6 October 2020
EMA/CVMP/527316/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-9 September 2020 meeting

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

Note on access to documents

Some documents mentioned in the agenda or 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).

Due to the COVID-19 pandemic, the September 2020 CVMP meeting took place by means of remote participation and decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of a new item under point 1.5.

ii. CVMP delegates list of intended participation and identified interests

The attendance list was completed, and no competing interests were identified for the September 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 presence of a quorum of members i.e. 17 or more members of the 32 members eligible to vote attended the meeting. 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the July 2020 meeting and the August written procedure were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- 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 in *fin fish* for **imidacloprid** (EMEA/V/MRL/004481/FULL/0002). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from the EU Reference Laboratory, the comments received from CVMP members and the summary of the 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

- There were no items for discussion.

1.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop period for submission of responses to the list of questions for the extension of MRLs for a substance (EMEA/V/MRL/004828/EXTN/0002) to chickens.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Librela** (EMEA/V/C/005180/0000), containing bedinvetmab, recommending the granting of a marketing authorisation. The product is indicated for the alleviation of pain associated with osteoarthritis in dogs. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- 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 **OvuGel**

(EMEA/V/C/005219/0000), containing triptorelin acetate, recommending the granting of a marketing authorisation. The product is a vaginal gel for synchronisation of ovulation in weaned sows. The Icelandic and Norwegian CVMP members 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 heard an oral explanation from the applicant concerning an application for a new vaccine (EMEA/V/C/005149/000). The Committee also discussed the comments on the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the October 2020 CVMP meeting.

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 product (EMEA/V/C/005660/0000) for dogs.

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 oral explanation for a new product (EMEA/V/C/005719/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 a type II variation for **Cytopoint** (EMEA/V/C/003939/II/0009), recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of pruritus associated with allergic dermatitis in dogs and amend the package leaflet. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.
- 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 a type II variation for **Nobilis IB Primo QX** (EMEA/V/C/002802/II/0008), recommending the variation of the marketing authorisation to amend the product information due to new data on the safe use during the egg laying period and to implement a minor editorial change. The Icelandic and Norwegian CVMP members 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 and endorsed the rapporteur's assessment report for a type II variation for **Zycortal** (EMEA/V/C/003782/II/0008), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Nasym** (EMEA/V/C/004897/II/0003/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 and the product information for **Nobivac L4** and **Canigen L4**, and endorsed the rapporteur's assessment report for a grouped type II variation subject to a worksharing procedure (EMEA/V/C/xxxxxx/WS1871/G), recommending the variation of the marketing authorisations to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 and endorsed the rapporteur's assessment report for a grouped type II variation subject to a worksharing procedure for **Suvaxyn Circo+MH RTU** and **Suvaxyn Circo** (EMEA/V/C/xxxxxx/WS1852/G), recommending the variation of the marketing authorisations to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Vectra 3D** and **Vectra Felis** (EMEA/V/C/xxxxxx/WS1876), recommending the variation of the marketing authorisations to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Simparica** and **MiPet Easecto** (EMEA/V/C/xxxxxx/WS1793), recommending the variation of the marketing authorisations to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 and endorsed the rapporteur's assessment report for a type IB grouped variation (subject to a worksharing procedure) for **NexGard Spectra, Afoxolaner Merial** and **NexGard** (EMEA/V/C/xxxxxx/WS1862/G), recommending the variation of the marketing authorisations to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 comments on the product information for a type II variation for **Exzolt** (EMEA/V/C/004344/II/0011) to amend the SPC.
- The Committee adopted a list of questions and comments on the product information for a type II grouped variation for **Circovac** (EMEA/V/C/000114/II/0017/G) concerning quality-related changes.
- The Committee adopted a list of questions and comments on the product information for a type II grouped variation for **Comfortis** (EMEA/V/C/002233/II/0023/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Ubac** (EMEA/V/C/004595/II/0004) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Clynav** (EMEA/V/C/002390) following a type II variation (EMEA/V/C/002390/II/0010) to extend the duration of immunity from 3 to 12 months.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Aivlosin** (EMEA/V/C/000083/0000) following a type II variation (EMEA/V/C/000083/II/0078) to add a new therapeutic indication for Aivlosin 625 mg/g granules for use in drinking water for pigs.

