17 April 2018
EMA/CVMP/246666/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 13-15 March 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 the addition of a new item, under point 5.6.

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

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

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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the February 2018 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 (29 members present of those eligible to vote) the CVMP opinion, including the EPMAR and the CVMP assessment report recommending the extension of MRLs to porcine species for **isoflurane** (EMEA/V/MRL/003647/EXTN/0002). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted 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

- The Committee adopted by consensus (29 members present of those eligible to vote) the final CVMP opinion including the EPMAR and the final CVMP assessment report for **diflubenzuron** (EMEA/V/MRL/003135/MODF/0003) recommending the modification of the current entry in table 1 (Allowed substances) of the Annex to Regulation (EU) No 37/2010 for diflubenzuron in *Salmonidae*, following the request from the European Commission under Article 11 of Regulation (EC) No 470/2009 for the review of the MRL for diflubenzuron due to concerns relating to the genotoxic potential of the metabolite 4-chloroaniline. The Committee noted the summary of opinion for publication.

1.5 Other issues

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for the establishment of MRLs (EMEA/V/MRL/004543/FULL/0001) in *equidae*.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- Following the oral explanation from the applicant, Intervet International B.V., 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 **Bravecto Plus** (EMEA/V/C/004440/0000), a new combination product of fluralaner and moxidectin for the treatment of tick and flea infestations and nematodes for cats, recommending the granting of a marketing authorisation. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- 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 **Semintra** (EMEA/V/C/002436/X/0008), recommending the extension of the marketing authorisation to add a new strength (10 mg/ml) oral solution and a new indication (treatment of systemic hypertension) for 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 heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/0002836/0000) for honey bees. 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 April 2018 CVMP meeting.
- The Committee heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/004265/0000) for horses. The Committee also discussed the draft product information and the rapporteurs' assessment of the informal applicant's responses to the list of outstanding issues. The adoption of the opinion is foreseen for the April 2018 CVMP meeting.
- The Committee adopted the updated scientific overview including a list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new vaccine (EMEA/V/C/004595/0000) for cows and heifers. The Committee 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 was informed of the revised EPAR module scientific discussion for **Oxybee** (EMEA/V/C/004296/0000) (EMA/132657/2018).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a grouped type II variation for **Onsior** (EMEA/V/C/000127/II/0018/G), recommending the variation of the marketing authorisation to add a new therapeutic indication (treatment of pain and inflammation associated with chronic musculo-skeletal disorders in cats) and to implement significant changes to the product information due to new preclinical data on the interchangeable use of tablets and solution for injection, interaction with other substances and accidental intravenous use. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.
- The Committee adopted by majority (28 members in favour out of the 30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Activyl Tick Plus** (EMEA/V/C/002234/II/0011), recommending the variation of the marketing authorisation to change conditions regarding

supply and use from prescription-only to non-prescription. G. Hahn, W. Schlumbohm and the Norwegian CVMP member signed divergent positions not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.

- 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 **Zolvix** (EMEA/V/C/000154/II/0023/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 workshared type II variation for **Naxcel** (and related nationally-authorised products) (EMEA/V/C/WS1241), recommending the variation of the marketing authorisation to implement changes in the ASMF. The Norwegian 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 a list of questions for a workshared type II variation for **LEUCOGEN, LEUCOFELIGEN FeLV/RCP** and **Nobivac LeuFel** (EMEA/V/C/WS1282), recommending the variation of the marketing authorisation to change the duration of immunity of the feline leukaemia component.

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 for a scientific opinion for **diethanolamine,** concerning the potential risk to the consumer resulting from the use of diethanolamine in veterinary

medicinal products for food-producing species and whether its use as an excipient should be subject to a maximum residue limit evaluation. The matter was referred to the Committee by Belgium following the removal of diethanolamine from the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009. The Committee agreed to start a procedure (EMEA/V/A/127) under Article 30(3) of Regulation (EC) No 726/2004, and appointed B. Urbain as rapporteur and G. Hahn as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable for the procedure, and agreed that a public consultation will be launched.

