



16 July 2024
EMA/CVMP/333236/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products Minutes of the 18-19 June 2024 meeting

Chair: G. J. Schefferlie – Vice-chair: F. Hasslung Wikström

Note on access to documents

Some documents mentioned in the 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/729522/2016](#)).

The meeting was held remotely.

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 18-19 June 2024

The attendance list was completed and competing interests were identified for the June 2024 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 discussed (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](#)).

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.

iv. Adoption of the minutes of the previous meeting

The minutes of the May 2024 meeting were adopted with no amendments.



v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

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

1. Maximum residue limits

1.1. Opinions

There were no items for discussion.

1.2. Oral explanations

There were no items for discussion.

1.3. List of outstanding issues

There were no items for discussion.

1.4. List of questions

There were no items for discussion.

1.5. Re-examination of CVMP opinions on maximum residue limits

There were no items for discussion.

1.6. Other issues

There were no items for discussion.

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

2.1.1. DIVENCE IBR Marker Live -infectious bovine rhinotracheitis vaccine (live recombinant) - EMEA/V/C/006260/0000 - cattle

Indication: vaccine intended for the active immunisation of cattle from 10 weeks of age to reduce virus shedding, hyperthermia and clinical signs caused by bovine herpesvirus type 1 (BoHV-1)

Action: For adoption

The Committee adopted the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendation.

Action: For information

The Committee noted the summary of opinion.

2.2. Oral explanations under Regulation (EU) 2019/6

There were no items for discussion.

2.3. List of outstanding issues under Regulation (EU) 2019/6

2.3.1. EMEA/V/C/006249/0000 – dogs, cats

Action: For decision

The CVMP agreed that an oral explanation was not needed at this time.

Action: For adoption

The Committee adopted the scientific overview, the list of outstanding issues and the comments on the product information

The Committee noted peer review reports and comments from CVMP members.

2.3.2. EMEA/V/C/006311/0000 – dogs

Action: For decision

The CVMP agreed that an oral explanation was not needed at this time.

Action: For adoption

The Committee adopted the scientific overview and list of outstanding issues, comments on the product information.

The Committee noted peer review reports and comments from CVMP members.

2.4. List of questions under Regulation (EU) 2019/6

2.4.1. EMEA/V/C/006442/0000 – chickens, embryonated chicken eggs

Action: For adoption

The Committee adopted the scientific overview including a list of questions and comments on the product information.

Committee noted peer review reports and the comments received from CVMP members.

2.4.2. EMEA/V/C/006439/0000 – dogs

Action: For adoption

The Committee adopted the scientific overview including a list of questions and the comments on the product information.

Committee noted peer review reports and the comments received from CVMP members.

2.5. Re-examinations of CVMP opinions under Regulation (EU) 2019/6

There were no items for discussion.

2.6. Other issues under Regulation (EU) 2019/6

2.6.1 EMEA/V/C/006288/0000 – chickens

Action: For adoption

The Committee agreed to the request from the applicant for an extension to a clock-stop.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Rabitec - rabies vaccine (live, oral) – EMEA/V/C/004387/VRA/0011 – foxes and raccoon dogs

Variation requiring assessment: to add a new strength including a new target species (dogs), a new composition of the bait and new vaccine container for dogs

Rapporteur: E. Werner, Co-rapporteur: K. Lehmann

Action: For adoption

The Committee adopted the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

3.1.2. Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0011/G – pigs

Variation requiring assessment: to change the product information related to the use in lactating sows and consequential adverse events in this subcategory of animals and to align the product information with version 9.0 of the QRD template.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

3.1.3. Daxocox – enflicoxib - EMEA/V/C/005354/VRA/0003/G – dogs

Variation requiring assessment: to add two new tablet strengths (140 and 200 mg) and to amend the dosing table for the currently approved tablet strengths (15, 30, 45, 70 and 100 mg).

Rapporteur: R. Breathnach, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

[3.1.4. Credelio / Aftab – lotilaner - EMA/VRA/0000177859 – cats, dogs](#)

Variation requiring assessment: to implement the outcome of the MAH's signal management process.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the CVMP opinion, Credelio product information and AdTab product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

[3.1.5. Stronghold Plus – selamectin / sarolaner - EMA/VRA/0000174657 – cats](#)

Variation requiring assessment: to add a new therapeutic indication for the treatment of notoedric mange (*Notoedres cati*).

Rapporteur: R. Breathnach, Co-Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted the CVMP opinion, the CVMP assessment report and the product information.

The Norwegian CVMP member agreed with the above-mentioned recommendations.

Action: For information

The Committee noted the summary of opinion.

3.2. Oral explanations under Regulation (EU) 2019/6

There were no items for discussion.

3.3. List of outstanding issues under Regulation (EU) 2019/6

There were no items for discussion.

