5 November 2024
EMA/CVMP/49655/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 8-10 October 2024 meeting

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 8-10 October 2024

The attendance list was completed and competing interests were identified for the October 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 September 2024 meeting were to be circulated after the meeting for adoption via written procedure.

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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. Duotic – betamethasone acetate, terbinafine – EMEA/V/C/006102/0000 – dogs

Indication: product for the treatment of otitis externa associated with *Malassezia pachydermatis* 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 peer review report from H. Bremer and the comments from a CVMP member.

2.1.2. Bravecto Triuno – fluralaner / moxidectin / pyrantel - EMEA/V/C/006311/0000 – dogs

Indication: product intended for dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm. The veterinary medicinal product is only indicated when used against ticks or fleas and one or more of the other target parasites is indicated at the same time.

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, two peer review reports and comments from CVMP members.

2.1.3. Vaxxon ND Clone - Newcastle disease virus, strain Clone, live - EMEA/V/C/006296/0000 – chickens

Indication: vaccine intended for the active immunisation of chickens from the age of day one to reduce mortality and clinical signs of disease caused by infection with Newcastle Disease virus.

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 reviewer 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/006230/0000 – cats

Action: For decision

The CVMP agreed that an oral explanation is needed and is expected to take place at the January 2025 Committee meeting.

Action: For adoption

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

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

2.3.2. EMEA/V/C/006142/0000 – chickens

Action: For decision

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

Action: For adoption

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

Action: For information

The Committee noted a peer review report.

2.3.3. EMEA/V/C/006288/0000 – chickens

Action: For decision

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

Action: For adoption

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

Action: For information

The Committee noted two peer review reports.

2.3.4. EMEA/V/C/006309/0000 – Atlantic salmon

Action: For decision

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

Action: For adoption

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

Action: For information

The Committee noted two peer review reports.

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

Action: For decision

The CVMP agreed to the applicant’s request for an oral explanation in November 2024.

Action: For adoption

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

The Committee noted comments from the CVMP members.

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

2.4.1. EMEA/V/C/006499/0000 – 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 three peer review reports and the comments from a CVMP member.

2.4.2. EMEA/V/C/006501/0000 – chickens

Action: For adoption

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

Action: For information

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

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

There were no items for discussion

2.2. 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 Bovilis Nasalgen-C – Bovine coronavirus vaccine, (live attenuated) - EMEA/V/C/005906/VRA/0002 – cattle

Variation requiring assessment: to add wording to the product information to indicate that Bovilis Nasalgen-C can be used during pregnancy.

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.

3.1.2 Eluracat – capromorelin tartrate - EMEA/V/C/005948/VRA/0002/G – cats

Variation requiring assessment: to implement the outcome of the MAH's signal management process and to move a warning for use of the product in cats with hypersomatotropism (acromegaly) from the special precautions section of the product information to the contraindications section.

Rapporteur: R. Carapeto García

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.

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

3.3.1. 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 decision

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

Action: For adoption

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

3.3.2. 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 decision

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

Action: For adoption

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

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

3.4.1. Innovax-ND-H5 - Newcastle disease, avian influenza and Marek's disease vaccine (live recombinant) - EMEA/V/C/006362/VRA/0001 – chickens and chicken embryonated eggs

Variation requiring assessment: to fulfil two outstanding specific obligations for Innovax-ND-H5 as agreed during the granting of the marketing authorisation.

Rapporteur: C. Muñoz Madero, Co-Rapporteur: M. Leitner

Action: For adoption

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

Action: For information

The Committee noted the comments from a CVMP member.

3.4.2. Porcilis ColiClos - E. coli and C. perfringens vaccine (inactivated) to provide passive immunity to pigs - EMEA/V/C/002011/VRA/0018/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner, Co-Rapporteur: K. Lehmann

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

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

5.5. Others

There were no items for discussion

6. Working parties

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

6.1. Antimicrobials Working Party (AWP)

6.1.1. Verbal report on the AWP meeting held on 24-25 September 2024

Action: For information

The Committee received a verbal report on the AWP meeting held on 24-25 September 2024 noting its final agenda together with minutes of AWP meeting held on 28-29 May 2024.

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 adoption

The Committee adopted the guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016) for release for a 4-month period of public consultation.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion

6.5. 3Rs Working Party (3RsWP)

There were no items for discussion

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 26-27 September 2024

Action: For information

The Committee received a verbal report on NTWP meeting held on 26-27 September 2024 and noted its final agenda together with the minutes from meeting held on 7 June 2024.

6.6.2. Concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations

Action: For adoption

The Committee adopted the overview of comments, received during public consultation, on the concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations.

6.6.3. NTWP Horizon scanning 2024

Action: For information

The Committee received a verbal report on the NTWP Horizon scanning 2024.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 24-25 September 2024

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 24-25 September 2024 and noted its draft agenda and the draft summary record. The Committee noted the draft PhVWP-V Work Plan 2025 together with the draft summary record of the July 2024 PhVWP-V meeting and final agenda of that meeting.

6.7.2. Verbal report on PhVWP-V Interested Parties meeting held on 25 September 2024

Action: For information

The Committee received a verbal report from the PhVWP-V Interested Parties meeting held on 25 September 2024 and noted its draft agenda and the summary of responses to evaluation form.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held on 15-16 July and 9-11 September 2024

Action: For information

The Committee received a verbal report on QWP meetings held on 15-16 July and 9-11 September 2024 and noted their minutes together with the minutes from the QWP meeting held on 17-18 June 2024.

