10 June 2025
EMA/CVMP/198789/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 8-9 April 2025 meeting

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 in person.

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 8-9 April 2025

The attendance list was completed and competing interests were identified for the April 2025 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).

Joao Duarte da Silva gave a proxy to Cristina Muñoz Madero from Tuesday afternoon until the end of the April 2025 meeting.

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.

There were no contacts declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the March 2025 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

2.1.1. Nobilis Multriva IBm+ND – avian infectious bronchitis virus and Newcastle disease virus vaccine (inactivated) - (EMEA/V/C/006589/0000) – chickens

Indication: for the active immunisation of chickens for reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype) and reduction of mortality and clinical signs caused by Newcastle disease virus (NDV).

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.

2.1.2. Nobilis Multriva Gm+REOm - Avian infectious bursal disease and avian reovirus vaccine (inactivated) - (EMEA/V/C/006614/0000) – chickens

Indication: for the active immunisation of chickens for passive immunisation of the progeny of the vaccinated chickens to reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal disease virus (IBDV), and to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.

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.

2.1.3. Emevet – maropitant - EMEA/V/C/006439/0000 – dogs

Indication: for the prevention of nausea induced by chemotherapy and the prevention of vomiting induced by motion sickness in dogs.

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.

2.2. Oral explanations

There were no items for discussion.

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006480/0000 – dogs

Action: For decision

The Committee agreed that there is no need for oral explanation.

Action: For adoption

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

Action: For information

The Committee noted a peer review report and the comments from CVMP members.

2.3.2. EMEA/V/C/006461/0000 – cattle, sheep, goats, pigs, horses, dogs, cats

Action: For decision

The Committee agreed that there is no need for oral explanation.

Action: For adoption

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

Action: For information

The Committee noted two peer review reports.

2.4. List of questions

2.4.1. – EMEA/V/C/006593/0000 – horses

Action: For adoption

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

Action: For information

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

2.5. Re-examinations of CVMP opinions

There were no items for discussion.

2.6. Other issues

2.6.1. Sirolimus TriviumVet – sirolimus – EMEA/V/C/006230/0000 – cats

Action: For information

The Committee noted the letter of withdrawal of the marketing authorisation application. A WEPAR will be prepared for publication.

3. Variations to marketing authorisations

3.1. Opinions

There were no items for discussion.

3.2. Oral explanations

There were no items for discussion.

3.3. List of outstanding issues

There were no items for discussion.

3.4. List of questions

3.4.1. Daxocox – enflicoxib - EMA/VRA/0000246340 – dogs

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one and alignment of the product information with version 9.1 of the QRD template.

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

Action: For adoption

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

3.5. Re-examinations of CVMP opinions on variations requiring assessment

There were no items for discussion.

3.6. Other issues

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/advice under Articles 141(1)(c), 141(1)(e) or 141(1)(i) 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

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

5.1.1. Signal evaluation and recommendations

Action: For adoption

The Committee adopted the outcome of the signal management process and the list of finalised signals.

5.1.2. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: C. Muñoz Madero

Action: For discussion

The Committee discussed the proposal on signal management process.

5.1.3. Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leppänen

Action: For adoption

The Committee adopted the outcome of the signal management process.

5.1.4. Zenalpha – medetomidine hydrochloride / vatinoxan hydrochloride

Rapporteur: R. Breathnach, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the outcome of the signal management process.

5.2. Post-authorisation measures

There were no items for discussion.

5.3. Inspections and controls

There were no items for discussion.

5.4. Re-examination of limited markets and exceptional circumstances authorisations

5.4.1. Innovax-ND-H5 – Newcastle disease, avian influenza and Marek's disease vaccine (live recombinant) - EMA/S/0000246877

Re-examination of the marketing authorisation for Innovax-ND-H5 in line with Article 27(3) of Regulation (EU) 2019/6.

