23 May 2018
EMA/CVMP/327674/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 17–19 April 2018 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 competing interests were identified for the April 2018 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

No contacts were declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the March 2018 meeting were adopted with minor 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

- 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Dany's BienenWohl** (EMEA/V/C/004667/0000), recommending the granting of a marketing authorisation. The product is a powder and solution for bee-hive dispersion, intended for the treatment of varroosis in honey bees. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication. This is an informed consent application.
- 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 **Credelio** (EMEA/V/C/004485/X/0001), recommending the extension of the marketing authorisation to add further lower tablet strengths of 12 mg and 48 mg, for the treatment of flea and tick infestations in a new target species (cats). The Norwegian CVMP member 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 adopted a list of remaining outstanding issues (EMA/CVMP/227667/2018) for a new product for horses (EMEA/V/C/004265/0000).
- 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 anti-inflammatory product for dogs (EMEA/V/C/004689/0000). The

Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

- The Committee heard an oral explanation from the applicant concerning an application for a new product for horses (EMEA/V/C/004328/0000). The adoption of the opinion is foreseen for the June 2018 CVMP meeting.
- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product for horses (EMEA/V/C/004727/0000). The Committee agreed that an oral explanation would not be requested, and noted three 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 an extension application for **Inflacam** (EMEA/V/C/002497/X/0015), to add a new pharmaceutical form and strength for cats. The Committee agreed that an oral explanation would not be requested, and noted a peer review report 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 an extension application for **Rheumocam** (EMEA/V/C/000121/X/0022), to add a new pharmaceutical form and strength for cats. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.
- There were no items for discussion.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/004902/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new product for cats (EMEA/V/C/004733/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/004794/0000). 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 discussed the request from the applicant for a 6-month extension to the clock-stop, following the oral explanation, for a new product for a musculo-skeletal disorder (EMEA/V/C/004222/0000).
- The Committee was informed of the formal notification from Vita (Europe) Limited of their decision to withdraw the application for a new marketing authorisation for **HopGuard Gold** (EMEA/V/C/0002836/0000), a new antiparasitic product for honey bees. More information

about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

- The Committee was informed of the formal notification from MERIAL of their decision to withdraw the marketing authorisation for **CERTIFECT** (EMEA/V/C/002002).
- The Committee was informed of the formal notification from Eli Lilly and Company Limited of their decision to withdraw the marketing authorisation for **Trifexis** (EMEA/V/C/002635).
- The Committee was informed of the formal notification from Eli Lilly and Company Limited of their decision to withdraw the marketing authorisation for **Meloxivet** (EMEA/V/C/000124).
- The Committee was informed of the formal notification from MERIAL of their decision to withdraw the marketing authorisation for **BTVPUR AlSap 1** (EMEA/V/C/002230).
- The Committee was informed of the formal notification from MERIAL of their decision to withdraw the marketing authorisation for **BTVPUR AlSap 8** (EMEA/V/C/000146).
- The Committee adopted the EPAR module 6 scientific discussion for **Clevor** (EMEA/V/C/004417/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the revised EPAR module 6 scientific discussion for **Suvaxyn Circo** (EMEA/V/C/004242/0000) 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 and endorsed the rapporteur's assessment report for a grouped type II variation for **Vectormune ND** (EMEA/V/C/003829/II/0009/G), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a worksharing type II variation for **Oncept IL-2, Parvoduk, ProteqFlu, Proteq West Nile, ProteqFlu Te, Purevax FeLV, Purevax Rabies, Purevax RC, Purevac RCP, Purevax RCP FeLV, Pu8revax RCPCh, Purevax RCPCh FeLV** and **Vaxxitek HVT+IBD** (EMEA/V/C/xxxxxx/WS1366), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0007), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues for a grouped type II variation for **Pexion** (EMEA/V/C/002543/II/0011/G), concerning the addition of a new therapeutic indication and quality changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a worksharing grouped type II variation for **NexGard** and **NEXGARD SPECTRA** (EMEA/V/C/002729/WS1338/G), to add new therapeutic indications.
- The Committee adopted a list of questions for a type II variation for **Galliprant** (EMEA/V/C/004222/II/0001), concerning quality changes.
- The Committee adopted a list of questions for a type II variation for **HALAGON** (EMEA/V/C/004201/II/0002/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

- There were no items for discussion.