6.8.2. Q&A on Ph. Eur. general chapter 2.2.46 Chromatographic separation techniques

Action: For adoption

The Committee adopted the Questions and Answers on Ph. Eur. general chapter 2.2.46 Chromatographic separation techniques.

6.8.3. Draft guideline on stability testing for variations for VMPs

Action: For discussion

The Committee discussed the draft guideline on stability testing for variations for VMPs after public consultation and the overview of comments. The adoption of the documents is foreseen to take place in November 2024.

6.9. Scientific Advice Working Party (SAWP-V)

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

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 4 October 2024 and noted the minutes of the meeting held on 6 September 2024.

6.10. Safety Working Party (SWP-V)

There were no items for discussion

6.11. Other working party and scientific group issues

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 noted the 'Programme Instrument for Pre-accession Assistance (IPA) advanced EMA training on Antimicrobial Resistance and One Health' and the latest version of the programme.

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

There were no items for discussion

8. Co-operation with other EU or International bodies

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

8.1. VICH

8.2. Codex Alimentarius

There were no items for discussion

8.3. Other EU bodies and international organisations

There were no items for discussion

9. Procedural and regulatory matters

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

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

9.1.1. Request for classification

Action: For classification

The Committee considered the request for a veterinary medicinal product for exotic animals. The Committee classified the product as intended for a limited market and not eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

9.1.2. Request for classification

Action: For classification

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

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

9.3. Regulatory matters

There were no items for discussion

10. Organisational and strategic matters

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

Action: For adoption

The Committee adopted the overview of comments following the targeted stakeholders' consultation on the 3-year work plan for the veterinary domain (2025-2027).

10.2. CVMP work plan 2025

Action: For discussion

The Committee discussed the CVMP work plan 2025. It will be discussed further in the Veterinary Domain meeting.

11. CMDv

There were no items for discussion

12. Legislation

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

Action: For adoption

The Committee adopted the guideline (EMA/CVMP/QWP/47285/2022) and the overview of comments (EMA/CVMP/QWP/50888/2024).

12.2. 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 adoption

The Committee adopted the guideline (EMA/CVMP/SWP/32027/2022) and the overview of comments (EMA/CVMP/SWP/46749/2024).

12.3. 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 adoption

The Committee adopted the guideline (EMA/CVMP/EWP/231668/2022) and the overview of comments (EMA/CVMP/EWP/44280/2024).

12.4. 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 adoption

The Committee adopted the guideline (EMA/CVMP/IWP/224724/2022) and the overview of comments (EMA/CVMP/IWP/53315/2024).

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

Action: For adoption

The Committee adopted the guideline (EMA/CVMP/IWP/228730/2022) and the overview of comments (EMA/CVMP/IWP/53990/2024).

12.6. QRD template update to v.9.1

Action: For adoption

The Committee proposed some changes to the QRD veterinary product-information ANNOTATED template version 9.1, the revised version will be tabled for the November CVMP meeting for adoption.

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

Action: For discussion

The Committee discussed the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products and the overview of comments.

12.8. 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

AOB

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

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Bovela – bovine viral diarrhoea vaccine (modified live) - EMA/VRA/0000224205 – cattle, sheep

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.

Enteroporc Coli AC – Neonatal piglet colibacillosis (recombinant, inactivated) and *Clostridium perfringens* vaccine (inactivated) - EMEA/V/C/005149/VRA/0006/G – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Mometamax Ultra – gentamicin / posaconazole / mometasone furoate – EMEA/V/C/004987/VRA/0003 – dogs

Variation requiring assessment: to update the instructions for use in the product information.

Rapporteur: K. Baptiste

Action: For adoption

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

The Norwegian member agreed with the above-mentioned recommendation.

EMEA/V/C/WS2667/G – 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 CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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 and embryonated chicken eggs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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 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

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 list of questions and the comments on the product information.

Action: For information

The Committee noted the comments from CVMP members.

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 list of questions and the comments on the product information.

Sedadex– dexmedetomidine- EMA/VRA/0000224259 – dogs, cats

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.

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 list of questions.

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 questions included in the rapporteur assessment report.

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

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

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

6.5. 3Rs Working Party (3RsWP)

Adopted minutes of the 3RsWP plenary meeting held on 21-22 May 2024

Action: for information

The Committee noted the adopted minutes of the 3RsWP plenary meeting held on 21–22 May 2024.

Adopted agenda of the 3RsWP plenary meeting held on 21–22 September 2024

Action: for information

The Committee noted the adopted agenda of the 3RsWP plenary meeting held on 21–22 September 2024.

6.8 Quality Working Party (QWP)

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

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 VICH Steering Committee:

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

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

ANNEX I

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

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	**Frida Hasslung Wikström**	**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	
Denmark	Keith Baptiste	Full involvement	
Spain	Ricardo Carapeto García	Full involvement	
Ireland	Rory Breathnach	Full involvement	
Ireland	Mary O'Grady	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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	
Germany	Sandra-Maria Wienhold	Full involvement	
Germany	Martina Kern	Full involvement	
Germany	Maren Osmers	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	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