10 June 2025
EMA/CVMP/199015/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 13-15 May 2025 meeting

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 13-15 May 2025

The attendance list was completed and competing interests were identified for the May 2025 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 April 2025 meeting will be circulated before the June meeting.

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

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

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance (lidocaine) – EMEA/V/MRL/003649/MODF/0004 – porcine

Action: For adoption

The Committee adopted the CVMP opinion including the EPMAR.

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

Action: For information

The Committee noted the summary of opinion.

1.2. Oral explanations

There were no items for discussion.

1.3. List of outstanding issues

1.3.1. Substance – EMEA/V/MRL/005009/MODF/0003 – bovine

Action: For decision

The Committee agreed that there was no need for an oral explanation.

Action: For adoption

The Committee adopted the scientific overview including the list of outstanding issues.

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

2.1.1. Innovax-ND-IBD-ILT – Newcastle disease, infectious bursal disease, avian infectious laryngotracheitis and Marek's disease vaccine (live recombinant)- EMEA/V/C/006442/0000 – chickens, embryonated chicken eggs

Indication: vaccine intended for the active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs:

- to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,

- to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus Marek's disease (MD) virus and infectious bursal disease (IBD) virus.

Action: For adoption

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

Action: For information

The Committee noted the summary of opinion.

2.1.2. Fluralaner Intervet – fluralaner – EMEA/V/C/006356 – dogs

Indication: a systemic insecticide and acaricide providing immediate and persistent flea (*Ctenocephalides canis* and *C. felis*) and tick (*Dermacentor reticulatus*, *Ixodes hexagonus*, *I. ricinus* and *Rhipicephalus sanguineus*) killing activity for 1 month; can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD); for reduction of the risk of infection with *Babesia canis canis* and *Dipylidium caninum* via transmission by *D. reticulatus* and *C. felis*, respectively, for 1 month - effect is indirect due to the product's activity against the vector.

Action: For adoption

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

Action: For information

The Committee noted the summary of opinion.

2.1.3. Nobilis Multriva IBm+ND+Gm+REOm+EDS– Avian infectious bronchitis, Newcastle disease, avian infectious bursal disease, avian reovirus and egg drop syndrome virus vaccine (inactivated)- EMEA/V/C/005987/0000 – chickens

Indication: for the active immunisation of chickens for reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B (GI-13 genotype); reduction of mortality and clinical signs caused by Newcastle disease virus (NDV); passive immunisation of the progeny of the vaccinated chickens to reduce mortality and clinical signs of disease caused by very virulent (CS89) and classical (STC) strains of infectious bursal disease virus (IBDV); reduction of viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.; reduction of egg drop and eggshell defects caused by eggdrop syndrome-1976 virus (EDSV).

Action: For adoption

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

Action: For information

The Committee noted the summary of opinion.

2.2. Oral explanations

There were no items for discussion.

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006481/0000 – dogs

Action: For decision

The Committee agreed that an oral explanation was not needed.

Action: For adoption

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

Action: For information

The Committed noted the comments from three CVMP members.

2.3.2. EMEA/V/C/006455/0000 – dogs

Action: For decision

The Committee agreed that an oral explanation was not needed.

Action: For adoption

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

Action: For information

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

2.4. List of questions

2.4.1. EMEA/V/C/006646/0000 – chickens

Action: For adoption

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

Action: For information

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

2.4.2. – EMEA/V/C/006645/0000 – chickens

Action: For adoption

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

Action: For information

The Committed noted two peer review reports and comments from three CVMP members.

2.5. Re-examinations of CVMP opinions

There were no items for discussion.

2.6. Other issues

2.6.1. Cunitraxx – fenbendazole - EMEA/V/C/006595/0000 – rabbits

Action: For information

The Committee noted the letter of withdrawal of the marketing authorisation application. A WEPAR will be prepared for publication.

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. NexGard Combo – esafoxolaner / eprinomectin / praziquantel – EMEA/V/C/005094/VRA/0012/G – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: treatment of infections with eye worms (*Thelazia callipaeda*) and immediate tick killing activity against *Ixodes hexagonus*

Rapporteur: A. Golombiewski, Co-Rapporteur: N.C. Kyvsgaard

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.