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 adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered to pigs** (EMEA/V/A/137), concluding that the available data is insufficient to support efficacy of the concerned products for the indication of prevention or metaphylaxis (when not associated with treatment) of swine dysentery caused by *B. hyodysenteriae* at the recommended dose. This was considered to pose a risk of ineffective treatment and antimicrobial resistance development. Consequently, the Committee recommended variations to the terms of the marketing authorisations for the concerned veterinary medicinal products to amend the product information to remove the above indication and dosing regimen from all relevant sections, and to amend the current indication to 'treatment and metaphylaxis of swine dysentery' at the approved dosing regimen for treatment. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

The following documents were circulated for information:

- **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names**, and generic products thereof – Article 35 referral (EMEA/V/A/136) – Questions and answers for publication;
- Referrals tracking table.

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 three recommendations for **Stelfonta** (EMEA/V/C/005018/REC/001-003), seeking additional information regarding REC-003. Recommendations REC-001 and REC-002 are considered completed.
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Cytopoint** (EMEA/V/C/003939/REC/014), seeking additional information**.**
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Prevexxion RN** (EMEA/V/C/005058/REC/001), which is now considered completed.
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Prevexxion RN+HVT+IBD** (EMEA/V/C/005057/REC/001), which is now considered completed.
- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a condition for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/REC/026.03), which is now considered completed.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 17.06.2020 – 10.09.2020:

Product	**Period**
Aivlosin (EMEA/V/C/000083)	09.09.2019 – 08.09.2020
Bovilis BTV8 (EMEA/V/C/000148)	06.09.2010 – 05.09.2020
Cardalis (EMEA/V/C/002524)	23.07.2019 – 22.07.2020
Cortacare (EMEA/V/C/004689)	27.08.2019 – 26.08.2020
Dexdomitor (EMEA/V/C/000070)	30.08.2019 – 29.08.2020
Emdocam (EMEA/V/C/002283)	18.08.2019 – 17.08.2020
Evicto (EMEA/V/C/004973)	19.07.2019 – 18.07.2020
Exzolt (EMEA/V/C/004344)	18.08.2019 – 17.08.2020

Product	Period
Fortekor Plus (EMEA/V/C/002804)	08.09.2019 – 07.08.2020
Innovax-ND-IBD (EMEA/V/C/004422)	22.08.2019 – 21.08.2020
Nasym (EMEA/V/C/004897)	29.07.2019 – 28.07.2020
Nobilis IB Primo QX (EMEA/V/C/002802)	04.09.2019 – 03.09.2020
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2019 – 31.08.2020
Nobivac Bb (EMEA/V/C/000068)	10.09.2019 – 09.09.2020
Nobivac Myxo-RHD (EMEA/V/C/002004)	07.09.2019 – 06.09.2020
Novaquin (EMEA/V/C/003866)	08.09.2019 – 07.09.2020
Osurnia (EMEA/V/C/003753)	31.07.2019 – 30.07.2020
Porcilis PCV ID (EMEA/V/C/003942)	28.08.2019 – 27.08.2020
Profender (EMEA/V/C/000097)	27.07.2019 – 26.07.2020
Proteq West Nile (EMEA/V/C/002005)	05.08.2019 – 04.08.2020
Sedadex (EMEA/V/C/004202)	12.08.2019 – 11.08.2020
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07.08.2019 – 06.08.2020
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24.08.2019 – 23.08.2020
Trocoxil (EMEA/V/C/000132)	09.09.2019 – 08.09.2020
Ubac (EMEA/V/C/004595)	26.07.2019 – 25.07.2020
UpCard (EMEA/V/C/003836)	31.07.2019 – 30.07.2020
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2019 – 08.08.2020
Vectormune ND (EMEA/V/C/003829)	08.09.2019 – 07.09.2020
Vepured (EMEA/V/C/004364)	17.08.2019 – 16.08.2020
Versican Plus L4 (EMEA/V/C/003680)	31.07.2019 – 30.07.2020
Versican Plus Pi/L4 (EMEA/V/C/003683)	31.07.2019 – 30.07.2020
Versican Plus Pi/L4R (EMEA/V/C/003682)	31.07.2019 – 30.07.2020
Zactran (EMEA/V/C/000129)	24.07.2019 – 23.07.2020

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2017-31.12.2019 for **Convenia** (EMEA/V/C/000098) with a recommendation to amend the section 4.5

`Special precautions for use' and section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.

