6 December 2016
EMA/CVMP/818284/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 November 2016 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 interests were identified for the November 2016 meeting. In accordance with the Agency's policy and procedure on the handling of declarations of 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 Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee 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 October 2016 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 adopted a list of outstanding issues that should be addressed at an oral explanation, for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004333/FULL/0001), following discussion of the rapporteurs' joint assessment of the responses to the list of questions and of two peer review reports. The adoption of the opinion is foreseen for the February 2017 meeting of the Committee.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in porcine species for a substance (EMEA/V/MRL/004479/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and of a peer review report.
- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in *Equidae* for a substance (EMEA/V/MRL/004543/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and of two peer review reports.
- The Committee adopted the scientific overview and list of questions for the extension of MRLs to chickens for a substance (EMEA/V/MRL/003517/EXTN/0003), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and of a peer review report.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee was informed of the date proposed by the applicant for the submission of responses to the list of questions for the application for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003596/FULL/0001). The date proposed would not be feasible and the Committee agreed on two alternative dates.
- The Committee agreed to the request from the applicant for a further 2-month extension to the clock-stop for the application for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004321/FULL/0001).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 **Coliprotec F4/F18** (EMEA/V/C/004225/0000), recommending the granting of a marketing authorisation. The product is a new live vaccine for the active immunisation of pigs against enterotoxigenic F4-positive and F18-positive *E. coli*. The Icelandic and Norwegian CVMP members 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 heard an oral explanation from the applicant concerning an application for a new vaccine for pigs (EMEA/V/C/003993/0000). The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the December 2016 CVMP meeting.

- The Committee discussed the rapporteur's assessment of the responses to the list of outstanding issues, the draft CVMP assessment report and the draft product information for a marketing authorisation application for a new antiparasitic product for cats (EMEA/V/C/004194/0000). The adoption of the opinion is foreseen for the December 2016 CVMP meeting.

2.3 Lists of questions

- There were no items for discussion.

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 **Draxxin** (EMEA/V/C/000077/X/0029) concerning an extension of the marketing authorisation.

- The Committee endorsed the EPAR module 6 scientific discussion for **HALAGON** (EMEA/V/C/004201/0000) concerning the granting of the initial marketing authorisation.

- The Committee endorsed the EPAR module 6 scientific discussion for **Cepedex** (EMEA/V/C/004376/0000) concerning the granting of the initial marketing authorisation.

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, the CVMP assessment report and the product information for a type II variation for **Trifexis** (EMEA/V/C/002635/II/0008), recommending the variation of the marketing authorisation to add a new therapeutic indication associated with *Angiostrongylus vasorum*. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion.

- 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 **Purevax RCPCh FeLV**, **Purevax RCP**, **Purevax RC**, **Purevax RCP FeLV** and **Purevax**

RCPCh (EMEA/V/C/00xxxx/WS1013), recommending the variation of the marketing authorisations to implement quality changes. The Icelandic and Norwegian CVMP members 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 II variation for **Cortavance** and **Easotic** (EMEA/V/C/00xxxx/WS0925), recommending the variation of the marketing authorisations to implement quality changes. The Icelandic and Norwegian CVMP members 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 grouped type II variation for **Metacam** (EMEA/V/C/000033/II/0123/G), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic and Norwegian CVMP members 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 informations for **Versican Plus DHPPi**, **Versican Plus DHPPi/L4** and **Versican Plus DHPPi/L4R** for a worksharing type II variation (EMEA/V/C/00xxxx/WS0936), recommending the variation of the marketing authorisations to implement quality changes. The Icelandic and Norwegian CVMP members 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 type II variation for **COXEVAC** (EMEA/V/C/000155/II/0011), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues to be addressed in writing for a grouped type II variation for **Stronghold** (EMEA/V/C/000050/II/0055/G), concerning quality changes.

3.3 Lists of questions

- There were no items for discussion.

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 rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Denagard 45% and associated names** (EMEA/V/A/114). The Committee agreed to the request by Elanco Animal Health c/o Novartis Animal Health Inc. to provide an oral explanation and adopted the revised timetable for the

procedure. The adoption of the CVMP opinion and assessment report is foreseen for the April 2017 meeting of the Committee.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by majority (24 members in favour out of the 26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** (EMEA/V/A/117), recommending the withdrawal periods for cattle (meat and milk) and pigs to be amended to provide assurance for consumer safety and also that the subcutaneous route should no longer be recommended for cattle and pigs since the depletion kinetics from the injection site remain unknown. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. J. Bureš and M. Azevedo Mendes signed a divergent position not supporting the aforementioned recommendation.
- The Committee discussed the written explanations from aniMedica GmbH for the referral procedure for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118). The adoption of the opinion is foreseen for the December 2016 meeting of the Committee.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle** (EMEA/V/A/119). The Committee adopted the list of outstanding issues for the applicant and marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp.** (EMEA/V/A/121). The Committee adopted the list of outstanding issues for the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted three peer review reports and the comments made by CVMP members.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.7 Other issues