3.1.2. Stronghold Plus – selamectin / sarolaner – EMA/VRA/0000243880 – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for one month after treatment.

Rapporteur: R. Breathnach, Co-Rapporteur: K. Boerkamp

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.

3.1.3. Bluevac BTV – Bluetongue virus vaccine (inactivated) - EMA/VRA/0000255727 – sheep

Variation requiring assessment: to change the posology for sheep, to vaccinate with one single dose of the bivalent vaccine BTV-1+4.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion and the comments on the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Action: For information

The Committee noted the summary of opinion.

3.1.4. Divence Penta – bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine - EMA/VRA/0000263803 – cattle

Variation requiring assessment: to implement the outcome of the MAH's signal management process to add new uncommon adverse events to the product information (milk production decrease, reduced food intake and decreased activity). Information on allowing the vaccine to reach room temperature before use was also added to the product information.

Rapporteur: J. Poot

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.2. Oral explanations

There were no items for discussion.

3.3. List of outstanding issues

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

Variation requiring assessment: to implement the following changes: an addition of new therapeutic indications or modification of an approved one and an addition of associated non-mixed use.

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

Action: For adoption

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

Action: For decision

The Committee agreed that there was a need for an oral explanation, which would take place during the June meeting of the Committee.

3.4. List of questions

There were no items for discussion.

3.5. Re-examinations of CVMP opinions on variations requiring assessment

There were no items for discussion.

3.6. Other issues

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/advice under Articles 141(1)(c), 141(1)(e) or 141(1)(i) 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

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

5.1.1. Signal evaluation and recommendations

Action: For adoption

The Committee adopted the outcome of the signal management process and the list of finalised signals.

5.1.2. Easotic – hydrocortisone aceponate / gentamicin sulfate / miconazole nitrate

Rapporteur: N.C. Kyvsgaard, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the outcome of the signal management process.

5.1.3. Apoquel - oclacitinib maleate

Rapporteur: R. Brethnach, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the outcome of the signal management process.

5.1.4. Divence Penta - Bovine viral diarrhoea (subunit), bovine parainfluenza 3 virus (inactivated), bovine respiratory syncytial virus and bovine herpesvirus type 1 (live) vaccine

Rapporteur: J. Poot, Co-Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the outcome of the signal management process.

5.2. Post-authorisation measures

There were no items for discussion.

5.3. Inspections and controls

There were no items for discussion.

5.4. Re-examination of limited markets and exceptional circumstances authorisations

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)

6.2.1. Election for chair of ERAWP

Action: For election

The Committee elected, unanimously, Mark Montforts as the chair of ERAWP for a 3-year mandate.

6.3. Efficacy Working Party (EWP-V)

There were no items for discussion.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion.

6.5. 3Rs Working Party (3RsWP)

6.5.1. Verbal report on 3RsWP annual stakeholder meeting

Action: For information

The Committee received a verbal report on the 3RsWP annual stakeholder meeting held on 2-3 April 2025. The CVMP noted its agenda together with the recording of the public session held on 2 April 2025 (event page).

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1. Verbal report on NTWP meeting held on 5 May 2025

Action: For information

The Committee received a verbal report on the NTWP meeting held on 5 May 2025 and noted its agenda.

6.6.2. Appointment of the Vice-Chair of NTWP

Action: For decision

The Committee elected, by majority, Anja Pfalzgraff as the Vice-chair of NTWP for a 3-year mandate.

6.6.3. Appointment of NTWP Operational Expert Group (OEG) experts on RNA interference and RNA antisense therapies

Action: For information

The Committee agreed to launch a call for nominations for CVMP Veterinary Novel Therapies and Technologies Working Party (NTWP) Operational Expert Group (OEG) experts on RNA interference and RNA antisense therapies, including its selection procedure and timetable.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1 Verbal report on PhVWP-V meeting held on 23 April 2025

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 23 April 2025 and noted its agenda.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings (February – April 2025)

Action: For information

The Committee received a verbal report on QWP meetings (February – April 2025) and noted the minutes of the QWP meeting held on 20-21 January 2025; the agenda and minutes of the QWP meeting held on 17-18 February 2025; the agenda and minutes of the QWP meeting held on 17-19 March 2025 together with the agenda of the QWP meeting held on 14-15 April 2025.

