13 July 2021
EMA/CVMP/397071/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 15-17 June 2021 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).

Due to the COVID-19 pandemic, the June 2021 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 three new items: one under point 6.2 and two under point 13.

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

The attendance list was completed and competing interests were identified for the June 2021 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 were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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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 May 2021 CVMP 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

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Fatrovax RHD** (EMEA/V/C/005301/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of rabbits from 28 days of age against rabbit haemorrhagic disease caused by rabbit haemorrhagic disease virus subtypes 1 and 2 (RHDV1 and RHDV2). The Icelandic 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Tessie** (EMEA/V/C/005427/0000), recommending the granting of a marketing authorisation. The product contains a new active substance (*tasipimidine*) for the short-term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure. 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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Strangvac**

(EMEA/V/C/005309/0000), recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of horses to reduce clinical signs of disease in the acute stage of infection with *Streptococcus equi*. 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 adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/005465/0000) for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/005464/0000) for cats. 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 for a marketing authorisation application for a new vaccine (EMEA/V/C/005596/0000) for pigs. 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 agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/005538/0000).

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 and endorsed the rapporteur's assessment report for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0012), 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 endorsed the rapporteur's assessment report for a type II grouped variation (subject to a worksharing procedure) for **Eryseng** and **Eryseng Parvo** (EMEA/V/C/xxxxx/WS1986/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 endorsed the rapporteur's assessment report for a type II grouped variation for **Locatim** (EMEA/V/C/000041/II/0017/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 endorsed the rapporteur's assessment report for a type II variation for **Baycox Iron** (EMEA/V/C/004794/II/0003), 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 endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **BTVPUR** and other related nationally authorised products (EMEA/V/C/002231/WS2017/0022), 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.

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 type II grouped variation for **NexGard Combo** (EMEA/V/C/005094/II/0002/G) to add new therapeutic indications.
- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **Meloxidyl** and **Zeleris** (EMEA/V/C/xxxxxx/WS2038) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Neocolipor** (EMEA/V/C/000035/II/0018/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Startvac** (EMEA/V/C/000130/II/0008/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Locatim** (EMEA/V/C/000041/II/0018) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Cortavance** (EMEA/V/C/000110/II/0015) concerning the variation of the marketing authorisation.

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

- 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 20 mg, 100 mg and 250 mg tablet strengths for the referral procedure for **Ronaxan and its associated names** (*doxycycline*) (EMEA/V/A/135), recommending the harmonisation of the product information for the concerned products. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

4.3 Article 35 of Directive 2001/82/EC

- The Committee considered the notification from Germany for a referral for **veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection**. Following the discussions at the CVMP meeting, Germany decided to withdraw the notification.

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 document was circulated for information:

- Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines – Article 35 referral (EMEA/V/A/142) – questions and answers for publication.

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 following to the Committee's recommendation for **Librela** (EMEA/V/C/005180/REC/004), which is now considered completed.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 13.05.2021 – 17.06.2021:

Product	Period
Baycox Iron (EMEA/V/C/004794)	20.05.2020 – 19.05.2021
Dany's BienenWohl (EMEA/V/C/004667)	14.06.2020 – 13.06.2021
Equilis West Nile (EMEA/V/C/002241)	06.06.2020 – 05.06.2021
Frontpro (EMEA/V/C/005126)	20.05.2020 – 19.05.2021
Leucogen (EMEA/V/C/000144)	17.06.2020 – 16.06.2021
Lydaxx (EMEA/V/C/005199)	18.05.2021 – 17.05.2021
MS-H Vaccine (EMEA/V/C/000161)	14.06.2020 – 13.06.2021

