10 June 2025
EMA/CVMP/197226/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 5-7 November 2024 meeting

Chair: J.G. 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 virtually.

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 5-7 November 2024

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

There were no contacts declared.

iv. Adoption of the minutes of the previous meeting

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

1.1.1. Substance (ketoprofen) – EMEA/V/MRL/003652/MODF/0005 – bovine, porcine, *Equidae*

Action: For adoption

The Committee adopted the CVMP opinion including EPMAR and the CVMP assessment report.

Action: For information

The Committee noted the summary of opinion.

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

1.4.1. Substance – EMEA/V/MRL/003052/MODF/0002– bovine and ovine

Action: For adoption

The Committee adopted the scientific overview including the list of questions.

1.4.2. Substance – EMEA/V/MRL/003125/MODF/0005 – all ruminants and *Salmonidae*

Action: For adoption

The Committee adopted the scientific overview including the list of questions.

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

There were no items for discussion.

Other issues

There were no items for discussion.

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

2.1.1. Carprofen Orion – carprofen – EMEA/V/C/006249/0000 – dogs, cats

Indication: dogs: for alleviation of inflammation and pain in musculoskeletal and joint disorders and after surgical operations (tablet). For perioperative alleviation of pain and inflammation especially in orthopaedic and soft tissue (including ocular) operations (solution for injection). Cats: for perioperative alleviation of pain (solution for injection).

Action: For adoption

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

The Norwegian CVMP member agrees with the above-mentioned recommendation of the CVMP.

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

2.2.1. EMEA/V/C/006306/0000 – chickens and chicken embryonated eggs

Action: Oral explanation held on 5 November 2024

The Committee adopted the rapporteurs' assessment of responses to the 2nd list of outstanding issues, the comments on the product information and noted the presentation from the applicant.

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

2.3.1. EMEA/V/C/006389/0000 – dogs, cats

Action: For decision

The Committee agreed that no oral explanation was needed.

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 reviewer report.

2.3.2. EMEA/V/C/006300/0000 – cats

Action: For decision

The Committee agreed that no oral explanation was needed.

Action: For adoption

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

The Committee noted the peer review reports and the CVMP comments.

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

2.4.1. EMEA/V/C/006480/0000 – dogs

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 one peer reviewer report and the CVMP comments.

2.4.2. EMEA/V/C/006457/0000 – dogs

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 two peer review reports and the CVMP comments.

2.4.3. EMEA/V/C/006455/0000 – dogs

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 two peer review reports and the CVMP comments.

2.4.4. EMEA/V/C/006522/0000 – chickens

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 two peer review reports and the CVMP comments.

2.4.5. EMEA/V/C/006513/0000 – cats

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 two peer review reports and the CVMP comments.

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/006230/0000 – cats

Action: For decision

The Committee agreed with the request from MAH to extend the clock stop.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. MS-H Vaccine – mycoplasma synoviae (live) - EMA/VRA/0000229456 – chickens

Variation requiring assessment: to update the pharmaceutical dose form and route of administration from ocular use to oculonasal use to align with the update of the definition of the EDQM standard term, and to amend section 3.5. of the summary of product characteristics to strengthen the warnings and clarifications on how to diagnose *M. synoviae*-free birds and on the special precaution to avoid spreading of the vaccine strain.

Rapporteur: F. Klein

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.

3.1.2. MS-H Vaccine – mycoplasma synoviae (live) - EMA/VRA/0000229769 – chickens

Variation requiring assessment: to amend section 3.5. of the summary of product characteristics to strengthen the warnings and to include a comment regarding PCR.

Rapporteur: F. Klein

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.

3.1.3. Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMA/VRA/0000221746 – dogs

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: E. Dewaele

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.

3.1.4. Rabitec – rabies vaccine (live) - EMEA/V/C/004387/VRA/0013/G – foxes, raccoon dogs and dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committed 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.

3.2. 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.

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

5.1.1. Daxocox – enflicoxib – EMA/VS/0000175158

Signal assessment

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

Action: For adoption

The Committee adopted the rapporteur's assessment report.

5.1.2. Senvelgo – velagliflozin - EMA/VS/0000225318

Annual statement assessment

Rapporteur: K. Baptiste, Co-Rapporteur: M. O'Grady

Action: For adoption

The Committee adopted the Rapporteur's assessment report.

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. 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. Concept paper for the revision of VICH GL27

Action: For adoption

The Committee adopted the concept paper for the revision of VICH GL27 - Guidance on the pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance.