6.8.2. Updated questions and answers to align to Regulation (EU) 2019/6

Action: For adoption

The Committee adopted the update to the questions and answers on 100% active substance VMPs and the questions and answers on powders and granules in one marketing authorisation.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 12 May 2025

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 12 May 2025.

6.9.2. Election for chair of SAWP-V

Action: For election

The Committee elected, unanimously, Dr Paul McNeill as the chair of SAWP-V for a 3-year mandate.

6.10. Safety Working Party (SWP-V)

6.10.1. Concept paper on the development of a guideline on consumer safety of active substances of immunological veterinary medicinal products acting against endogenous targets

Action: For adoption

The Committee adopted a draft concept paper on the development of a guideline on consumer safety of active substances of immunological veterinary medicinal products acting against endogenous targets for release for a 3-month period of public consultation.

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

There were no items for discussion.

7.2. Environmental risk assessment

There were no items for discussion.

7.3. Antimicrobial resistance

7.4. Pharmacovigilance

There were no items for discussion.

7.5. Vaccine antigen master file (VAMF) certification

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 – dogs

Action: For classification

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

9.1.2. Request for classification – (non-food producing) horses

Action: For classification

The Committee discussed the veterinary medicinal product for (non-food producing) horses. 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. Election for chair of CVMP

Action: For election

The Committee re-elected Johan Schefferlie, unanimously, as the CVMP chair for a further 3-year mandate.

10.3. Draft agenda CVMP Interested Parties meeting (14 May 2025)

Action: For information

The Committee noted the draft agenda of the CVMP Interested Parties meeting to be held on 14 May 2025.

11. CMDv

11.1. Verbal report from Chair of CMDv on the CMDv plenary meeting held on 15-16 April 2025

Action: For information

The Committee received a verbal report from the Chair of CMDv on the CMDv plenary meeting held on 15-16 April 2025 and noted its final agenda together with the draft agenda of the CMDv meeting to be held on 21-22 May 2025.

12. Legislation

12.1. Reflection Paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations

Action: For adoption

The Committee adopted the reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (EMA/CVMP/55240/2025) together with the overview of comments received during public consultation (EMA/CVMP/99773/2023).

12.2. 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 adoption

The Committee adopted 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).

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights (link)

14. Annex

2.6. Other issues

EMEA/V/C/006457/0000 – dogs

Action: For decision

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

3. Variations to marketing authorisations

3.1. Opinions

Pexion – imepitoin - EMEA/V/C/002543/VRA/0019/G – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Melovem – meloxicam - EMA/VRA/0000244473 – cattle, horses, pigs

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

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the 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.

EMA/VRA/0000224998 (WS) – Profender, Procox, Felpreva - cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Profender – praziquantel / emodepside - EMA/VRA/0000243831 - cats, dogs

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

Rapporteur: R. Breathnach

Action: For adoption

The Committee adopted the 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.

DogStem – equine umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244394 – 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 the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

HorStem – equine allogeneic umbilical cord-derived mesenchymal stem cells - EMA/VRA/0000244486 – horses

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

Rapporteur: A. C. Golombiewski

Action: For adoption

The Committee adopted the 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.

Oncept IL-2 – active Canarypox virus, strain vCP1338, expressing feline interleukin-2 gene, live - EMA/VRA/0000244261 – cats

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

Rapporteur: C. Miras

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.

Coxatab – firocoxib - EMA/VRA/0000247285 – dogs

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

Rapporteur: L. Nepejchalová

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.

Mirataz – mirtazapine - EMA/VRA/0000243883 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.4. List of questions

Evicto – selamectin – EMA/VRA/0000257048 – dogs, cats

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: J.G. Beechinor

Action: For adoption

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

Evanovo / Gumbohatch – EMA/VRA/0000244052 – chickens

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

Action: For adoption

The Committee adopted the list of questions and the comments on the product information for Evanovo, comments on the product information for Gumbohatch.

