19 January 2016
EMA/CVMP/48390/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 December 2015 meeting

Chair: A. Holm – Vice-chair: D. Murphy

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 December 2015 meeting. In accordance with the Agency's revised 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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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the November 2015 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

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in all food producing species for **copper carbonate** (EMEA/V/MRL/004268/FULL/0001). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted two peer review reports and the summary of opinion for publication.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in ovine and caprine species for **eprinomectin** (EU/10/173/MER), further to the establishment of provisional MRLs. The Committee also agreed to extrapolate these MRLs to all ruminants. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU Reference Laboratory, a peer review report, the comments received from CVMP members and the summary of opinion for publication.

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 by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zactran** (EMEA/V/C/000129/X/0027), recommending the extension of the marketing authorisation to add a new food producing species (pigs). The Icelandic and Norwegian CVMP members agreed

with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by majority (20 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for **Bravecto** (EMEA/V/C/002526/X/0005), recommending the refusal of the extension of the marketing authorisation to add a new pharmaceutical form (spot-on solution) for dogs and a new target species (cats) for this spot-on formulation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. E. Augustynowicz, K. Baptiste, R. Breathnach, C. Ibrahim, H. Jukes, E. Lander Persson, C. Munoz, and D. Murphy signed a divergent position not supporting the aforementioned recommendation. 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 and benefit-risk assessment including the list of outstanding issues for an extension application for **DRAXXIN** (EMEA/V/C/000077/X/0029), to include a new target species to add to the solution for injection form. The Committee discussed the draft product information and noted a peer review report.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for an extension application for **Poulvac E. coli** (EMEA/V/C/002007/X/0008), to include a new target species. The Committee discussed the draft product information, and noted a peer review report and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new vaccine in dogs (EMEA/V/C/003685/0000). The Committee discussed the draft product information, and noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new immunological product for chickens (EMEA/V/C/004013/0000). The Committee discussed the draft product information, and noted two peer review reports and the comments received from CVMP members.

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 **Simparica** (EMEA/V/C/003991/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Inflacam** (EMEA/V/C/002497/X/0009) concerning an extension of the marketing authorisation.
- The Committee agreed to the request from the applicant for a 3-month extension to the clock-stop for a new antiparasitic product for bees (EMEA/V/C/002723/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a quality type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0003), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped worksharing type II variation for **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R**, **Versican Plus Pi/L4R**, **Versican Plus DHPPi**, **Versican Plus Pi** and **Versican Plus Pi/L4** (EMEA/V/C/xxxxxx/WS/0754/G), recommending the variation of the marketing authorisations. The Icelandic 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 **Aivlosin** (EMEA/V/C/000083/II/0064), to change the withdrawal period for eggs.
- The Committee adopted the list of questions for a type II variation for **Profender** (EMEA/V/C/000097/II/0032), to add therapeutic indications for Profender spot-on solution for cats.
- The Committee adopted the list of questions for a quality type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0005).
- The Committee adopted the list of questions for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0006), to change the vaccination schedule
- The Committee adopted the list of questions for a grouped type II variation for **BTVPUR AlSap 1-8** (EMEA/V/C/002231/II/0007/G).
- The Committee adopted the list of questions for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0007), to update the section 4.6 "Adverse reactions" of the SPC.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to the request from the MAH for an extension to the clock-stop for a type II variation for **Trifexis** (EMEA/V/C/002635/II/0008), to add a new indication.

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 agreed to the request from Elanco Animal Health for a 3-month extension to the clock-stop for the referral procedure for **Denagard 45% and associated names** (EMEA/V/A/114), and adopted the revised timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally** (EMEA/V/A/111). The Committee adopted a list of outstanding issues for the applicants/marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted the peer review reports and the comments made by CVMP members.
- The Committee agreed to the request from Zoetis Belgium SA for a 2-month extension to the clock-stop for the referral procedure for **all veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses** (EMEA/V/A/116), and adopted a revised timetable for the procedure.

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

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Purevax Rabies** (EMEA/V/C/002003/REC/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 11.11.2015 – 10.12.2015:

Product	Period
Acticam (EMEA/V/C/000138)	09/12/2014 – 08/12/2015

Product	Period
Broadline (EMEA/V/C/002700)	04/12/2014 – 03/12/2015
Contacera (EMEA/V/C/002612)	06/12/2014 – 05/12/2015
DRAXXIN (EMEA/V/C/000077)	11/11/2014 – 10/11/2015
Easotic (EMEA/V/C/000140)	20/11/2014 – 19/11/2015
Equip WNV (EMEA/V/C/000137)	21/11/2014 – 20/11/2015
Inflacam (EMEA/V/C/002497)	09/12/2014 – 08/12/2015
Masivet (EMEA/V/C/000128)	17/11/2014 – 16/11/2015
Meloxivet (EMEA/V/C/000124)	14/11/2014 – 13/11/2015
Meloxoral (EMEA/V/C/000151)	19/11/2014 – 18/11/2015
Oxyglobin (EMEA/V/C/000045)	29/11/2014 – 28/11/2015
Panacur AquaSol (EMEA/V/C/002008)	09/12/2014 – 08/12/2015
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2014 – 15/11/2015
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2014 – 06/11/2015
Quadrisol (EMEA/V/C/000032)	04/12/2014 – 03/12/2015
Stronghold (EMEA/V/C/000050)	25/11/2014 – 24/11/2015
Vectra 3D (EMEA/V/C/002555)	04/12/2014 – 03/12/2015

