11 March 2025
EMA/CVMP/125927/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 11-13 March 2025 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 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 11-13 March 2025

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

Cristina Muñoz Madero gave a proxy to Ricardo Carapeto García for the whole March 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 February 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+EDS - infectious bronchitis, Newcastle disease and egg drop syndrome virus vaccine (inactivated) - EMEA/V/C/006522/0000 – 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);
- reduction of mortality and clinical signs caused by Newcastle disease virus (NDV);
- reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV).

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, peer review comments and comments from a CVMP member.

2.1.2. Prevestrus vet – finrozole – EMEA/V/C/006235/0000 – dogs

Indication: To shorten the pro-oestrus and oestrus period, reduce clinical signs of heat and reduce the risk of pregnancy.

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, a peer review report and comments from a CVMP member.

2.1.3. Prazivetin – praziquantel - EMEA/V/C/006247/0000 – sea bream

Indication: For the treatment of ectoparasitic infestations of the gills caused by the monogenean *Sparicotyle chrysophrii.*

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, peer review reports and comments from a CVMP member.

2.1.4. Hepizovac – Epizootic haemorrhagic disease vaccine (inactivated) - EMEA/V/C/006592/0000 – cattle

Indication: For the active immunisation of cattle to prevent viraemia caused by serotype 8 of the epizootic Haemorrhagic disease virus.

Exceptional circumstances

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, peer review reports and comments from CVMP members.

2.2. Oral explanations

2.2.1. EMEA/V/C/006230/0000 – cats

Action: Oral explanation

The Committee noted the rapporteurs' assessment of responses to list of outstanding issues, comments on the product information and the presentation from the applicant.

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006332/0000 – dogs

Action: For decision

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

Action: For adoption

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

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

2.3.2. EMEA/V/C/006336/0000 – pigs

Action: For decision

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

Action: For adoption

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

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

2.3.3. EMEA/V/C/006358/0000 – dogs

Action: For decision

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

Action: For adoption

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

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

2.4. List of questions

2.4.1. EMEA/V/C/006520/0000 – cats

Action: For adoption

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

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

2.5. Re-examinations of CVMP opinions

There were no items for discussion.

2.6. Other issues

There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Rheumocam – meloxicam - EMEA/V/C/000121/VRA/0038 – cats

Variation requiring assessment: To add a new strength: 2 mg/ml solution for injection for cats.

Rapporteur: S. Louet, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the CVMP opinion, 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. Veraflox – pradofloxacin - EMA/VRA/0000236570 – dogs and cats

Variation requiring assessment: To align the product information with version 9.0 of the QRD template and the CVMP Guideline on the SPC for antimicrobial medicinal products (EMA/CVMP/383441/2005-Rev.1 Corr) and to update the MIC data available in the SPC.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.1.3. Osurnia – terbinafine / florfenicol / betamethasone acetate- EMA/VRA/0000247996 – dogs

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

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.2. Oral explanations

There were no items for discussion.

3.3. List of outstanding issues

3.3.1. Nobivac L4, Nobivac LoVo L4 - canine leptospirosis vaccine (inactivated) - WS/2673 – dogs

Variation requiring assessment: To implement the following changes: G.I.7 – change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one. G.I.4 – addition of associated non-mixed use.

Rapporteur: E. Dewaele, Co-Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of outstanding issues and the comments on the product information for Nobivac L4 and Nobivac LoVo L4.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.3.2. NexGard Combo – esafoxolaner / eprinomectin / praziquantel – EMEA/V/C/005094/VRA/0012/G – cats

Variation requiring assessment: Change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one.

Rapporteur: A. Golombiewski, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

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

3.4. List of questions

3.4.1. Poulvac E. coli – avian colibacillosis vaccine (live) - EMA/VRA/0000243824 – chickens

Variation requiring assessment: To add new information to the product information.

Rapporteur: E. Werner, Co-Rapporteur: E. Augustynowicz

Action: For adoption

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

3.4.2. Stronghold Plus – selamectin / sarolaner – EMA/VRA/0000243880 – cats

Variation requiring assessment: Change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one.

