11 February 2025
EMA/CVMP/15527/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 3-5 December 2024 meeting

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

Note on access to documents

Some documents mentioned in the minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

The meeting was held 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 3-5 December 2024

The attendance list was completed and competing interests were identified for the December 2024 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters discussed (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I).

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

iv. Adoption of the minutes of the previous meeting

The minutes of the December 2024 meeting will be adopted at the January 2025 meeting.

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

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

1. Maximum residue limits

1.1. Opinions

There were no items for discussion.

1.2. Oral explanations

There were no items for discussion.

1.3. List of outstanding issues

There were no items for discussion.

1.4. List of questions

There were no items for discussion.

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

There were no items for discussion.

1.6. Other issues

There were no items for discussion.

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

2.1.1. Icthiovac ERM – inactivated vaccine against yersiniosis - EMEA/V/C/006309/0000 – Atlantic salmon

Indication: vaccine intended for the active immunisation against yersiniosis in Atlantic salmon to reduce the mortality caused by O1BT1, O2BT1 and O1BT2 strains of *Yersinia ruckeri*.

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 and the comments from CVMP members.

2.1.2. Poulvac Procerta HVT-IBD-ND – Live recombinant turkey herpes virus, strain HVT-IBD-ND, expressing the VP2 protein of IBDV and the F protein of NDV - EMEA/V/C/006306/0000 – chickens and chicken embryonated eggs

Indication: vaccine intended for active immunisation of one day old chickens and 18-19-day old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus; reduce mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus; and reduce mortality and clinical signs caused by Newcastle disease (ND) virus.

Action: For adoption

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

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

Action: For endorsement

The Committee endorsed the vPTMF certificate.

Action: For information

The Committee noted the summary of opinion and the comments from peer reviewers.

2.1.3. Tolfenamic acid VMD – tolfenamic acid – EMEA/V/C/006234/0000 – cattle, pigs, dogs, cats

Indication: NSAID used as adjunct in the treatment of pneumonia and acute mastitis (cattle), adjunct in the treatment of metritis mastitis agalactia syndrome (pigs), symptomatic treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems and reduction of post-surgical pain (dogs) and treatment of febrile syndromes (cats).

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 and the peer review comments.

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

There were no items for discussion.

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

2.3.1. EMEA/V/C/006235/0000 – dogs

Action: For decision

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

Action: For adoption

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

Action: For information

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

2.3.2. EMEA/V/C/006247/0000 – sea bream

Action: For decision

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

Action: For adoption

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

Action: For information

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

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

2.4.1. EMEA/V/C/005890/0000 – cats

Action: For adoption

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

Action: For information

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

2.4.2. EMEA/V/C/006535/0000 - dogs

Action: For adoption

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

Action: For information

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

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

There were no items for discussion.

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

There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Librela – bedinvetmab - EMA/VRA/0000234237 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process. In addition, the MAH took this opportunity to update the list of local representatives/contact details to report suspected adverse reactions in the package leaflet and to introduce editorial changes to the product information.

Rapporteur: F. Hasslung Wikström

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 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

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

Variation requiring assessment: to modify the therapeutic indications.

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

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 under Regulation (EU) 2019/6

There were no items for discussion.

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

3.6.1. Vectra 3D – dinotefuran / pyriproxyfen / permethrin - EMEA/V/C/002555/VRA/0026/G – dogs

Variation requiring assessment: to add a new therapeutic indication and to update the pharmacodynamics section of the SPC.

Rapporteur: A. Golombiewski, Co-Rapporteur: H. Bremer

Action: For information

The Committee noted the letter of withdrawal of the application from the marketing authorisation holder.

4. Referrals and related procedures

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

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

4.7. Other issues

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

There were no items for discussion.

4.7.1. Referrals under Regulation (EU) 2019/6

There were no items for discussion.

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

There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

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

5.1. Pharmacovigilance under Regulation (EU) 2019/6

5.1.1. Librela – bedinvetmab - EMA/VRA/0000234237 – dogs

Signal assessment

Rapporteur: F. Hasslung Wikström, Co-Rapporteur: J. Poot

Action: For adoption

The Committee adopted the rapporteur's assessment report.

5.1.2. Senvelgo – velagliflozin - EMA/VS/0000225318 - cats

Annual statement assessment

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

Action: For re-adoption

The Committee re-adopted the CVMP assessment report.

5.1.3 Targeted signal management (TSM) report for injectable veterinary medicinal products and anaphylactic reactions in cattle

Final TSM Report

Action: For adoption

The Committee adopted the final 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)

6.1.2. AWP work plan for 2025

Action: For adoption

The Committee adopted the AWP work plan for 2025.