5.4 Renewals

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **BLUEVAC BTV8** (EMEA/V/C/000156/R/0006), and agreed that the authorisation should now be indefinite. The authorisation was originally granted under exceptional circumstances and since the specific obligations for BLUEVAC BTV8 are now fulfilled, the Committee also recommended the conversion to a standard marketing authorisation for this product. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the list of outstanding issues for the renewal of **Zuprevo** (EMEA/V/C/002009/R/0010).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the targeted PSUR for the period 01.05.2004 – 30.06.2015 for **Advocate** (EMEA/V/C/000076) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2015 – 30.06.2015 for **Vectra 3D** (EMEA/V/C/002555) with a recommendation to amend the SPC.

- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage:

Product	Period
Cimalgex (EMEA/V/C/000162)	01.09.2014 – 31.08.2015
ECOPORC SHIGA (EMEA/V/C/002588)	01.02.2015 – 31.07.2015
NEXGARD SPECTRA (EMEA/V/C/003842)	15.01.2015 – 31.07.2015
ProZinc (EMEA/V/C/002634)	01.02.2015 – 31.07.2015
Reconcile (EMEA/V/C/000133)	01.08.2014 – 31.07.2015
Rheumocam (EMEA/V/C/000121)	01.08.2014 – 31.07.2015
Suvaxyn PCV (EMEA/V/C/000149)	01.02.2015 – 31.07.2015
Versican Plus L4 (EMEA/V/C/003680)	01.02.2015 – 31.07.2015

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

5.6 Supervisions and sanctions

Information relating to supervisions 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 VICH guideline 50 on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use, for sign-off by the VICH Steering Committee at step 3 of the VICH process.
- The Committee nominated N. Bridoux as the EU expert for the VICH EWG on anthelmintics.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee discussed the EFSA mandate on the risk for the development of AMR from raw milk due to feeding of calves with milk containing residues of antibiotics – *see also 8.3*.
- The Committee was informed of the draft EFSA scientific opinion on *Echinococcus multilocularis* infections in animals.

The following documents were circulated for information:

- Mission report from VICH Steering Committee meeting on 23-30 October 2015;
- Status of active VICH guidelines;

- Externally organized projects and events of potential relevance to the safety assessment and assessment methodologies in general.

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 8 December 2015, and noted the agenda of the meeting.
- The Committee appointed S. Louet as an additional member of the SAWP-V.

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 1–3 December 2015, and noted the agenda of the meeting.
- The Committee adopted the revised mandate, objectives and rules of procedure for the joint CHMP/CVMP QWP.
- The Committee adopted the question and answer document on the use of powders and granules in medicinal products composed of 100% active substance.

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 3-4 December 2015, and noted the agenda of the meeting.
- The Committee noted the draft revised guideline on the approach towards harmonisation of withdrawal periods and agreed that the document will be further discussed at SWP-V.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee endorsed the draft programme for the aquaculture workshop on the environmental risk assessments of veterinary medicines for use in aquaculture planned for 2016, which will involve ERAWP and CVMP members, and identified specialists from national authorities and academia.
- The Committee received feedback on the topical scientific workshop on soil risk assessment organised by ECHA/EFSA, on 7-8 October 2015 in Helsinki, Finland. The workshop was attended by regulators and scientists that discussed challenges and possibilities to improve soil risk assessments, mainly for substances used as biocides, pesticides and industrial chemicals, and of relevance to VMPs given the similarities on the soil risk assessment with pesticides.
- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP ERAWP (EMA/CVMP/ERAWP/705470/2009-Rev.3).

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 1-2 December 2015, and noted the agenda of the meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 2-3 December 2015, and noted the agenda of the meeting.
- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP AWP (EMA/CVMP/AWP/749774/2012-rev.2).
- The Committee re-elected H. Jukes as chair of the AWP for a further 3-year mandate.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP IWP (EMA/CVMP/IWP/208689/2004).
- The Committee adopted the concept paper on guidance on statistical principles for clinical trials for veterinary immunological medicinal products (EMA/CVMP/IWP/309514/2015) for a 3-month period of public consultation.

