5 September 2017
EMA/CVMP/587890/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 11-13 July 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. There were no competing interests for the July 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.

No contacts were declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the June 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

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003596/FULL/0001), and adopted a list of outstanding issues that should be addressed in writing and, potentially, at an oral explanation. The Committee noted the comments from the EU Reference Laboratory concerning the analytical method.
- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in Equidae for a substance (EMEA/V/MRL/004543/FULL/0001), and adopted a list of outstanding issues that should be addressed in writing and, potentially, at an oral explanation.
- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in porcine species for a substance (EMEA/V/MRL/004113/FULL/0001), and adopted a list of outstanding issues that should be addressed in writing and, potentially, at an oral explanation.

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

- There were no items for discussion.

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 for musculo-skeletal disorders in dogs (EMEA/V/C/004375/0000). The Committee agreed to invite the applicant for an oral explanation in October 2017. The Committee 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 marketing authorisation application for a new vaccine for pigs (EMEA/V/C/004242/0000). 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 marketing authorisation application for a new vaccine for cattle (EMEA/V/C/004595/0000). 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 withdrawal EPAR, following the formal notification from the applicant to withdraw their application for **Somnena** (EMEA/V/C/004293/0000), a pharmaceutical product for cats, which was proposed for the control of post-operative pain.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **ZULVAC 1+8 Ovis**, **ZULVAC 1+8 Bovis** and **ZULVAC 1 Bovis** (EMEA/V/C/xxxxxx/WS/1096), recommending the variation of the marketing authorisations to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **ZULVAC 8 Bovis** and **ZULVAC 8 Ovis** (EMEA/V/C/xxxxxx/WS/1097), 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 type II variation for **Imrestor** (EMEA/V/C/002763/II/0005), concerning quality changes.
- The Committee adopted the list of questions for a grouped type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0006/G), concerning quality changes.
- The Committee adopted the list of questions for a type II variation for **SevoFlo** (EMEA/V/C/000072/II/0020), to add a new target species.
- The Committee adopted the list of questions for a type II variation for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/II/0009), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee noted the formal notification from Eli Lilly and Company of their decision to withdraw the application for a type II variation for **Comfortis** (EMEA/V/C/002233/II/0017), to change the legal status regarding supply and use.

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 adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Lincocin and its associated names** (EMEA/V/A/123), recommending the harmonisation of the product information for the concerned products. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Zanil and associated names, and generic products thereof** (EMEA/V/A/124), recommending the withdrawal periods (milk, meat and offal) for cattle, sheep and goats to be amended to provide assurance for consumer safety. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

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.

The following documents were circulated for information:

- Denagard 45% and its associated names – Article 34 referral (EMEA/V/A/114) – questions and answers for publication;
- Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for use in the target species cattle – Article 35 referral (EMEA/V/A/119) – questions and answers for publication;
- Veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp. – Article 35 referral (EMEA/V/A/121) – questions and answers for publication;
- Veterinary medicinal products containing zinc oxide to be administered orally to food producing species – Article 35 referral (EMEA/V/A/118) – questions and answers for publication.

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 16.06.2017 – 13.07.2017:

Product	Period
Canigen L4 (EMEA/V/C/004079)	03/07/2015 - 02/07/2017
Circovac (EMEA/V/C/000114)	21/06/2007- 20/06/2017
Convenia (EMEA/V/C/000098)	19/06/2006 - 18/06/2017
Equilis Prequenza (EMEA/V/C/000094)	08/07/2005 - 07/07/2017
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2005 - 07/07/2017
Equilis Te (EMEA/V/C/000093)	08/07/2005 - 06/07/2017
EQUIOXX (EMEA/V/C/000142)	25/06/2008 - 24/07/2017
ERYSENG (EMEA/V/C/002761)	04/07/2014 - 03/07/2017
ERYSENG PARVO (EMEA/V/C/002762)	08/07/2014 - 07/07/2017
Innovax-ILT (EMEA/V/C/003869)	03/07/2015 - 02/07/2017
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25/06/2009 - 24/06/2017
LEUCOGEN (EMEA/V/C/000144)	17/06/2009 - 16/06/2017
Melovem (EMEA/V/C/000152)	07/07/2009 - 06/07/2017
Posatex (EMEA/V/C/000122)	23/06/2008 - 22/06/2017
ProZinc (EMEA/V/C/002634)	12/07/2013 - 11/07/2017
Reconcile (EMEA/V/C/000133)	08/07/2008 - 07/07/2017
Sevohale (EMEA/V/C/004199)	21/06/2016 - 20/06/2017
Spironolactone Ceva (EMEA/V/C/000105)	20/06/2007 - 19/06/2017
Suprelorin (EMEA/V/C/000109)	10/07/2007 - 09/07/2017
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2014 - 03/07/2017
Versican Plus Pi (EMEA/V/C/003681)	04/07/2014 - 03/07/2017