Product	Period
Naxcel (EMEA/V/C/000079)	19.05.2020 – 18.05.2021
Nobilis IB 4-91 (EMEA/V/C/000036)	09.06.2020 – 08.06.2021
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2020 – 13.06.2021
Porcilis Pesti (EMEA/V/C/000046)	09.06.2020 – 08.06.2021
Poulvac E. coli (EMEA/V/C/002007)	15.06.2020 – 14.06.2021
Respiporc FLUpan H1N1 (EMEA/V/C/003993)	17.05.2020 – 16.05.2021
Sileo (EMEA/V/C/003764)	10.06.2020 – 09.06.2021
Vectra Felis (EMEA/V/C/002746)	06.06.2020 – 05.06.2021
Zeleris (EMEA/V/C/004099)	15.05.2020 – 14.05.2021

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 **Sedadex** (EMEA/V/C/004202/R/0005), and recommended that the authorisation should now be indefinite. 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, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Eravac** (EMEA/V/C/004239/R/0007), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted a recommendation for changes to the SPC for **Bravecto spot on** based on the outcome of signal detection activities.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2018-31.12.2020 for **Cerenia** (EMEA/V/C/000106) with a recommendation to amend section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.01.2018-31.12.2020 for **Prevomax** (EMEA/V/C/004331) with a recommendation to amend section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.07.2020-31.12.2020 for **Vectra Felis** (EMEA/V/C/002746) with a recommendation to amend 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 information or other regulatory actions were required for:

Product	Period
Aservo EquiHaler (EMEA/V/C/004991)	01.08.2020-31.01.2021
Credelio (EMEA/V/C/004247)	01.02.2020-31.01.2021
Equilis Te (EMEA/V/C/000093)	01.02.2018-31.01.2021
Evicto (EMEA/V/C/004973)	19.07.2019-31.01.2021
Halagon (EMEA/V/C/004201)	01.01.2020-31.12.2020
HorStem (EMEA/V/C/004265)	01.07.2020-31.12.2020
Isemid (EMEA/V/C/004345)	01.08.2020-31.01.2021
Nasym (EMEA/V/C/004897)	01.08.2020-31.01.2021
Neptra (EMEA/V/C/004735)	01.07.2020-31.12.2020
Nobivac Myxo RHD Plus (EMEA/V/C/004989)	01.06.2020-30.11.2020
Sedadex (EMEA/V/C/004202)	01.03.2020-28.02.2021
Stelfonta (EMEA/V/C/005018)	01.08.2020-31.01.2021
Stronghold (EMEA/V/C/000050)	01.01.2018-31.01.2021
Syvazul BTV (EMEA/V/C/004611)	01.08.2020-31.01.2021
Ubac (EMEA/V/C/004595)	01.08.2020-31.01.2021
Ypozane (EMEA/V/C/000112)	01.02.2018-31.01.2021
Zactran (EMEA/V/C/000129)	01.02.2020-31.01.2021

- 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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee discussed the draft EU comments on a draft VICH guideline on target animal safety evaluation for veterinary monoclonal antibody products with a view to adopting the EU comments at the July 2021 CVMP meeting.

6.2 Codex Alimentarius

6.3 Other EU bodies and international organisations

The following document was/were circulated for information:

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

- Consideration of alternative intake calculation models for estimation of consumer exposure to residues - minutes from the enlarged expert group's 3rd meeting held on 26 April 2021.

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 14 June 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP vice-chair on the meeting held on 25-27 May 2021 and noted the agenda of the meeting and the minutes of meeting held on 1-2 March 2021.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the concept paper for the revision of residues guidelines to align with the new definition for withdrawal periods provided in Regulation (EU) 2019/6 (EMA/CVMP/SWP/265238/2021) for a one-month period of public consultation.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- The Committee adopted the revised guideline on the summary of product characteristics for veterinary medicinal products containing antimicrobial substances and the overview of comments received. The revised guideline will come into effect on 28 January 2022. - *see also agenda point 7.6*

7.6 Antimicrobials Working Party (AWP)

- The Committee received a report from the AWP chair on the meeting held on 25-26 May 2021 and noted the agenda of the meeting.
- The Committee adopted the revised guideline on the summary of product characteristics for veterinary medicinal products containing antimicrobial substances and the overview of comments received. The revised guideline will come into effect on 28 January 2022. - *see also agenda point 7.5*

