19 February 2019
EMA/CVMP/22361/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 22-24 January 2019 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 section 5.4.

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

The attendance list was completed and competing interests were identified for the January 2019 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 December 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

- 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

- The Committee adopted the scientific overview and list of questions for the extension of MRLs in porcine for a substance (EMEA/V/MRL/003649/EXTN/0002), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and of a peer review report.

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 revised scientific overview including the list of outstanding issues and agreed comments on the draft product information for an extension application for **Innovax-ND-IBD** (EMEA/V/C/004422/X/0001), to add a new route of administration. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the 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 pigs (EMEA/V/C/004794/0000). The Committee noted two peer review reports and the comments received from CVMP members.

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 product for horses. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee adopted a list of questions to the ad hoc expert group (AHEG) and discussed the draft rapporteurs' assessment report for the re-examination of the negative CVMP opinion adopted for **HorStem** (EMEA/V/C/004265/0000), a pharmaceutical veterinary product intended for the treatment of osteoarthritis in horses.

2.5 Other issues

- The Committee adopted the EPAR module scientific discussion for **Syvazul BTV** (EMEA/V/C/004611/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **Zulvac BTV** (EMEA/V/C/004185/X/0001) concerning the granting of the extension to the marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **Isemid** (EMEA/V/C/004345/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the EPAR module scientific discussion for **Kriptazen** (EMEA/V/C/004868/0000) concerning the granting of the initial marketing authorisation.
- The Committee adopted the refusal EPAR for **LongRange** (EMEA/V/C/004291/0000) 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 the CVMP assessment report for a type II variation (subject to a worksharing procedure) for **Purevax RC**, **Purevax RCP**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV** and **Purevax RCPCh** (EMEA/V/C/xxx/WS1517), recommending the variation of the marketing authorisations 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 a list of outstanding issues for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0015), to add a new target species.
- The Committee adopted a list of outstanding issues for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0016), concerning quality changes.
- The Committee adopted a list of outstanding issues for a type II grouped variation for **CYTOPOINT** (EMEA/V/C/003939/II/0003/G), concerning quality changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Bravecto Plus** (EMEA/V/C/004440/II/0003), to add a new therapeutic indication.
- The Committee adopted a list of questions for a type II grouped variation for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/II/0004/G), concerning the onset duration of immunity, and to implement changes relating to in the SPC and package leaflet.

- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **LEUCOFELIGEN FeLV/RCP**, **LEUCOGEN** and **Nobivac LeuFel** (EMEA/V/C/xxxxx/WS1483), to modify the approved indication.
- The Committee adopted a list of questions for a type II variation for **Broadline** (EMEA/V/C/002700/II/0023), concerning quality changes.
- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **Porcilis PCV M Hyo** (EMEA/V/C/003796/WS1467), concerning changes in the SPC and package leaflet.
- The Committee adopted a list of questions for a type II variation for **Suprelorin** (EMEA/V/C/00109/II/0022) concerning quality changes.
- The Committee adopted a list of questions for a type II variation for **Rhiniseng** (EMEA/V/C/000160/II/0009) concerning quality changes.
- The Committee adopted a list of questions for a type II grouped variation for **CLYNAV** (EMEA/V/C/002390/II/0004/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 discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep** (EMEA/V/A/126). The adoption of the CVMP opinion is foreseen for the February 2019 meeting of the Committee.
- The Committee considered the notification from France for a referral procedure for **veterinary medicinal products containing tylosin presented as solution for injection to be administered intramuscularly to pigs**. The referral concerns the appropriateness of the current withdrawal period in pigs for the aforementioned veterinary medicinal products containing tylosin base as a single active substance. The Committee agreed to start a referral procedure (EMEA/V/A/131) under Article 35 and appointed S. Louet as rapporteur and L. Nepejchalová as co-rapporteur for the procedure. The Committee adopted a list of questions and the timetable for the procedure.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **CLYNAV** (EMEA/V/C/002390/REC/008).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **CLYNAV** (EMEA/V/C/002390/REC/001.2).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/REC/025).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Vectormune ND** (EMEA/V/C/003829/REC/012).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **ZULVAC SBV** (EMEA/V/C/002781/ANX/004.5).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 07.12.2018–24.01.2019:

Product	Period
Acticam (EMEA/V/C/000138)	09.12.2017 – 08.12.2018
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2018 – 08.01.2019
Bovela (EMEA/V/C/003703)	22.12.2017 – 21.12.2018
BTVPUR (EMEA/V/C/002231)	17.12.2017 – 16.12.2018
Cepedex (EMEA/V/C/004376)	13.12.2017 – 12.12.2018
Coliprotec F4/F18 (EMEA/V/C/004225)	09.01.2018 – 08.01.2019
Contacera (EMEA/V/C/002612)	06.12.2017 – 05.12.2018
CORTAVANCE (EMEA/V/C/000110)	09.01.2018 – 08.01.2019
Galliprant (EMEA/V/C/004222)	09.01.2018 – 08.01.2019
HALAGON (EMEA/V/C/004201)	13.12.2017 – 12.12.2018

