10 September 2024
EMA/CVMP/423075/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the of 16-18 July 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 16-18 July 2024

The attendance list was completed and competing interests were identified for the July 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 June 2024 meeting were adopted with no amendments.

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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

1.4.1. Lidocaine – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: For adoption

The Committee adopted the scientific overview and 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. Cepeloron – spironolactone – EMEA/V/C/0006254/0000 - dogs

Indication: treatment of congestive heart failure caused by degenerative mitral valve disease, in combination with standard therapy (including diuretic support, where necessary) 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.

The Committee noted the comments from CVMP members.

2.1.2. Cevac Salmune ETI K – *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis vaccine (inactivated) – EMEA/V/C/006118/0000 – chickens

Indication: active immunisation of chickens (breeders and layers) from 10 weeks of age to reduce faecal excretion of *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis.

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 the comments from CVMP members.

2.1.3. Porcilis PCV M Hyo ID – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMEA/V/C/006289/0000 – pigs

Indication: vaccine intended for the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, and faecal virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. To reduce the loss of daily weight gain during the finishing period in face of infections with PCV2 and/or *Mycoplasma hyopneumoniae* (as observed in clinical trials).

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 the comments from CVMP members.

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/006102/0000 – dogs

Action: For adoption

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

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

Action: For decision

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

2.3.2. EMEA/V/C/006296/0000 – chickens

Action: For adoption

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

The Committee noted peer review report.

Action: For decision

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

2.3.3. EMEA/V/C/006131/0000 – pigs

Action: For adoption

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

The Committee noted the comments from CVMP members.

Action: For decision

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

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

Action: For adoption

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

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

Action: For decision

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

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

2.4.1. EMEA/V/C/006336/0000 – pigs

Action: For adoption

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

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

2.4.2. EMEA/V/C/006358/0000 – dogs

Action: For adoption

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

The Committee noted peer review reports and 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. Clomicalm – clomipramine hydrochloride - EMEA/V/C/000039/VRA/0042/G – dogs

Variation requiring assessment: to align the product information with the version 9.0 of the QRD template and to update the adverse events section due to the outcome of signal management.

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. EMEA/V/C/WS2690 - Profender – cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.1.3. Posatex – posaconazole / mometasone furoate / orbifloxacin - EMEA/V/C/000122/VRA/0031/G – dogs

Grouped variation requiring assessment: to update the product information to include details on the extractable volume of the veterinary medicinal product compared to the fill volume and 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, the CVMP assessment report and the product information.

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

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

Grouped 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 adoption

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

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

Variation requiring assessment: to add a new strength.

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

Action: For adoption

The Committee adopted the scientific overview including list of questions and 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. Poulvac Procerta HVT-IBD – live recombinant turkey herpes virus, strain HVT-IBD, expressing the VP2 protein of infectious bursal disease virus - EMEA/V/C/006000/VRA/0001/G – chickens, embryonated chicken eggs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee agreed to a request from the applicant for an extension to the clock-stop.

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

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

5.1.2. Senvelgo – velagliflozin - EMEA/V/C/005972 – direct animal healthcare professional communication (DaHPC) and topic-specific communication plan

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

Action: For endorsement

The Committee endorsed the direct animal healthcare professional communication (DaHPC) and a topic-specific communication plan following a review of cases of diabetic ketoacidosis (DKA, a potentially fatal complication of diabetes mellitus) in cats given the medicine Senvelgo. If used under certain circumstances (e.g. in cats that are already insulin-dependent), the VMP may increase the risk of diabetic ketoacidosis, which is a potentially fatal complication of diabetes. Before starting treatment with Senvelgo, cats must be screened for DKA and the VMP shouldn't be given if clinical signs indicative of DKA are present. Veterinary professionals should inform cat owners of the risks and ensure they can monitor their cat's condition closely. Immediate veterinary attention must be sought if any symptoms of DKA are observed.