- 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 07.10.2016 – 10.11.2016:

Product	Period
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	05/11/2015 – 04/11/2016
Halocur (EMEA/V/C/000040)	29/10/2015 – 28/10/2016
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2015 – 06/11/2016
Simparica (EMEA/V/C/003991)	06/11/2015 – 05/11/2016
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06/11/2015 – 05/11/2016
Virbagen Omega (EMEA/V/C/000061)	06/11/2015 – 05/11/2016
ZOLVIX (EMEA/V/C/000154)	04/11/2015 – 03/11/2016
Zycortal (EMEA/V/C/003782)	06/11/2015 – 05/11/2016

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the status of the surveillance of **Bravecto** (EMEA/V/C/002526) considering potential serious adverse events in dogs, and adopted a revised timetable for the assessment of the PSUR.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.05.2013 - 30.04.2016 for **Metacam** (EMEA/V/C/000033) and **Novem** (EMEA/V/C/000086) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 13.07.2013 – 12.07.2016 for **Porcilis PCV** (EMEA/V/C/000135) with a recommendation to amend the SPC.
- The Committee adopted the following CVMP assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Bovela (EMEA/V/C/003703)	01.01.2016 – 30.06.2016
Inflacam (EMEA/V/C/002497)	01.07.2015 – 30.06.2016
Poulvac E. coli (EMEA/V/C/002007)	01.01.2016 – 30.06.2016

Prac-tic (EMEA/V/C/000103)	01.07.2015 – 30.06.2016
Sileo (EMEA/V/C/003764)	01.01.2016 – 30.06.2016
Vectra 3D (EMEA/V/C/002555)	01.01.2016 – 30.06.2016
Vectra Felis (EMEA/V/C/002746)	01.01.2016 – 30.06.2016
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	01.12.2015 – 31.05.2016

- 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 final draft VICH GL 54 on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for sign-off by the VICH Steering Committee at step 6 of the VICH process.
- The Committee endorsed the draft VICH GL 56 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for sign-off by the VICH Steering Committee at step 3 of the VICH process.

6.2 Codex Alimentarius

- The Committee deferred the report on the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) meeting held on 17-21 October 2016 in Houston, USA to the December 2016 CVMP meeting.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

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 on the meeting held on 8 November 2016, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the 80th Joint CHMP/CVMP QWP meeting held on 19–21 September 2016, and noted the agenda of the meeting, and the agenda of the joint Meeting of the GMP/GDP Inspectors Working Group and CHMP/CVMP QWP held on 21 September 2016.
- The Committee adopted the draft guideline on the chemistry of active substances (EMA/CVMP/QWP/637000/2016) for a 6-month period of public consultation.
- The Committee adopted a minor update to the guideline on process validation for finished products - information and data to be provided in regulatory submissions.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 22-23 September 2016, and noted the agenda of the meeting.
- The Committee was informed of the upcoming election of the chair of the SWP-V for a 3-year term at the December 2016 CVMP meeting, and noted the call for nominations.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the chair of the ERAWP on the meeting held on 11-12 October 2016, and noted the agenda of the meeting. The chair of the ERAWP also reported on the training of assessors on environmental risk assessment: tier II effects assessment.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the vice-chair of the EWP-V on the meeting held on 13-14 September 2016.
- The Committee was informed of the upcoming election of the chair and the vice-chair of the EWP-V for a 3-year term at the January and February 2017 CVMP meetings.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 19-20 October 2016, and noted the agenda of the meeting.
- The Committee was informed of the upcoming election of the chair of the IWP for a 3-year term at the December 2016 CVMP meeting, and noted the call for nominations.

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 27-28 September 2016, and noted the agenda and the draft minutes of the meeting.
- The Committee was informed of the upcoming election of the chair of the PhVWP-V for a 3-year term at the December 2016 CVMP meeting, and noted the call for nominations and the nomination received for Baukje Schat.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- There were no items for discussion.

7.11 Other working party and scientific group issues

The Committee was informed of the draft work plans of the CVMP working parties, foreseen to be adopted at the December 2016 meeting of the Committee:

- The SAWP-V draft work plan for 2017;
- The QWP draft work plan for 2017;
- The EWP-V draft work plan for 2017;
- The IWP draft work plan for 2017;
- The ADVENT draft work plan for 2017;
- The AWP draft work plan for 2017;
- The SWP-V draft work plan for 2017;
- The JEG 3Rs draft work plan for 2017;
- The ERAWP draft work plan for 2017;
- The PhVWP-V draft work plan for 2017.

