs.

- The Committee adopted the EPAR module scientific discussion for **Inflacam** (EMEA/V/C/002497/X/0015) concerning the granting of the extension of the marketing authorisation.

- The Committee adopted the EPAR module scientific discussion for **Rheumocam** (EMEA/V/C/000121/X/0022) concerning the granting of the extension of the marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- No items.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues for a grouped type II variation for HALAGON (EMEA/V/C/004201/II/0002/G) concerning quality changes, and noted the comments from CVMP members.

3.3 Lists of questions

- The Committee adopted a list of questions for a grouped type II variation for **Cytopoint** (EMEA/V/C/003939/II/0003/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

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the revised rapporteur's assessment report following the marketing authorisation holder' responses to the list of outstanding issues for the referral procedure for **veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep** (EMEA/V/A/126). The Committee adopted a further list of outstanding issues for the marketing authorisation holders and the revised timetable for the procedure. The Committee noted a peer review report and the comments received from CVMP members.

- The Committee considered the notification from Belgium for a referral procedure for **veterinary medicinal products containing paromomycin to be administered parenterally to pigs**. The referral concerns the appropriateness of the current indications, posology and withdrawal periods. The Committee agreed to start a referral procedure (EMEA/V/A/129) under Article 35 and appointed B. Urbain as rapporteur and S. Louet as co-rapporteur, and adopted a list of questions and the timetable.

- The Committee considered the notification from the Netherlands for a referral procedure for **veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep**. The referral concerns the appropriateness of the current withdrawal periods (milk, meat and offal) in sheep. The Committee agreed to start a referral procedure (EMEA/V/A/130) under Article 35 and appointed G. J. Schefferlie as rapporteur and S. Louet as co-rapporteur. The Committee adopted a list of questions and the timetable.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee discussed the revised rapporteur's assessment report for the procedure for **veterinary medicinal products containing gentamicin for parenteral administration to horses** (EMEA/V/A/128). The Committee agreed that no outstanding issues remained and noted a peer review report and comments received from CVMP members. The opinion is foreseen to be adopted at the November 2018 CVMP meeting.

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

- The Committee adopted the rapporteur's assessment report, including a list of questions, on the data submitted concerning a condition for **ZULVAC SBV** (EMEA/V/C/002781/ANX-004.4).
- The Committee adopted the rapporteur's assessment report, including a list of questions, on the data submitted concerning a recommendation for **Bravecto Plus** (EMEA/V/C/004440/REC/007).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Fevaxyn Pentofel** (EMEA/V/C/000030/REC/027.2).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 14.09.2018 – 11.10.2018:

Product	Period
Cerenia (EMEA/V/C/000106)	29/09/2017 – 28/09/2018
COXEVAC (EMEA/V/C/000155)	20/09/2017 – 19/09/2018
ERAVAC (EMEA/V/C/004239)	22/09/2017 – 21/09/2018
Palladia (EMEA/V/C/000150)	23/09/2017 – 22/09/2018
RHINISENG (EMEA/V/C/000160)	16/09/2017 – 15/09/2017
Trifexis (EMEA/V/C/002635)	19/09/2017 – 18/09/2018 (expired)

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Loxicom** (EMEA/V/C/000141/R/0031).
- 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 **NexGard** (EMEA/V/C/002729/R/0023), 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 **Bravecto** (EMEA/V/C/2526/R/0028), and recommended that a further five-year renewal would be required. 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 01.09.2017–28.02.2018 for **Bravecto** (EMEA/V/C002526) 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
BLUEVAC BTV8 (EMEA/V/C/000156)	01.07.2017 – 30.06.2018
BTVPUR Alsap1 (EMEA/V/C/002230)	01.01.2017 – 31.05.2018
BTVPUR Alsap8 (EMEA/V/C/000146)	01.04.2017 – 31.05.2018
DRAXXIN (EMEA/V/C/000146)	01.12.2017 – 31.05.2018
EQUIP WNV (EMEA/V/C/000137)	01.06.2017 – 31.05.2018
Meloxivet (EMEA/V/C/000124)	01.06.2015 – 31.05.2018
Meloxoral (EMEA/V/C/000151)	20.05.2015 – 19.05.2018
Porcilis AR-T-DF (EMEA/V/C/000055)	01.06.2015 – 31.05.2018
Porcilis PCV M Hyo (EMEA/V/C/003796)	01.06.2017 – 31.05.2018
RESPIPORC FluPan H1N1 (EMEA/V/C/003993)	01.12.2017 – 31.05.2018
SevoFlo (EMEA/V/C/000072)	01.12.2017 – 31.05.2018
Suvaxyn Circo MH RTU (EMEA/V/C/003925)	01.12.2017 – 31.05.2018