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. Other issues

There were no items for discussion.

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

There were no items for discussion.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 25–26 June 2024

Action: For information

The Committee received a verbal report on the plenary meeting held on 25–26 June 2024 together with the minutes from the meeting held on 18–19 March 2024.

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 determining the fate of veterinary medicinal products in manure' (EMA/CVMP/ERA/430327/2009-Rev.1) and the revised 'Reflection paper on poorly extractable and/or non-radiolabelled substances' (EMA/CVMP/ERA/349254/2014-Rev.1).

6.3. Efficacy Working Party (EWP-V)

6.3.1. Concept paper on the revision of the guideline on dossier requirements for anticancer medicinal products for dogs and cats

Action: For adoption

The Committee adopted a concept paper on the revision of the guideline on dossier requirements for anti-cancer medicinal products for dogs and cats (EMA/CVMP/EWP/259765/2024) for release for a 3-month period of public consultation. This concept paper addresses the need for a thorough revision of the guideline, in line with current scientific knowledge in the field and regulatory requirements.

6.3.2. Concept paper on the revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees

Action: For adoption

The Committee adopted a concept paper on the revision of the guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees (EMA/CVMP/EWP/247519/2024) for release for a 3-month period of public consultation. This concept paper addresses the need for a comprehensive revision of the guideline, in line with current scientific knowledge in the field and regulatory requirements.

6.3.3. Concept paper on the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products

Action: For adoption

The Committee adopted a concept paper on the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/256158/2024) for release for a 3-month period of public consultation. This concept paper addresses the need for a thorough revision of the guideline, in line with current scientific knowledge in the field and current regulatory requirements.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion.

6.5. 3Rs Working Party (3RsWP)

There were no items for discussion.

6.6. Novel Therapies & Technologies Working Party (NTWP)

There were no items for discussion.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V 19 June and 9-10 July 2024 meetings

Action: For information

The Committee received a verbal report on the June and July 2024 PhVWP-V meetings and noted their agendas together with the draft summary record of the June 2024 PhVWP-V meeting.

6.7.2. Revised VeDDRA documents

Action: For adoption

The Committee adopted the revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/10418/2009 -Rev.15 EVVet v.20), the list of changes to combined VeDDRA list of clinical terms (EMA/CVMP/PhVWP/228098/2024) together with the guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007) and the non-current VeDDRA LLT terms and codes (EMA/CVMP/PhVWP/360871/2010).

The implementation of the standard lists in EudraVigilance Veterinary is provisionally scheduled for 1 October 2024.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (May and June 2024)

Action: For information

The Committee received a verbal report on the QWP meetings held in May and June 2024, and noted the minutes of the meeting held on 15-16 April 2024, the agenda and minutes of the meeting held on 23-24 May 2024 together with the agenda of the QWP meeting held on 17-18 June 2024.

6.8.2. Draft guideline on development and manufacture of synthetic oligonucleotides

Action: For adoption

The Committee adopted the draft guideline on development and manufacture of synthetic oligonucleotides for a 6-month period of public consultation (EMA/CHMP/CVMP/QWP/262313/2024).

6.8.3. Q&A on co-processed excipients

Action: For adoption

The Committee adopted the Questions and Answers document on co-processed excipients used in solid oral dosage forms for a 3-month period of public consultation. The aim of this Q&A has been to harmonise and clarify requirements for CoPEs using a risk-based approach; the Q&As are applicable to human and veterinary solid oral dosage forms. Retrospective application of the Q&As is not intended for marketed products, unless there are changes to the formulation (e.g. introducing a CoPE or changes to the applied CoPE).

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 15 July 2024

Action: For information

The Committee received a verbal report of the meeting held on 15 July 2024 and noted its agenda together with the final minutes of the SAWP-V meeting held on 14 June 2024.