3.4. List of questions under Regulation (EU) 2019/6

There were no items for discussion.

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

There were no items for discussion.

3.6. Other issues under Regulation (EU) 2019/6

There were no items for discussion.

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

There were no items for discussion.

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

There were no items for discussion.

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

There were no items for discussion.

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

There were no items for discussion.

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

There were no items for discussion.

4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6

There were no items for discussion.

4.7. Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

There were no items for discussion.

4.7.1. Referrals under Regulation (EU) 2019/6

There were no items for discussion.

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

Information relating to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections.

5.1. Pharmacovigilance under Regulation (EU) 2019/6

There were no items for discussion.

5.2. Post-authorisation measures under Regulation (EU) 2019/6

There were no items for discussion.

5.3. Inspections and controls under Regulation (EU) 2019/6

There were no items for discussion.

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

There were no items for discussion.

5.5. Other issues

There were no items for discussion.

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

6.1.1. Election of the Vice-chair of AWP

Action: For decision

B. Catry was unanimously elected vice-chair of the AWP for a 3-year mandate.

6.1.2. Verbal report on the AWP meeting held on 28-29 May 2024

Action: For information

The Committee noted the agenda and the verbal report on the AWP meeting held on 28-29 May 2024 and the minutes of the AWP meeting held on 5-6 March 2024.

6.2. Environmental Risk Assessment Working Party (ERAWP)

There were no items for discussion.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP meeting held on 12 June 2024

Action: For information

The Committee noted the agenda and the verbal report on the EWP meeting held on 12 June 2024 and the minutes of the meeting held on 20-21 February 2024.

6.3.2. Revision of efficacy guidelines in line with the definitions in Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis and prophylaxis

Action: For adoption

The Committee adopted the draft revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and the draft revised guideline on the conduct of efficacy studies for intramammary products for use in cattle for release for a 4-month period of public consultation.

6.3.3. Concept paper on the revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats

Action: For discussion

The Committee discussed the concept paper on the revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats. Adoption is expected for the July 2024 CVMP meeting.

[6.3.4. Concept paper on the revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees](#)

Action: For discussion

The Committee discussed the concept paper on the revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees. Adoption is expected for the July 2024 CVMP meeting.

[6.3.5. Concept paper on the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products](#)

Action: For discussion

The Committee discussed the concept paper on the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products. Adoption is expected for the July 2024 CVMP meeting.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion.

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

[6.6.1. Verbal report on NTWP meeting on meeting held on 7 June 2024](#)

Action: For information

The Committee received a verbal report and noted the agenda of the NTWP meeting held on 7 June 2024 and the minutes from the meeting held on 28 February 2024.

6.7. Pharmacovigilance Working Party (PhVWP-V)

[6.7.1. Verbal report on PhVWP-V meeting held on 28-29 May 2024](#)

Action: For information

The Committee noted the agenda and the verbal report of the PhVWP-V meeting held on 28-29 May 2024 and the draft summary record of the same meeting.

6.8. Quality Working Party (QWP)

[6.8.1. Guideline on development and manufacture of synthetic oligonucleotides](#)

Action: For discussion

The Committee discussed the draft guideline on development and manufacture of synthetic oligonucleotides.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 14 June 2024

Action: For information

The Committee noted the agenda and the verbal report of the meeting held on 14 June 2024 together with the minutes of the SAWP-V meeting held on 17 May 2024.

6.10. Safety Working Party (SWP-V)

There were no items for discussion.

6.11. Other working party and scientific group issues

6.11.2. Verbal report on the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group meeting held on 22-23 May 2024

Action: For information

The Committee noted the agenda and verbal report on the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group meeting held on 22-23 May 2024 and the minutes of the February 2024 meeting.

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential

7.1. MRL issues

There were no items for discussion.

7.2. Environmental risk assessment

There were no items for discussion.

7.3. Antimicrobial resistance

There were no items for discussion.

7.4. Pharmacovigilance

There were no items for discussion.

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

There were no items for discussion.

7.7. Other issues

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.2. Codex Alimentarius

There were no items for discussion.

8.3. Other EU bodies and international organisations

8.3.1. Call for volunteers to contribute to the development of the calculation tool for human dietary exposure to residues from veterinary medicinal products, feed additives and pesticides

Action: For decision

The Committee agreed to have C. Bergman as the CVMP representative in the EFSA working group.

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

There were no items for discussion.

9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

9.3. Regulatory matters

9.3.1. Q&A Paper on Product Classification

Action: For adoption

The Committee adopted the Q&A paper on product classification.

10. Organisational and strategic matters

10.1 Joint resolution regarding scientific committee conduct

Action: For information

The Committee noted the joint resolution regarding scientific committee conduct.