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leitner

Action: For adoption

The Committee adopted the list of questions

5.5. Others

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. Verbal report on the AWP meeting held on 18-19 March 2025

Action: For information

The Committee received a verbal report on the AWP meeting held on 18-19 March 2025 and noted its agenda together with the minutes of AWP meeting held on 26-27 November 2024.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Election for chair of ERAWP

Action: For election

The Committee noted that there were no nominations received and the call for nominations was extended for another month.

6.2.2. Draft Concept paper for the development of a reflection paper on the environmental risk assessment of antimicrobial resistance in the environment

Action: For adoption

The Committee adopted the draft 'Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product' for release for public consultation.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 25 February 2025

Action: For information

The Committee received a verbal report on the EWP-V meeting held on 25 February 2025 and noted its agenda together with the minutes of the meeting held on 15-16 October 2024.

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 19-20 March 2025

Action: For information

The Committee received a verbal report on the IWP meeting held on 19-20 March 2025 and noted its agenda together with the minutes of the IWP meeting held on 21-22 October 2024.

6.5. 3Rs Working Party (3RsWP)

There were no items for discussion.

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Appointment of a new member

Action: For decision

The Committee elected, by majority, A. Pfalzgraff as a member of NTWP.

6.6.2. Call for nomination of the Vice-Chair of NTWP

Action: For information

The Committee noted the call for nomination of the Vice-Chair of NTWP.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 25-26 March 2025

Action: For information

The Committee received a verbal report on the meeting held on 25-26 March 2025 together with its draft summary record.

6.7.2. Appointment of new Pharmacovigilance (PhVWP-V) members for the operational expert group (OEG) on surveillance

Action: For endorsement

The Committee endorsed the recommendation from the selection committee for new PhVWP-V members for the OEG on surveillance.

6.7.3. Endorsement of PhVWP-V membership and appointment of new Pharmacovigilance (PhVWP-V) member (replacement of previous member)

Action: For endorsement

The Committee endorsed the nomination of M. Chilingirova and F. Grosjean as new members of the PhVWP-V.

6.8. Quality Working Party (QWP)

There were no items for discussion.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 4 April 2025

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 4 April 2025 and noted the agenda of that meeting together with the minutes of the SAWP-V meeting held on 7 March 2025.

6.9.2. Election for new member of SAWP

Action: For decision

The Committee elected H. Bremer, by majority as a new member of SAWP.

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 20-21 March 2025

Action: For information

The Committee received a verbal report on the SWP-V meeting held on 20-21 March 2025 and noted its agenda together with the minutes of the meeting held on 27-28 June 2024.

6.11. Other working party and scientific group issues

There were no items for discussion.

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

7.1.1. Request for inclusion of dibutyl sebacate in the list of substances considered as not falling within the scope of Regulation No. 470/2009

Action: For adoption

The Committee adopted the CVMP assessment report and agreed to include dibutyl sebacate in the list of substances considered as not falling within the scope of Regulation No. 470/2009, under the excipients heading.

The Committee adopted the list of substances considered as not falling within the scope of Regulation No. 470/2009, version 57.

7.2. Environmental risk assessment

There were no items for discussion.

7.3. Antimicrobial resistance

7.3.1. Dosage review and adjustment of selected antibiotic veterinary medicines (ADRA)

Action: For information

The Committee was informed on the upcoming information session for veterinary pharmaceutical industry (online on 22 May 2025) on Dosage review and adjustment of selected antibiotic veterinary medicines – EMA event page.

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

There were no items for discussion.

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

There were no items for discussion.

8.2. Codex Alimentarius

There were no items for discussion.

8.3. Other EU bodies and international organisations

There were no items for discussion.

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

10. Organisational and strategic matters

10.1. CVMP/CMDv meeting under the Polish EU Presidency, Warsaw, 8-9 May 2025

Action: For adoption

The Committee adopted the agenda (CVMP and CVMP-CMDv sessions).

10.4. Joint EU medicines agencies' network strategy to 2028 (EMANS)

Action: For information

The Committee received a presentation on the joint EU medicines agencies' network strategy to 2028 (EMANS) following its adoption by the HMA and the EMA Management Board. The updated document will guide the European medicines regulatory network over the next few years to meet the challenges ahead, including preparing for, and responding to, public health emergencies and threats such as antimicrobial resistance. EMA website news item link.