Recocam – meloxicam - EMA/VRA/0000255256 – cattle, horses, pigs

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

Rapporteur: J.G. Beechinor

Action: For adoption

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

Bovela – bovine viral diarrhoea vaccine (modified live) - EMA/VRA/0000256950 – cattle

Variation requiring assessment: quality-related changes.

Rapporteur: F. Klein

Action: For adoption

The Committee adopted the list of questions.

Suprelorin – deslorelin acetate - EMA/VRA/0000263609 – dogs, cats, ferrets

Variation requiring assessment: quality-related changes.

Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the list of questions.

Zulvac 8 Ovis – Bluetongue vaccine (inactivated) - EMA/VRA/0000256429 – sheep

Variation requiring assessment: to align the product information with version 9.1 of the QRD template.

Rapporteur: F. Marsilio

Action: For adoption

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

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.3 Inspections and controls

6. Working parties

6.2 Environmental Risk Assessment Working Party (ERAWP)

ERA ESEC Nominations

Action: For adoption

The Committee adopted the ERA ESEC nominations.

6.5 3Rs Working Party (3RsWP)

Minutes of the 3RsWP meeting held on 4-5 February 2025

Action: For information

The Committee noted the minutes of the 3RsWP meeting held on 4-5 February 2025.

Minutes of the OEG - 3RsWP - Batch release testing meeting held on 28 January 2025

Action: For information

The Committee noted the minutes of the OEG - 3RsWP - Batch release testing meeting.

NC and NAMs ESEC nominations

Action: For information

The Committee noted the NC and NAMs ESEC nominations.

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

The Committee adopted the list of nominations for the Quality Chemical ESEC.

7. Other scientific matters

7.7. Other issues

Azole Resistance in *Aspergillus*: publication of two peer-reviewed articles which have been published as part of the 12-months EMA-funded study on *Aspergillus*

Action: For information

The Committee noted the publication of two peer-reviewed articles: Azole resistance in *Aspergillus* isolates from animals or their direct environment (2013–2023): a systematic review (link); *Aspergillus* spp., aspergillosis and azole usage in animal species in Europe: results from a multisectoral survey and review of recent literature (link).

8. Co-operation with other EU or International bodies

8.1. VICH

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

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

9.3. Regulatory matters

Invented names

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the May 2025 meeting, which was held in person.

An asterisk (*) after the role, in the first column, signals that the participant attended virtually.
Additional experts participated in (part of) the meeting, remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
G. Johan Schefferlie	**Chair**	**CHAIR**	**No interests declared**	
Petra Falb	Member	Austria	No interests declared	
Manuela Leitner	Alternate	Austria	No interests declared	
Els Dewaele	Member	Belgium	No interests declared	
Krasimir Zlatkov	Member	Bulgaria	No interests declared	
Frane Božić	Member	Croatia	No interests declared	
Leona Nepejchalová	Member	Czechia	No interests declared	
Niels Christian Kyvsgaard	Member	Denmark	No interests declared	
Merete Blixenkrone-Møller	Alternate	Denmark	No interests declared	
Toomas Tiirats	Member	Estonia	No interests declared	
Minna Leppänen	Member	Finland	No interests declared	
Sylvie Louet	Member	France	No interests declared	
Christine Miras	Alternate	France	No interests declared	
Esther Werner	Alternate	Germany	No interests declared	
Spyridon Farlopoulos	Member	Greece	No interests declared	
Gábor Kulcsár	Member	Hungary	No interests declared	
Paul McNeill	Member	Ireland	No interests declared	
Fulvio Marsilio	Member	Italy	No interests declared	
Renate Kuske	Alternate	Latvia	No restrictions applicable to this meeting	
Despoina Iatridou*	Alternate	Luxembourg	No interests declared	
Caroline Coner*	Member	Luxembourg	No interests declared	
Jacqueline Poot	Member	Netherlands	No interests declared	
Kim Boerkamp	Alternate	Netherlands	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Hanne Bergendahl	Member	Norway	No interests declared	
Knud Sveen Torjesen*	Alternate	Norway	No interests declared	
Ewa Augustynowicz	Alternate	Poland	No interests declared	
Marcin Glanda*	Alternate	Poland	No interests declared	
João Pedro Duarte Da Silva*	Member	Portugal	No interests declared	
Gabriela Tuchila	Member	Romania	No interests declared	
Eva Chobotová	Member	Slovakia	No interests declared	
Urska Peunik	Alternate	Slovenia	No interests declared	
Cristina Muñoz Madero	Member	Spain	No interests declared	
Frida Hasslung Wikström	Member (Vice-Chair)	Sweden	No interests declared	
Hanna Bremer	Alternate	Sweden	No interests declared	
Keith Baptiste	Co-opted member	Denmark	No interests declared	
Ricardo Carapeto García	Co-opted member	Spain	No interests declared	
Rory Breathnach	Co-opted member	Ireland	No interests declared	
Mary O'Grady	Co-opted member	Ireland	No interests declared	
Carina Bergman	Co-opted member	Sweden	No interests declared	