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

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.

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

5.1.1. Signal evaluation and recommendations

Action: For adoption

The Committee adopted the outcomes of the signal management processes presented during the meeting.

The Committee noted the format for monthly signal outcomes going forward, the process signal management and the draft assessment report template.

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

There were no items for discussion.

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)

There were no items for discussion.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Election for chair of ERAWP

Action: For election

The committee noted that no nomination has been received. The call will be extended another month.

6.2.2. Verbal report on ERAWP meeting held on 20-21 February 2025

Action: For information

The Committee received a verbal report on the ERAWP meeting held on 20–21 February 2025 and noted the agenda of that meeting, together with the minutes from the meeting held on 16–17 October 2024.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Appointment of new EWP-V members

Action: For endorsement

The Committee endorsed the selection committee recommendation to CVMP regarding the appointment of Bryan Deane and Jens Barthel as new EWP-V members.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion.

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 NTWP member

Action: For decision

The Committee endorsed the procedure and timetable for the call for nominations for a new expert following the resignation of Dr. Susana Casado.

6.6.2. Verbal report on NTWP meeting held on 18 February 2025

Action: For information

The Committee received a verbal report on NTWP meeting held on 18 February 2025 and noted its agenda and the final minutes from meeting held on 26-27 September 2024.

6.7. Pharmacovigilance Working Party (PhVWP-V)

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

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 26 February 2025 and noted its final agenda together with its draft summary record.

6.7.2. Revised PhVWP-V mandate

Action: For adoption

The Committee adopted the revised PhVWP-V mandate.

6.7.3. Appointment of operational expert group (OEG) on surveillance

Action: For endorsement

The Committee endorsed the procedure and timetable for the establishment of the operational expert group on surveillance.

6.8. Quality Working Party (QWP)

6.8.1. Appointment of new QWP member

Action: For endorsement

The Committee noted the recommendation from the Quality Domain Governance members and endorsed the appointment of A. Montón Silva as the new QWP member.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 7 March 2025

Action: For information

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

6.9.2. Information on forthcoming election of a new member of SAWP-V

Action: For information

The Committee was informed that an election for a new member of SAWP-V will be held at the April CVMP meeting following the resignation of Dr. Susana Casado. A call for nominations will be launched after the March CVMP meeting.

6.10. Safety Working Party (SWP-V)

There were no items for discussion.

6.11. Other working party and scientific group issues

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

Action: For adoption

The Committee adopted the first annual surveillance report on European sales and use of antimicrobials for veterinary medicine (ESUAvet) with 2023 data.

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.

7.5.1. EMEA/V/VAMF/0011

Action: For adoption

The Committee adopted the VAMF evaluation report and the list of questions.

7.5.2. EMEA/V/VAMF/00012

Action: For adoption

The Committee adopted the VAMF evaluation report and the list of questions.

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.

7.6.1. EMEA/V/PTMF/0003

Action: For adoption

The Committee adopted the vPTMF Assessment report.

Action: For endorsement

The Committee endorsed the vPTMF certificate.

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

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

9.1.1. Request for classification

Action: For classification

The Committee classified a veterinary medicinal product for cats as not intended for a limited market according to Article 4(29) and not eligible for authorisation according to Article 23 (Applications for limited markets).

9.1.2. Request for classification

Action: For classification

The Committee classified a veterinary medicinal product for European seabass as intended for a limited market according to Article 4(29) and not eligible for authorisation according to Article 23 (applications for limited markets).

9.1.3. Request for classification

Action: For classification

The Committee classified a veterinary medicinal product for common carp as intended for a limited market according to Article 4(29) and eligible for authorisation according to Article 23 (Applications for limited markets).

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

10. Organisational and strategic matters

11. CMDv

11.1. Verbal report from Chair of CMDv on the CMDv plenary meetings held on 23-24 January and 19-20 February 2025

Action: For information

The Committee received the verbal report from Chair of CMDv on the CMDv plenary meetings held on 23-24 January and 19-20 February 2025.