6.1.3. Verbal report on AWP meeting held on 26-27 November 2024

Action: For information

The Committee received a verbal report on the AWP meeting held on 26-27 November 2024, noting its draft agenda.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. ERAWP work plan for 2025

Action: For adoption

The Committee adopted the ERAWP work plan for 2025.

6.2.2. Update of relevant guidance documents in order to align them with provisions outlined in Regulation (EU) 2019/6

Action: For adoption

The Committee adopted the revised 'Guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater'.

6.3. Efficacy Working Party (EWP-V)

6.3.2. EWP-V work plan for 2025

Action: For adoption

The Committee adopted the EWP-V work plan for 2025.

6.4. Immunologicals Working Party (IWP)

6.4.1. Guideline on live recombinant vector vaccines for veterinary use

Action: For adoption

The Committee adopted the revised guideline on live recombinant vector vaccines for veterinary use and the overview of comments from public consultation. This revised guideline has been developed to provide advice on the data to be presented in applications for a marketing authorisation for veterinary live recombinant vector vaccines, taking into account the scientific and regulatory developments and experience gained since the previous version of the guideline was published. The revised guideline will come into effect in June 2025.

6.4.2. Concept paper for the revision of the Guideline on the requirements for combined vaccines and associations of IVMPs

Action: For adoption

The Committee adopted the concept paper for the revision of the guideline on the requirements for combined vaccines and associations of IVMPs for release for a 3-month period of public consultation.

6.4.3. Concept paper for the development of a Guideline on quality aspects of mRNA vaccines for veterinary use

Action: For adoption

The Committee adopted the concept paper for the development of a guideline on quality aspects of mRNA vaccines for veterinary use for release for a 3-month period of public consultation.

6.4.4. IWP-V work plan for 2025

Action: For adoption

The Committee adopted the IWP-V work plan for 2025.

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP meeting and nominations

Action: For decision

The Committee endorsed the nomination of new members.

Action: For information

The Committee received a verbal report on the 3RsWP meeting held on 20-21 November 2024, noting its draft agenda.

6.5.2. 3Rs WP work plan for 2025-2027

Action: For discussion

The Committee discussed the NC-Domain workplan for 2025-2027.

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. NTWP work plan for 2025

Action: For adoption

The Committee adopted the NTWP work plan for 2025.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 26-27 November 2024 and noted its agenda and draft summary report.

6.7.2. PhVWP-V workplan for 2025

Action: For adoption

The Committee adopted the PhVWP-V workplan for 2025.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (October and November 2024)

Action: For information

The Committee received a verbal report on the QWP meetings held on 7-8 October and 4-5 November 2024 and noted the agendas of these meetings and the minutes of the meetings held on 7-8 October and 9-11 September 2024.

6.8.2. QWP workplan for 2025-2027

Action: For adoption

The Committee adopted the QWP workplan for 2025-2027.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 29 November 2024

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 29 November 2024 and noted the final minutes of the SAWP-V meeting held on 4 November 2024.

6.9.3. SAWP-V work plan for 2025

Action: For adoption

The Committee adopted the SAWP-V work plan for 2025.

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 14-15 November 2024

Action: For information

The Committee received a verbal report on the SWP-V meeting held on 14-15 November 2024 and noted the minutes of the meeting held on 27-28 June 2024.

6.10.2. SWP-V work plan 2025

Action: For adoption

The Committee adopted the SWP-V work plan 2025.

6.11. Other working party and scientific group issues

6.11.1. Verbal report on the ESUAvet WG meeting held on 14-15 November 2024

Action: For information

The Committee received a verbal report on the ESUAvet WG meeting held on 14-15 November 2024 and noted the minutes of the meeting held on 5 September 2024.

6.11.2. ESUAvet WG work plan for 2025

Action: For adoption

The Committee adopted the ESUAvet WG work plan for 2025.

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

7.2. Environmental risk assessment

There were no items for discussion.

7.3. Antimicrobial resistance

7.3.1. Scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp.

Action: For adoption

The Committee adopted the scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp.

7.3.2. CVMP Strategy on antimicrobials 2026-2030

Action: For discussion

The Committee discussed the CVMP Strategy on antimicrobials 2026-2030.

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.

7.6.1. EMEA/V/PTMF/0003

Action: For adoption

The Committee adopted the assessment report with list of questions.

The Committee noted the comments from a peer reviewer.

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

8.1.2. Feedback from VICH Steering Committee, Forum and Conference meetings of 10-15 November 2024

Action: For information

The Committee noted the report from Steering Committee and Forum meetings of 10-15 November 2024.

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

10.2. Verbal report on Veterinary Domain meeting held on 22 October 2024

Action: For information

The Committee received a verbal report on the Veterinary Domain meeting held on 22 October 2024, and noted the agenda of the meeting and the minutes of the 3 July 2024 meeting.

