8 October 2024
EMA/CVMP/49328/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the of 10-12 September 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 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 10-12 September 2024

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

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

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

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

1. Maximum residue limits

1.1. Opinions

There were no items for discussion

1.2. Oral explanations

There were no items for discussion

1.3. List of outstanding issues

There were no items for discussion

1.4. List of questions

1.4.1. Fluralaner – EMA/V/MRL/004380/EXTN/0002

Action: For adoption

The Committee adopted the scientific overview with list of questions.

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

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. Arthricox – firocoxib – EMEA/V/C/005993/0000 – dogs

Indication: product intended for the relief of pain and inflammation associated with osteoarthritis in dogs. For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

Action: For adoption

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

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

Action: For information

The Committee noted the summary of opinion.

2.1.2. Cirbloc M Hyo – *Mycoplasma hyopneumoniae*, strain 2940 and recombinant baculo-PCV2 virus VLP antigen (ORF2 capsid protein) - EMEA/V/C/006131/0000 – pigs

Indication: vaccine intended for active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection and to reduce the loss in body weight gain.

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.

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

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

There were no items for discussion

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

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

Action: For adoption

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

The Committee noted two peer review reports and comments from a CVMP member.

2.4.2. EMEA/V/C/005987/0000 – chickens

Action: For adoption

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

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

2.4.3. EMEA/V/C/006481/0000 – dogs

Action: For adoption

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

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

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

There were no items for discussion

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

2.6.1. Equilis EHV 1+4 - Equine herpesvirus vaccine (inactivated) - EMEA/V/C/006147/0000 – horses

Indication: vaccine intended for active immunisation of horses to reduce the severity and duration of clinical signs of respiratory disease (rhinopneumonitis).

Withdrawal at D120

Action: For information

The Committee noted the letter of withdrawal of the marketing authorisation application from the applicant. A WEPAR will be published.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1 NexGard Combo – esafoxolaner / eprinomectin / praziquantel - EMEA/V/C/005094/VRA/0010 – cats

Variation requiring assessment: to implement changes in the product information to further clarify the method of administration.

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.

3.1.2 YURVAC RHD – rabbit haemorrhagic disease and RHDV2 vaccine (recombinant) – EMEA/V/C/005992 – rabbits

Variation requiring assessment: addition of a new therapeutic indication for passive immunisation against RHDV2 (not demonstrated against highly virulent strains) of the offspring of the vaccinated does for at least 30 days.

Rapporteur: R. Carapeto Garcia, Co-rapporteur: L. Nepejchalová

Action: For adoption

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

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

The Committee noted the comments from two CVMP members.

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

Variation requiring assessment: to add a new therapeutic indication.

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

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

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.

4.7.1. Referrals under Regulation (EU) 2019/6

There were no items for discussion

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

There were no items for discussion

5. Post-authorisation issues for marketing authorisations

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

5.1. Pharmacovigilance under Regulation (EU) 2019/6

There were no items for discussion

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

There were no items for discussion

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

There were no items for discussion

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

There were no items for discussion

5.5. 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)

There were no items for discussion

6.3. Efficacy Working Party (EWP-V)

6.3.1. Revision of the guideline on anticoccidials used for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a)

Action: For discussion

6.4. Immunologicals Working Party (IWP)

6.5. 3Rs Working Party (3RsWP)

6.6. Novel Therapies & Technologies Working Party (NTWP)

There were no items for discussion

6.7. Pharmacovigilance Working Party (PhVWP-V)

There were no items for discussion

6.8. Quality Working Party (QWP)

6.8.1. Guideline on risk management requirements for elemental impurities in veterinary medicinal products

Action: For adoption

The Committee adopted the draft guideline on risk management requirements for elemental impurities in veterinary medicinal products (EMA/CVMP/426245/2023) for release for a 4-month period of public consultation. This guideline has been developed to provide recommendations on how the risk management may be conducted for elemental impurities for veterinary medicinal products (VMPs) authorised or to be authorised in the European Union in order to comply with the requirement of the European Pharmacopeia (Ph. Eur.) General Monograph 2619 for Pharmaceutical Preparations.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 6 September 2024

Action: For information

The Committee received a verbal report of the SAWP-V meeting held on 6 September 2024 and noted its agenda, together with the final minutes of the meeting held on 15 July 2024.