The Committee noted the draft agenda of the CMDv meeting to be held on 19 and 20 March 2025.

12. Legislation

12.1. 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 information

The Committee received a verbal report from the expert group's chair 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). Discussion of the report is expected at the April CVMP plenary followed by its adoption at the May CVMP meeting.

The Committee noted the minutes of the meeting held on 29 January 2025, the minutes of the meeting held on 17 February 2025 together with the agenda of meeting held on 24 February 2025.

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights link

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Quadrisol – vedaprofen - EMEA/V/C/000032/VRA/0040 – horses

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

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Sevohale – sevoflurane - EMA/VRA/0000236258 – dogs, cats

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

Rapporteur: J. G. Beechinor

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Bravecto – fluralaner - EMA/VRA/0000248764 – dogs

Variation requiring assessment: Quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

EMEA/V/C/WS2760 – Forceris, Gleptosil – pigs

Variation requiring assessment: Quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Sevohale – sevoflurane - EMA/VRA/0000247321 – dogs, cats

Variation requiring assessment: Quality-related changes.

Rapporteur: J.G. Beechinor

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

EMEA/V/C/WS2768 – Porcilis ColiClos, Porcilis Porcoli Diluvac Forte, Porcilis AR-T DF – pigs

Variation requiring assessment: Quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.4. List of questions

Mirataz – mirtazapine - EMA/VRA/0000243883 – cats

Variation requiring assessment: Quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the rapporteur's assessment report including List of questions and the product information.

Melovem – meloxicam - EMA/VRA/0000244473– cattle, horses, pigs

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

Rapporteur: R. Breathnach

Action: For adoption

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

Profender – praziquantel / emodepside - EMA/VRA/0000243831– cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

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

Oncept IL-2 – active Canarypox virus, strain vCP1338, expressing feline interleukin-2 gene, live - EMA/VRA/0000244261 – cats

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

Rapporteur: C. Miras

Action: For adoption

The Committee adopted the List of questions, comments on product information.

Action: For endorsement

The Committee endorsed the assessment report.

DogStem – equine umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244394 – 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, comments on product information.

Action: For endorsement

The Committee endorsed the assessment report.

HorStem – equine allogeneic umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244486 – horses

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

Rapporteur: A. C. Golombiewski

Action: For adoption

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

Action: For endorsement

The Committee endorsed the assessment report.

EMA/VRA/0000225508 (WS) - Tulaven (Tulapro) – tulathromycin -– cattle, pigs, sheep

Variation requiring assessment: Quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of questions.

3.6 Other issues

Corrigendum to opinion - Suvaxyn PRRS MLV - Porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0013/G – pigs

Variation requiring assessment: To add a 100-dose presentation with a volume of 0.5 ml per dose/ Quality-related changes.

Rapporteur: E. Werner

SL: J. Pozo

Action: For adoption

The Committee adopted the corrigendum of CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the Rapporteur's assessment report.

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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.

6.5 3Rs Working Party (3RsWP)

Minutes of the OEG - 3RsWP - Batch release testing meeting held on 18 October 2024

Action: For information

Agenda of the OEG - 3RsWP - Batch release testing meeting held on 28 January 2025

Action: For information

Draft Agenda of the 3RsWP Stakeholder Meeting to be held 2 April 2025

Action: For information

The Committee noted the draft agenda 3RsWP Stakeholder meeting to be held 2 April 2025.

NC and NAMs ESEC nominations

Action: For information

The Committee noted the NC and NAMs ESEC 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.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

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

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 March 2025 meeting, which was held in person.