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 **Onsior** (EMEA/V/C/000127/REC/006-007).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 16.02.2018 – 15.03.2018:

Product	Period
Activyl (EMEA/V/C/000163)	18.02.2017 – 17.02.2018
Bovalto Ibraxion (EMEA/V/C/000051)	09.03.2017 – 08.03.2018
CaniLeish (EMEA/V/C/002232)	14.03.2017 – 13.03.2018
Cimalgex (EMEA/V/C/000162)	18.02.2017 – 17.02.2018
Econor (EMEA/V/C/000042)	12.03.2017 – 11.03.2018
Equisolon (EMEA/V/C/002382)	12.03.2017 – 11.03.2018
Fungitraxx (EMEA/V/C/002722)	12.03.2017 – 11.03.2018
Melosus (EMEA/V/C/002001)	21.02.2017 – 20.02.2018
Novem (EMEA/V/C/000086)	02.03.2017 – 01.03.2018
Pexion (EMEA/V/C/002543)	25.02.2017 – 24.02.2018
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	29.02.2017 – 28.02.2018
ProteqFlu (EMEA/V/C/000073)	06.03.2017 – 05.03.2018
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2017 – 05.03.2018
Purevax Rabies (EMEA/V/C/002003)	18.02.2017 – 17.02.2018

Product	Period
Purevax RC (EMEA/V/C/000091)	23.02.2017 – 22.02.2018
Purevax RCP (EMEA/V/C/000090)	23.02.2017 – 22.02.2018
Purevax RCP FeLV (EMEA/V/C/000089)	23.02.2017 – 22.02.2018
Purevax RCPCh (EMEA/V/C/000088)	23.02.2017 – 22.02.2018
Purevax RCPCh FeLV (EMEA/V/C/000085)	23.02.2017 – 22.02.2018
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08.03.2017 – 07.03.2018
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14.03.2017 – 13.03.2018

5.4 Renewals

- 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 the renewal of the marketing authorisation for **Meloxidolor** (EMEA/V/C/002590/R/0007), and recommended that the authorisation should now be indefinite. 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 01.03.2017-31.08.2017 for **Bravecto** (EMEA/V/C/002526) with a recommendation to amend the product information of Bravecto spot-on solution.
- 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
CYTOPOINT (EMEA/V/C/003939)	25.04.2017 - 31.10.2017
Evalon (EMEA/V/C/004013)	01.05.2017-31.10.2017
LETIFEND (EMEA/V/C/003865)	01.05.2017-31.10.2017
NexGard (EMEA/V/C/002729)	01.09.2016-31.08.2017
Rabigen SAG2 (EMEA/V/C/000043)	01.11.2014-31.10.2017
Vectormune ND (EMEA/V/C/003829)	01.04.2017-30.09.2017

- 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 draft revised VICH GL18(R) on residual solvents in new veterinary medicinal products, active substances and excipients, for circulation to the VICH EWG at step 4 of the VICH process.
- The Committee endorsed the draft EU comments on the revised VICH guidelines on efficacy of anthelmintics: Group 3 topic - Helminth numbers; GL16 proposal - Field studies for swine; and GL21 proposal - Field studies for poultry, for circulation to the VICH EWG.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

Information relating to certain topics discussed under section 6.3 at this meeting cannot be released at the present time as it is deemed to be confidential.

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 Chicago, US, between 23-27 April 2018.

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 SAWP-V secretariat on the meeting held on 13 March 2018, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP vet vice-chair on the Joint CHMP/CVMP QWP meeting held on 27 February – 1 March 2018, and noted the agenda of the meeting and the minutes of the QWP meeting held on 28–30 November 2017.

7.3 Safety Working Party (SWP-V)

- The Committee discussed the guideline on user safety of topically-administered veterinary medicinal products, which is foreseen to be adopted at the April 2018 meeting of the Committee.
- The Committee discussed the guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater, which is foreseen to be adopted at the April 2018 meeting of the Committee - *see also 7.4*
- The Committee was informed of the upcoming election of the chair of the SWP-V at the April 2018 CVMP meeting and noted the call for nominations.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater, which is foreseen to be adopted at the April 2018 meeting of the Committee - *see also 7.3*

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 20-21 February, and noted the agenda and the draft minutes of the meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 20-21 February 2018, and noted the agenda and the draft minutes of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 28 February – 1 March 2018, and noted the agenda of the meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the Veterinary Pharmacovigilance Public bulletin 2017 (EMA/697615/2017) for publication.

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, which is foreseen to be adopted at the April 2018 CVMP meeting.

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

- The Committee endorsed N. Bridoux as a core member of J3RsWG and J. G. Beechinor as a co-opted member.