6.1.2. AWP work plan for 2025

Action: For discussion

The Committee discussed the draft AWP work plan 2025.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 16-17 October 2024

Action: For information

The Committee received a verbal report on the ERAWP meeting held on 16–17 October 2024 and noted its agenda together with the minutes from the meeting held on 25–26 June 2024.

6.2.2. ERAWP work plan for 2025

Action: For discussion

The Committee discussed the draft ERAWP work plan for 2025.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 15-16 October 2024

Action: For information

The Committee received a verbal report on the EWP-V meeting held on 15-16 October 2024 and noted its agenda together with the minutes of the meeting held on 12 June 2024.

6.3.2. EWP-V work plan for 2025

Action: For discussion

The Committee discussed the draft EWP-V work plan for 2025.

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 21-22 October 2024

Action: For information

The Committee received a verbal report on the IWP meeting held on 21-22 October 2024 and noted its agenda together with the minutes of the IWP meeting held on 24-25 April 2024.

6.4.2. IWP interested parties meeting

Action: For information

The Committee noted the agenda of the IWP interested parties meeting held on 22 October 2024.

6.4.3. IWP-V work plan for 2025

Action: For discussion

The Committee discussed the draft IWP-V work plan for 2025.

6.4.4. Guideline on live recombinant vector vaccines for veterinary use

Action: For discussion

The Committee discussed the draft revised guideline on live recombinant vector vaccines for veterinary use (EMA/CVMP/IWP/390313/2023) and the overview of comments received during public consultation of the revised guideline.

6.5. 3Rs Working Party (3RsWP)

There were no items for discussion.

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2025

Action: For discussion

The Committee discussed the draft NTWP work plan for 2025.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 23 October 2024

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 23 October 2024 and noted its agenda together with the draft summary record and the agenda of the PhVWP-V meeting held on 24-25 September 2024.

6.8. Quality Working Party (QWP)

6.8.1. Guideline on stability testing for variations for VMPs

Action: For adoption

The Committee adopted the guideline on stability testing for variations for VMPs (EMA/CVMP/QWP/515653/2023) and the overview of comments (EMA/CVMP/QWP/416589/2024) received during the public consultation.

6.8.2. QWP workplan for 2025-2027

Action: For discussion

The Committee discussed the draft QWP work plan for 2025-2027.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 4 November 2024

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 4 November 2024 and noted its agenda together with the final minutes of the SAWP-V meeting held on 4 October 2024.

6.9.7. SAWP-V work plan for 2025

Action: For discussion

The Committee discussed the draft SAWP-V work plan for 2025.

6.10. Safety Working Party (SWP-V)

6.10.1. Safety WP work plan for 2025

Action: For discussion

The Committee discussed the draft SWP work plan 2025.

6.11. Other working party and scientific group issues

6.11.1. ESUAvet annual report draft outline

Action: For adoption

The Committee adopted the ESUAvet annual report draft outline on antimicrobial sales and use data in animals linked to Article 57 of Regulation (EU) 2019/6.

6.11.2. ESUAvet WG work plan for 2025

Action: For discussion

The Committee discussed the ESUAvet WG work plan for 2025.

6.11.3. Draft Work Plan for the drafting group on veterinary biosimilars

Action: For discussion

The Committee discussed the draft work plan for the drafting group on veterinary biosimilars.

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

7.4. Pharmacovigilance

There were no items for discussion.

7.5. Vaccine antigen master file (VAMF) certification

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.

7.6.1. EMEA/V/VPTMF/0001

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

CVMP classified the veterinary medicinal product for dogs as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

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

9.3. Regulatory matters

There were no items for discussion.

10. Organisational and strategic matters

10.1. Identification of expertise for the upcoming appointment of co-opted members

Action: For adoption

The Committee noted the CVMP list of expertise and agreed on the CVMP expertise required for two co-opted members.

10.2. CVMP work plan 2025

Action: For adoption

The Committee adopted the CVMP work plan for 2025.

10.3. P-SMEG final report and process recommendations

Action: For endorsement

The Committee endorsed the P-SMEG final report and process recommendations.

10.4. Update on the signal management process for CAPs

Action: For information

The Committee received a verbal update on the signal management process for CAPs and noted the template for rapporteur's assessment report for signals.

