16 March 2021
EMA/CVMP/162693/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 16-17 February 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 February 2021 CVMP meeting took place by means of remote participation and decision making.

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 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 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 2021 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 need for an oral explanation and noted the rapporteur's assessment after the responses to the list of questions and the rapporteur's EPMAR for the extension of MRLs in chickens for a substance (EMEA/V/MRL/004828/EXTN/0002). It was agreed that no outstanding issue remained to be addressed by the applicant. The adoption of the opinion is foreseen for the March 2021 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 was informed of the formal notification from the applicant of their decision to withdraw the application for establishment of MRLs in horses for a substance (EMEA/V/MRL/005302/FULL/0001).

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 **Credelio Plus** (EMEA/V/C/005325/0000), recommending the granting of a marketing authorisation. The antiparasitic product, containing lotilaner and milbemycin oxime, is indicated for oral use in dogs with, or at risk from, mixed infestations/infections of ticks, fleas, gastrointestinal nematodes, heartworm and/or lungworm. 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 **Daxocox**

(EMEA/V/C/005354/0000), recommending the granting of a marketing authorisation. The product, containing a new active substance (enflicoxib), is indicated for the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) 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 **Ultifend ND IBD** (EMEA/V/C/005347/0000) recommending the granting of a marketing authorisation. The product is a new vaccine for the active immunisation of chickens or chicken embryonated eggs to reduce mortality, clinical signs and lesions caused by Newcastle disease virus and to reduce virus shedding; to reduce mortality, clinical signs and bursa lesions caused by very virulent infectious bursal disease virus (IBDV); and to reduce mortality, clinical signs and lesions caused by classical Marek's disease 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Emdocam** (EMEA/V/C/002283/X/0012), recommending the extension of the marketing authorisation to add a new strength (5mg/ml solution for injection) and new target species (cats and 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 **Emdocam** (EMEA/V/C/002283/X/0013), recommending the extension of the marketing authorisation to add a new strength (15 mg/ml) and new pharmaceutical form (oral suspension) for horses. 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 vaccine (EMEA/V/C/005301/0000). 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.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions for a new generic product (EMEA/V/C/005606/0000) for cattle, pigs and sheep. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions for an extension application for **Apoquel** (EMEA/V/C/002688/X/0019) to add a new pharmaceutical form. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions for a new vaccine (EMEA/V/C/005538/0000) for dogs. The Committee noted three peer review reports 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 was informed of the formal notification from Elanco GmbH of their decision to withdraw the application for a new marketing authorisation for **Lotilaner/Milbemycin Elanco** (EMEA/V/C/005660/0000), an antiparasitic product, containing lotilaner and milbemycin oxime, for oral use in dogs, with, or at risk from, mixed infestations/infections of ticks, fleas, gastrointestinal nematodes, heartworm and/or lungworm. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

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 the CVMP assessment report for a type II variation for **Equioxx** (EMEA/V/C/000142/II/0024), recommending the variation of the marketing authorisation to introduce a new pharmacovigilance system. 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 a type II variation for **Zactran** (EMEA/V/C/000129/II/0045), 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 **ProteqFlu-Te** (EMEA/V/C/000074/II/0030/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, and endorsed the rapporteur's assessment report for a type II variation (subject to a worksharing procedure) for **Vectormune ND** and other related nationally authorised products (EMEA/V/C/003829/WS1892), 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 (27 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **Aivlosin** (EMEA/V/C/000083/II/0085/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 **Suvaxyn CSF Marker** (EMEA/V/C/002757/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 endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Eurican Herpes 205** and other related nationally authorised products (EMEA/V/C/000059/WS1971/0029), 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

- There were no items for discussion.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

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

- There were no items for discussion.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

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

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Zulvac SBV** (EMEA/V/C/002781/REC/019).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 20.01.2021 – 18.02.2021:

Product	Period
Activyl (EMEA/V/C/000163)	18.02.2020 – 17.02.2021
Aservo EquiHaler (EMEA/V/C/004991)	28.01.2020 – 27.01.2021
Bravecto (EMEA/V/C/002526)	11.02.2020 – 10.02.2021
Cimalgex (EMEA/V/C/000162)	18.02.2020 – 17.02.2021
Comfortis (EMEA/V/C/002233)	11.02.2020 – 10.02.2021
Evant (EMEA/V/C/004902)	05.02.2020 – 04.02.2021
Fevaxyn Pentofel (EMEA/V/C/000030)	05.02.2020 – 04.02.2021
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27.01.2020 – 26.01.2021
Ingelvac CircoFLEX (EMEA/V/C/000126)	13.02.2020 – 12.02.2021
Kexxtone (EMEA/V/C/002235)	28.01.2020 – 27.01.2021
Kriptazen (EMEA/V/C/004868)	08.02.2020 – 07.02.2021
Loxicom (EMEA/V/C/000141)	10.02.2021 – 09.02.2021
MiPet Easecto (EMEA/V/C/004732)	31.01.2020 – 30.01.2021
NexGard (EMEA/V/C/002729)	11.02.2020 – 10.02.2021
Nobilis OR inac (EMEA/V/C/000062)	24.01.2020 – 23.01.2021
Oxybee (EMEA/V/C/004296)	01.02.2020 – 31.01.2021
Pirsue (EMEA/V/C/000054)	29.01.2020 – 28.01.2021
Purevax Rabies (EMEA/V/C/002003)	18.02.2020 – 17.02.2021
Semintra (EMEA/V/C/002436)	13.02.2020 – 12.02.2021
Startvac (EMEA/V/C/000130)	11.02.2020 – 10.02.2021
Stronghold Plus (EMEA/V/C/004194)	09.02.2020 – 08.02.2021
Suvaxyn Circo (EMEA/V/C/004242)	07.02.2020 – 06.02.2021
Suvaxyn CSF Marker (EMEA/V/C/002757)	10.02.2020 – 09.02.2021
VarroMed (EMEA/V/C/002723)	02.02.2020 – 01.02.2021
Zulvac SBV (EMEA/V/C/002781)	06.02.2020 – 05.02.2021