6.10. Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

6.11.1 Verbal report on the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group meeting held on 5 September 2024

Action: For information

The Committee received a verbal report of the ESUAvet WG meeting held on 10-12 September 2024 and noted its agenda together with the minutes of the meeting held on 22-23 May 2024.

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

7.3.2. EU enlargement – European Medicines Regulatory Network (EMRN) support to candidate and potential candidate countries

Action: For information

The Committee received a verbal report on the EU enlargement and related initiatives such as the 'Instrument for Pre-accession Assistance (IPA) advanced EMA training on Antimicrobial Resistance and One Health' that will be held at EMA on 21 and 22 October 2024.

7.3.3. Update on the scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of resistance in *Aspergillus* spp.

Action: For information

The Committee received an update on the scientific report on the impact on the use of azole fungicides, other than as human medicines, on the development of resistance in *Aspergillus spp.*

7.4. Pharmacovigilance

There were no items for discussion

7.5. Vaccine antigen master file (VAMF) certification

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

There were no items for discussion

7.6. Platform technology master file (PTMF) certification

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

There were no items for discussion

7.7. Other issues

8. Co-operation with other EU or International bodies

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

8.1. VICH

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

Action: For endorsement

The Committee endorsed the following guidelines for sign-off by the EWG member:

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

8.2. Codex Alimentarius

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 the veterinary medicinal product for honey bees as limited market and eligible for authorisation according to Article 23 of Regulation (EU) 2019/6.

9.1.2. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for European sea bass as limited market and eligible for authorisation according to Article 23 of Regulation (EU) 2019/6.

9.1.3. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for dogs as limited market and eligible for authorisation according to Article 23 of Regulation (EU) 2019/6.

9.1.4. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for cats as limited market and eligible for authorisation according to Article 23 of Regulation (EU) 2019/6.

9.1.5. Request for classification

Action: For classification

The Committee deferred the request for the veterinary medicinal for exotic animals.

9.1.6. Request for classification

Action: For classification

The Committee deferred the request for the veterinary medicinal product for dogs.

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. Reflection Paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Action: For adoption

The Committee adopted the Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle.

10.3. Stakeholders' consultation on the 3-year work plan for the veterinary domain (2025-2027)

Overview of comments.

Action: For discussion

The Committee discussed the overview of comments received during the stakeholders' consultation on the 3-year work plan for the veterinary domain (2025-2027) which is expected to be adopted at the October CVMP meeting.

11. CMDv

11.1. Verbal report from CMDv chair on the 27-28 June and 25-26 July 2024 CMDv meetings

Action: For information

The Committee received a verbal report from the CMDv chair on the CMDv meetings held on 27-28 June and 25-26 July 2024 and noted the draft agenda of the CMDv meeting to be held on 19-20 September 2024.

12. Legislation

12.1. Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6

Action: For adoption

The Committee adopted the revised guideline on safety and residue data requirements (EMA/CVMP/345237/2020-Rev.1) to align with Guidance to Applicants.

12.2. Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6

Action: For adoption

The Committee adopted the revised guideline on efficacy and target animal safety data requirements (EMA/CVMP/52665/2020-Rev.1) to align with Guidance to Applicants.

12.3. Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of the Regulation (EU) 2019/6

Action: For adoption

The Committee adopted the revised guideline on data requirements for applications for immunological veterinary medicinal products (EMA/CVMP/59531/2020-Rev.1) to align with Guidance to Applicants.

12.4. Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets

Action: For discussion

The Committee discussed the revised guideline on quality data requirements for applications for veterinary medicinal products and the overview of comments.

The adoption is foreseen for the October meeting.

12.5. Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For discussion

The Committee discussed the guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products and the overview of comments.

The adoption is foreseen for the October meeting.

12.6. Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For discussion

The Committee discussed the guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products and the overview of comments.

The adoption is foreseen for the October meeting.

12.7. Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6

Action: For discussion

The Committee discussed the guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products and the overview of comments.

The adoption is foreseen for the October meeting.

12.8. Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets

Action: For discussion

The Committee discussed the guideline on quality data requirements for applications for biological veterinary medicinal products and the overview of comments.

The adoption is foreseen for the October meeting.

13. Any other business

13.1. AOB

There were no items for discussion

13.2. Meeting highlights

Action: For comments

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

14. Annex

1. Maximum Residue Limits

1.6 Other issues

Lidocaine– EMEA/V/MRL/003649/EXTN/0002 – porcine species

Action: For adoption

The Committee adopted the corrigendum to the EPMAR.

