16 June 2020
EMA/CVMP/326595/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 18-20 May 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).

The Committee agreed by consensus that, due to the COVID-19 pandemic, the May 2020 CVMP meeting takes place by means of remote participation and decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of four new items: under point 2.5 regarding a request from the applicant for a clock-stop extension concerning a new product (EMEA/V/C/005719/0000); under point 5.6 regarding a follow up letter from the MAH on temporary supply interruption for a product; under point 12 concerning organisational matters and another on Regulation.

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

The attendance list was completed, and no competing interests were identified for the May 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. 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 April 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

- There were no items for discussion.

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 extension of MRLs in cattle for a substance (EMEA/V/MRL/003649/EXTN/0003) and adopted a list of outstanding issues. The adoption of the opinion is foreseen for the July 2020 meeting of the Committee.
- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in cattle for a substance (EMEA/V/MRL/005009/FULL/0002). The Committee agreed that there was no need for a list of outstanding issues. The adoption of the opinion is foreseen for the June 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

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (29 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Prevexxion RN+HVT+IBD** (EMEA/V/C/005057/0000), recommending the granting of a marketing authorisation. The product is a live recombinant viral vaccine for subcutaneous use for the active immunisation of one-day-old chicks to prevent mortality and clinical signs and reduce lesions caused by Marek's disease (MD) virus (including very virulent MD virus), and to prevent mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus. 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 (29 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Prevexxion RN** (EMEA/V/C/005058/0000), recommending the granting of a marketing authorisation. The product is a live recombinant viral vaccine for subcutaneous use in chickens for active immunisation of one-day-old chicks to prevent mortality and clinical signs and reduce lesions caused by MD virus (including very virulent MD virus). 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 and agreed comments on the draft product information for a marketing authorisation application for a new generic product (EMEA/V/C/005305/0000) for pigs and cattle. 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 generic product (EMEA/V/C/005076/0000) for pigs and cattle. 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 vaccine (EMEA/V/C/005272/0000) for pigs. 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 vaccine (EMEA/V/C/005190/0000) for chickens. 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 and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/005219/0000) 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/005719/0000) for cats.
- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new vaccine (EMEA/V/C/005149/0000) for pigs.
- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new vaccine (EMEA/V/C/005148/0000) for pigs.

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/005094/0000) for cats.
- The Committee was informed of minor updates to the European public assessment reports (EPARs) 'scientific discussion' for **Tulissin** (EMEA/V/C/005073/0000), **Tulaven** (EMEA/V/C/005153/0000) and **Lydaxx** (EMEA/V/C/005199/0000) concerning the granting of initial marketing authorisations.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by majority (18 members in favour out of the 28 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0078), recommending the variation of the marketing authorisation to add a new indication. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Norwegian CVMP member disagreed with the above-mentioned recommendation of the CVMP. E. Werner, N. C. Kyvsgaard, L. Nepejchalová, C. Muñoz Madero, K. Baptiste, R. Carapeto García, K. Štraus, P. Falb, J. Hederová, B. Urbain and H. Bergendahl signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (28 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Zulvac BTV** (EMEA/V/C/004185/II/0004), recommending the variation of the marketing authorisation to vary the existing multi-strain dossier in order to allow the use of the current monovalent vaccine against serotype 4 in cattle and update Annex II of the product information. 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 (29 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Leucofeligen FeLV/RCP** (EMEA/V/C/000143/II/0012), recommending the variation of the marketing authorisation to change the onset of immunity for the calicivirus component of the vaccine from 4 weeks after primary vaccination to 3 weeks after first vaccine injection of primary vaccination. 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 (29 members attending 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 **Metacam** and **Novem** (EMEA/V/C/xxxxxx/WS1813), recommending the variation of the marketing authorisations to implement changes in the SPC and the package leaflet following assessment of a PSUR. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Reconcile** (EMEA/V/C/000133/II/0033), 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 (29 members attending of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation (subject to a worksharing procedure) for **Eryseng Parvo**, **Eryseng** and **Rhiniseng** (EMEA/V/C/xxxx/WS1686),

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 (29 members attending of those eligible to vote) the CVMP opinion, the product information for **Purevax RCPCH**, **Purevax RC** and **Purevax RCP**, and endorsed the rapporteur's assessment report for a type II grouped variation (subject to a worksharing procedure) (EMEA/V/C/xxxxx/WS1732/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 (29 members attending of those eligible to vote) the CVMP opinion the product information for **Purevax FeLV**, **Purevax RCP FeLV** and **Purevax RCPCh FeLV** and endorsed the rapporteur's assessment report for a type II grouped variation (subject to a worksharing procedure) (EMEA/V/C/xxxxx/WS1733/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

- The Committee adopted a list of outstanding issues for a type II grouped variation for **Posatex** (EMEA/V/C/000122/II/0028/G) concerning quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions and agreed comments on the draft product information for a type II grouped variation for **Nasym** (EMEA/V/C/004897/II/0003/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type IB variation (subject to a worksharing procedure) for **Simparica** and **MiPet Easecto** (EMEA/V/C/xxxxx/WS1793) 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 discussed the rapporteur's assessment report and the co-rapporteur's assessment report following the marketing authorisation holder's response to the list of outstanding issues for the referral procedure **for Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof** (EMEA/V/A/136). The Committee agreed that there was no need for a further list of outstanding issues. The Committee noted two peer

review reports and the comments received from CVMP members**.** The adoption of the CVMP opinion and assessment report is foreseen for the June 2020 meeting of the Committee.