11. CMDv

11.1 Verbal report from the CMDv Chair on the meetings held on 19-20 September and 17-18 October 2024

Action: For information

The Committee received a verbal report from the CMDv Chair on the meetings held on 19-20 September and 17-18 October 2024 and noted the draft agenda of the CMDv meeting to be held on 14-15 November 2024, the agenda of the CMDv meeting held on 17-18 October 2024 together with the minutes of the CMDv Interested parties meeting held on 31 May 2024.

12. Legislation

12.1. Revision of the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products

Action: For adoption

The Committee adopted the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products and the overview of comments received during public consultation.

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 information

The Committee received a verbal report from the expert group's chair and noted the minutes of the meeting held on 4 October 2024, the minutes of the meeting held on 14 October 2024; together with the agenda of the meeting held on 28 October 2024.

12.3. QRD template update to version 9.1

Action: For adoption

The Committee adopted the QRD veterinary product-information ANNOTATED template version 9.1.

12.4. Implementation plan for the QRD template version 9.1

Action: For information

The Committee noted the implementation plan for the QRD template version 9.1.

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

Rexxolide – tulathromycin – EMA/VRA/0000221089 – cattle, pigs, sheep

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

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 rapporteur's assessment report.

Equisolon – prednisolone - EMEA/V/C/002382/VRA/0012 - horses

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

Rapporteur: N.C. Kyvsgaard

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.

Baycox Iron – toltrazuril / iron(III) ion - EMA/VRA/0000230683 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

The Committee adopted the CVMP opinion and the CVMP assessment report.

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

WS2730 – Eurican L4, Eurican DAPPI LMULTI, Eurican LMULTI, Eurican DAP LMULTI - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Kollár-Nagy

Action: For adoption

The Committee adopted the CVMP opinion and the Annex B.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.1.5. RenuTend – tesrivetcel - EMEA/V/C/005428/VRA/0005/G – horses

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

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.

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

Profender – praziquantel / emodepside – EMEA/V/C/000097/VRA/0056/G – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of outstanding issues.

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

Hydrocortisone aceponate Ecuphar – hydrocortisone aceponate - EMA/VRA/0000166782 – dogs

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

Rapporteur: S. Louet

Action: For adoption

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

Clevor – ropinirole - EMA/VRA/0000227231 – 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.

Bluevac BTV – bluetongue virus vaccine (inactivated) - EMEA/V/C/000156/VRA/0013– cattle, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the list of questions.

Quadrisol – vedaprofen – EMEA/V/C/000032/VRA/0039 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of questions.

Strangvac – Streptococcus equi vaccine (recombinant proteins) – EMEA/V/C/005309/VRA/0008/G – horses

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

The Committee adopted the list of questions.

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

Rabitec – EMEA/V/C/004387/REC/013

Rapporteur: E. Werner

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.

6.5. 3Rs Working Party (3RsWP)

Minutes of the tOEG - 3RsWP - Batch release testing meeting held on 6 September 2024

Action: For information

The Committee noted the minutes of the tOEG - 3RsWP - Batch release testing meeting held on 6 September 2024.

Agenda of the tOEG - 3RsWP - Batch release testing meeting held on 18 October 2024

Action: For information

The Committee noted the agenda of the tOEG - 3RsWP - Batch release testing meeting held on 18 October 2024.

Agenda of the New Approach Methodologies ESEC webinar held on 16 October 2024

Action: For information

The Committee noted the agenda of the New Approach Methodologies ESEC webinar held on 16 October 2024.

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

VICH Revision of VICH GLs 7, 12, 13, 14, 15, 16, 19, 20, 21 on efficacy of anthelmintics

Action: For adoption

The Committee adopted the final guidelines for publication: VICH GL7(R) on Efficacy of anthelmintics – general requirements

VICH GL12(R) on Efficacy of anthelmintics – specific recommendations for bovines

VICH GL13(R) on Efficacy of anthelmintics – specific recommendations for ovines

VICH GL14(R) on Efficacy of anthelmintics – specific recommendations for caprines

VICH GL15(R) on Efficacy of anthelmintics – specific recommendations for equines

VICH GL16(R) on Efficacy of anthelmintics – specific recommendations for porcines

VICH GL19(R) on Efficacy of anthelmintics – specific recommendations for canines

VICH GL20(R) on Efficacy of anthelmintics – specific recommendations for felines

VICH GL21(R) on Efficacy of anthelmintics – specific recommendations for chickens

VICH Revision of VICH GL8 Stability testing for medicated premixes

Action: For endorsement

The Committee endorsed the revised VICH GL8 on Stability testing for medicated premixes for sign off at step 3 by Steering Committee for public consultation.