10.3. Consolidated 3-year work plan for the veterinary domain (2025-2027)

Action: For adoption

The Committee adopted the consolidated 3-year work plan for the veterinary domain (2025-2027).

10.4. P-SMEG final report and signal management process recommendations

Action: For information

The Committee noted the P-SMEG final report and the recommendations for processes related to signal management and surveillance.

11. CMDv

There were no items for discussion.

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).

12.2 Update with regards the scientific advice on Article 115(5) of Regulation (EU) 2019/6 - list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months

Action: For information

The Committee noted the feedback from the discussion of the advice at the Standing Committee meeting of 27 November 2024.

13. Any other business

13.2. Meeting highlights

Action: For comments

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

Annex

1. Maximum residue limits

1.6. Other issues

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

Action: For information

2. Marketing authorisations

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

EMEA/V/C/005902 – dogs

Action: For decision

The Committee agreed to the request from the applicant for a further extension of the clock stop.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

NexGard Combo – esafoxolaner / eprinomectin / praziquantel - EMEA/V/C/005094/VRA/0009 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion.

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

Osurnia – terbinafine / florfenicol/ betamethasone acetate – EMEA/V/C/003753/VRA/0026/G – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the CVMP opinion.

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

Bonqat – pregabalin – EMEA/V/C/005489/VRA/0006 – cats

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

Rapporteur: M. O'Grady

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.

EMEA/V/C/WS2703 - Zeleris, Florkem – cattle, cattle and pigs

Variation requiring assessment: quality related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

WS2753 - Prevexxion RN+HVT, Prevexxion RN+HVT+IBD, Prevexxion RN – Marek's disease vaccine (live recombinant) infectious bursal disease and Marek's disease vaccine (live recombinant) - Marek's disease vaccine (live recombinant) – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

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.

Pexion – imepitoin – EMEA/V/C/002543/VRA/0018 – 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 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.

Ecoporc Shiga – genetically modified STx2e antigen vaccine - EMEA/V/C/002588/VRA/0014 – pigs

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.

Cerenia – maropitant / maropitant citrate – EMEA/V/C/000106/VRA/0046 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

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 under Regulation (EU) 2019/6

Fortekor Plus – pimobendane / benazepril hydrochloride – EMEA/V/C/002804/VRA/0024 – dogs

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 list of questions and the comments on the product information.

ProZinc – insulin human - EMEA/V/C/002634/VRA/0030 – cats and 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.

Increxxa – tulathromycin - EMA/VRA/0000231564 – cattle, pigs and sheep

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 the comments on the product information.

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

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

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

Cardalis – benazepril hydrochloride / spironolactone - EMEA/V/C/002524/VRA/0015 – 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.

Sileo – dexmedetomidine hydrochloride - EMEA/V/C/003764/VRA/0026 – dogs

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

Rapporteur: H. Bremer

Action: For adoption

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

Felpreva – tigolaner / emodepside / praziquantel - EMA/VRA/0000227250 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of outstanding issues, included in the rapporteur assessment report.

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

RESPIVAC aMPV – EMEA/V/C/006160/REC/001

Post-authorisation recommendation

Rapporteur: E. Werner

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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)

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.

6.11. Other working party and scientific group issues

Nomination to the new HMA/EMA Joint Network Data Steering Group

Action: For information

The Committee noted the nomination to HMA/EMA Joint Network Data Steering Group.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

Revision of VICH GL8 on Stability testing for medicated premixes

Action: For adoption

The Committee adopted the VICH GL8(R) on Stability testing for medicated premixes.

VICH status of guidelines

Action: For information

The Committee noted the VICH status of guidelines.

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

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 12-13 December 2024; the final agenda of the CMDv meeting held on 14-15 November 2024; the final agenda of the Joint CMDh/CMDv meeting held on 14 November 2024; and the final minutes of the CMDv meeting held on 19-20 September 2024.

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the December 2024 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.