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

- The Committee considered the request from the Executive Director of the Agency for a scientific opinion on the need for inclusion of a maximum limit for histamine in the active substance and/or finished product specifications for **gentamicin**-containing medicinal products for parenteral administration to horses. The Committee agreed to start a procedure (EMEA/V/A/128) under Article 30(3), and appointed M. O'Grady as rapporteur and W. Schlumbohm as co-rapporteur for the procedure. The Committee adopted a list of questions for the marketing authorisation holders and another one for the active substance manufacturers as well as the timetable for the procedure.

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 endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Suprelorin** (EMEA/V/C/000109/REC/015.1).
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Fevaxyn Pentofel** (EMEA/V/C/000030/REC/027.1).
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a condition for **ZULVAC SBV** (EMEA/V/C/002781/ANX/004.3).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 16.03.2018 - 19.03.2018:

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2017 – 01.04.2018
BLUEVAC BTV8 (EMEA/V/C/000156)	14.04.2017 – 13.03.2018
BTVPUR AlSap 8 (EMEA/V/C/000146)	17.03.2017 – 16.03.2018
Clomicalm (EMEA/V/C/000039)	01.04.2017 – 31.03.2018
Coliprotec F4 (EMEA/V/C/003797)	16.03.2017 – 15.03.2018
Ecoporc SHIGA (EMEA/V/C/002588)	10.04.2017 – 09.04.2018
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2017 – 25.03.2018
Evalon (EMEA/V/C/004013)	18.04.2017 – 17.04.2018
Incurin (EMEA/V/C/000047)	24.03.2017 – 23.03.2018
Locatim (EMEA/V/C/000041)	29.03.2017 – 28.03.2018
Neocolipor (EMEA/V/C/000035)	14.04.2017 – 13.03.2018
Parvoduk (EMEA/V/C/002740)	11.04.2017 – 10.04.2018
Purevax FeLV (EMEA/V/C/000056)	13.04.2017 – 12.04.2018
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2017 – 05.04.2018
Veraflox (EMEA/V/C/000159)	12.04.2017 – 11.04.2018

5.4 Renewals

- The Committee adopted by consensus (31 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 **AFTOVAXPUR DOE** (EMEA/V/C/002292/R/0009). The Committee concluded that a further 5-year renewal would be required, based on pharmacovigilance

grounds (no post-marketing safety information). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.09.2016 - 31.08.2017 for **Pexion** (EMEA/V/C/002543) with a recommendation to amend the product information.
- The Committee discussed adverse reactions reported after accidental eye exposure to **Osurnia** (EMEA/V/C/003753) and agreed on a written communication from Elanco Europe Ltd to be circulated to veterinarians and other healthcare professionals regarding this issue. The subject of the communication would also be reflected in a public health communication on the Agency's website.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Oncept IL-2 (EMEA/V/C/002562)	01.12.2016 - 30.11.2017
Palladia (EMEA/V/C/000150)	01.12.2014 - 30.11.2017
SevoFlo (EMEA/V/C/000072)	01.12.2015 - 30.11.2017
Simparica (EMEA/V/C/003991)	01.06.2017 - 30.11.2017
Zeleris (EMEA/V/C/004099)	15.05.2017 - 30.11.2017

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

5.6 Supervision and sanctions

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

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 guideline 56 on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for sign-off by the EWG at step 5 of the VICH process.
- The Committee adopted the draft annex to the VICH GL3(R) on stability studies for climatic zones III and IV, for sign-off by the VICH Steering Committee at step 3 of the VICH process.
- The Committee discussed the letter from the JECFA secretariat to the VICH secretariat commenting on VICH GL36 on the general approach to establishing a microbiological ADI and highlighting that JECFA now uses a different figure for the volume of the human colon.
- The Committee noted the draft training materials for VICH GL52 on bioequivalence: blood level bioequivalence study, and the comments made by EWP-V experts. The Committee agreed that

the slides could be endorsed with the proposed amendments. The EU comments will be forwarded to the VICH Steering Committee.