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**	**Full involvement**	
Petra Falb	Member	Austria	No interests declared	
Manuela Leitner*	Alternate	Austria	No interests declared	
Els Dewaele	Member	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	
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	
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	EMA/VS/0000225318 WS2730 EMEA/V/C/005428/VRA/0005/G
Paul McNeill	Member	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Zanda Auce	Member	Latvia	No interests declared	
Caroline Coner	Member	Luxembourg	No interests declared	
Despoina Iatridou*	Alternate	Luxembourg	No interests declared	
Jacqueline Poot	Member	Netherlands	No interests declared	
Kim Boerkamp	Alternate	Netherlands	No interests declared	
Hanne Bergendahl	Member	Norway	No interests declared	
Anna Wachnik-Święcicka*	Member	Poland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
João Pedro Duarte Da Silva*	Member	Portugal	No interests declared	
Gabriela Tuchila	Member	Romania	No interests declared	
Katarina Massányiová	Alternate	Slovakia	No interests declared	
Katarina Straus*	Member	Slovenia	No interests declared	
Urska Peunik*	Alternate	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Frida Hasslung Wikström	Member (Vice-Chair)	Sweden	No interests declared	
Hanna Bremer	Alternate	Sweden	No interests declared	
Keith Baptiste	Co-opted	Denmark	No interests declared	
Ricardo Carapeto García	Co-opted	Spain	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Dusan Palic	Expert	Germany	No restrictions applicable to this meeting	
Guillaume Grach	Expert	France	No restrictions applicable to this meeting	
Anne-Marie Jacques	Expert	France	No interests declared	
Anne Sagnier	Expert	France	No interests declared	
Florence Pillet	Expert	France	No interests declared	
Trine Sidonia Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Frida Martin	Expert	Sweden	No interests declared	
Jukka Pakkanen	Expert	Finland	No interests declared	
Hanna Kankkonen	Expert	Finland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Tommi Nurminen	Expert	Finland	No interests declared	
Stella Attia	Expert	Finland	No interests declared	
Kathrin Schirmann	Expert	Germany	No interests declared	
Christine Schwarz	Expert	Germany	No interests declared	
Ana Isabel Olías Molero	Expert	Spain	No interests declared	
Christopher Janich	Expert	Germany	No interests declared	
Michel Goret	Expert	Belgium	No interests declared	
Judith Romberg	Expert	Germany	No interests declared	
Brigitte Kuechler	Expert	Germany	No interests declared	
Monika Hofmann	Expert	Germany	No interests declared	
Dagmar Sommer	Expert	Germany	No interests declared	
Rosario Bullido	Expert	Spain	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Francisca Moya	Expert	Spain	No interests declared	
Luis González Rivas	Expert	Spain	No interests declared	
Raul Belmar Liberato	Expert	Spain	No interests declared	
Belén Gutiérrez	Expert	Spain	No interests declared	
Susana Casado	Expert	Spain	No interests declared	
Jesus Alberto Sanchez Rodriguez	Expert	Spain	No interests declared	
Beatriz Corcho	Expert	Spain	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Gavin Ryan	Expert	Ireland	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Rhona McHugh	Expert	Ireland	No interests declared	
Tatyana Devine	Expert	Ireland	No interests declared	
Uta Herbst	Expert	Germany	No interests declared	
Daniel Benesh	Expert	Germany	No interests declared	
Anke Finnah	Expert	Germany	No interests declared	
Jan Brosda	Expert	Germany	No interests declared	
Antje Gerofke	Expert	Germany	No interests declared	
Roswitha Merkel	Expert	Germany	No interests declared	
Svenja Rieke	Expert	Germany	No interests declared	
Werner Terhalle	Expert	Germany	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	
Malin Öhlund	Expert	Sweden	No interests declared	
Kirsten Thomsen	Expert	Denmark	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Anja Silke Christensen	Expert	Denmark	No interests declared	
Susanne Havn Aamand	Expert	Denmark	No interests declared	
Eva Pomezna	Expert	Czech Republic	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
3Rs (J3RsWP)	Sarah Adler-Flindt *(veterinary vice chair)**
ESUAvetWG	Sara Sacristán*
CMDv	Laetitia Le Letty*
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.