8 December 2015
EMA/CVMP/829802/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 4-6 November 2015 meeting

The meeting was chaired by D. Murphy (CVMP vice-chair)

Note on access to documents

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

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of two new items under points 6.3 and 12.

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

The attendance list was completed and interests were identified for the November 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the October 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 noted the letter from the applicant (EXT/732921/2015) requesting the withdrawal of their application for a substance (EMEA/V/MRL/004047/FULL/0001) regarding the establishment of MRLs in caprine species, *Equidae*, fin fish and rabbits.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion including the EPMAR, recommending a 2-year extension to the provisional MRL status for **rafoxanide** (EU/ART27/11/192/IMB) in bovine and ovine milk in order to allow for the completion of the ongoing work for the validation of the analytical method for monitoring of residues in milk. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee discussed the rapporteur's assessment report including the critique from the co-rapporteur, the draft EPMAR and two peer review reports for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004268/FULL/0001), and agreed that a list of questions was not necessary. The adoption of the opinion is foreseen for the December 2015 meeting of the Committee.

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 and benefit-risk assessment including the list of outstanding issues for an extension application for **Zactran** (EMEA/V/C/000129/X/0027), to add a new food producing species. The Committee agreed that

an oral explanation would not be requested. The Committee discussed the draft product information and noted a peer review report and the comments received from CVMP members.

- The Committee heard an oral explanation from Intervet International B.V. concerning an extension application for **Bravecto** (EMEA/V/C/002526/X/0005), to add a new pharmaceutical form for dogs and to add a new target species. The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. An opinion is foreseen for the December 2015 CVMP meeting.

2.3 Lists of questions

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new anaesthetic product for dogs (EMEA/V/C/004199/0000). The Committee noted a peer review report 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 **Zycortal** (EMEA/V/C/003782/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Suvaxyn Circo MH+RTU** (EMEA/V/C/003924/0000) 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 and the CVMP assessment report for a quality type II variation for **Vectormune ND** (EMEA/V/C/003829/II/0001), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members 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 quality grouped type II variation for **Metacam** (EMEA/V/C/000033/II/0118/G).
- The Committee adopted the list of questions for a type II variation for **Trifexis** (EMEA/V/C/002635/II/0008), to add a new indication.
- The Committee adopted the list of questions for a worksharing type II variation for **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R** (EMEA/V/C/xxxxxx/WS/0785), concerning changes in the SPC, labelling and package leaflet.

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

- The Committee adopted by majority (28 members in favour out of the 29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys** (EMEA/V/A/112), concluding that the objections raised by Denmark during the decentralised procedure should not prevent the granting of a marketing authorisation, subject to changes in the product information concerning additional information on solubility and advice on prudent use. E-M. Vestergaard signed a divergent position not supporting the aforementioned recommendation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP, whereas the Norwegian CVMP member signed the divergent position.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report with the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** (EMEA/V/A/095). The Committee adopted the list of outstanding issues for the applicants/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 with the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** (EMEA/V/A/110). 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 four peer review reports and the comments made by CVMP members.
- The Committee considered the notification from Germany for a referral procedure for **all veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** regarding concerns that moxidectin may have persistent, bioaccumulative and toxic properties and, consequently, a potential serious risk to the environment may arise from the use of products containing the substance. The Committee agreed to start a referral procedure (EMEA/V/A/116) under Article 35 and appointed C. Ibrahim as rapporteur and C. Muñoz Madero as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable for the procedure, and noted the list of products concerned. The adoption of the opinion is foreseen for the May 2016 meeting of the Committee.

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 document was circulated for information:

- Gutal 1000 g/kg premix for medicated feeding stuff for piglets - Article 33(4) referral (EMEA/V/A/108) – Questions and answers for publication (EMA/709250/2015).