Lidocaine– EMEA/V/MRL/003649/EXTN/0003 – bovine species

Action: For adoption

The Committee adopted the corrigendum to the EPMAR.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Cimalgex – cimicoxib - EMEA/V/C/000162/VRA/0010 – dogs

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

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Novem – meloxicam - EMEA/V/C/000086/VRA/0029 – cattle, pigs

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

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) – EMEA/V/C/004276/VRA/0012/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Locatim – immunoglobulins against *Escherichia coli F5* - EMEA/V/C/000041/VRA/0027 – cattle

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Letifend – canine leishmaniasis vaccine (recombinant protein) – EMEA/V/C/003865/VRA/0030 – 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 CVMP opinion and comments on the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

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

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Strangvac – *Streptococcus equi* vaccine (recombinant proteins) - EMEA/V/C/005309/VRA/0007/G – horses

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Mhyosphere PCV ID – *Mycoplasma hyopneumoniae* and porcine circovirus vaccine (inactivated, recombinant) - EMEA/V/C/005272/VRA/0005/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

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

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

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

Rapporteur: E. Dewaele

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Rheumocam – meloxicam - EMEA/V/C/000121/VRA/0039 – cats, dogs, cattle, pigs, horses

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 member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Inflacam – meloxicam - EMEA/V/C/002497/VRA/0030 – cats, dogs, cattle, pigs, horses

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 member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Felpreva – tigolaner / emodepside / praziquantel - EMEA/V/C/005464/VRA/0008 – cats

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

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Metacam – meloxicam - EMEA/V/C/000033/VRA/0153 – cats, cattle, dogs, guinea pigs, horses, pigs

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

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Panacur AquaSol - fenbendazole - EMEA/V/C/002008/VRA/0024/G – pigs, chickens

Variation requiring assessment: quality-related changes.

Rapporteur: J. Poot

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Cerenia – maropitant / maropitant citrate - EMEA/V/C/000106/VRA/0045 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Simparica, Simparica Trio – sarolaner, moxidectin, pyrantel embonate – EMEA/VRA/0000175976 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: J. Beechinor

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Solensia – frunevetmab – EMEA/V/C/005179/VRA/0009/G – cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Zenalpha – medetomidine hydrochloride/vatinoxan hydrochloride– EMEA/VRA/0000223452 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the Rapporteur's assessment report.

3.4. List of questions 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 list of questions.

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 list of questions and the comments on the product information.

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 list of questions and the comments on the product information.

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 list of questions and the comments on the product information.

EMEA/V/C/WS2730 - Eurican L4 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Kollár-Nagy

Action: For adoption

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

Eurican L4 - canine leptospirosis vaccine (inactivated) – EMEA/V/C/005944/VRA/0002 - dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Kollár-Nagy

Action: For adoption

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

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

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the list of questions.

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

Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMEA/V/C/004735/VRA/0010 – dogs

Rapporteur: C. Muñoz Madero

Action: For information

The Committee noted the withdrawal letter from the applicant.

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance under Regulation (EU) 2019/6

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

Nobivac L4 – EMEA/V/C/002010/REC/004

Rapporteur: E. Dewaele

Action: For endorsement

The Committe endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for Nobivac L4 which is considered fulfilled.

Trilocur – EMEA/V/C/006128/REC/001

Rapporteur: M. O'Grady

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for Trilocur which is considered fulfilled.

Trilorale – EMEA/V/C/006124/REC/001

Post-authorisation recommendation

Rapporteur: M. O'Grady

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for Trilorale which is considered fulfilled.

Neoleish – EMEA/V/C/005538/REC/002.1

Rapporteur: C. Miras

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for Neoleish which is considered fulfilled.

Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS – EMEA/V/VAMF/0001-0008

Post-authorisation recommendation for VAMFs 0001-0008

Rapporteur: J. Poot

Action: For endorsement

The Committe endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS which is considered fulfilled.

