4 October 2016
EMA/CVMP/657341/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 6-8 September 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 the addition of a new item, under point 9.

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

The attendance list was completed and interests were identified for the September 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 July 2016 meeting and the August 2016 meeting by written procedure 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 chickens for a substance (EMEA/V/MRL/004380/FULL/0001), as well as the comments from the EU Reference Laboratory concerning the analytical method and agreed that there were no outstanding issues left. The adoption of the opinion is foreseen for the October 2016 meeting of the Committee.

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 vaccine for pigs (EMEA/V/C/004225/0000). The Committee agreed that an oral explanation would not be requested. The Committee noted two peer review reports and the comments received from CVMP members.
- 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 antiparasitic product for cats (EMEA/V/C/004194/0000). The Committee agreed that an oral explanation would not be requested. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee heard an oral explanation from the applicant concerning an application for a new antiparasitic product for honey bees (EMEA/V/C/002723/0000). 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 October 2016 CVMP meeting.

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 an antiemetic product intended for cats and dogs (EMEA/V/C/004331/0000). The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee adopted by majority (25 members in favour out of the 26 members present of those eligible to vote) the final CVMP opinion, the final CVMP assessment report and the final product information for **Draxxin** (EMEA/V/C/000077/X/0029), recommending the extension of the marketing authorisation to add a new target species (sheep) to the 100 mg/ml solution for injection. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. K. Baptiste signed a divergent position not supporting the aforementioned recommendation. The Committee reached the above decision following an oral explanation from the applicant, Zoetis Belgium SA, and taking into account advice from the ad hoc expert group meeting held on 1 September 2016. The Committee also noted the summary of opinion for publication.

2.5 Other issues

- The Committee agreed the terms 'powder and solution for bee-hive solution' and 'bee-hive dispersion' to be used for pharmaceutical forms of products used for honey bees.
- The Committee endorsed the EPAR module 6 scientific discussion for **Metacam** (EMEA/V/C/000033/X/0119) concerning the extension of the marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Sedadex** (EMEA/V/C/004202/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **ERAVAC** (EMEA/V/C/004239/0000) concerning the granting of the initial marketing authorisation.

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 type II variation for **Draxxin** (EMEA/V/C/000077/II/0035), recommending the variation of the marketing authorisation to implement changes to the SPC. 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 a grouped worksharing type IB variation for **Inflacam** and **Rheumocam** (EMEA/V/C/xxxxxx/WS/0933/G), recommending the variation of the marketing authorisations to implement quality changes. The Icelandic CVMP member 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 informations for a worksharing type IB variation for **Versican Plus DHPPi** and **Versican Plus Pi** (EMEA/V/C/xxxxxx/WS/0958), recommending the variation of the marketing authorisations to implement changes to the SPC and package leaflet. The Icelandic CVMP member 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 informations for a worksharing type IB variation for **Versican Plus DHPPi/L4**, **Versican Plus L4** and **Versican Plus Pi/L4** (EMEA/V/C/xxxxxx/WS/0959), recommending the variation of the marketing authorisations to implement changes to the SPC and package leaflet. The Icelandic CVMP member 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 and the CVMP assessment report for a grouped type II variation for **Bovela** (EMEA/V/C/003703/II/0005/G), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic CVMP member 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 worksharing type II variation for **CORTAVANCE** and **Easotic** (EMEA/V/C/xxxxxx/WS/0925) concerning quality changes.

3.3 Lists of questions

- The Committee adopted the list of questions for a worksharing type II variation for **Versican Plus DHPPi/L4**, **Versican Plus DHPPi** and **Versican Plus DHPPi/L4R** (EMEA/V/C/xxxxxx/WS/0936), concerning changes to the product information.

- The Committee adopted the list of questions for a type II variation for **Broadline** (EMEA/V/C/002700/II/0011), concerning quality changes.

- The Committee adopted the list of questions for a grouped type II variation for **Aivlosin** (EMEA/V/C/000083/II/0067/G), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee considered the notification from France for a referral procedure for **Zanil and associated names, and generic products thereof**, regarding concerns related to the withdrawal periods set for these products. The Committee agreed to start a referral procedure (EMEA/V/A/124) under Article 35 and appointed S. Louet as rapporteur and W. Schlumbohm 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.

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:

- Background summary on **Velactis** (EMA/566363/2016), notification of Commission Decision.

