17 March 2020
EMA/CVMP/142728/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 18-20 February 2020 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

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 February 2020 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 the presence of a quorum of members, i.e. 22 or more members of the 32 members eligible to vote were present in the room. It was noted that
17 members were needed for an absolute majority.

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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.

iv. Adoption of the minutes of the previous meeting

The minutes of the January 2020 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 (26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs for **bupivacaine** (EMEA/V/MRL/005009/FULL/0001) in pigs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

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 modification of MRLs in bovine for a substance (EMEA/V/MRL/003652/MODF/0003) and agreed that no outstanding issues remained. The adoption of the opinion is foreseen for the March 2020 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

- The Committee discussed the rapporteurs' assessment report and adopted a list of questions to be addressed by the Ad Hoc Expert Group (AHEG) for the establishment of MRLs in *Salmonidae* for a substance (EMEA/V/MRL/004481/FULL/0002). The Committee also endorsed the list of AHEG members.
- The Committee discussed the rapporteurs' assessment report and adopted a list of questions to be addressed by the Ad Hoc Expert Group (AHEG) for the extension of MRLs in porcine for a substance (EMEA/V/MRL/003649/EXTN/0002). The Committee also endorsed the list of AHEG members.

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 **Vectormune FP ILT + AE**

(EMEA/V/C/005077/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of chickens to reduce skin lesions due to fowlpox, clinical signs and tracheal lesions resulting from avian infectious laryngotracheitis, and to prevent egg production losses due to avian encephalomyelitis. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the 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 the generic product **Tulissin** (EMEA/V/C/005073/0000), recommending the granting of a marketing authorisation. The product is indicated for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease, and treatment of the early stages of infectious pododermatitis in sheep. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the 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 the generic product **Tulaven** (EMEA/V/C/005153/0000), recommending the granting of a marketing authorisation. The product is indicated for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease, and treatment of the early stages of infectious pododermatitis in sheep. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- 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 vaccine for pigs (EMEA/V/C/005149/0000). 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 a list of questions and agreed comments on the draft product information for a new generic product (EMEA/V/C/005364/0000), for cattle, pigs and sheep. The Committee noted the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new generic product (EMEA/V/C/005305/0000), for cattle, pigs and sheep. 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 agreed to the request from the applicant for an extension to the clock-stop for a new vaccine (EMEA/V/C/005301/0000) for rabbits.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee heard an oral explanation and adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Clynav** (EMEA/V/C/002390/II/0010), recommending the variation of the marketing authorisation to extend the duration of immunity from 3 to 12 months after vaccination. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the 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 a type II variation (subject to a worksharing procedure) for **Porcilis PCV M Hyo** (EMEA/V/C/003796/WS1717), recommending the variation of the marketing authorisation to modify the product information to include associated use combinations for Porcilis PCV M Hyo, Porcilis Lawsonia and Porcilis PRRS. 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 type IB variation (subject to a worksharing procedure) for **Bravecto, Exzolt** and **Bravecto Plus** (EMEA/V/C/xxxxxx/WS1764), recommending the variation of the marketing authorisation to implement quality related-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 type IB variation (subject to a worksharing procedure) for **Vaxxitek HVT+IBD** and other related nationally authorised products (EMEA/V/C/xxxxxx/WS1763), recommending the variation of the marketing authorisation to implement quality related-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 type II variation for **Panacur AquaSol** (EMEA/V/C/002008/II/0017), recommending the variation of the marketing authorisation to implement quality related 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 type II variation for **Imrestor** (EMEA/V/C/002763/II/0012), recommending the variation of the marketing authorisation to implement quality related 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 rapporteur's assessment report for a type II variation for **Evicto** (EMEA/V/C/004973/II/0001), recommending the variation of the marketing authorisation to implement quality related changes. 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 and agreed on the comments on the product information for a type II variation for **Zulvac BTV** (EMEA/V/C/004185/II/0004) to vary the existing multi-strain dossier and update the product information.
- The Committee adopted a list of questions for a type II grouped variation for **Aivlosin** (EMEA/V/C/000083/II/0080/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Posatex** (EMEA/V/C/000083/II/0080/G) concerning quality-related changes.
- The Committee adopted a list of questions and agreed on the comments on the product information for a type II grouped variation (subject to a worksharing procedure) for **Purevax RCPCh FeLV, Purevax FeLV** and **Purevax RCP FeLV** (EMEA/V/C/xxxxx/WS1733/G) concerning quality-related changes.
- The Committee adopted a list of questions and agreed on the comments on the product information for a type II grouped variation (subject to a worksharing procedure) for **Purevax RC, Purevax RCP** and **Purevax RCPCH** (EMEA/V/C/xxxxx/WS1732/G) concerning quality-related 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 Germany for a referral for **Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, and generic products (including hybrid generic products) thereof**. The referral concerns the appropriateness of the current withdrawal periods (milk, meat and offal) in cattle for the aforementioned veterinary medicinal products containing 100 mg albendazole per ml. The Committee agreed to start a referral procedure (EMEA/V/A/140) under Article 35 and appointed A. Golombiewski as rapporteur and J. G. Beechinor 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