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 24-25 November 2015, and noted the agenda and the draft minutes of the meeting.
- The Committee adopted the revised questions and answers document on adverse event reporting (EMA/CVMP/PhVWP/145186/2013-Rev.1).
- The Committee elected B. Schat as vice-chair of the PhVWP-V for a further 3-year mandate.

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 upcoming election of a new chair for the Joint CHMP/CVMP/CMDh/CMDv ASMF working group and noted the call for nominations that had been circulated by the CMDh secretariat.

The following documents were circulated for information:

- Final minutes of the SAWP-V meeting held on 4 November 2015;
- Final minutes of the QWP meeting held on 30 September – 2 October 2015;
- Final minutes of the EWP-V meeting held on 15-16 September 2015;
- Draft agenda of the ADVENT meeting to be held on 10 December 2015.

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 **N-(2-deoxy-2-L-leucylamino-β-D-glucopyranosyl)-N-octadecyl-dodecanoylamide hydroacetate** 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. The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.32).

8.2 Environmental risk assessment

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

8.3 Antimicrobial resistance

- The Committee discussed the EFSA mandate on the risk for the development of AMR from raw milk due to feeding of calves with milk containing residues of antibiotics– *see also 6.3*.
- The Committee received a verbal report and discussed the recently published data on the emergence of plasmid-mediated colistin resistance mechanism MCR-1 in animals and human beings in China, including a microbiological and molecular biology study and an article from the Lancet, 'Colistin resistance: a major breach in our last line of defence'. The Committee agreed on the need to update the 2013 advice on the substance and requested to re-convene the Antimicrobial Advice Ad Hoc Expert Group (AMEG), who prepared the 2013 advice.
- The Committee received a report on the EC workshop on the impact on public health and animal health of the use of antibiotics in animals, and noted the agenda of the workshop.

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.

- The Committee deferred the verbal update on the first meeting of the ad hoc expert group on RD114 held on 2-3 December 2015 and noted the agenda of the meeting.

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 the question and answer document on solvents in the centralised procedure (EMA/CVMP/550607/2015) for a 3-month period of public consultation.

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

- The Committee noted the draft minutes of the meeting held on 5-6 November 2015 as well as the draft agenda of the meeting held on 10-11 December 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the guideline on the principles for preparing assessment reports for veterinary medicinal products (EMA/CVMP/450781/2015) for publication and the template guidance for scientific overview and list of questions for pharmaceutical veterinary medicinal products (EMA/441473/2015) to be implemented in procedures as soon as possible. Immediate feedback would be encouraged from assessors and feedback would also be collected following some time in use. In addition, the Committee agreed for a training plan to be prepared, aiming at training sessions focussing on different parts of the application. Concerning the existing CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products, the Committee considered that this document is valid also following the work now completed on the above guideline, however agreed still to analyse such impact and to evaluate the actual need for revision. As a next step, a template guidance for scientific overview and list of questions for immunological veterinary medicinal products would need to be developed.
- The Committee adopted the minutes of the CVMP Presidency meeting and the minutes of the joint CVMP/CMDv Presidency meeting, held on 21-22 September 2015 in Luxembourg.
- The Committee adopted the CVMP planning tool for on-going and future activities.
- The Committee re-elected Keith Baptiste as a co-opted member for a further 3-year mandate to complement its expertise in antimicrobials and antimicrobial resistance. The Committee elected Jason Weeks as a co-opted member for a 3-year mandate to complement its expertise in environmental risk assessment.
- The Committee discussed the draft public CVMP work plan for 2016.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 9 December 2015, and noted the agenda of the December 2015 meeting and the minutes of the meeting held on 8 October 2015.

- The Committee was informed of the draft programme of the EMA/IFAH-Europe Info Day to be held on 17-18 March 2016.
- The Committee noted the table of actions following the November 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the December 2015 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 December 2015 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 5.5 ProZinc PSUR
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	Christian Friis	Full involvement	
Co-opted	Boris Kolar	Full involvement	
Co-opted	Wilhelm Schlumbohm	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
ES	Consuelo Rubio Montejano	Cannot act as rapporteur or peer reviewer for:	• 2.1 Bravecto (EMEA/V/C/002526/X/0005) • 3.1 Porcilis PCV M Hyo (EMEA/V/C/003796/II/0003) • 3.3 Bravecto (EMEA/V/C/002526/II/0007) • 4.3 Colistin (EMEA/V/A/111) • 5.4 Zuprevo (EMEA/V/C/002009/R/0010) • 10.1 one item
FR	Sylvie Louet	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 3.3 Profender (EMEA/V/C/000097/II/0032) • 5.5 Advocate PSUR
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	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.			
ES	Marta Martín Juárez	Full involvement	
ES	Javier Martínez de Velasco	Full involvement	
NL	Jacqueline Poot	Full involvement	
UK	Sharon Reynolds *(remotely)*	Full involvement	
UK	John Mitchell *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	--
ERAWP	--
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	Piet-Hein Overhaus *(Vet vice chair)*
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