10.5. Veterinary Medicine Safety Day campaign

Action: For information

The Committee noted that the timeline for the launch of the Veterinary Medicine Safety Day campaign.

11. CMDv

There were no items for discussion.

12. Legislation

13. Any other business

13.1. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

2.6. Other issues

EMEA/V/C/006513/0000 – cats

Action: For decision

The Committee agreed to 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

Clevor – ropinirole – EMA/VRA/0000257048 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Newflend ND H9 – Newcastle disease and avian influenza vaccine (live, recombinant) -ك
EMEA/V/C/005860/VRA/0003 - chickens

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

Rapporteur: J. Poot

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

ReproCyc ParvoFLEX – porcine parvovirosis vaccine (inactivated) - EMA/VRA/0000247569 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Zycortal – desoxycortone pivalate - EMA/VRA/0000240475 – dogs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: H. Bergendahl

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0019 – chickens

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

Rapporteur: F. Klein

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Posatex – posaconazole / mometasone furoate / orbifloxacin - EMA/VRA/0000255315 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Equioxx – firocoxib – EMA/VRA/0000247013 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: J.G. Beechinor

Action: For adoption

The Committee adopted the list of questions.

Ecoporc Shiga – genetically modified STx2e antigen vaccine - EMA/VRA/0000247420 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

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

ProZinc – insulin human – EMA/VRA/0000247545 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of questions.

Meloxidyl – meloxicam - EMA/VRA/0000246351 – cats, dogs, horses, 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.

Coxatab – firocoxib - EMA/VRA/0000247285 – dogs

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

Rapporteur: L. Nepejchalová

Action: For adoption

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

Mometamax Ultra – gentamicin / posaconazole / mometasone furoate - EMA/VRA/0000247986 – dogs

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: K. Baptiste

Action: For adoption

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

Imoxat – imidacloprid / moxidectin - EMA/VRA/0000247407 – cats, dogs, ferrets

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: J.G. Beechinor

Action: For adoption

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

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

Innovax-ILT-IBD - EMA/PAM/0000252918

Post-authorisation recommendation

Rapporteur: J. Poot

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation which is now considered fulfilled.

Neoleish - EMA/PAM/0000253312

Post-authorisation recommendation

Rapporteur: C. Miras

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation, which is now considered fulfilled.

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

The Committee adopted the ERA ESEC Expert nominations.

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

The Committee adopted the list of nominations for the Quality Chemical ESEC.

6.11. European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group

Publication of the first ESUAvet report; 2023 data

Action: For information

The Committee noted the publication of the first ESUAvet report related to 2023 data European sales and use of antimicrobials for veterinary medicine - Annual surveillance report for 2023, together with the news item, First report on EU-wide sales and use of antimicrobials in animals | European Medicines Agency (EMA), the new ESUAvet webpage: European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance reports | European Medicines Agency (EMA) and the LinkedIn post: link.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9.3. Regulatory matters

Invented names

11. CMDv

Report from the Chair of CMDv

Action: To note

The Committee noted the draft agenda of the CMDv meeting to be held on 15-16 April 2025, the final agenda of the CMDv meeting held on 19-20 March 2025 and the report for release December 2024-January 2025 (link).

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the April 2025 meeting, which was held virtually.