- The Committee noted the draft agenda of the 36th VICH Steering Committee meeting to be held on 25-26 and 28 June 2018 in Bruges, and the draft agenda of the 10th VICH Outreach Forum meeting to be held on 26-27 June 2018 in Bruges.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee deferred the discussion of the rapporteur's report on the appropriateness of the existing 'No MRL required' classification of theophylline to the May 2018 CVMP meeting.
- The Committee deferred the update on the European Chemicals Agency (ECHA) recommendation to include N-methyl-pyrrolidone in the list of substances subject to authorisation to the May 2018 CVMP meeting.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 17 April 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee deferred the verbal presentation of the reflection paper on the requirements for selection and justification of starting materials for the manufacture of chemical active substances (EMA/CHMP/CVMP/QWP/826771/2016), which has become invalid as a result of the entry into force of the Q&A on ICH GL11, to the May 2018 CVMP meeting.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the guideline on user safety of topically administered veterinary medicinal products and the overview of comments received. The new guideline will come into effect in November 2018.
- The Committee adopted the guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater and the overview of comments received. The new guideline will come into effect in November 2018. - *see also 7.4*
- The Committee agreed that the SWP-V will revise the guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market, following the comments received from the public consultation on the concept paper proposing the revision.

- The Committee adopted Questions and Answers (EMA/CHMP/CVMP/SWP/232746/2018) on implementation of risk-based prevention of cross contamination in production related to the CXMP 'Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities'. The Questions and Answers support the parent guideline by providing clarifications relating to the setting of health based exposure levels and their use.
- The Committee elected S. Scheid as chair of the SWP-V for a 3-year term.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater and the overview of comments received. The new guideline will come into effect in November 2018. - *see also 7.3*

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted a revised guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1) for a 5-month period of public consultation. - s*ee also 7.6*
- The Committee agreed that the EWP-V will revise the SPC guideline for anthelmintics following the comments received from the public consultation on the concept paper proposing the revision.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted a revised guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/383441/2005-Rev.1) for a 5-month period of public consultation. - s*ee also 7.5*

7.7 Immunologicals Working Party (IWP)

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 20-21 March 2018, and noted the agenda of the meeting.
- The Committee received a verbal report from the EMA Secretariat on the pilot for the revised recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data for centrally authorised products (CAPs).
- The Committee discussed the revised recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data for centrally authorised products (CAPs) and the overview of comments received, taking into account the feedback from the pilot for the revised recommendation. The recommendation is foreseen to be adopted at the May 2018 CVMP meeting.
- The Committee endorsed the revision of the EVVet access policy related to the EVVET3 project for public consultation. A 2-month consultation period (instead of the standard 6 months) was agreed due to the project needs.

7.9 Novel therapy groups and related issues

- The Committee discussed the question and answer document on stem cell-based products for veterinary use: specific questions on target animal safety to be addressed by ADVENT, and

agreed for the document to be revised further by ADVENT to take into account the CVMP comments.

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

- The Committee noted the EU-NTC assessors training on the 3Rs and Immunological Veterinary Medicinal products (Challenges and opportunities for the application of 3Rs to the regulation of IVMPs) to be held on 25 – 26 June 2018, and noted the agenda of the meeting.

7.11 Other working party and scientific group issues

- The Committee endorsed the revised IWP work plan for 2018 to reflect the change of a meeting date.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 13 March 2018.
- Draft minutes of the IWP meeting held on 28 February – 1 March 2018.
- Minutes from ADVENT meeting held on 7 December 2017.
- Draft minutes from ADVENT meeting held on 15 February 2018.