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 the 24-month shelf-life for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/REC/011).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 24.01.2020 – 20.02.2020:

Product	Period
Activyl (EMEA/V/C/000163)	18.02.2019 – 17.02.2020
Bravecto (EMEA/V/C/002526)	11.02.2019 – 10.02.2020
Cimalgex (EMEA/V/C/000162)	18.02.2019 – 17.02.2020
Comfortis (EMEA/V/C/002233)	11.02.2019 – 10.02.2020
Evant (EMEA/V/C/004902)	05.02.2019 – 04.02.2020
Fevaxyn Pentofel (EMEA/V/C/000030)	05.02.2019 – 04.02.2020
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27.01.2019 – 26.01.2020
Ingelvac CircoFLEX (EMEA/V/C/000126)	13.02.2019 – 12.02.2020
Kexxtone (EMEA/V/C/002235)	28.01.2019 – 27.01.2020
Kriptazen (EMEA/V/C/004868)	08.02.2019 – 07.02.2020
Loxicom (EMEA/V/C/000141)	10.02.2019 – 09.02.2020
MiPet Easecto (EMEA/V/C/004732)	31.01.2019 – 20.01.2020
NexGard (EMEA/V/C/002729)	11.02.2019 – 10.02.2020
Nobilis OR inac (EMEA/V/C/000062)	24.01.2019 – 23.01.2020
Oxybee (EMEA/V/C/004296)	01.02.2019 – 31.01.2020
Pirsue (EMEA/V/C/000054)	29.01.2019 – 28.01.2020
Purevax Rabies (EMEA/V/C/002003)	18.02.2019 – 17.02.2020

Product	Period
Semintra (EMEA/V/C/002436)	13.02.2019 - 12.02.2020
Startvac (EMEA/V/C/000130)	11.02.2019 – 10.02.2020
Stronghold Plus (EMEA/V/C/004194)	09.02.2019 – 08.02.2020
Suvaxyn Circo (EMEA/V/C/004242)	07.02.2019 – 06.02.2020
Suvaxyn CSF Marker (EMEA/V/C/002757)	10.02.2019 – 09.02.2020
VarroMed (EMEA/V/C/002723)	02.02.2019 – 01.02.2020
Zulvac SBV (EMEA/V/C/002781)	06.02.2019 – 05.02.2020

5.4 Renewals

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Canigen L4** (EMEA/V/C/004079/R/0007), and recommended that a further renewal would be required on pharmacovigilance grounds (ongoing monitoring and limited data). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 **Sileo** (EMEA/V/C/004079/R/0014), and recommended that the authorisation should now be indefinite. 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 **Innovax ILT** (EMEA/V/C/003869/R/0005), and recommended that the authorisation should now be indefinite. The Norwegian 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 **Upcard** (EMEA/V/C/003836/R/0004).

5.5 Pharmacovigilance – PSURs and SARs

- 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
Arti-Cell Forte (EMEA/V/C/004727)	29.03.2019-30.09.2019
Forceris (EMEA/V/C/004329)	23.04.2019-30.09.2019
Fortekor Plus (EMEA/V/C/0028804)	01.10.2018-30.09.2019
Imrestor (EMEA/V/C/002763)	01.10.2018-30.09.2019
Incurin (EMEA/V/C/000047)	01.10.2016-30.08.2019

Previcox (EMEA/V/C/000082)	29.03.2019-30.09.2019
Suvaxyn PRRS MLV (EMEA/V/C/004276)	01.03.2019-31.08.2019

- 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 EU response to the chair of the expert working group (EWG) on the VICH GL23 on 'Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing.
- The Committee endorsed the EU comments in response to the opening message from the VICH Expert Working Group Chair following the adoption of the concept paper for the revision of VICH GL22 on reproduction toxicity testing.
- The Committee nominated Frida Hasslung Wikström as an adviser to E. Werner for the development of a VICH guideline for safety evaluation of biotechnology-derived/biological products.
- The Committee nominated Kathrin Schirmann as adviser to work on development of a VICH discussion document on signal detection and signal management.
- The Committee noted the draft EU comments on the revision of the VICH anthelmintic guidelines on the following topics: Arithmetic and Geometric Means (dose confirmation studies); GL7 on the Age of Field Isolates and Laboratory Strains; GL7 on adequacy of infection - Statistical Justification; GL12, GL13, GL14, GL15, GL19 and GL20 on adequacy of infection/Helminth numbers; GL12 (bovine), GL13 (ovine), GL14 (caprine), GL15 (equine) on faecal egg count reduction test; GL16 (porcine) on claims for *Ascaris suum* L3 larvae; GL19-20 (cats, dogs) on persistent efficacy; and CVMP statistical essential points.
- The Committee noted the need for new EU experts to join the VICH safety Expert Working Group (EWG) and the VICH metabolism and residues kinetics EWGs.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

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 cannot be released at the present time as it is deemed to be commercially confidential.