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 27-28 June 2024

Action: For information

The Committee received a verbal report on the SWP-V meeting held on 27–28 June 2024 and noted its agenda together with the minutes of the meeting held on 21–22 March 2024.

6.10.2. Concept paper on the revision of the guideline on user safety for pharmaceutical veterinary medicinal products

Action: For adoption

The Committee adopted the concept paper on the revision of the guideline on user safety for pharmaceutical veterinary medicinal products for release for a 3-month period of public consultation (EMA/CVMP/SWP/564774/2023).

6.11. Other working party and scientific group issues

There were no items for discussion.

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential

7.1. MRL issues

7.1.1. Q&A on standard animal weights for estimating worst-case consumer exposure scenarios to complement the guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling withing the scope of Regulation (EC) No 470/2009

This Q&A is intended to provide standardised animal body weights for use in consumer safety exposure evaluations submitted as part of requests for inclusion of substances in the out of scope list.

Presenter: I. Madero

Action: For adoption

The Committee adopted the Q&A on standard animal weights for estimating worst-case consumer exposure scenarios (EMA/250170/2024).

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

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/VPTMF/0001

Action: For adoption

The Committee adopted the assessment report and the list of outstanding issues.

Action: For decision

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

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

8.1.5. EU expert in Quality and Medicated Premixes Expert Working Groups

Action: For endorsement

The Committee endorsed the nomination of new experts: namely C. Janich as EU expert to join VICH Quality EWG; P. Macours as EU adviser to join VICH Quality EWG; M-H. Sabinotto as EU expert to join VICH Medicated Premixes EWG and C. Kühne as EU adviser to join VICH Medicated Premixes EWG.

8.1.6. EU expert in Metabolism & Residue Kinetics Expert Working Groups (MRK EWG)

Action: For endorsement

The Committee endorsed D. Banesh as EU expert to join VICH MRK EWG.

8.2. Codex Alimentarius

There were no items for discussion.

8.3. Other EU bodies and international organisations

8.3.1. EC mandate on the development of a harmonised tool for calculating human dietary exposure to residues from veterinary medicinal products, feed additives and pesticides

Action: For information

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

There were no items for discussion.

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

9.3. Regulatory matters

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 3 July 2024

Action: For information

The Committee received a verbal report on the Veterinary Domain meeting held on 3 July 2024 and noted the agenda of the meeting together with the minutes of the 8 May 2024 meeting.

10.2. Draft consolidated 3-year work plan for the veterinary domain (2025-2027)

Action: For endorsement

The Committee endorsed the draft consolidated 3-year work plan for the veterinary domain (2025-2027) following stakeholders' consultation, expected to be adopted at the December 2024 meeting of the Committee. This document will be the basis of the CVMP and its working parties' workplans for 2025.

10.3. CVMP/CMDv Presidency meeting under the Belgian Presidency, Ghent, 10–11 April 2024

Action: For adoption

The Committee adopted the minutes of the CVMP and CVMP-CMDv joint sessions.

10.6. Update on IRIS for core Regulatory Procedures

Action: For information

11. CMDv

There were no items for discussion.

12. Legislation

12.2. Scientific advice on Article 115 (5) of Regulation (EU) 2019/6 as regards the 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

Verbal report from the expert group's chair.

Action: For adoption

The Committee adopted the scientific advice under Article 115(5) of Regulation (EU) 2019/6 for the establishment of a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available, and for which the withdrawal period for equine species shall be six months (EMA/CVMP/159047/2023).

12.3. 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

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.

14. Annex

Introduction

i. Adoption of the updated agenda of June CVMP meeting

1. Maximum Residue Limits

1.6. Other issues

Bupivacaine – EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For decision

The Committee approved the request from the applicant for an extension of the clock stop.

2. Marketing authorisations and extensions

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

EMEA/V/C/005993/0000 – dogs

Action: For decision

The Committee approved the request from the applicant for an extension of the clock stop.