7.11 Other working party and scientific group issues

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 13 February 2018.
- Draft agenda for the PhVWP-V meeting to be held on 20-21 March 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 agreed to release to industry stakeholders the CVMP review relating to the removal of diethanolamine from the list of substances considered as not falling within the scope of Regulation (EC) No 470/3009.
- The Committee adopted the corrigendum to the MRL summary report for isoflurane in Equidae (EMA/CVMP/222/1997-Corr.).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee received a verbal report from H. Jukes on the meeting of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) held on 22 February 2018, and noted the agenda and the draft minutes of the meeting.

8.4 Pharmacovigilance

- The Committee was informed of the joint EMA/VMD response to "Alfie's petition" regarding Lepto 4 vaccines, which includes answers to a number of detailed questions regarding concerns raised related to serious adverse reactions, including death, potentially related to the use of Lepto 4 vaccines. A number of questions related to the conduct of veterinarians in particular in the UK for which the EMA has no particular mandate and advice was provided to address those issues directly with the local Member States' veterinary profession organisations.

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 documents were circulated for information:

- Contribution of CVMP by written procedure to ECHA's PBT Expert Group discussion paper on 'Non Extractable Residues' (EMA/124756/2018)
- European Parliament Draft report - A European One Health Action Plan against Antimicrobial Resistance (AMR) - Committee on the Environment, Public Health and Food Safety - link
- VetCAST publication: En Route towards European Clinical Breakpoints for Veterinary Antimicrobial Susceptibility Testing: A Position Paper Explaining the VetCAST Approach - link

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.

- The Committee was informed of a regulatory update with regard to eligibility requests based on Articles 3(2)a or 3(2)b of Regulation 726/2004 for fixed combination products whereby, for eligibility requests for fixed combination products containing known active substances, applicants will be asked to justify their request for access to the centralised procedure in accordance with the optional scope, Article 3(2)b of Regulation (EC) No 726/2004, under either significant therapeutic, technical, scientific innovation or in the interest of animal health at Community level.

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.

- There were no items for discussion.

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

- The Committee noted the draft minutes of the meeting held on 15-16 February 2018 as well as the draft agenda of the meeting held on 15-16 March 2018.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Medicinal Products for Veterinary use (CVMP) (EMA/466102/2007).
- The Committee noted the draft agenda of the Veterinary Innovation Day to be held on 19 April 2018, and the draft agenda of the update on Brexit regulatory preparedness activities for veterinary companies to be held on 20 April 2018.
- The Committee received a verbal update on the change to timing of Scientific Committee chair and vice-chair elections.
- The Committee was informed about a status update on the revision of the document: exception to the VNees format.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the March 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 March 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**	
AT	Brigitte Hauser	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	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 Orion Oyj.	• None
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	• 5.4 Meloxidolor
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	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	• None

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
		or formally appointed peer reviewer in relation to any medicinal product from Olainfarm JSC	
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 Bayer	• None
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
FI	Kristina Lehmann	Full involvement	
FR	Sylvie Louet	Full involvement	
IT	Antonio Battisti	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Maja Turk	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.			
BE	Koenraad Brusselmans	Full involvement	
BE	Frédéric Klein- *remotely*	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Andrea Golombiewski- *remotely*	Full involvement	
DE	Heike Gyra- *remotely*	Full involvement	
DE	Uta Herbst- *remotely*	Full involvement	
DE	Birgit Kegel- *remotely*	Full involvement	
DE	Babett Kobe- *remotely*	Full involvement	
DE	Stefan Scheid- *remotely*	Full involvement	
ES	Rosario Bullido- *remotely*	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
ES	Gloria García Lorente- *remotely*	Full involvement	
ES	Mercedes Conradi Monner- *remotely*	Full involvement	
ES	Miguel Llorens Picher	Involvement only in discussions with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product.	• None
FI	Kristina Lehmann- *remotely*	Full involvement	
FI	Martti Nevalainen- *remotely*	Full involvement	
FR	Nathalie Bridoux- *remotely*	Full involvement	
IE	Mary O'Grady - *remotely*	Full involvement	
NL	Anita Bottger- *remotely*	Full involvement	
SE	Helena Back- *remotely*	Full involvement	
SI	Maja Golobič- *remotely*	Full involvement	
SI	Boris Kolar- *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	John Mitchell	Full involvement	
UK	Javier Pozo- *remotely*	Full involvement	
UK	Jason Weeks- *remotely*	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

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	--
ERAWP	Jason Weeks- *remotely*
EWP-V	Cristina Munoz Madero
IWP	Esther Werner
PhVWP-V	Els Dewaele - *remotely*
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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