- 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
Zolvix (EMEA/V/C/000154)	01.05.2017-30.04.2020
Equilis StrepE (EMEA/V/C/000078)	01.04.2017-31.03.2020
Letifend (EMEA/V/C/003865)	01.05.2019-30.04.2020
Forceris (EMEA/V/C/004329)	01.11.2019-30.04.2020

- 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 documents were 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 document VICH GL59 on harmonisation of criteria to waive laboratory animal batch safety testing for veterinary vaccines for veterinary use for circulation to the VICH expert working group following public consultation.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee discussed the mandate from the European Commission to the EMA and to EFSA to develop a common approach on exposure assessment for residues of VMPs, feed additives and pesticides.

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 7 September 2020 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

- The Committee adopted the revised mandate, objectives and rules of procedure for the SWP-V (EMA/CVMP/SWP/131613/2004).

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the revised mandate, objectives and rules of procedure for the EWP-V (EMA/CVMP/EWP/208686/2004-Rev.5).

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the IWP work plan for 2020 (EMA/CVMP/IWP/244361/2020).

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 13 July 2020;
- Draft agenda of the IWP meeting to be held on 22-23 September 2020.

8. OTHER SCIENTIFIC MATTERS

8.1 MRL issues

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

- The Committee agreed to correct the CAS Registry number published for **diethylaminoethyl (DEAE)-dextran** in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009.
- The Committee agreed to include **sodium polynaphthalene sulfonate** and **sodium lauryl ether sulfate** 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 excipients.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009-Rev.45).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- There were no items for discussion.

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.

- The Committee received an update on the report (link) of the lessons learnt exercise from the presence of nitrosamines in sartans for human use.
- The Committee received an update on the CHMP opinion under article 5(3) of Regulation (EC) No 726/2004 on nitrosamines impurities in human medicinal products and on the article 31 referral procedure for ranitidine.

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 (co-)rapporteurships from P. Hekman to either K. Boerkamp or J. Poot.

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.

- The Committee endorsed the revised procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions.

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

- The Committee received a verbal report from the chair of CMDv and noted the draft minutes of the meeting held on 16-17 July 2020 as well as the draft agenda of the meeting to be held on 10-11 September 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 7 September 2020 and noted the agenda of the September meeting and the minutes of the meeting held on 15 June 2020.
- The Committee discussed the draft agenda of the CVMP Presidency meeting to be held virtually on 20 October 2020.

13. LEGISLATION

- The Committee received a verbal report from the expert group leader, on work progress concerning provision of scientific recommendations on delegated and implementing acts to

Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans.

- The Committee received a verbal report from the expert group leader, on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6)).

14. ANY OTHER BUSINESS

- Upon the completion of the September 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 September 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	Svetoslav Branchev	Full involvement	
DE	Esther Werner	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
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	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	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	
IS	Peter Zsolt Fekete	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	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Kim Boerkamp	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	Annelin Aksdal Bjelland	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	Hilde Nelis	Full involvement	
BE	Michel Goret	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Anne Schöppner	Full involvement	
DE	Christina Bredtmann	Full involvement	
DE	Christine Schwarz	Full involvement	
DE	Christopher Janich	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Sabine Kalweit	Full involvement	
DE	Sabine Klee	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
DK	Trine Jensen	Full involvement	
ES	Susan Casado	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
ES	Rosario Bullido	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Gerard Moulin	Full involvement	
FR	Nathalie Bridoux	Full involvement	
PL	Marcin Glanda	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Jennie Sandberg	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Malin Öhlund	Full involvement	

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