11 July 2017
EMA/CVMP/440948/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 13-15 June 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 June 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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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the May 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

- 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 a 2-month extension to the clock-stop for the application for the extension of MRLs to chickens 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 **Innovax-ND-IBD** (EMEA/V/C/004422/0000), recommending the granting of a marketing authorisation. The product is a new live vaccine for the active immunisation of one-day-old chicks by subcutaneous injection in order to reduce mortality and clinical signs caused by Newcastle disease virus, to prevent mortality, to reduce clinical signs and lesions of infectious bursal disease, and to reduce mortality, clinical signs and lesions caused by Marek's disease virus. 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **VEPURED** (EMEA/V/C/004364/0000), recommending the granting of a marketing authorisation. The product is a new inactivated vaccine for the active immunisation of pigs to prevent mortality and reduce clinical signs of oedema disease caused by Shiga-like toxin Stx2e produced by *E. coli*. 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Exzolt**

(EMEA/V/C/004344/0000), recommending the granting of a marketing authorisation. Exzolt is a new antiparasitic product containing fluralaner for the treatment of poultry red mite (*Dermanyssus gallinae*) infestation in pullets, breeders and layer hens. 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/0000), recommending the granting of a marketing authorisation. The product is a new live vaccine for the active immunisation of clinically healthy pigs in a Porcine Reproductive & Respiratory Syndrome (PRRS) virus contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus. 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 product (EMEA/V/C/004296/0000) for bees. The Committee agreed that an oral explanation would not be requested, and noted two peer review reports 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 (EMEA/V/C/002774/0000) for a musculo-skeletal disorder in horses. The Committee noted two peer review reports 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 endorsed the EPAR module 6 scientific discussion for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **CLYNAV** (EMEA/V/C/002390/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Prevomax** (EMEA/V/C/004331/0000) 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 **Pexion** (EMEA/V/C/002543/II/0009), recommending the variation of the marketing authorisation to implement changes to the SPC and package leaflet. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Porcilis**

PCV (EMEA/V/C/000135/II/0011/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/II/0005/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **ProteqFLu**, **Purevax FeLV**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV**, **Oncept IL-2**, **Proteq West Nile**, **ProteqFlu-Te** and **Purevax Rabies** (EMEA/V/C/xxxxxx/WS/1095), recommending the variation of the marketing authorisations 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 worksharing type II variation for **Eurican Herpes 205**, **Purevax RCPCh**, **Bovalto Ibraxion**, **Purevax RCP FeLV**, **Purevax RC**, **Purevax RCP**, **BTVPUR AlSap 2-4**, **BTVPUR**, **Parvoduk** and **Purevax RCPCh FeLV** (EMEA/V/C/xxxxxx/WS/1151), concerning quality changes.
- The Committee adopted the list of questions for a type II variation for **Reconcile** (EMEA/V/C/000133/II/0017), 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 discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122). The Committee agreed to the request by Elanco Animal Health to provide an oral explanation and adopted the list of outstanding issues for the marketing authorisation holder to address in writing and at an oral explanation, and the revised timetable for the procedure. The Committee noted the comments made by CVMP members.
- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Lincocin and its associated names** (EMEA/V/A/123). The Committee agreed that no outstanding issues remained. The adoption of

the CVMP opinion and assessment report is foreseen for the July 2017 meeting of the Committee.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Zanil and associated names, and generic products thereof** (EMEA/V/A/124). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the July 2017 meeting of the Committee.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the follow-up assessment procedure in relation to conditions set by the Commission Implementing Decision C(2014) 1484 following the referral procedure for **veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** (EMEA/V/A/089). The Committee adopted a list of questions for the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted a peer review report 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

- There were no items for discussion.