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 11.02.2014 – 31.12.2016 for **Bravecto** (EMEA/V/C/002526) with a recommendation to amend the product information, to include convulsions as a new adverse reaction occurring very rarely, and to advise caution when using Bravecto in animals with pre-existing epilepsy.
- 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
Activyl Tick Plus (EMEA/V/C/002234)	01.02.2016 – 31.01.2017
Equilis StrepE (EMEA/V/C/000078)	01.04.2014 – 31.03.2017
Equisolon (EMEA/V/C/002382)	13.09.2016 – 12.03.2017
Nobilis IB 4-91 (EMEA/V/C/000036)	01.10.2016 – 31.03.2017
Nobilis IB Primo QX (EMEA/V/C/002802)	01.10.2016 – 31.03.2017
Masivet (EMEA/V/C/000128)	01.12.2013 – 30.11.2016
Osurnia (EMEA/V/C/003753)	01.08.2016 – 31.01.2017
Vectormune ND (EMEA/V/C/003829)	01.10.2016 – 31.03.2017
Zulvac 1 Bovis (EMEA/V/C/002334)	01.03.2016 – 28.02.2017
Zulvac 1 Ovis (EMEA/V/C/002335)	01.03.2016 – 28.02.2017
Zulvac SBV (EMEA/V/C/002781)	01.09.2016 – 28.02.2017

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

5.6 Supervision and sanctions

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

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the draft EU response to the comments received in relation to the ongoing discussions on whether to incorporate the extended one-generation reproductive toxicity study (EOGRTS) into VICH GL 22 on studies to evaluate the safety of residues of veterinary drugs in human food: reproduction testing.
- The Committee endorsed the draft explanation of EU objections to the extended version of the draft 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 (proposed by IFAH-EU in 2012). The explanation will be forwarded to the VICH Steering Committee and the Biologicals Quality Monitoring Expert Working Group, and discussions between the EU experts and the VICH topic lead will be arranged.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee discussed the draft proposal for the harmonised classification and labelling of theophylline under consideration by ECHA, and appointed G. Hahn to consider whether the ECHA activity would impact on the appropriateness of the MRL status of theophylline and report back at a future CVMP meeting.
- The Committee was informed of the final JECFA guidance document for the establishment of acute reference dose (ARfD) for veterinary drug residues in food (link).

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 11 July 2017, and noted the agenda of the meeting.
- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP Scientific Advice Working Party (SAWP-V) (EMA/CVMP/SAWP/676117/2010).

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 22–24 May 2017, and noted the agenda of the meeting and also the agenda of the Interested Parties meeting held on 23 May 2017.
- The Committee endorsed Keith Pugh as chair of the QWP for a 3-year mandate, following his election by the CHMP.
- The Committee adopted a reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action (EMA/CHMP/CVMP/QWP/336031/2017), and the overview of comments received (EMA/CHMP/CVMP/QWP/257305/2017).
- The Committee adopted a reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances (EMA/CVMP/QWP/3629/2016) in marketing authorisation applications for veterinary medicinal products, and the overview of comments received (EMA/CVMP/QWP/112656/2017).
- The Committee adopted the question and answer document on elemental impurities in veterinary medicinal products.
- The Committee endorsed the Joint GMP/GDP IWG and QWP letters and questionnaires to marketing authorisation holders and industry organisations regarding qualification of active substance manufacturers as required by Article 46 of Directive 2001/83 (as amended) and Article 50 of Directive 2001/82 (as amended). The topic is due for adoption by the CHMP at their July meeting.

7.3 Safety Working Party (SWP-V)

- The Committee received verbal feedback on the workshop with industry on generation and use of health based exposure limits, held on 20-21 June 2017.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- The Committee endorsed the efficacy training curriculum for veterinary efficacy assessors (pharmaceuticals) of the Network Training Centre.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the draft reflection paper on off-label use of antimicrobials in veterinary medicine (EMA/CVMP/AWP/237294/2017) for a 6-month period of public consultation.
- The Committee adopted the draft reflection paper on aminoglycosides (EMA/CVMP/AWP/721118/2014) for a 3-month period of public consultation.
- The Committee agreed to the participation of H. Jukes in the Antimicrobial resistance EMA Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting to be held on 19 September 2017, and noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 21-22 June 2017, and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the revised reflection paper on promotion of pharmacovigilance reporting (EMA/CVMP/PhVWP/390033/2014-Rev1).

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 extraneous agents (EMA/CVMP/ADVENT/803494/2016).

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

- The Committee endorsed the core and co-opted members of the J3RsWG. The Committee also endorsed Ellen-Margrethe Vestergaard as chair and Susanne Brendler-Schwaab as vice-chair of the group, following their election at the J3RsWG meeting held on 20 June 2017.

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 13 June 2017;
- Final minutes of the CVMP IWP meeting held on 1-2 February 2017;
- Draft agenda of the PhVWP-V meeting to be held on 18-19 July 2017;

- Draft minutes of the CVMP ADVENT meeting held on 15 June 2017.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential.

- There were no items for discussion.