An asterisk (*) after the role, in the first column, signals that the participant attended in person.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Katja Boxberger	Expert	Germany	No interests declared	
Kathrin Dietze	Expert	Germany	No interests declared	
Charlotte Smith Bonde	Expert	Denmark	No restrictions applicable to this meeting	
Alma Moffett	Expert	Ireland	No interests declared	
Anita Bottger	Expert	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Anne-Marie Jacques	Expert	France	No interests declared	
Florence Pillet	Expert	France	No restrictions applicable to this meeting	
Tiphaine Moreac-Pesselier	Expert	France	No interests declared	
Jonathan Bergman	Expert	Sweden	No restrictions applicable to this meeting	
Frida Martin	Expert	Sweden	No interests declared	
Dusan Palic	Expert	Germany	No restrictions applicable to this meeting	
Catarina Eriksson	Expert	Sweden	No interests declared	
Svenja Rieke	Expert	Germany	No interests declared	
Werner Terhalle	Expert	Germany	No interests declared	
Viviane Filor	Expert	Germany	No restrictions applicable to this meeting	
Roswitha Merkel	Expert	Germany	No interests declared	
Kerstin Cramer	Expert	Germany	No interests declared	
Silke Hickmann	Expert	Germany	No interests declared	
Christina Bredtmann	Expert	Germany	No interests declared	
Jana Pantzke	Expert	Germany	No interests declared	
Carolin Schulte	Expert	Germany	No interests declared	
Vanditi Rajan	Expert	Germany	No interests declared	
Eva Pomezna	Expert	Czech Republic	No interests declared	
Theis Moeslund Jensen	Expert	Denmark	No restrictions applicable to this meeting	
Kirsten Thomsen	Expert	Denmark	No interests declared	
Malene Nissen	Expert	Denmark	No interests declared	
Kathrine Just Andersen	Expert	Denmark	No interests declared	
Judith Romberg	Expert	Germany	No interests declared	
Sandra Schack	Expert	Germany	No interests declared	
Babett Kobe	Expert	Germany	No interests declared	
Emily Hams	Expert	Ireland	No interests declared	
Sarah Buckley	Expert	Ireland	No interests declared	
Alice Blennerhassett	Expert	Ireland	No interests declared	
Bryan Deane	Expert	Ireland	No interests declared	
Veronica Devesa	Expert	Spain	No interests declared	
Maria Dominguez Nicolas	Expert	Spain	No interests declared	
Elena Lucas Roldan	Expert	Spain	No interests declared	
Ana Isabel Olías	Expert	Spain	No interests declared	
Carlos Ballesteros	Expert	Spain	No interests declared	
Alberto de Prado Lopez	Expert	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Maria Jose Ferrer	Expert	Spain	No interests declared	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard*
ERAWP	Ricardo Carapeto García
PhVWP-V	James Mount*
IWP	Esther Werner
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)**
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
EWP	Cristina Muñoz Madero
3Rs	Sarah Adler-Flindt *(vet vice-chair)**
CMDv	Laetitia le Letty *(chair)**
A representative from the European Commission attended the meeting.	
Two observers from SwissMedic (Switzerland) attended the meeting.	
Meeting run with support from the relevant EMA staff.	

Experts' declared interests were evaluated against the agenda topics or activities they participated in.