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 **OSURNIA** (EMEA/V/C/003752/REC/010).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning three recommendations for **Simparica** (EMEA/V/C/003991/REC/008-010).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning ten recommendations for **ZOLVIX** (EMEA/V/C/000154/REC/001-010).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 08.07.2016 – 08.09.2016:

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2015 – 14/07/2016
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2015 – 05/09/2016
Cardalis (EMEA/V/C/002524)	23/07/2015 – 22/07/2016
Dexdomitor (EMEA/V/C/000070)	30/08/2015 – 29/08/2016

Product	Period
Emdocam (EMEA/V/C/002283)	18/08/2015 – 17/08/2016
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2015 – 07/09/2016
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2015 – 03/09/2016
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2015 – 31/08/2016
Nobivac L4 (EMEA/V/C/002010)	16/07/2015 – 15/07/2016
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2015 – 06/09/2016
Novaquin (EMEA/V/C/003866)	08/09/2015 – 07/09/2016
OSURNIA (EMEA/V/C/003753)	31/07/2015 – 30/07/2016
Porcilis PCV ID (EMEA/V/C/003942)	28/08/2015 – 27/08/2016
Profender (EMEA/V/C/000097)	27/07/2015 – 26/07/2016
Proteq West Nile (EMEA/V/C/002005)	05/08/2015 – 04/08/2016
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2015 – 06/08/2016
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2015 – 23/07/2016
UpCard (EMEA/V/C/003836)	31/07/2015 – 30/07/2016
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2015 – 08/08/2016
Vectormune ND (EMEA/V/C/003829)	08/09/2015 – 07/09/2016
Versican Plus L4 (EMEA/V/C/003680)	31/07/2015 – 30/07/2016
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2015 – 30/07/2016
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2015 – 30/07/2016
ZACTRAN (EMEA/V/C/000129)	24/07/2015 – 23/07/2016
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2015 – 04/08/2016
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2015 – 04/08/2016

5.4 Renewals

- 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 the marketing authorisation for **Inflacam** (EMEA/V/C/002497/R/0011), and recommended that the authorisation should now be indefinite. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Activyl Tick Plus** (EMEA/V/C/002234/R/0009).

5.5 Pharmacovigilance – PSURs and SARs

- 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
Bravecto (EMEA/V/C/002526)	01.09.2015 – 29.02.2016
HALOCUR (EMEA/V/C/000040)	30.04.2013 – 29.04.2016
Meloxidolor (EMEA/V/C/002590)	23.10.2015 – 22.04.2016
Parvoduk (EMEA/V/C/002740)	01.11.2015 – 30.04.2016
Recuvyra (EMEA/V/C/002239)	01.05.2015 – 30.04.2016
Velactis (EMEA/V/C/003739)	09.12.2015 – 30.06.2016

- 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 endorsed the revised draft VICH GL54 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 EWG at step 5 of the VICH process.
- The Committee received a verbal report on the 33rd VICH Steering Committee meeting and the 7th Outreach Forum meeting held on 20-23 June 2016, in Brussels.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Provisional agenda for the Codex Committee on Residues of Veterinary Drugs in Food meeting to be held in Houston, US, on 16-23 October 2016.

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 6 September 2016, and noted the agenda of the meeting.
- The Committee was informed of the upcoming election of the vice-chair of the Scientific Advice Working Party (SAWP-V) for a 3-year term at the October 2016 CVMP meeting.

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee agreed that the ERAWP vice-chair, S. Hickmann, would represent CVMP and give a presentation on environmental risk assessment of VMPs at the International Fresenius Conference on Environmental Risk Assessment of Biocides in March 2017, Germany.
- The Committee was informed of the draft programme for the October 2016 training of assessors on environmental risk assessment: tier II effects assessment. The deadline for registration has been extended to 23 September 2016.
- The Committee was informed of the upcoming appointment of two new members for the ERAWP at the October 2016 CVMP meeting, and noted the call for nominations.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the vice-chair of the EWP-V on the stakeholder focus group meeting on anthelmintic resistance held on 13 June 2016, in relation to the consultation on the draft CVMP reflection paper on anthelmintics resistance.
- The Committee discussed the overview of comments received following the close of the public consultation on the revised reflection paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013-Rev.1-post-consultation) and agreed for the EWP-V to continue the revision of the paper.
- The Committee adopted the draft minutes on the stakeholder focus group meeting on anthelmintic resistance organised by EWP-V as part of public consultation on the revised reflection paper on anthelmintic resistance, held on 13 June 2016.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 25-26 May 2016.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 29-30 June 2016, and noted the agenda of the meeting.

- The Committee adopted the reflection paper on the risks that should be considered prior to the use of unauthorised vaccines in emergency situations (EMA/CVMP/IWP/49593/2013) taking into account comments received during a targeted consultation and agreed for the document to be published on the Agency's website.
- The Committee discussed the overview of comments received following the close of the public consultation on the concept paper for development of a guideline to replace the Note for guidance on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use (EMA/CVMP/IWP/867401/2015), and agreed for the IWP to continue the revision of the guideline.
- The Committee adopted the concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD) (EMA/CVMP/IWP/867388/2015) for a 3-month period of public consultation.
- The Committee adopted the concept paper for the revision of the note for guidance on the use of adjuvanted immunological veterinary medicinal products (EMA/CVMP/IWP/867395/2015) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meetings held on 24-25 May 2016 and on 5-6 July 2016 and noted the agenda of the May and the July meetings.
- The Committee received a verbal report from the workshop chair, J. Olaerts, on the surveillance workshop held on 25 May 2016.
- The Committee discussed the reflection paper on causality assessment as part of the electronic surveillance strategy and agreed that the document will be used as a working document since no new methodology has been introduced.