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 **Sevohale** (EMEA/V/C/004199/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 the CVMP assessment report of the PSUR for the period 01.09.2019-31.08.2020 for **Stronghold Plus** (EMEA/V/C/004194) and **Felisecto Plus** (EMEA/V/C/005093) 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 literature or other regulatory actions were required for:

Product	Period
Aivlosin (EMEA/V/C/000083)	01.10.2019-30.09.2020
Coliprotec F4/F18 (EMEA/V/C/004225)	01.08.2019-31.07.2020
Cortacare (EMEA/V/C/004689)	01.11.2017-30.10.2020
Eurican Herpes 205 (EMEA/V/C/000059)	01.10.2017-30.09.2020
Fortekor Plus (EMEA/V/C/002804)	01.10.2019-30.09.2020
Leucofeligen FeLV RCP (EMEA/V/C/000143)	01.07.2017-30.06.2020
Pexion (EMEA/V/C/002543)	01.09.2017-31.08.2020

- 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 document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal.

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

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 February 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted a reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products (EMA/CVMP/ERA/632109/2014) and the overview of comments received during the public consultation (EMA/CVMP/ERA/268948/2020) – *see also point 7.6.*

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted a reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/842786/2015) and the overview of comments received during the public consultation (EMA/CVMP/AWP/902538/2019).
- The Committee adopted a reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products (EMA/CVMP/ERA/632109/2014) and the overview of comments received during the public consultation (EMA/CVMP/ERA/268948/2020) – *see also point 7.4.*

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 26-27 January 2021 and noted the agenda and summary record of the meeting.

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 document was circulated for information:

- Minutes of the SAWP-V meeting held on 18 January 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

- 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.

- 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.

- The Committee adopted a reflection paper on eligibility criteria for limited markets (EMA/CVMP/235292/2020) for a 3-month period of public consultation – *see also point 13.*
- The Committee adopted guidelines on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/345237/2020) and on safety and residue data requirements for the establishment of maximum residue limits in minor species (EMA/CVMP/345236/2020) for a 3 month period of public consultation, as well as the overview of comments received during the previous public consultation (EMA/CVMP/57188/2020) – *see also point 13.*
- The Committee adopted a guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (EMA/CVMP/52665/2020) for a 3-month period of public consultation – *see also point 13.*
- The Committee adopted a guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (EMA/CVMP/IWP/59531/2020) for a 3-month period of public consultation – *see also point 13.*
- The Committee endorsed the 11th Annual report on Veterinary MUMS/Limited markets for adoption by Management Board on 11 March 2021.

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 minutes of the 21-22 January 2021 CMDv meeting as well as the draft agenda of the meeting to be held on 18-19 February 2021 and CMDv reply to EDQM Request for supplementary information on change of editorial rules.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee was informed of the EMA/AnimalhealthEurope Info Day to be held on 25 March 2021. The focus of this Info Day will be on the implementation of Regulation (EU) 2019/6. The Info Day will be held via WebEx and the registration for the event will be open until 18 March 2021.

13. LEGISLATION

- The Committee adopted a reflection paper on eligibility criteria for limited markets (EMA/CVMP/235292/2020) for a 3-month period of public consultation – *see also point 9.*
- The Committee adopted guidelines on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6 (EMA/CVMP/345237/2020) and on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species (EMA/CVMP/345236/2020) for a 3-month period of public consultation, as well as the overview of comments received during the previous public consultation (EMA/CVMP/57188/2020) – *see also point 9.*
- The Committee adopted a guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (EMA/CVMP/52665/2020) for a 3-month period of public consultation – *see also point 9.*
- The Committee adopted a guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (EMA/CVMP/IWP/59531/2020) for a 3-month period of public consultation – *see also point 9.*

14. ANY OTHER BUSINESS

- Upon the completion of the February 2021 CVMP meeting, the draft news highlights of the meeting 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 February 2021 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	
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	
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
AT	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	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	
HR	Hrvoje Pasavovic	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Carina Bergman	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.			
CZ	Eva Pomezná	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
DE	Anja Merle Pfalzgraff	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Julia Hackenberg	Full involvement	
DE	Sandra Bertulat	Full involvement	
DK	Helle Mulvad	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	
DK	Mette Tranholm	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
ES	Alberto de Prado López	Full involvement	
ES	Beatriz Guerra	Full involvement	
ES	Cristina Villegas	Full involvement	
ES	María José Ferrer	Full involvement	
ES	Patricia Vera Luque	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Susana Casado	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Mariette Saléry	Full involvement	
IE	Aideen Brownen	Full involvement	
NL	Engeline van Duijkeren	Full involvement	
NL	Peter Hekman	Full involvement	
NL	René van Herwijnen	Full involvement	
PT	Luisa Vieira Peixe	Full involvement	
SI	Katarina Glogoški	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
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 *(Vet vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Stefan Scheid

Observers from the European Commission	
Present	

Observers from Swissmedic	
Present	

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