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 13.05.2017 – 15.06.2017:

Product	Period
Equilis West Nile (EMEA/V/C/002241)	06/06/2016 – 05/06/2017
MS-H Vaccine (EMEA/V/C/000161)	14/06/2016 – 13/06/2017
Naxcel (EMEA/V/C/000079)	19/05/2016 – 18/05 2017

Product	Period
Nobilis IB 4-91 (EMEA/V/C/000036)	09/06/2016 – 08/06/2017
Porcilis ColiClos (EMEA/V/C/002011)	14/06/2016 – 13/06/2017
Porcilis Pesti (EMEA/V/C/000046)	09/06/2016 – 08/06/2017
Poulvac E. coli (EMEA/V/C/002007)	15/06/2016 – 14/06/2017
Sileo (EMEA/V/C/003764)	10/06/2016 – 09/06/2017
Vectra Felis (EMEA/V/C/002746)	06/06/2016 – 05/06/2017

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2016 – 31.12.2016 for **Cerenia** (EMEA/V/C/000106) with a recommendation to add a new warning in Section 4.5 of the SPC Special precautions to be taken by the person administering the veterinary medicinal product.
- 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
Canigen L4 (EMEA/V/C/004079)	01.08.2016 – 31.01.2017
Melovem (EMEA/V/C/000152)	01.02.2014 – 31.01.2017
NEXGARD SPECTRA (EMEA/V/C/003842)	01.08.2016 – 31.01.2017
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.03.2016 – 28.02.2017
Nobivac L4 (EMEA/V/C/002010)	01.08.2016 – 31.01.2017
Novaquin (EMEA/V/C/003866)	09.09.2016 – 08.03.2017
Porcilis PCV ID (EMEA/V/C/003942)	01.09.2016 – 28.02.2017
Sedadex (EMEA/V/C/004202)	12.08.2016 - 12.02.2017
Versican Plus L4 (EMEA/V/C/003680)	01.08.2016 – 31.01.2017
Versican Plus Pi (EMEA/V/C/003681)	01.08.2016 – 31.01.2017
Versican Plus Pi L4 (EMEA/V/C/003683)	01.08.2016 – 31.01.2017
Versican Plus Pi L4/R (EMEA/V/C/003682)	01.08.2016 – 31.01.2017
ZACTRAN (EMEA/V/C/004202)	01.08.2016 – 31.01.2017

- 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.

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 the VICH guideline 50 on harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use, following the sign-off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process.
- The Committee adopted the VICH guideline 55 on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use, following the sign-off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process.
- The Committee discussed the EU position in relation to the development of a guideline on use of cell cultures for the detection of extraneous viruses in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines. It was agreed that a document clarifying the EU position would be brought to CVMP for endorsement at its July meeting.
- The Committee appointed a new expert for the VICH Electronic Standards Implementation Expert Working Group.

6.2 Codex Alimentarius

- There were no items for discussion.

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 chair of the SAWP-V on the meeting held on 13 June 2017, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

- The Committee endorsed the participation of a CVMP/SWP-V representative at a workshop with stakeholders, organised by GMP inspectors, focusing on generation of health based exposure limits, to be held on 20-21 June 2017. The workshop will focus on comments received during the consultation period on the Q&A document on risk-based prevention of cross contamination in production and 'Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' (EMA/CHMP/CVMP/SWP/463311/2016)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 18-19 May 2017, and noted the agenda of the meeting.
- The Committee was informed of the programme for the assessors training on genotoxicity testing, to be held on 21 September 2017.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 30-31 May 2017, and noted the agenda of the meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee elected Christine Schwarz as vice-chair for the AWP for a 3-year term.
- The Committee received a verbal report from the chair of the AWP on the meeting held on 23-24 May 2017, and noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 16-17 May 2017, and noted the agenda and draft minutes of the meeting.
- The Committee adopted the CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009-Rev.9) used for electronic reporting, following the yearly review and update. Implementation of the VeDDRA list in EudraVigilance Veterinary is scheduled for 1 October 2017. The revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.10), and a revised call for comments on the VeDDRA standard list for EVVet (EMA/CVMP/PhVWP/123352/2004 – Rev.10) were also adopted.

7.9 Novel therapy groups and related issues

- The Committee adopted the questions and answers on stem cell-based products for veterinary use: specific questions on sterility (EMA/CVMP/ADVENT/751229/2016).

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

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 10 May 2017;
- Final agenda of the 83rd Joint CHMP/CVMP QWP meeting held on 22-24 May 2017; final agenda of the Joint CHMP/CVMP QWP Interested Parties meeting held on 23 May 2017; final minutes from the 82nd Joint CHMP/CVMP QWP meeting held on 31 January – 2 February 2017;

- Draft agenda of the CVMP IWP meeting to be held on 21–22 June 2017;
- Draft minutes of the CVMP IWP meeting held on 1–2 February 2017;
- Draft agenda of the CVMP ADVENT meeting to be held on 15 June 2017;
- Draft agenda of the J3RsWG meeting to be held on 20 June 2017;
- Draft minutes of the last JEG3Rs meeting held on 18-19 October 2016.