An asterisk (*) after the role, in the second column, signals that the participant attended in virtually. 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	
Leona Nepejchalová	Member	Czechia	No interests declared	
Niels Christian Kyvsgaard	Member	Denmark	No interests declared	
Merete Blixenkrone-Møller*	Alternate	Denmark	No interests declared	
Minna Leppänen	Member	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	
Esther Werner*	Alternate	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No participation in discussions, final deliberations and voting on: Boehringer Ingelheim	7.6.1. EMEA/V/PTMF/0003 3.1.2. EMEA/V/C/005094/VRA/0012/G 9.1.1. Request for classification 9.2.5. Decision on the accelerated assessment request 9.2.6. Decision on the accelerated assessment request

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Paul McNeill	Member	Ireland	No interests declared	
Jeremiah Gabriel Beechinor	Alternate	Ireland	No interests declared	
Fulvio MARSILIO	Member	Italy	No interests declared	
Renate Kuske	Alternate	Latvia	No interests declared	
Vaida Kurapkiene*	Alternate	Lithuania	No interests declared	
Caroline Coner	Member	Luxembourg	No interests declared	
Despoina Iatridou*	Alternate	Luxembourg	No interests declared	
Kim Boerkamp	Alternate	Netherlands	No interests declared	
Hanne Bergendahl	Member	Norway	No interests declared	
Ewa Augustynowicz	Member	Poland	No interests declared	
João Pedro Duarte Da Silva*	Member	Portugal	No interests declared	
Gabriela Tuchila	Member	Romania	No interests declared	
Eva Chobotová	Member	Slovakia	No interests declared	
Consuelo Rubio Montejano*	Alternate	Spain	No interests declared	
Frida Hasslung Wikström	Member	Sweden	No interests declared	
Hanna Bremer*	Alternate	Sweden	No interests declared	
Keith Baptiste	Co-opted	Denmark	No interests declared	
Rory Breathnach	Co-opted	Ireland	No interests declared	
Mary O'Grady	Co-opted	Ireland	No interests declared	
Carina Bergman	Co-opted	Sweden	No interests declared	
Ricardo Carapeto Garcia	Co-opted	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Caroline Guittre	Expert	France	No interests declared	
Mariette Salery	Expert	France	No interests declared	
Anita Bottger	Expert	Netherlands	No interests declared	
Daniel Benesh	Expert	Germany	No interests declared	
Dusan Palic	Expert	Germany	No restrictions applicable to this meeting	
Barbara Chirullo	Expert	Italy	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Gavin Ryan	Expert	Ireland	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	
Alice Blennerhassett (in person)	Expert	Ireland	No interests declared	
Catarina Eriksson	Expert	Sweden	No interests declared	
Martina Kern	Expert	Germany	No interests declared	
Wiebke Weiher	Expert	Germany	No interests declared	
Maren Osmers	Expert	Germany	No interests declared	
Katja Boxberger	Expert	Germany	No interests declared	
Werner Terhalle	Expert	Germany	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	
Svenja Rieke	Expert	Germany	No interests declared	
Roswitha Merkel	Expert	Germany	No interests declared	
Jan Pridöhl	Expert	Germany	No interests declared	
Jens Schönfeld	Expert	Germany	No interests declared	
Thea Neumann	Expert	Germany	No interests declared	
Radka Smítalová	Expert	Czech Republic	No interests declared	
Jitka Chumchalova	Expert	Czech Republic	No interests declared	
Vilma Dosedlová	Expert	Czech Republic	No interests declared	
Charlotte Smith Bonde	Expert	Denmark	No restrictions applicable to this meeting	
Trine Sidonia Jensen	Expert	Denmark	No restrictions applicable to this meeting	
John Jensen	Expert	Denmark	No interests declared	
Soes Lysgaard	Expert	Denmark	No interests declared	
Malene Nissen	Expert	Denmark	No interests declared	
Henriette Rau	Expert	Germany	No interests declared	
Alberto de Prado Lopez	Expert	Spain	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Luis Agote Casado	Expert	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Elena Lucas Roldan	Expert	Spain	No interests declared	
Francisca Moya	Expert	Spain	No interests declared	
Sonia Gil Morales	Expert	Spain	No interests declared	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Patricia Vera Luque	Expert	Spain	No interests declared	
Thomas Drapier	Expert	Belgium	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*
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)**
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
ESUAvet	Sara Sacristán Álvarez *(co-chair)**
A representative from the European Commission attended the meeting	
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.