7.7 Immunologicals Working Party (IWP)

- The Committee received a report from the IWP chair on the meeting held on 26-27 May 2021 and noted the agenda of the meeting.
- The Committee adopted the draft revised guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines (EMA/CVMP/IWP/105506/2007 Rev. 2) for a 3-month period of public consultation.
- The Committee adopted the draft guideline on data requirements for vaccine antigen master files (EMA/CVMP/IWP/258755/2021) for a 3-month period of public consultation.
- The Committee adopted a concept paper for the revision of the 'Guideline on requirements for the production and control of immunological veterinary medicinal products' (EMA/CVMP/IWP/284316/2021) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 25-26 May 2021 and noted the agenda and summary record of the meeting.
- The Committee adopted the revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/10418/2009 - Rev. 12), the list of changes to combined VeDDRA list of clinical terms (EMA/CVMP/PhVWP/214371/2021), the guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007 - Rev. 13), the non-current VeDDRA Low Level Terms and codes (EMA/102082/2021- Rev.5) and an updated template for submission of VeDDRA proposals.
- The Committee endorsed the proposals for managing the transition from PSURs to signal management for centrally authorised products.

7.9 Novel therapy groups and related issues

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

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 14 April 2021;
- Information on the SAWP-V written procedure in May 2021;

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.

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

- 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.

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 noted the draft agenda of the CMDv meeting to be held on 17-18 June 2021 and the minutes of the CMDv meeting held on 11-12 May 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Veterinary Domain on the meeting held on 7 June 2021 and noted the agenda of that meeting and the minutes of the 9 April 2021 meeting.

13. LEGISLATION

- The Committee adopted the draft veterinary good pharmacovigilance practice (VGVP) modules on collection and recording of suspected adverse events for veterinary medicinal products (EMA/635856/2020), on signal management (EMA/307620/2021), on veterinary pharmacovigilance communication (EMA/63454/2021), on controls and pharmacovigilance inspections (EMA/264458/2021), on pharmacovigilance systems, their quality management systems and pharmacovigilance system master files (EMA/257136/2021) and Annex Glossary (EMA/118227/2021) for a two-month period of public consultation.
- The Committee received a verbal report on work progress concerning provision of scientific recommendations on implementing acts as required by Regulation (EU) 2019/6 and in line with the mandates received from the European Commission.
- The Committee noted the publication of the Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council in the Official Journal of the European Union.

14. ANY OTHER BUSINESS

- Upon the completion of the June 2021 CVMP meeting, the draft news highlights were circulated for members to provide 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 June 2021 CVMP 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 Valentinov Branchev	Full involvement	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	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	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for: Bayer	2.2 One item
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 – Vice-Chair	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
AT	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CY	Alia Michaelidou-Patsia	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	Full involvement	
SK	Eva Chobotová	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Sandy Vermout	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Zdenka Malanová	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Babett Kobe	Full involvement	
DE	Birgit Kegel	Full involvement	
DE	Dagmar Sommer	Full involvement	
DE	Heike Gyra	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Kathrin Schirmann	Full involvement	
DE	Katja Kaulich	Full involvement	
DE	Martina Kern	Full involvement	
DE	Nadine Matzmohr	Full involvement	
DE	Sandra Schack	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Sonja Haase	Full involvement	
DE	Stefan Scheid	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Wiebke Weiher	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Anne H. Buur	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Kathrine Just Andersen	Full involvement	
DK	Malene Nissen	Full involvement	
DK	Martin Oleksiewicz	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
ES	Maria José Ferrer	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Susana Casado	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Caroline Guittré	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Mathilde Harvey	Full involvement	
FR	Meg-Anne Moriceau	Full involvement	
IE	Aideen Brownen	Full involvement	
IE	Joseph deCourcey	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Susan Reid	Full involvement	
IE	Sarah Buckley	Full involvement	
NL	Piet-Hein Overhaus	Full involvement	
NO	Adam Lillicrap	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Malin Öhlund	Full involvement	
* Experts were only evaluated against the topics they have been invited to talk about.			

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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