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

- The Committee adopted by majority (25 members in favour out of the 27 members attending of those eligible to vote) the CVMP opinion and the CVMP assessment report for the procedure under Art. 45 of Commission Regulation (EC) No. 726/2004 concerning **Suvaxyn PRRS MLV** (EU/2/17/215/001-003), concluding that there is no product-specific concern identified for Suvaxyn PRRS MLV and the benefit-risk balance of the product remains favourable, subject to risk mitigation measures that should be included in the product information. Therefore, the CVMP recommended the variation to the terms of the marketing authorisation. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. N. C. Kyvsgaard and K. Baptiste signed a divergent position not supporting the aforementioned recommendation.

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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 24.04.2020 – 20.05.2020:

Product	Period
Afoxolaner Merial (EMEA/V/C/005126)	20.05.2019 – 19.05.2020
Baycox Iron (EMEA/V/C/004794)	20.05.2019 – 19.05.2020
Bravecto Plus (EMEA/V/C/004440)	08.05.2019 – 07.05.2020
Credelio (EMEA/V/C/004247)	25.04.2019 – 24.04.2020
Cytopoint (EMEA/V/C/003939)	25.04.2019 – 24.04.2020
Equilis StrepE (EMEA/V/C/000078)	07.05.2019 – 06.05.2020
Felisecto Plus (EMEA/V/C/005093)	26.04.2019 – 25.04.2020
Improvac (EMEA/V/C/000136)	11.05.2019 – 10.05.2020

Product	Period
Naxcel (EMEA/V/C/000079)	19.05.2019 – 18.05.2020
Oncept IL-2 (EMEA/V/C/002562)	03.05.2019 – 02.05.2020
ReproCyc ParvoFLEX (EMEA/V/C/004858)	26.04.2019 – 25.04.2020
Respiporc FLUpan H1N1 (EMEA/V/C/003993)	17.05.2019 – 16.05.2020
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07.05.2019 – 06.05.2020
Versican Plus DHPPi/L4R (EMEA/V/C/002759	07.05.2019 – 06.05.2020
Zeleris (EMEA/V/C/004099)	15.05.2019 – 14.05.2020
Zulvac BTV (EMEA/V/C/004185)	25.04.2019 – 24.04.2020
Zuprevo (EMEA/V/C/002009)	06.05.2019 – 05.05.2020

5.4 Renewals

- The Committee adopted by consensus (29 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Fortekor Plus** (EMEA/V/C/002804/R/0018), 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 (29 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Vectormune ND** (EMEA/V/C/003829/R/0013), 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 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
Clynav (EMEA/V/C/002390)	01.07.2019-31.12.2019
Draxxin (EMEA/V/C/000077)	01.12.2018-30.11.2019
Halagon (EMEA/V/C/004201)	01.07.2019-31.12.2019
Isemid (EMEA/V/C/004345)	01.08.2019-31.01.2020
Porcilis ColiClos (EMEA/V/C/002011)	01.01.2017-31.12.2019
Poulvac E. coli (EMEA/V/C/002007)	01.01.2019-31.12.2019
Syvazul BTV (EMEA/V/C/004611)	01.08.2019-31.01.2020
Vectra Felis (EMEA/V/C/002746)	01.01.2019-31.12.2019

- 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

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 15 May 2020 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP vice-chair (veterinary) on the meeting held on 4-6 May 2020 and noted the agenda of the meeting.
- The Committee discussed the guideline on water for pharmaceutical use and the overview of comments. CVMP members were invited to send comments before the June 2020 meeting of the Committee when the adoption of the guideline is foreseen.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee discussed the question and answer document on management of extraneous agents in immunological veterinary medicinal products. The adoption of the document is foreseen for the June 2020 meeting of the Committee.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 12-13 May 2020 and noted the agenda 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, the list of changes to the combined VeDDRA list of clinical terms and guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans.

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 20 April 2020;
- Minutes of the 91st QWP meeting held on 5-6 February 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

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee discussed the draft CVMP strategy on antimicrobials 2021-2025.

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.

- 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 minutes of the 23 April 2020 meeting, as well as the draft agenda of the meeting held on 19-20 May 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- EC/HMA/EMA Notice to Stakeholders with questions and answers on regulatory expectations for veterinary medicinal products during the COVID-19 pandemic (link).

13. LEGISLATION

- The Committee adopted the scientific recommendations for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practices.
- The Committee adopted the scientific recommendations for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding the pharmacovigilance system master file.
- 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 2019/6 on veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the May 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 May 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	
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	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	
NL	Peter Hekman	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	
BG	Svetoslav Branchev	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Katariina Kivilahti-Mantyla	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Christine Miras	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SE	Carina Bergman	Full involvement	
SK	Eva Chobotová	Full involvement	
NO	Annelin Askdal 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.			
AT	Roland Reimann	Full involvement	
BE	Hilde Nelis	Full involvement	
CZ	Dana Halová	Full involvement	
CZ	Dana Studená	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Jakub Stejkora	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
DE	Andrea Winchenbach	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Anna Schöppner	Full involvement	
DE	Christopher Janich	Full involvement	
DE	Ingum Lemke	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Kathrin Schirmann	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Sonja Haase	Full involvement	
DE	Uta Herbst	Full involvement	
ES	Carles Cristofol	Full involvement	
ES	Maria Teresa Gomez Martinez	Full involvement	
ES	Susana Casado	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Anne Sagnier	Full involvement	
FR	Anne Marie Jacques	Full involvement	
FR	Gerard Moulin	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Martine Redureau	Full involvement	
FR	Mathilde Harvey	Full involvement	
NL	Anita Bottger	Full involvement	
NL	Kari Grave	Full involvement	
SE	Fredrik Hultén	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
SE	Jenny Larsson	Full involvement	

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 *(Veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Stefan Scheid

Observer from the European Commission	
Remotely	

Observers from Swissmedic	
Remotely	

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