10.2. Targeted stakeholder consultation - Draft consolidated 3-year work plan for the veterinary domain (2025-2027)

Action: For discussion

The Committee considered the comments from stakeholders which will be further discussed during the stakeholders meeting on 24 June 2024.

11. CMDv

11.1. Verbal report on the CMDv meetings held on 25-26 April 2024 and 30-31 May 2024

Action: For information

The Committee received a verbal report from the Chair of CMDv on the CMDv meetings held on 25-26 April 2024 and 30-31 May 2024 and noted the agenda of the CMDv meeting to be held on 27-28 June 2024, the agenda of the CMDv meeting held on 30-31 May 2024, the agenda and minutes of the CMDv meeting held on 25-26 April 2024.

12. Legislation

12.1. Scientific advice on Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months

Action: For information

The Committee noted the verbal report from the expert group's chair.

Action: For discussion

The Committee discussed the draft scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months.

12.2. Verbal report on the work progress of the expert group for the scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with Article 114(1)

Action: For discussion

The Committee noted the verbal report from the expert group's chair.

Action: For decision

The Committee agreed to nominate volunteers to review the high-level assessment of non-priority substances.

13. Any other business

13.2. Meeting highlights

Action: For comments

Upon the completion of the CVMP meeting, the draft meeting highlights were circulated for members to provide comments within 24 hours.

14. Annex

2. Marketing authorisations

2.6. Other issues under Regulation (EU) 2019/6

[EMEA/V/C/006332/0000 – dogs](#)

Action: For adoption

The Committee adopted the request from the applicant for an extension of the clock stop.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

[MS-H Vaccine – *Mycoplasma synoviae* \(live\) - EMEA/V/C/000161/VRA/0021/G - chickens](#)

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

[Leucofeligen FeLV/RCP, Leucogen, Nobivac LeuFel – feline calicivirus vaccine, feline viral rhinotracheitis vaccine, feline infectious enteritis \(feline panleucopenia\) vaccine \(live\), feline leukaemia vaccine \(recombinant protein\), feline leukaemia vaccine \(inactivated\) – WS2580 – cats](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Variation requiring assessment: quality-related changes.

Rapporteur: F. Marsilio

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

The Committee adopted the CVMP opinion, the Prevexxion RN product information, the Vaxxitek HVT+IBD product information, the Prevexxion RN+HVT product information and the Prevexxion RN+HVT+IBD product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

[Exzolt – fluralaner - EMEA/V/C/004344/VRA/0017 – chickens](#)

Variation requiring assessment: quality related changes.

Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.4. List of questions under Regulation (EU) 2019/6

[Letifend – canine leishmaniasis vaccine \(recombinant protein\) – EMEA/V/C/003865 – dogs](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Respiporc FLU3 – swine influenza vaccine \(inactivated\) - EMEA/V/C/000153/VRA/0024/G – pigs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkroner-Møller

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Cimalgex – cimicoxib - EMEA/V/C/000162/VRA/0010 – dogs](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Novem – meloxicam- EMEA/V/C/000086/VRA/0029 – cattle, pigs](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Metacam – meloxicam - EMEA/V/C/000033/VRA/0153 – cats, cattle, dogs, guinea pigs, horses, pigs](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Purevax FeLV – feline leukaemia vaccine \(live recombinant\) - EMEA/V/C/000056/VRA/0032 – cats](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: E. Dewaele

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Respiporc FLU3 – swine influenza vaccine \(inactivated\) - EMEA/V/C/000153/VRA/0025 – pigs](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: M. Blixenkron-Møller

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Equilis West Nile – West Nile fever vaccine \(inactivated recombinant\) - EMEA/V/C/002241/VRA/0009 – horses](#)

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Poulvac Procerta HVT-IBD – live recombinant turkey herpes virus, strain HVT-IBD, expressing the VP2 protein of infectious bursal disease virus - EMEA/V/C/006000/VRA/0001/G – chickens, embryonated chicken eggs](#)

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the list of questions and the comments on the product information.

[Strangvac – streptococcus equi vaccine \(recombinant proteins\) - EMEA/V/C/005309/VRA/0007/G – horses](#)

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkron-Møller

Action: For adoption

The Committee adopted the list of questions.

Variation requiring assessment: quality-related changes.

Rapporteur: J. Beechinor

Action: For adoption

The Committee adopted the rapporteur's assessment report including list of questions.

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

The Committee adopted the list of questions.

3.6. Other issues under Regulation (EU) 2019/6

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For decision

The Committee approved the request from the applicant for an extension of the clock stop.

Variation requiring assessment: to align the product information with version 9.0 of the QRD template.

Rapporteur: S. Louet

Action: For information

The Committee noted the letter of withdrawal of the application.

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.3. Inspections and controls under Regulation (EU) 2019/6

6. Working parties

6.2. Environmental Risk assessment Working Party (ERAWP)

6.5. 3Rs Working Party (3RsWP)

6.8 Quality Working Party (QWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH GL23(R2) – Safety: Genotoxicity testing

Action: For adoption

The Committee adopted the VICH GL23 studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing (revision 2) for release for public consultation.