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 agreed to include **dipropylene glycol monomethyl ether** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant, and adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.36).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

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.

The following documents were circulated for information:

- EC workshop with EMA in Brussels on 26 April 2017: Data collection on consumption of veterinary antimicrobials in Europe – achievements, challenges and way forward: http://ec.europa.eu/dgs/health_food-safety/amr/events/ev_20170426.htm
  Summary report of the workshop's outcome: http://ec.europa.eu/dgs/health_food-safety/amr/docs/ev_20170426_workshop-sum.pdf;
- Guidance on provision of data on antimicrobial use by 4 animal species from national data collection systems for consultation until 24 September 2017 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224492.pdf;
- First draft of the Joint Interagency (ECDC/EFSA/EMA) Antimicrobial Consumption and Resistance Analysis Report (JIACRA II).

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 the draft agenda, the draft list of experts, the revised concept note and the list of questions for the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, to be held on 22-23 June 2017 at EMA, London, UK.

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 received a verbal report on the meetings held on 16-17 March 2017, 11-12 April 2017 and 11-12 May 2017, and noted the draft minutes of the May meeting as well as the draft agenda of the meeting held on 15-16 June 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the CVMP work planning for 2018.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 14 June 2017, and noted the agenda of the meeting and the minutes of the meeting held on 11 April 2017.
- The Committee was informed of the launch of MNATs in post-authorisation procedures, and in particular phase I which will be launched as of 1 September 2017.
- The Committee deferred the update on the HMA/EMA Task Force on timetables: revised best practice guide on measures improving predictability of submissions/responses and adherence to communicated submission/responses deadlines following public consultation to the July CVMP meeting.
- The Committee received a presentation on requests for supplementary information (RSI) for type II variations.
- The Committee noted the draft agenda of the informal CVMP/CMDv meeting, to be held on 26-27 June 2017 in Rotterdam, the Netherlands.

13. LEGISLATION

- The Committee noted the Commission Regulation (EU) 2017/880 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species,

in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (link). Given that this document includes a formal description of the approach CVMP will take in relation to extrapolation of MRLs, the Committee noted that there will be a need to update relevant SWP-V guidelines, in particular the MUMS guideline that make reference to extrapolation in order to bring these in line with the new regulation. The templates for CVMP MRL assessment reports and EPMARs will also be updated.

14. ANY OTHER BUSINESS

- Upon the completion of the June 2017 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 June 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	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	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:	• 4.3 Enrofloxacin • 5.6 V-PhV inspection programme
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Katarina Straus	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
IT	Antonio Battisti	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of 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	
DE	Karin Duchow – *remotely*	Full involvement	
DE	Ingun Lemke – *remotely*	Full involvement	
DE	Nikola Lange – *remotely*	Full involvement	
DE	Stefan Scheid – *remotely*	Full involvement	
DE	Yasemin Süzer – *remotely*	Full involvement	
DE	Werner Terhalle – *remotely*	Full involvement	
ES	Lucía Bans Pereira - *remotely*	Full involvement	
ES	María Domínguez Nicolás – *remotely*	Full involvement	
ES	Rocio Fernandez Granda	Full involvement	
ES	Aránzazu González Canga – *remotely*	Full involvement	
ES	Gloria Montes Freilich – *remotely*	Full involvement	
ES	Patricia Vera Luque – *remotely*	Full involvement	
FR	Martine Redureau – *remotely*	Full involvement	
FR	Khadija Selouaoui – *remotely*	Full involvement	
SI	Maja Golobic – *remotely*	Full involvement	
SI	Vesna Kadunc Kos – *remotely*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SI	Petra Kramaric – *remotely*	Full involvement	
SI	Petra Segina – *remotely*	Full involvement	
SI	Bojana Stavar Mocnik – *remotely*	Full involvement	
SI	Maja Turk - *remotely*	Full involvement	
UK	John Mitchell	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero
IWP	Esther Werner
PhVWP-V	Elisabeth Begon (vice-chair) - *remotely*
QWP	--
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