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 noted the draft minutes of the Incident Review Group (IRG) meeting on diethanolamine held on 6 April 2018.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee agreed for H. Jukes to participate, as an EMA/CVMP representative, at the "TOPRA Annual Symposium 2018" – Antimicrobial resistance session and give a lecture on "Update on the new AMEG mandate and CVMP's Guideline for risk assessment of antimicrobials".
- The Committee was informed of the progress on the pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation (PPHOVA) and noted the minutes of the Adobe meeting held on 16 March 2018.
- The Committee noted the minutes of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) adobe connect meeting held on 20 March 2018 and the questionnaire for Stakeholders on early hazard characterisation/Preliminary Risk Profile (PRP).

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.

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 in February and March 2018, and noted the draft minutes of the meeting held on 15-16 March 2018 as well as the draft agenda of the meeting held on 19 April 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee endorsed the draft minutes of the CVMP Interested Parties meeting held on 6 September 2017.
- The Committee discussed the EMA letter sent to the CVMP Chair regarding the Rules of Procedure of standing working parties.
- The Committee received an update on the EMA relocation preparedness.
- The Committee received a verbal report on the EMA working group on operational preparedness for veterinary medicines.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 18 April 2018, and noted the agenda of the meeting and the minutes of the meeting held on 14 February 2018.
- The Committee noted the agenda of the EMA veterinary medicines innovation day held on 19 April 2018.
- The Committee noted the agenda of the stakeholders meeting on Brexit regulatory preparedness for veterinary medicinal products in the centralised procedure held on 20 April 2018.
- The Committee noted the agenda for the upcoming presidency meeting (to be held during the Bulgarian presidency) on 7-8 May 2018 in Madrid, Spain.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the April 2018 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 April 2018 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**	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou-Patsia	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Genera Research**	• None
HU	Gábor Kulcsár	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	**Involvement only in discussions** i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from **Olainfarm JSC**	• None
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement only in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer in relation to any medicinal product from	• 02.3 – one item • 10.1 – one item

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
		Bayer	
RO	Lollita Taban	Full involvement	
SI	Katarina Straus	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	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	**No involvement** i.e. no part in discussions, final deliberations and voting as appropriate with respect to the medicinal product **Salmosan**, and cannot act as rapporteur or peer reviewer for this product	• None
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Petra Falb	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FI	Katariina Kivilahti-Mantyla	Full involvement	
FR	Sylvie Louet	Full involvement	
IE	Mary O'Grady	Full involvement	
IT	Antonio Battisti	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Frida Hasslung Wikström	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	Kathrin Dietze	Full involvement	
DE	Karin Duchow - *remotely*	Full involvement	
DE	Andrea Christina Golombiewski - *remotely*	Full involvement	
DE	Sonja Haase - *remotely*	No involvement with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting for medicinal products from Triveritas Germany	• None
DE	Birgit Kegel - *remotely*	Full involvement	
DE	Kristin Schallschmidt - *remotely*	Full involvement	
DE	Nadine Matzmohr – *remotely*	No involvement with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting for medicinal products from Baxalta/Shire	• None
ES	Carlos Ballesteros – *remotely*	Full involvement	
ES	Rosario Bullido – *remotely*	Full involvement	
ES	Raul Belmar Liberato – *remotely*	Full involvement	
ES	Javier Martínez de Velasco – *remotely*	Full involvement	
ES	Sonia Gil Morales	Full involvement	
FR	Elisabeth Begon – *remotely*	Full involvement	
FR	Benoit Courty	Full involvement	
FR	Lise Laborieux – *remotely*	Full involvement	
FR	Anne Sagnier - *remotely*	Full involvement	
FR	Khadija Selouaoui - *remotely*	Full involvement	
NL	Kim Boerkamp	Full involvement	
PL	Marcin Glanda – *remotely*	Full involvement	
SE	Helena Back	Full involvement	
SE	Andrea Barbu	Full involvement	
UK	Rory Cooney - *remotely*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Javier Pozo	Full involvement	
UK	Jean-Paul Schmidt	Full involvement	
UK	Claire Stratford	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady *(Vet vice chair)*
SAWP-V	Rory Breathnach
SWP-V	Stefan Scheid

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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