9.3. Regulatory matters

Invented names

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the June 2024 meeting, which was held virtually.

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	G. Johan Schefferlie*	Full involvement	
Austria	Petra Falb	Full involvement	
Austria	Manuela Leitner	Full involvement	
Belgium	Els Dewaele	Full involvement	
Belgium	Frederic Klein	Full involvement	
Bulgaria	Nadya Ognyanova Vladimirova	Full involvement	
Croatia	Hrvoje Pavasovic	Full involvement	
Czechia	Leona Nepejchalová	Full involvement	
Denmark	Niels Christian Kyvsgaard	Full involvement	
Denmark	Merete Blixenkroner-Møller	Full involvement	
Estonia	Toomas Tiirats	Full involvement	
Finland	Minna Leppänen	Full involvement	
France	Sylvie Louet	Full involvement	
France	Christine Miras	Full involvement	
Germany	Andrea Christina Golombiewski	Full involvement	
Germany	Esther Werner	Full involvement	
Greece	Spyridon Farlopoulos	Full involvement	
Hungary	Gábor Kulcsár	Full involvement	
Ireland	Paul McNeill	Full involvement	
Italy	Fulvio Marsilio	Full involvement	
Latvia	Zanda Auce	Full involvement	
Netherlands	Jacqueline Poot	Full involvement	
Netherlands	Kim Boerkamp	Full involvement	
Norway	Hanne Bergendahl	Full involvement	
Norway	Knud Sveen Torjesen	Full involvement	
Poland	Anna Wachnik-Święcicka	Full involvement	
Romania	Gabriela Tuchila	Full involvement	
Slovakia	Eva Chobotová	Full involvement	
Slovakia	Katarina Massányiová	Full involvement	
Slovenia	Katarina Straus	Full involvement	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	Full involvement	
Sweden	Hanna Bremer	Full involvement	
Denmark	Keith Baptiste	Full involvement	
Spain	Ricardo Carapeto García	Full involvement	
Ireland	Rory Breathnach	Full involvement	
Ireland	Mary O'Grady	Full involvement	
Sweden	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
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* Experts were evaluated against the topics they have been invited to talk about.

Austria	Martin Kinberg	Full involvement	
Germany	Kathrin Schmidt	Full involvement	
Germany	Dusan Palic	Full involvement	
Spain	Irene de la Casa Resino	Full involvement	
Spain	Susana Casado	Full involvement	
Germany	Jens Barthel	Full involvement	
Ireland	Alice Stack	Full involvement	
Ireland	Bryan Deane	Full involvement	
Ireland	Sarah Beesley	Full involvement	
Finland	Jukka Pakkanen	Full involvement	
Finland	Katariina Kivilahti-Mäntylä	Full involvement	
France	Nathalie Bridoux	Full involvement	
Germany	Sandra Bertulat	Full involvement	
Spain	Luis Agote Casado	Full involvement	
Germany	Maren Osmer	Full involvement	
Germany	Katja Boxberger	Full involvement	
Czech Republic	Josef Suchy	Full involvement	
Germany	Ingun Lemke	Full involvement	
Germany	Monika Hofmann	Full involvement	
Germany	Daniela Loos	Full involvement	
Germany	Judith Romberg	Full involvement	
Spain	Rosario Bullido	Full involvement	
Spain	Jaime García Sánchez	Full involvement	
Spain	Maria Esperanza Herreros Avila	Full involvement	
Spain	Cristina Benito Sastre	Full involvement	
Spain	Alberto de Prado Lopez	Full involvement	
Spain	Francisca Moya	Full involvement	
Spain	Adrian Fandiño Lopez	Full involvement	
Spain	Rocío Fernández Granda	Full involvement	
Spain	Jesus Alberto Sanchez Rodriguez	Full involvement	
Spain	Luis González Rivas	Full involvement	
Spain	Raul Belmar Liberato	Full involvement	
Denmark	Anne Malene Nissen	Full involvement	
Denmark	Kirsten Brolin Thomsen	Full involvement	
Denmark	Kathrine Just Andersen	Full involvement	
Belgium	Sandy Vermout	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
PhVWP-V	James Mount
QWP	Marie-Hélène Sabinotto (<i>veterinary vice chair</i>)
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
J3Rs WP	Sarah Adler-Flindt (<i>veterinary vice chair</i>)
ESUAVet WG	Sara Sacristan (<i>ESUAVet WG CVMP co-chair</i>)
CMDv	Laetitia Le Letty

Observer from the European Commission	
Present	
Observers from Swissmedic	
Present	
<i>European Medicines Agency support</i>	
Meeting run with support from the relevant EMA staff	