The following documents were circulated for information:

- Draft agenda of the SAWP-V meeting to be held on 4 October 2016;
- Invitations to a break out session with the Joint CHMP/CVMP QWP meeting on the draft Ph. Eur. general monograph on co-processed excipients;
- Draft agenda for the 81st Joint CHMP/CVMP QWP meeting to be held on 29 November to 1 December 2016;
- Draft minutes of the EWP-V meeting held on 13-14 September 2016;
- Draft minutes of the AWP meeting held on 22-23 September 2016;
- Final minutes of the IWP meeting held on 29–30 June 2016;
- Draft agenda for the 2016 European Partnership for Alternative Approaches to Animal Testing (EPAA) Annual Conference to be held on 5 December 2016 in Brussels, Belgium.

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

Information relating to certain topics discussed under section 8.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

8.3 Antimicrobial resistance

- The Committee discussed the EMA and EFSA joint scientific opinion on the measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA). The opinion is foreseen to be adopted at the December 2016 CVMP meeting, following the adoption by EFSA on 1 December 2016.
- The Committee received a verbal report on the 6th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report published on 14 October 2016 and including data on the sales of veterinary antimicrobial agents in 29 European countries in 2014.
- The Committee noted the presentation on the updated AMEG advice on the use of colistin products in animals within the European Union, to be given by H. Jukes on behalf of EMA at the European Antibiotic Awareness Day launch event to be held on 18 November 2016 in Brussels.
- The Committee noted the 2nd International Symposium Alternatives to Antibiotics (ATA), Challenges and Solutions in Animal Production, organised by the World Organization for Animal Health (OIE), to be held on 13-15 December 2016 in Paris.

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 document was circulated for information:

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.

- The Committee adopted version 8.1 of the English QRD veterinary product information annotated template (EMA/433504/2016), also foreseen for adoption by the CMDv at their November meeting, after which time it would be translated and published (early in 2017) on the EMA's website along with the implementation plan for this new version.
- The Committee adopted the QRD veterinary pictogram guidance (approved 'catalogue' of pictograms) (EMA/QRD/448184/2016) for a 3-month period of public consultation.

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 on 14-15 July, 8-9 September and 6-7 October 2016, and noted the final minutes of the September and the draft minutes of the October meetings, as well as the draft agenda of the meeting held on 10-11 November 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft public CVMP work plan for 2017, which is foreseen to be adopted at the December 2016 CVMP meeting.
- The Committee discussed the HMA/EMA Task Force on timetables: draft best practice guide on measures improving predictability of submissions and adherence to communicated submission deadlines.
- The Committee was informed of the EMA's intention to extend the Common Repository to all veterinary submissions in the centralised procedure, and noted the draft statement of intent.
- The Committee was informed of the guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company (EMA/267183/2016).
- The Committee received an update on multi-national assessment teams for post-authorisation procedures.
- The Committee was informed of the revision of dossier submission requirements for marketing authorisation and MRL applications to EMA and to CVMP members.
- The Committee was informed of the EMA Veterinary Medicines Info Day to be held on 16-17 March 2017, and noted the first announcement with the outline of the programme.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the November 2016 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.
- The Committee noted the planned date of the CVMP Christmas party (7 December 2016).

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the November 2016 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	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 5.5 PSURs for Bovela, Metacam, Novem
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	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	
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	P. Hekman	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stanko Srčič	Cannot act as rapporteur or peer reviewer for:	• 3.1 Easotic (EMEA/V/C/xxxxxx/WS0925) • 4.3 Gentamicin (EMEA/V/A/118)
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	
IS	Jóhann Lenharðsson	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	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Maria Azevedo Mendes	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.			
DE	Sabine Klee	Full involvement	
UK	Sam Fletcher	Full involvement	
UK	Steve Spencer - *remotely*	Full involvement	
DK	Christian Friis - *remotely*	Full involvement	
PL	Anna Wachnik-Swiecicka - *remotely*	Full involvement	
IE	Mary O'Grady – *remotely*	Full involvement	
ES	Luis Agote Casado – *remotely*	Full involvement	
ES	María Concepción Porrero – *remotely*	Full involvement	
UK	Ken Stapleton – *remotely*	Full involvement	
UK	Rutendo Manyarara – *remotely*	Full involvement	
UK	Jean-Paul Schmidt – *remotely*	Full involvement	
FI	Martti Nevalainen – *remotely*	Full involvement	
NL	Willie Peijnenburg – *remotely*	Full involvement	
DE	Nikola Lange - *remotely*	Full involvement	
DE	Stefan Scheid - *remotely*	Full involvement	
FI	Kristina Lehmann -	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
	remotely		
FR	Elisabeth Begon - *remotely*	Full involvement	
FR	Damien Bouchard - *remotely*	Full involvement	
DK	Maria Krog Pedersen - *remotely*	Full involvement	
DE	Anke Finnah - *remotely*	Full involvement	
BE	Sandy Vermout - *remotely*	Full involvement	
FI	Katarina Kivilahti-Mantyla - *remotely*	Full involvement	
UK	Sharon Reynolds - *remotely*	Full involvement	
PL	Marcin Glanda	Full involvement	
SE	Fredrik Hultén- *remotely*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Jason Weeks
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	Mary O'Grady *(Vet vice chair - remotely)*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

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