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie***	**Full involvement**	
Austria	Petra Falb	Full involvement	
Austria	Manuela Leitner	Full involvement	
Belgium	Els Dewaele	Full involvement	
Belgium	Frederic Klein	Full involvement	
Bulgaria	Krasimir Zlatkov	Full involvement	
Bulgaria	Nadya Ognyanova Vladimirova	Full involvement	
Croatia	Frane Božić	Full involvement	
Croatia	Hrvoje Pavasovic	Full involvement	
Czechia	Leona Nepejchalová	Full involvement	
Denmark	Niels Christian Kyvsgaard	Full involvement	
Denmark	Merete Blixenkrone-Møller	Full involvement	
Estonia	Toomas Tiirats	Full involvement	
Finland	Minna Leppänen	Full involvement	
France	Sylvie Louet	Full involvement	
France	Christine Miras	Full involvement	
Germany	Andrea Christina Golombiewski	Full involvement	
Germany	Esther Werner	Full involvement	
Greece	Spyridon Farlopoulos	Full involvement	
Hungary	Gábor Kulcsár	Full involvement	
Ireland	Paul McNeill	Full involvement	
Italy	Fulvio Marsilio	Full involvement	
Luxembourg	Despoina Iatridou	Full involvement	
Luxembourg	Caroline Coner	Full involvement	
Netherlands	Jacqueline Poot	Full involvement	
Netherlands	Kim Boerkamp	Full involvement	
Norway	Hanne Bergendahl	Full involvement	
Poland	Anna Wachnik-Święcicka	Full involvement	
Portugal	João Pedro Duarte Da Silva	Full involvement	
Romania	Gabriela Tuchila	Full involvement	
Slovakia	Eva Chobotová	Full involvement	
Slovenia	Katarina Straus	Full involvement	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	Full involvement	
Sweden	Hanna Bremer	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
Denmark	Keith Baptiste	Full involvement	
Spain	Ricardo Carapeto García	Full involvement	
Ireland	Rory Breathnach	Full involvement	
Ireland	Mary O'Grady	Full involvement	
Sweden	Carina Bergman	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were evaluated against the topics they have been invited to talk about.			
Germany	Sandra Bertulat	Full involvement	
France	Khadija Seloaoui	Full involvement	
France	Nathalie Bridoux	Full involvement	
France	Jean-Christophe Faucon	Full involvement	
France	Martine Redureau	Full involvement	
France	Pascale Macours	Full involvement	
France	Beatrice Leroux	Full involvement	
France	Florence Pillet	Full involvement	
France	Anne Sagnier	Full involvement	
France	Walid Oumessad	Full involvement	
Germany	Dusan Palic	Full involvement	
Belgium	Sonja Beken	Full involvement	
Slovakia	Renata Kovacova	Full involvement	
Netherlands	Trintje van der Velde	Full involvement	
Germany	Christine Schwarz	Full involvement	
France	Kathrin Schirmann	Full involvement	
Belgium	Koenraad Brusselmans	Full involvement	
Sweden	Frida Martin	Full involvement	
Sweden	Anna-Karin Klocker	Full involvement	
Germany	Monika Hofmann	Full involvement	
Germany	Dagmar Sommer	Full involvement	
Germany	Brigitte Kuechler	Full involvement	
Germany	Heike Gyra	Full involvement	
Germany	Jana Hundt	Full involvement	
Germany	Sandra Schack	Full involvement	
Germany	Maike Goemmel	Full involvement	
Spain	Marta Martin Juárez	Full involvement	
Denmark	Kathrine Just Andersen	Full involvement	
Denmark	Susanne Havn Aamand	Full involvement	
Denmark	Helene Godiksen	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
Denmark	John Jensen	Full involvement	
Denmark	Trine Sidonia Jensen	Full involvement	
Spain	Cristina Benito Sastre	Full involvement	
Spain	Carlos Ballesteros	Full involvement	
Spain	Rocio Fernandez Granda	Full involvement	
Spain	Sonia Gil Morales	Full involvement	
Spain	Elena Lucas Roldán	Full involvement	
Spain	Jose Ignacio Garcia	Full involvement	
Spain	Luis Agote Casado	Full involvement	
Spain	Aranzazu González-Canga	Full involvement	
Ireland	Gavin Ryan	Full involvement	
Germany	Sandra-Maria Wienhold	Full involvement	
Germany	Martina Kern	Full involvement	
Germany	Andrea Springer	Full involvement	
Germany	Christian Kühne	Full involvement	
Germany	Jan Pridöhl	Full involvement	
Germany	Katja Boxberger	Full involvement	
Germany	Anke Finnah	Full involvement	
Germany	Svenja Rieke	Full involvement	
Germany	Kerstin Cramer	Full involvement	
Germany	Kathrin Dietze	Full involvement	
Germany	Nuria Doñamayor Alonso	Full involvement	
Germany	Julia Hackenberg	Full involvement	
Germany	Caroline Bitterlich	Full involvement	
Germany	Theresa Bergann	Full involvement	
Ireland	Sarah Buckley	Full involvement	
Ireland	Bryan Deane	Full involvement	
Ireland	Emily Hams	Full involvement	
Czech Republic	Josef Suchy	Full involvement	
Czech Republic	Petra Kubová	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard
ERAWP	Ricardo Carapeto García
PhVWP-V	James Mount
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner

CVMP working parties and CMDv	Chair
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
J3Rs WP	Sarah Adler-Flindt *(veterinary vice chair)*
ESUAvetWG	Sara Sacristan Alvarez

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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