- 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 endorsed the draft EU comments on the latest proposals in relation to the revision of the VICH anthelmintics guidelines: Defining the age of field isolates and laboratory

strains, field studies for swine (GL16), field studies for poultry (GL21), and Adequacy of infection/helminth numbers, for submission to the VICH Expert Working Group.

- The Committee endorsed the draft EU comments on draft 2 of the new VICH guideline on fixed combination products for submission to the VICH Expert Working Group.
- The Committee endorsed the comments on the draft training slides on VICH quality GL3, GL4, GL5 and GL8, for submission to the VICH Steering Committee.
- The Committee endorsed the draft revised VICH GL on Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use (LABST) to be forwarded for discussion to the VICH Expert Working Group.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee noted the EFSA public consultation relating to diflubenzuron for use as a pesticide active substance (link).

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 SAWP-V vice-chair on the meeting held on 9 October 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP veterinary vice-chair on the meeting held on 27-28 September, and noted the agenda of the meeting.
- The Committee agreed to extend the consultation period of the draft guideline (EMA/CVMP/QWP/798401/2015-Rev.1) on the manufacture of veterinary finished dosage form until the end of August 2019.
- The Committee discussed the draft reflection paper on risk management requirements for elemental impurities in veterinary medicinal products and a revised document on the implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products. Both documents are foreseen to be adopted at the November CVMP meeting, after which the draft reflection paper will be published for consultation.
- The Committee discussed a question and answer on requirements for selection and justification of starting materials for the manufacture of chemical active substances in veterinary medicinal products, which is foreseen to be adopted at the November CVMP meeting.

- The Committee discussed the revised guideline on active substance master file procedure, which is foreseen to be adopted at the November CVMP meeting.
- The Committee deferred the discussion of the draft revised guideline on the conduct of bioequivalence studies for veterinary medicinal products to the November 2018 meeting of the Committee.

7.3 Safety Working Party (SWP-V)

- The Committee deferred the discussion of the draft revised guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market to the November 2018 CVMP meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee deferred the discussion of the draft reflection paper on the environmental risks of veterinary medicinal products used in EU aquaculture to a future CVMP meeting.
- The Committee discussed the draft reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products, which is foreseen to be adopted for release for public consultation at the November 2018 CVMP meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee deferred the verbal report from the EWP-V chair on the meeting held on 18-19 September, to the November 2018 CVMP meeting.
- The Committed deferred the discussion of the draft revised guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances to the November 2018 CVMP meeting.
- The Committee deferred the discussion of the draft revised guideline on the conduct of bioequivalence studies for veterinary medicinal products to the November 2018 meeting of the Committee.
- The Committee deferred the discussion of a new question and answer document on the CVMP guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees to the November 2018 CVMP meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee deferred the verbal report from the AWP chair on the meeting held on 18-19 September to the November 2018 CVMP meeting.
- The Committee discussed the reflection paper on off-label use of antimicrobials in veterinary medicines in the European Union, which is foreseen to be adopted at the November 2018 CVMP meeting.
- The Committee deferred the verbal update on the Risk Assessment Guideline Focus Group meeting, held on 19 September 2018, to the November 2018 CVMP meeting.
- The Committee discussed the draft reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products, which is foreseen to be adopted for release for public consultation at the November 2018 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee deferred the verbal report from the IWP chair on the meeting held on 25 September to the November 2018 CVMP meeting.
- The Committee deferred the discussion of the revised guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot-and-mouth disease and the overview of comments received following the close of public consultation to the November 2018 CVMP meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee deferred the verbal report from the PhVWP-V chair on the plenary meeting held on 25-26 September 2018 and the PhVWP-V Interested Parties meeting held on 26 September 2018 to the November 2018 CVMP meeting.
- The Committee deferred the discussion of the problem statement on products containing permethrin authorised for use in dogs and adverse reactions in cats to the November 2018 CVMP meeting.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Draft minutes of the SAWP-V meeting held on 11 September 2018.
- Agenda of the 88th joint CHMP/CVMP QWP-V meeting held on 27-28 September 2018 and minutes of the 87th joint CHMP/CVMP QWP-V meeting held on 5-7 June 2018.
- Minutes of the IWP meeting held on 28 February – 1 March 2018.
- Agenda and minutes of J3RsWG meeting held on 24 April 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.