7.1 Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 18 February 2020 and noted the agenda of the meeting.
- The Committee appointed as SAWP-V members A. Golombiewski to complement its expertise in general efficacy, M. O'Grady to complement its expertise in pharmaceutical quality, and S. Casado to complement its expertise in safety of immunologicals and biologicals.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP veterinary vice-chair on the meeting held on 5-6 February 2020 and noted the agenda and minutes of the November 2019 meeting.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed a concept paper on the environmental risk assessment for antiparasitic veterinary medicinal products authorised for use in companion animals.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee noted the call for nominations for new AWP members.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 28-29 January 2020 and noted the agenda of the meeting.
- The Committee reappointed E. Begon as vice-chair of the PhVWP-V for a 3-year term.

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 document was circulated for information:

- Minutes of the SAWP-V meeting held on 21 January 2020.

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 commercially confidential

- There were no items for discussion.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

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 be commercially confidential.

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 (co-)rapporteurships and peer reviewer responsibilities from F. Hasslung Wikström and E. Lander Persson to C. Bergman; from J.-C. Rouby to C. Miras; and from G. Hahn to A. Golombiewski.

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 (CMDv)

- The Committee noted the draft agenda of the meeting to be held on 20-21 February 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 19 February 2020 and noted the agenda of the meeting and the minutes of the meeting held on 6 November 2019.
- The Committee noted the invitation to the upcoming informal presidency CVMP/CMDv meeting to be held during the Croatian EU Presidency on 4-5 June 2020 at Maisons-Alfort, France.
- The Committee noted the minutes of the meeting between the veterinary training coordination group and the curriculum leads held on 23 January 2020.

- The Committee noted the programme (link) for the 3rd international awareness session on science and regulation for animal health and welfare, public health and the environment scheduled to take place on 2-3 April 2020 at the EMA, Amsterdam (link).
- The Committee noted the Veterinary Info Day and CVMP interested parties' meeting scheduled to take place on 18-19 June 2020 at the EMA, Amsterdam.

13. LEGISLATION

- The Committee received verbal reports from the expert group leaders on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6 on veterinary medicinal products.
- The Committee noted the agreement from the European Commission to extend the deadline for finalising the scientific advice regarding the implementing measures under Article 77(6) of Regulation (EU) 2019/6 for rules on oral administration.
- The Committee received a verbal report from the CVMP chair on the 'Expectations of the Annex 2 proposal of Regulation 2019/6' meeting held on 6-7 February 2020 at Munich, Germany and noted the agenda of the meeting.

14. ANY OTHER BUSINESS

- Upon the completion of the February 2020 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 February 2020 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	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Involvement only in discussions in relation to any medicinal product from Orion oyj:	5.4 Sileo
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LT	Snieguolė Trumpickaitė Dzekčiorienė	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Mary O'Grady	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
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
FR	Christine Miras	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
RO	Gabriela Tuchila	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SE	Carina Bergman	Full involvement	
SK	Eva Chobotová	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.			
AT	Roland Reimann (remotely)		
BE	Frédéric Klein (remotely)		
BE	Hilde Nelis (remotely)		
CZ	Dana Studená (remotely)		
CZ	Dana Halová (remotely)		
CZ	Eva Pomezná (remotely)		
CZ	Lucie Pokludová (remotely)		
CZ	Radka Smítalová (remotely)		
CZ	Zdenka Mašková (remotely)		
DE	Sabine Kalweit (remotely)		
DE	Svenja Rieke (remotely)		
DE	Uta Herbst (remotely)		
DK	Anja Silke Christensen (remotely)		
DK	Ellen-Margrethe Vestergaard (remotely)		
ES	Belen Gutierrez (remotely)		
ES	Cristina Villegas (remotely)		
ES	Gema Cortes (remotely)		
ES	Maria Dominguez (remotely)		
ES	Marina Mateo (remotely)		
ES	Mercedes Ureña (remotely)		
ES	Patricia Vera (remotely)		
ES	Raul Belmar (remotely)		
ES	Rosario Bullido (remotely)		
ES	Teresa Gómez (remotely)		
FR	Benoit Courty (remotely)		
FR	Gérard Moulin (remotely)		
FR	Jean-Christophe Faucon (remotely)		
IE	Sarah Buckley (remotely)		
IE	Susan Reid (remotely)		
NL	Anita Bottger (remotely)		
NO	Kari Grave (remotely)		

CVMP working parties and CMDv	Chair
ADVENT	---
AWP	---
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(Vet vice chair)*
SAWP-V	Frida Hasslung Wikström
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