EMEA/V/C/006234/0000 – cattle, pigs, dogs, cats

Action: For decision

The Committee approved the request from the applicant for an extension of the clock stop.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Eluracat – capromorelin tartrate – EMEA/V/C/005948/VRA/0001 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: R. Carapeto Garcia

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.

Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0018 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

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.

WS2682 - Versican Plus DHPPi/L4R, Versican Plus Pi/L4, Versican Plus Pi/L4, Versican Plus Pi/L4R, Versican Plus L4 – dogs

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.

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

Zycortal – desoxycortone pivalate - EMEA/V/C/003782/VRA/0014 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bergendahl

Action: For adoption

The Committee adopted the list of questions.

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 list of questions.

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 list of questions.

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 list of questions and the comments on the product information.

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 list of questions and the comments on the product information.

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 list of questions and the comments on the product information.

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 list of questions.

WS2667 – Cortavance, Easotic – hydrocortisone aceponate; hydrocortisone aceponate/gentamicin – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

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

Bravecto – EMEA/V/C/002526/REC/023-025

Rapporteur: K. Boerkamp

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendations for Bravecto which are considered fulfilled.

Librela – EMEA/V/C/005180/REC/006

Rapporteur: F. Hasslung Wikström

Action: For endorsement

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

5. Post-authorisation issues for marketing authorisations

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

6. Working parties

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9.3. Regulatory matters

Invented names

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	
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	
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	Eva Chobotová*	Full involvement	
Slovakia	Katarina Massányiová	Full involvement	
Slovenia	Boris Kolar	Full involvement	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	Full involvement	
Denmark	Keith Baptiste	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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.			
France	Karen Millet	Full involvement	
France	Walid Oumessad	Full involvement	
France	Anne Sagnier	Full involvement	
Denmark	Anja Silke Christensen	Full involvement	
Denmark	Theis Moeslund Jensen	Full involvement	
Denmark	Kirsten Thomsen	Full involvement	
Denmark	Charlotte Smith Bonde	Full involvement	
Denmark	Susanne Havn Aamand	Full involvement	
Sweden	Frida Martin	Full involvement	
Netherlands	Erik den Hertog	Full involvement	
Netherlands	Sandra ten Voorde	Full involvement	
Netherlands	Anita Bottger	Full involvement	
Spain	Ana Isabel Olías Molero	Full involvement	
Germany	Christopher Janich	Full involvement	
Spain	Sonia Gil Morales	Full involvement	
Spain	Susana Casado	Full involvement	
Germany	Dusan Palic	Full involvement	
Spain	Irene de la Casa Resino	Full involvement	
Czech Republic	Josef Suchy	Full involvement	
France	Benoit Courty	Full involvement	
Belgium	Sandy Vermout	Full involvement	
Germany	Ingun Lemke	Full involvement	
Germany	Monika Hofmann	Full involvement	
Greece	Dagmar Sommer	Full involvement	
Germany	Babett Kobe	Full involvement	
Germany	Rolf Beckmann	Full involvement	
Germany	Maike Goemmel	Full involvement	
Germany	Daniela Loos	Full involvement	
Germany	Judith Romberg	Full involvement	
Germany	Wiebke Weiher	Full involvement	
Germany	Roswitha Merkel	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	Sandra-Maria Wienhold	Full involvement	
Germany	Martina Kern	Full involvement	
Germany	Maren Osmers	Full involvement	
Germany	Gunther Speichert	Full involvement	
Czech Republic	Jana Fluksová	Full involvement	
Czech Republic	Vilma Dosedlova	Full involvement	
Czech Republic	Lucie Pokludova	Full involvement	
Spain	Rosario Bullido	Full involvement	
Spain	Maria Jose Ferrer	Full involvement	
Spain	Jaime García Sánchez	Full involvement	
Spain	Veronica Devesa	Full involvement	
Spain	Maria Dominguez Nicolas	Full involvement	
Germany	Uta Herbst	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)*

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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