- The Committee deferred the endorsement of the revised templates for MRL scientific overview and list of questions and MRL assessment report to the November 2018 CVMP meeting.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee deferred the verbal update on the development of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) scientific advice to the November 2018 CVMP meeting.

8.4 Pharmacovigilance

- The Committee deferred the update on the alert issued by the United States Food and Drug Administration (FDA) (link) to veterinarians and pet owners about potential neurologic adverse reactions in dogs and cats receiving flea and tick treatment from the isoxazoline class of drugs and fact sheet (link)for pet owners and veterinarians to the November 2018 CVMP meeting.

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.

The following document was circulated for information:

- Final report of the EU Parliament "A European One Health Action Plan against Antimicrobial Resistance" (link).

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.

- There were no items for discussion.

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

- The Committee received a verbal report from the chair of CMDv on the meetings held in July and September 2018, and noted the draft minutes of the meeting on 13-14 September 2018 as well as the draft agenda of the meeting held on 11-12 October 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the upcoming appointment of CVMP co-opted members at the December 2018 meeting for the identification of additional expertise necessary for CVMP to accomplish its mandate (EMA/416688/2013-Rev.3). The Committee agreed to appoint two co-opted members, retaining the same areas of expertise (i.e. antimicrobial resistance and environmental risk assessment). A call for nominations will be circulated by the secretariat shortly after the meeting.

- The Committee noted the draft agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held during the Austrian presidency on 25-26 October 2018 in Helsinki, Finland.

- The Committee deferred the update on the Regulatory Science Strategy 2020-2025 to the November CVMP 2018 meeting.
- The Committee deferred the update on the EMA working group on operational preparedness for veterinary medicines - impact on the supply of medicines and cut-off dates for post-authorisation procedures, to the November 2018 CVMP meeting.
- The Committee noted the CVMP meeting dates for 2019-2021.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

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

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the October 2018 meeting.

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	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	
FI	Tita-Maria Muhonen	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 5.4 - Loxicom
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 5.4 - Loxicom
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
SE	Frida Hasslung Wikström	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	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	
BG	Svetoslav Branchev	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 4.3 - Closantel • 4.6 - Gentamicin

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	
IE	Mary O'Grady	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SI	Maja Turk	Full involvement	
SK	Eva Chobotová	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	Koenraad Brusselmans	Full involvement	
CZ	Ivana Haunerova *(remotely)*	Full involvement	
DE	Christine Schwarz	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DE	Gerd Werner	Full involvement	
DE	Kathrin Dietze *(remotely)*	Full involvement	
DE	Birgit Kegel *(remotely)*	Full involvement	
DE	Daniela Loos *(remotely)*	Full involvement	
DE	Ingun Lemke *(remotely)*	Full involvement	
DK	John Jensen *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
ES	Ricardo Carapeto Garcia	Full involvement	
ES	Rocio Fernández *(remotely)*	Full involvement	
ES	Rosario Bullido *(remotely)*	Full involvement	
ES	Carlos Ballesteros *(remotely)*	Full involvement	
ES	Raúl Belmar *(remotely)*	Full involvement	
IE	Sarah Buckley *(remotely)*	Full involvement	
IE	Susan Reid *(remotely)*	Full involvement	
IE	Pieter Brama (remotely)	Full involvement	
NL	Anita Bottger *(remotely)*	Full involvement	
NL	Kim Boemkamp *(remotely)*	Full involvement	
SE	Andreea Barbu *(remotely)*	Full involvement	
UK	Rory Cooney	Full involvement	
UK	Stephen Spencer *(remotely)*	Full involvement	
UK	Nicholas Taylor *(remotely)*	Full involvement	

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

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	–---
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	---
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