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

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

6.8 Quality Working Party (QWP)

7. Other scientific matters

7.7. Other issues

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

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

9.3. Regulatory matters

Invented names

12. Legislation

ANNEX I

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

An asterisk (*) after the role, in the second column, signals that the participant attended remotely.
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	
Croatia	Frane Božić	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	
Finland	Kristina Lehmann*	Full involvement	
Luxembourg	Caroline Coner*	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	
Greece	Amalia Papadaki*	Full involvement	
Hungary	Gábor Kulcsár	Full involvement	
Ireland	Paul McNeill	Full involvement	
Italy	Fulvio Marsilio	Full involvement	
Latvia	Zanda Auce	Full involvement	
Netherlands	Jacqueline Poot	Full involvement	
Netherlands	Kim Boerkamp	Full involvement	
Norway	Hanne Bergendahl	Full involvement	
Norway	Knud Sveen Torjesen	Full involvement	
Poland	Ewa Augustynowicz	Full involvement	
Portugal	João Pedro Duarte Da Silva*	Full involvement	
Romania	Gabriela Tuchila*	Full involvement	
Slovakia	Ewa Chobotová	Full involvement	
Slovakia	Katarina Massányiová*	Full involvement	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	Full involvement	

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

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were evaluated against the topics they have been invited to talk about.			
Denmark	Kirsten Thomsen	Full involvement	
Denmark	Charlotte Smith Bonde	Full involvement	
Netherlands	Erik den Hertog	Full involvement	
Netherlands	Sandra ten Voorde	Full involvement	
Netherlands	Anita Bottger	Full involvement	
Germany	Monika Hofmann	Full involvement	
Germany	Maike Goemmel	Full involvement	
Germany	Martina Kern	Full involvement	
Germany	Gunther Speichert	Full involvement	
Germany	Jan Brosda	Full involvement	
Spain	Maria Dominguez Nicolas	Full involvement	
Denmark	Kathrine Just Andersen	Full involvement	
Denmark	Anne Hasle Buur	Full involvement	
France	Nathalie Bridoux	Full involvement	
Austria	Haru Kroneis	Full involvement	
Germany	Kathrin Dietze	Full involvement	
Ireland	Sarah Buckley	Full involvement	
Ireland	Emily Hams	Full involvement	
Ireland	Susan Reid	Full involvement	
Ireland	Alice Stack	Full involvement	
Ireland	Sarah Beesley	Full involvement	
Germany	Katja Boxberger	Full involvement	
Germany	Svenja Rieke	Full involvement	
Germany	Sonja Haase	Full involvement	
Germany	Miriam Schrader	Full involvement	
Germany	Sarah Gadkarim	Full involvement	
Germany	Andrea Orhmann	Full involvement	
Germany	Christine Schwartz	Full involvement	
Germany	Sandra Bertulat	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
Germany	Daniela Benesh	Full involvement	
Germany	Juliane Bauch	Full involvement	
Germany	Katja Kaulich	Full involvement	
Germany	Caroline Bitterlich	Full involvement	
Germany	Jens Schönfeld	Full involvement	
Germany	Kerstin Cramer	Full involvement	
Austria	Richard Cejka-Scheidl	Full involvement	
Austria	Ines Lindner	Full involvement	
Austria	Elvira Zimre-Grabensteiner	Full involvement	
Finland	Jukka Pakkanen	Full involvement	
Finland	Stella Attia	Full involvement	
Finland	Hanna Kankkonen	Full involvement	
Netherlands	Alejandro Montón Silva	Full involvement	
Germany	Heike Gyra	Full involvement	
Netherlands	Sandy Vermout	Full involvement	
Denmark	Anne Malene Nissen	Full involvement	
Denmark	Susanne Havn Aamand	Full involvement	
Denmark	Anja Silke Christensen	Full involvement	
Denmark	Trine Sidonia Jensen	Full involvement	
Slovenia	Bojana Stavar Mocnik	Full involvement	
Slovenia	Katarina Glogoski	Full involvement	
Slovenia	Urska Peunik	Full involvement	
Spain	Maria Jose Ferrer	Full involvement	
Spain	Jaime García Sánchez	Full involvement	
Spain	Maria Esperanza Herreros Avila	Full involvement	
Spain	Cristina Benito	Full involvement	
Spain	Elena Lucas Roldán	Full involvement	
Spain	Alberto de Prado Lopez	Full involvement	
Ireland	Bryan Deane	Full involvement	
Czech Republic	Jitka Chumchalova	Full involvement	
Czech Republic	Radka Smítalová	Full involvement	
Czech Republic	Vilma Dosedlova	Full involvement	
Czech Republic	Zdenka Mašková	Full involvement	
Spain	Rosario Bullido	Full involvement	
Sweden	Gabriel Westman	Full involvement	
Germany	Anke Finnah	Full involvement	

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

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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