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 09.10.2015 – 06.11.2015:

Product	Period
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	05/11/2014 – 04/11/2015
Halocur (EMEA/V/C/000040)	29/10/2014 – 28/10/2015
Virbagen Omega (EMEA/V/C/000061)	06/11/2014 – 05/11/2015
ZOLVIX (EMEA/V/C/000154)	04/11/2014 – 04/11/2015

5.4 Renewals

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Procox** (EMEA/V/C/002006/R/0012), and agreed that the authorisation should now be indefinite. 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 information for the renewal of **ZULVAC 1+8 Ovis** (EMEA/V/C/002251/R/0014), and agreed that the authorisation should now be indefinite. 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 information for the renewal of **Melosus** (EMEA/V/C/002001/R/0006), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Activyl** (EMEA/V/C/000163/R/0008), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **CaniLeish** (EMEA/V/C/002232/R/0004), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Cimalgex** (EMEA/V/C/000162/R/0002), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Comfortis** (EMEA/V/C/002233/R/0015), and agreed that the authorisation should now be indefinite. 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 information for the renewal of **Veraflox** (EMEA/V/C/000159/R/0006), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the recommendation from PhVWP-V to the MAH following the surveillance analysis findings for **SevoFlo** (EMEA/V/C/000072).
- The Committee endorsed the rapporteur's assessment report of the PSUR for the period 02.04.2013 – 30.06.2015 for **Advocate** (EMEA/V/C/000076) requesting further clarification from the MAH.
- The Committee adopted the draft CVMP assessment report of the PSUR for the period 01.01.2015 – 30.06.2015 for **Vectra 3D** (EMEA/V/C/002555) requesting further clarification from the MAH.

- 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 for:

Product	Period
Acticam (EMEA/V/C/000138)	01.07.2014 – 30.06.2015
Broadline (EMEA/V/C/002700)	01.01.2015 – 30.06.2015
Cerenia (EMEA/V/C/000106)	01.01.2015 – 30.06.2015
Certifect (EMEA/V/C/002002)	01.06.2014 – 31.05.2015
ERYSENG (EMEA/V/C/002761)	01.02.2015 – 31.07.2015
ERYSENG PARVO (EMEA/V/C/002762)	01.02.2015 – 31.07.2015
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	01.08.2014 – 31.07.2015
Inflacam (EMEA/V/C/002497)	01.07.2014 – 30.06.2015
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	01.08.2012 – 31.07.2015
Prac-tic (EMEA/V/C/000103)	01.07.2014 – 30.06.2015
RevitaCAM (EMEA/V/C/002379)	01.03.2015 – 31.08.2015
Trifexis (EMEA/V/C/002635)	05.01.2015 – 04.07.2015
Versican Plus DHPPi (EMEA/V/C/003679)	01.02.2015 – 31.07.2015
Versican Plus Pi (EMEA/V/C/003681)	01.02.2015 – 31.07.2015
Versican Plus Pi/L4 (EMEA/V/C/003683)	01.02.2015 – 31.07.2015
Versican Plus Pi/L4R (EMEA/V/C/003682)	01.02.2015 – 31.07.2015
ZULVAC 8 Bovis (EMEA/V/C/000145)	01.02.2015 – 31.07.2015
ZULVAC 8 Ovis (EMEA/V/C/000147)	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 received a verbal report on the Biologicals Quality Monitoring Expert Working Group meeting held on 25-27 October 2015 in Tokyo, Japan and on the 32nd VICH Steering Committee meeting, the 6th VICH Outreach Forum meeting and the 6th VICH Conference, held on 25-30 October 2015 in Tokyo, Japan.

6.2 Codex Alimentarius

Information relating to certain topics discussed under section 6.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

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.
- The Committee received feedback from the EFSA's 2nd scientific conference 'Shaping the future of food safety, together', held on 14-16 October 2015 in Milan, Italy.

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 vice-chair of the SAWP-V on the meeting held on 4 November 2015, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee endorsed the QWP response to the EDQM request for an opinion on new information on alkyl sulfonates. The QWP reviewed the article from Snodin *et al*. QWP acknowledges the scientific rationale in this article and that the formation of alkyl sulfonates is very low and very much depends on the reaction conditions. This makes the presence of these mutagenic impurities at toxicologically significant levels unlikely. However, as the presence and formation of these alkyl sulfonates cannot be totally excluded, QWP proposes the following approach: marketing authorisation holders should justify via Risk Assessment that alkyl sulfonates are not expected to be present for their product, which may be sufficient.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP secretariat on the meeting held on 13-14 October 2015, and noted the agenda of the meeting.