7.9 Novel therapy groups and related issues

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 discussed the overview of comments received following the close of the public consultation on the draft revised guidelines on data requirements for veterinary medicinal products intended for minor use or minor species, and agreed for the relevant working parties to proceed with the revision of the guidelines.
- The Committee endorsed the appointment of Nienke Rodenhuis as chair of the joint CVMP/CHMP/CMDv/CMDh working group on Active Substance Master File Procedures (ASMF WG).

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 12 July 2016;
- Draft agenda of the Joint CHMP/CVMP QWP meeting to be held on 19–21 September 2016;
- Draft agenda of the joint meeting of the GMP/GDP Inspectors Working Group and CHMP/CVMP QWP to be held on 21 September 2016;

- Draft agenda of the EWP-V meeting to be held on 13–14 September 2016;
- Draft agenda of the ADVENT meeting to be held on 24 August 2016.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

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

- There were no items for discussion.

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 endorsed the presentation on the CVMP strategy on Antimicrobials 2016 – 2020, to be given by the AWP chair during the 4th International Conference on Responsible Use of Antibiotics in Animals to be held on 26-28 September 2016, in the Hague.
- The Committee discussed the overview of comments received following the close of the public consultation on the CVMP strategy on antimicrobials 2016-2020. The document is foreseen to be adopted at the October 2016 meeting of the Committee.
- The Committee received feedback from the AWP chair on the 2nd web meeting of EFSA BIOCONTAM – BIOHAZ Working Group concerning the request for a scientific opinion on the risk for the development of antimicrobial resistance due to feeding of calves with milk, held on 23 August 2016.
- The Committee received a verbal report on the teleconferences held on 14 June, 28 June, 11 July and 2 September 2016 for the preparation of the 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA).
- The Committee received a verbal report from the AWP chair on the Reduction of the Need for Antimicrobials in Food Producing Animals (RONAFA) remote group meeting held on 22 June 2016.

8.4 Pharmacovigilance

- The Committee was informed of the UK press articles concerning serious adverse events following vaccination with Nobivac L4.
- The Committee received a verbal report on the simulation exercise for the incident management plan for medicines for veterinary use.

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 discussed the letter regarding the CVMP summary of opinion on ERAVAC (EMEA/V/C/004239/0000) published in July 2016. The Committee agreed on the response letter.

The following documents were circulated for information:

- Publication of the updated advice of the AMEG group on the use of colistin products in animals within the EU (EMA/CVMP/CHMP/231573/2016); overview of comments (EMA/CVMP/CHMP/390632/2016) received on the publication of the updated advice on the use of colistin during the consultation period; press release on 27 July 2016.
- Official Journal of the European Union; Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance (2016/C 269/05), 23.7.2016.

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 was informed of the draft agenda of the CMDv meeting held on 8-9 September 2016 and noted the draft minutes of the meeting held on 14-15 July 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the upcoming appointment of CVMP co-opted members at the October 2016 meeting, for the identification of additional expertise necessary for CVMP to accomplish the mandate. The Committee agreed to appoint three co-opted members, retaining the same areas of expertise (i.e. general clinical veterinary practice, MRLs/residues, quality of pharmaceuticals). A call for nominations will be circulated by the secretariat shortly after the meeting.
- The Committee received a verbal report on the survey results concerning the appointment of rapporteurs for CVMP procedures, and noted the summary report and the compilation of individual responses.
- The Committee received a verbal update from R. Breathnach on the Scientific Co-ordination Board meeting held on 10 June 2016, and noted the agenda of the meeting.

13. LEGISLATION

- The Committee received a progress report on the development of CVMP recommendations for methodological principles for the risk assessment and risk management recommendations with regard to the establishment of maximum residue limits (which will replace “Volume 8”).

14. ANY OTHER BUSINESS

- Upon the completion of the September 2016 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 September 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:	• 2.5 Metacam • 3.1 Bovela • 10.1 two items
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	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	Ljiljana Markuš-Cizelj	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 5.4 Activyl Tick Plus • 9. one item
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	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	
FR	Sylvie Louet	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
IT	Antonio Battisti	Full involvement	
NL	G. Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SK	Eva Chobotová	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.			
UK	Sharon Reynolds	Full involvement	
FI	Kristina Lehmann - *remotely*	Full involvement	
FR	Benoit Courty – *remotely*	Full involvement	
	Marie-Hélène Sabinotto – *remotely*	Full involvement	
	Xenia von Krueger – *remotely*	Full involvement	
	Katrin Kirsch – *remotely*	Full involvement	
	Inke Reimer – *remotely*	Full involvement	
	Didier Concordet - *remotely*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	--
ERAWP	Jason Weeks
EWP-V	--
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