Product	Period
Imrestor (EMEA/V/C/002763)	09.12.2017 – 09.12.2018
Inflacam (EMEA/V/C/002497)	09.12.2017 – 08.12.2018
MELOXIDYL (EMEA/V/C/000115)	15.01.2018 – 14.01.2019
Metacam (EMEA/V/C/000033)	07.01.2018 – 06.01.2019
NEXGARD SPECTRA (EMEA/V/C/003842)	15.01.2018 – 14.01.2019
Nobilis OR inac (EMEA/V/C/000062)	24.01.2018 – 23.01.2019
Onsior (EMEA/V/C/000127)	16.12.2017 – 15.12.2018
Panacur AquaSol (EMEA/V/C/002008)	09.12.2017 – 08.12.2018
Porcilis PCV (EMEA/V/C/000135)	12.01.2018 – 11.01.2019
Prac-tic (EMEA/V/C/000103)	18.12.2017 – 17.12.2018
RESPIPORC FLU3 (EMEA/V/C/000153)	14.01.2018 – 13.01.2019
Rheumocam (EMEA/V/C/000121)	10.01.2018 – 09.01.2019
SevoFlo (EMEA/V/C/000072)	11.12.2017 – 10.12.2018
Ypozane (EMEA/V/C/000112)	11.01.2018 – 10.01.2019
ZULVAC 8 Bovis (EMEA/V/C/000145)	15.01.2018 – 14.01.2019
ZULVAC 8 Ovis (EMEA/V/C/000147)	15.01.2018 – 14.01.2019

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/R/0014).
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Versican Plus DHPPi/L4** (EMEA/V/C/003678/R/0013).
- 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 the marketing authorisation for **Versican Plus DHPPi** (EMEA/V/C/003679/R/0013), and recommended that a further five-year renewal would be required based on pharmacovigilance grounds. 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Versican Plus Pi** (EMEA/V/C/003681/R/0011), and recommended that a further five-year renewal would be required based on pharmacovigilance grounds. 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Fungitraxx** (EMEA/V/C/002722/R/0004), and recommended that

the renewal 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 01.08.2017-31.07.2018 for **NEXGARD SPECTRA** (EMEA/V/C/003842) with a recommendation to amend the product information.
- 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
Bovela (EMEA/V/C/003703)	01.07.2017-30.06.2018
CERTIFECT (WD) (EMEA/V/C/002002)	01.06.2016-31.08.2018
Ingelvac CircoFLEX (EMEA/V/C/000126) and **Ingelvac PCV FLEX** (EMEA/V/C/004645)	01.09.2015-31.08.2017 and 24.05.2018-31.08.2018
Innovax ND IBD (EMEA/V/C/004422)	01.03.2018-31.08.2018
Prac-Tic (EMEA/V/C/000103)	01.07.2018-30.06.2018
Sedadex (EMEA/V/C/004202)	13.02.2018-12.08.2018
Stronghold Plus (EMEA/V/C/004194)	01.03.2018-31.08.2018
Suvaxyn Circo (EMEA/V/C/004242)	07.02.2018-31.08.2018
Suvaxyn PRRS MLV (EMEA/V/C/004276)	01.03.2018-31.08.2018
ZULVAC SBV (EMEA/V/C/002781)	01.09.2017-31.08.2018

- 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 GL57 studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species, for sign-off by the Expert Working Group at step 5 of the VICH process.
- The Committee endorsed draft EU comments, relating to the review of the VICH anthelmintics guidelines, on adequacy of infection – statistical justification, and on use of faecal egg count reduction test.

- The Committee noted the post-teleconference notes on the arithmetic versus geometric means from the meeting of the VICH anthelmintic expert working group. The topic will be discussed at the February 2019 CVMP meeting.
- The Committee noted the draft agenda of the 37th VICH Steering Committee meeting to be held on 24-25 February and 1 March 2019, the draft agenda of the 11th VICH Outreach Forum meeting to be held on 25-26 February 2019 and the draft programme of 6th VICH Conference to be held on 27-28 February in Cape Town, South Africa.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee agreed to nominate a CVMP representative to participate in discussions relating to 4-chloroaniline, the genotoxic metabolite of diflubenzuron, following the invitation from EFSA.