7.5 Efficacy Working Party (EWP)

- The Committee adopted the revised EWP mandate, objectives and rules of procedure (EMA/CVMP/208686/2004-Rev.3).

7.6 Antimicrobials Working Party (AWP)

- The Committee was informed of the upcoming election of the chair of the AWP for a 3-year term at the December 2015 CVMP meeting. A call for nominations would be circulated by the Secretariat.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 20–21 October 2015, and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the concept paper for the revision of the recommendation for the basic surveillance of EudraVigilance Veterinary data (EMA/CVMP/PhVWP/590073/2015) for a 3-month period of public consultation.
- The Committee was informed of the upcoming election of the vice-chair of the PhVWP-V for a 3-year term at the December 2015 CVMP meeting. A call for nominations would be circulated by the Secretariat.

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)

- The Committee received a verbal report from the chair of the JEG-3Rs on the meeting held on 15-16 October 2015, and noted the agenda of the meeting.

7.11 Other working party and scientific group issues

- The Committee adopted the work plans for 2016 for the CVMP working parties: SAWP-V (EMA/CVMP/SAWP/618140/2015), SWP-V (EMA/CVMP/SWP/596760/2015), ERAWP (EMA/CVMP/ERA/477367/2015), EWP-V (EMA/CVMP/EWP/495860/2015), IWP (EMA/CVMP/IWP/431540/2015), AWP (EMA/CVMP/AWP/457853/2015) and PhVWP-V (EMA/CVMP/PhVWP/371239/2015) as well as for ADVENT (EMA/CVMP/ADVENT/429214/2015) and the Joint CHMP/CVMP QWP (EMA/CHMP/CVMP/QWP/479335/2015).

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 6 October 2015;
- Final minutes of the IWP meeting held on 17-18 June 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 **didodecyl 3,3'-sulfanediyldipropanoate**, **dolomite (calcium magnesium carbonate)**, **erucamide**, **pentaerythrityl tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]**, **poly(ethylene-vinyl acetate)**, **polypropylene**, and **styrene-butadiene block copolymer** as a new entries 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 also agreed to include **di-n-butyl-adipate** as a new entry in the list under the heading of excipients, following a scientific advice procedure. 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.31).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted the CVMP Strategy on Antimicrobials 2016-2020 (EMA/CVMP/209189/2015) for a 3-month period of public consultation.
- The Committee received a verbal report on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety) virtual meeting held on 29 October 2015.
- The Committee received a verbal report on the forthcoming EC workshop on "The impact on public health and animal health of the use of antibiotics in animals – Analysis of the EMA scientific advice", to be held on 26 November 2015 in Brussels, Belgium, and noted the draft agenda.

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:

- Uppsala Health Summit 2015: A world without antibiotics (Post-conference report).

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.

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 10-11 September 2015 and on 8-9 October 2015, and noted the draft minutes of the meeting held on 8-9 October 2015 as well as the draft agenda of the meeting held on 5-6 November 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee noted the draft guideline on the principles for preparing assessment reports for veterinary medicinal products and the template guidance for the scientific overview and list of questions, and the intended actions for finalisation of the documents aiming to be adopted at the December 2015 meeting of the Committee.
- 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 October 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the November 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 November 2015 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
Vice-chair	**David Murphy**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 3.3 Metacam (EMEA/V/C/000033/II/0118/G)
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	
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	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Pedro Duarte da Silva	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	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
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio	Cannot act as rapporteur	• 2.2 Bravecto

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
	Montejano	or peer reviewer for:	(EMEA/V/C/002526/X/0005) • 4.3 Altrenogest (EMEA/V/A/095) • 5.4 Activyl (EMEA/V/C/000163/R/0008) • 5.5 PSUR for Porcilis Porcoli Diluvac Forte
FR	Sylvie Louet	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
NL	Peter Hekman	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Sandy Vermout *(remotely)*	Full involvement	
DE	Sabine Kalweit *(remotely)*	Full involvement	
DE	Gerd Maack	Full involvement	
ES	Ricardo Carapeto Garcia *(remotely)*	Full involvement	
NL	Johan Schefferlie *(remotely)*	Full involvement	
NL	Sandra ten Voorde *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	--
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström
QWP	--
SAWP-V	--
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

European Medicines Agency support

Meeting run with relevant support from the EMA staff