An asterisk (*) after the role, in the second column, signals that the participant attended in person.
Additional experts participated in (part of) the meeting, remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
G. Johan Schefferlie*	**Chair**	**CHAIR**	**No interests declared**	
Petra Falb	Member	Austria	No interests declared	
Manuela Leitner	Alternate	Austria	No interests declared	
Els Dewaele	Member	Belgium	No interests declared	
Frederic Klein	Alternate	Belgium	No interests declared	
Krasimir Zlatkov	Member	Bulgaria	No interests declared	
Frane Božić	Member	Croatia	No interests declared	
Hrvoje Pavasovic	Alternate	Croatia	No interests declared	
Leona Nepejchalová	Member	Czechia	No interests declared	
Niels Christian Kyvsgaard	Member	Denmark	No interests declared	
Merete Blixenkrone-Møller	Alternate	Denmark	No interests declared	
Toomas Tiirats	Member	Estonia	No interests declared	
Minna Leppänen	Member	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	
Andrea Christina Golombiewski	Member	Germany	No interests applicable to this meeting	
Esther Werner	Alternate	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No interests declared	
Paul McNeill	Member	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Zanda Auce	Member	Latvia	No interests declared	
Renate Kuske	Alternate	Latvia	No interests declared	
Vaida Kurapkiene	Alternate	Lithuania	No interests declared	
Despoina Iatridou	Alternate	Luxembourg	No interests declared	
Jacqueline Poot	Member	Netherlands	No interests declared	
Kim Boerkamp	Alternate	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Knud Sveen Torjesen	Alternate	Norway	No interests declared	
Ewa Augustynowicz	Member	Poland	No interests declared	
Gabriela Tuchila	Member	Romania	No interests declared	
Eva Chobotová	Member	Slovakia	No interests declared	
Katarina Massányiová	Alternate	Slovakia	No interests declared	
Katarina Straus	Member	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Frida Hasslung Wikström	Member (Vice-Chair)	Sweden	No interests declared	
Keith Baptiste	Co-opted member	Denmark	No interests declared	
Ricardo Carapeto García	Co-opted member	Spain	No interests declared	
Rory Breathnach	Co-opted member	Ireland	No interests declared	
Mary O'Grady	Co-opted member	Ireland	No interests declared	
Carina Bergman	Co-opted member	Sweden	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Irene de la Casa Resino	Expert	Spain	No interests declared	
Catarina Eriksson	Expert	Sweden	No interests declared	
Gavin Ryan	Expert	Ireland	No interests declared	
Dusan Palic	Expert	Germany	No restrictions applicable to this meeting	
Saila Antila	Expert	Finland	No interests declared	
David Murphy	Expert	Ireland	No interests declared	
Emilie Elisabeth Pouplier	Expert	Denmark	No interests declared	
Benoit Courty	Expert	France	No interests declared	
Anne Sagnier	Expert	France	No interests declared	
Anne-Marie Jacques	Expert	France	No interests declared	
Tiphaine Moreac-Pesselier	Expert	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Pascale Macours	Expert	France	No interests declared	
Helena Back	Expert	Sweden	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Rhona McHugh	Expert	Ireland	No interests declared	
Alice Blennerhassett	Expert	Ireland	No interests declared	
Hannah Pratt	Expert	Ireland	No interests declared	
Alma Moffett	Expert	Ireland	No interests declared	
Sandra-Maria Wienhold	Expert	Germany	No interests declared	
Miriam Schrader	Expert	Germany	No interests declared	
Juliane Bauch	Expert	Germany	No interests declared	
Jan Brosda	Expert	Germany	No interests declared	
Maren Osmers	Expert	Germany	No interests declared	
Katja Boxberger	Expert	Germany	No interests declared	
Svenja Rieke	Expert	Germany	No interests declared	
Jens Schönfeld	Expert	Germany	No interests declared	
Jana Fluksova	Expert	Czech Republic	No interests declared	
Radka Smitalova	Expert	Czech Republic	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Maria Jose Ferrer	Expert	Spain	No interests declared	
Nuria Sanchez Ranchel	Expert	Spain	No interests declared	
Rocio Fernandez Granda	Expert	Spain	No interests declared	
Raul Belmar Liberato	Expert	Spain	No restrictions applicable to this meeting	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Beatriz Martinez	Expert	Spain	No interests declared	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard
ERAWP	Ricardo Carapeto García
PhVWP-V	James Mount
IWP	Esther Werner
EWP	Cristina Muñoz Madero
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
A representative from the European Commission attended the meeting.	

CVMP working parties and CMDv	Chair
An observer from SwissMedic (Switzerland) attended the meeting.	
Meeting run with support from the relevant EMA staff.	

Experts' declared interests were evaluated against the agenda topics or activities they participated in.