8.2 Environmental risk assessment

- The Committee received a report from the meeting on developing priorities for WHO activities on antimicrobial resistance and the environment, held on 5-6 July 2017 in Nieuwegein, the Netherlands, and noted the agenda of the meeting.

8.3 Antimicrobial resistance

- The Committee received a verbal report from the 3rd meeting of the pilot project on dose optimization in the context of SPC harmonization of established veterinary antibiotics, held on 16 June 2017, and noted the minutes of the meeting.
- The Committee endorsed the comments received on the draft paper on EU clinical breakpoint for veterinary antimicrobial susceptibility testing.
- The Committee was informed of the publication of the assessment of the risk to public health due to use of antimicrobials in pigs - an example of pleuromutilins in Denmark (26 May 2017) (link).
- The Committee discussed the ESGVM (European Society of Microbiology and Infectious Diseases Study Group for Veterinary Microbiology) guidelines/consensus papers on antimicrobial use in veterinary infectious diseases.
- The Committee received a verbal report on the ECDC/EFSA/EMA second joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA II).
- The Committee was informed of the European One Health action plan against AMR 2017.
- The Committee was informed about the new AMEG (Antimicrobial Advice Ad Hoc Expert Group) mandate concerning the request from the European Commission for an update of the advice on the impact on public health and animal health of the use of antibiotics in animals (categorisation of antimicrobials and early hazard characterisation).

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.

- The Committee received feedback on the breakout session with the FishMed Plus Coalition, during which the main issues and challenges/barriers and solutions were presented. The Committee discussed the EMA and CVMP responses to the recommendations made by the FishMed Plus Coalition and agreed that a small number of recommendations relating primarily to vaccines and MRLs could be followed up by the Committee, but the Coalition or other stakeholders would need to take the first step and initiate the relevant request with supporting grounds. This was communicated to the Coalition during the break out session.
- The Committee received an update from the secretariat and the CVMP Chair on the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, held on 22-23 June 2017, and noted the final programme. The Chair considered the meeting very successful with fruitful discussions between regulators, industry and academia. The outcome of the meeting (in a form of a report) will be available to the CVMP for its September meeting, and on the basis of the outcome, recommendations for appropriate follow up will be made by the Joint EMA/HMA Steering Group on veterinary vaccine availability.

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 co-rapporteurship of a product from G. J. Schefferlie to J. Poot.

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 draft minutes of the meeting held on 15-16 June 2017 as well as the draft agenda of the meeting held on 13-14 July 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the proposals for agenda topics for the CVMP interested parties meeting to be held on 6 September 2017.
- The Committee were informed that a comprehensive report on the conclusions and recommendations from the CVMP/CMDv Presidency meeting, held on 26-27 June 2017 in the Netherlands, will be provided at the September CVMP meeting.
- The Committee discussed the draft CVMP work plan for 2018, following its discussion at the Strategic Planning Group (SPG), and agreed the general principles and priorities of the Committee for 2018.

- The Committee received a verbal report from the chair of the SPG on the meeting held on 12 July 2017, and noted the agenda of the meeting and the minutes of the meeting held on 14 June 2017.
- The Committee received a verbal update from the EMA working group on operational preparedness for veterinary medicines.
- The Committee was informed of the best practice guide on measures improving predictability of submissions/responses and adherence to communicated submission/responses deadlines.
- The Committee was informed of the potential issues or procedures that would require CVMP decision via written procedure during August 2017.
- The Committee noted the update on MNATs in relation to phase I of post-authorisation procedures, which will be launched as of 1 September 2017.
- The Committee noted the CVMP dates in 2018 (link).

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the July 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 July 2017 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SK	Judita Hederová	Full involvement	
UK	Helen Jukes	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
AT	Petra Falb	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FR	Sylvie Louet	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SE	Frida Hasslung Wikström	Full involvement	
SI	Maja Turk	Full involvement	
UK	Noemi Garcia del Blanco	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	
DE	Klaus Cussler – *remotely*	Full involvement	
DE	Luela Froehlich – *remotely*	Full involvement	
DE	Maike Goemmel – *remotely*	Full involvement	
DE	Uta Herbst – *remotely*	Full involvement	
DE	Sabine Kalweit – *remotely*	Full involvement	
DE	Nikola Lange – *remotely*	Full involvement	
DE	Stefan Scheid – *remotely*	Full involvement	
DK	Christian Friis – *remotely*	Full involvement	
FI	Katariina Kivilahty-Mantyla - *remotely*	Full involvement	
FI	Kristina Lehmann - *remotely*	Full involvement	
IE	Gavin Ryan – *remotely*	Full involvement	
NL	Engeline van Duijkeren - *remotely*	Full involvement	
NO	Tora Gauslaa – *remotely*	Full involvement	
PL	Anita Piwowarczyk	Full involvement	
SI	Lucija Peterlin Masic – *remotely*	Full involvement	
UK	Kenneth Stapleton	Full involvement	
UK	Gavin Hall	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	Lisbet Vesterager Borge - *remotely*

CVMP working parties and CMDv	Chair
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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