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 SAWP-V chair on the meeting held on 22 January 2019, and noted the agenda of the meeting. The Committee agreed to the request of the SAWP-V to seek nominations for one extra member, following the resignation of N. Garcia del Blanco. It was agreed that the expertise sought is in the area of clinical trials design and conduct. A call for nominations will be launched shortly by the CVMP secretariat and the appointment of the new SAWP-V member will take place at the February 2019 CVMP meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the revised mandate, objectives and rules of procedure for the joint CHMP/CVMP QWP (EMA/CHMP/CVMP/QWP/65702/2016–Rev.1) following its adoption by CHMP in December 2018.
- The Committee was informed of the upcoming election of the veterinary vice-chair of the joint CHMP/CVMP QWP for a 3-year term, renewable once, at the February 2019 CVMP meeting. A call for nominations was circulated by the Secretariat.
- The Committee was informed of the upcoming election of the QWP chair for a 3-year term, renewable once, at the February 2019 CVMP meeting. A call for nominations was circulated by the Secretariat.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the revised mandate, objectives and rules of procedure for the CVMP ERAWP (EMA/CVMP/ERA/705470/2009-Rev.6).
- The Committee was informed of the upcoming election of the chair of the ERAWP for a 3-year term, renewable once, at the February 2019 CVMP meeting. A call for nominations was circulated by the Secretariat.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee was informed of the overview of comments received during the public consultation on the draft reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the EU (EMA/CVMP/AWP/842786/2015). It was noted that the review of comments, finalisation and adoption of the reflection paper are foreseen by CVMP/AWP by the end of 2019 (due to the Agency's BCP, work on this document has been temporarily suspended). The Committee also noted that these comments would be sent to the Antimicrobial Advice Ad Hoc Expert Group (AMEG) for their information for the finalisation of the scientific advice on the categorisation of antimicrobials (EMA/682198/2017).
- The Committee was informed of the upcoming election of the chair of the AWP for a 3-year term at the January 2019 CVMP meeting. A call for nominations was circulated by the Secretariat.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 4 December 2018.
- Draft agenda for the PhVWP-V meeting to be held on 29-30 January 2019.
- Draft agenda for the ADVENT meeting to be held on 29 January 2019.

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 **polyacrylamide hydrogel** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of substances that act by purely physical mechanisms, and adopted a revised list (EMA/CVMP/519714/2009–Rev.39).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted a revised draft scientific advice on the categorisation of antimicrobials (EMA/CVMP/CHMP/682198/2017), in the context of the European Commission request for an update of the previous scientific advice on the impact on public health and animal health of the use of antibiotics in animals (EMA/381884/2014). The advice is also foreseen to be adopted by CHMP at their January 2019 meeting and then released for public consultation until 30 April 2019. The purpose of the revision is to take into account the experience gained since the initial publication of the categorisation of antimicrobials in 2014.

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.

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 agreed to the transfer of all peer reviewer responsibilities from M. Azevedo Mendes to J. P. Duarte da Silva.

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 October, November and December 2018, and noted the draft minutes of the meeting held on 6-7 December 2018 as well as the draft agenda of the meeting held on 24-25 January 2019.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee deferred the discussion of the follow-on actions to the revised guidance on 'Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products' and the CVMP (Co-)Rapp assessment teams form to the February 2019 CVMP meeting.
- The Committee was informed of the upcoming election of the vice-chair of the Committee for Veterinary Use (CVMP) (3-year term, renewable once) at the February 2019 CVMP meeting.
- The Committee noted the request from the CVMP chair for proposals for topics to be included in the draft agenda of the CVMP/CMDv informal presidency to be held in Hungary in May 2019, under the Romanian Presidency of the Council of the European Union; a discussion will be scheduled for the February 2019 CVMP meeting.
- The Committee noted the draft minutes of the SPG November 2018 meeting.

13. LEGISLATION

14. ANY OTHER BUSINESS

- Upon the completion of the January 2019 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 January 2019 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	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou-Patsia	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
MT	Stephen Spiteri	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 2.2 – one item
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	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	Ricardo Carapeto García	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	
CZ	Leona Nepejchalová	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	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Sylvie Louet	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Cristina Gonçalves Santos	Full involvement	
UK	Rory Cooney	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	Christine Schwarz	Full involvement	
DE	Anke Finnah *(remotely)*	Full involvement	
DE	Uta Herbst *(remotely)* >	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
DK	Anja Silke Christensen *(remotely)*	Full involvement	
DK	Bettina Bryde Nielsen *(remotely)*	Full involvement	
DK	Mette Madsen *(remotely)*	Full involvement	
ES	Carles Cristòfol	Full involvement	
ES	Teresa Gómez *(remotely)*	Full involvement	
ES	Gema Cortés *(remotely)*	Full involvement	
ES	Rosario Bullido *(remotely)*	Full involvement	
ES	Antonio Lópes Navas *(remotely)*	Full involvement	
FR	Mathilde Harvey *(remotely)*	Full involvement	
FR	Florence Pillet *(remotely)*	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
FR	Gerard Moullin *(remotely)*	Full involvement	
IE	Sarah Buckley *(remotely)*	Full involvement	
IE	Susan Reid *(remotely)*	Full involvement	
NL	Kim Boerkamp *(remotely)*	Full involvement	
NL	Sandra ten Voorde *(remotely)*	Full involvement	
NL	Cornelia Otte *(remotely)*	Full involvement	
NO	Hans Christina Østensen *(remotely)*	Full involvement	
NO	Annelin Bjelland *(remotely)*	Full involvement	
PL	Marcin Glanda *(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
PL	Anita Piwowarczyk *(remotely)*	Full involvement	
SE	Carina Bergman *(remotely)*	Full involvement	
SE	Andreea Barbu *(remotely)*	Full involvement	
UK	Claire Straford *(remotely)*	Full involvement	
UK	Jean-Paul Schmidt *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	Ellen-Margrethe Vestergaard
PhVWP-V	Els Dewaele - *remotely*
QWP	---
SAWP-V	Rory Breathnach
SWP-V	Stefan Scheid - *remotely*

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

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