11 March 2025
EMA/CVMP/90258/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 11-12 February 2025 meeting

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

Note on access to documents

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

The meeting was held virtually.

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 11-12 February 2025

The attendance list was completed and competing interests were identified for the February 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).

Spyridon Farlopoulos gave a proxy to Andrea Golombiewski for the whole meeting.
Ricardo Carapeto García gave a proxy to Cristina Muñoz Madero for the afternoon of Wednesday, 12 February 2025.

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.

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iv. Adoption of the minutes of the previous meeting

The minutes of the January 2025 meeting were adopted with no amendments.

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

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

1. Maximum residue limits

1.1. Opinions

1.1.1. Substance (fluralaner) – EMA/V/MRL/004380/EXTN/0002 - *salmonidae* and other fin fish

Action: For adoption

The Committee adopted the CVMP opinion including 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/003649/MODF/0004 – porcine

Action: For decision

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

Action: For adoption

The Committee adopted the scientific overview and 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. Omeprazole TriviumVet – omeprazole – EMEA/V/C/005345/0000 – dogs

Indication: as an aid in the treatment of NSAID-induced gastric ulceration in dogs.

Action: For adoption

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

Action: To note

The Committee noted the divergent opinion from Niels Kyvsgaard, Keith Baptiste and Minna Leppänen. The Norwegian CVMP member supported the divergent opinion.

Action: For information

The Committee noted the summary of opinion.

2.1.2. Elmaro – maropitant citrate monohydrate – EMEA/V/C/006389/0000 – dogs, cats

Indication: for the treatment and prevention of nausea and vomiting in dogs and cats.

Action: For adoption

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

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

Action: For information

The Committee noted the summary of opinion.

2.1.3. Vectormune HVT-AIV – avian influenza vaccine (live, recombinant) - EMEA/V/C/006288/0000 – chickens

Indication: vaccine intended for the active immunisation of one-day-old chickens to reduce mortality, clinical signs, and virus excretion due to infection with highly pathogenic avian influenza (HPAI) virus of the H5 sub-type.

Action: For adoption

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

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

Action: For information

The Committee noted the summary of opinion.

2.2. Oral explanations

There were no items for discussion.

2.3. List of outstanding issues

2.3.1. EMEA/V/C/006442/0000 – chickens, embryonated chicken eggs

Action: For decision

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

Action: For adoption

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

The Committee noted two peer review reports.

2.3.2. EMEA/V/C/006356 – dogs

Action: For decision

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

Action: For adoption

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

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

2.3.3. EMEA/V/C/006439/0000 – dogs

Action: For decision

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

Action: For adoption

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

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

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

Action: For decision

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

Action: For adoption

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

2.4. List of questions

2.4.1. EMEA/V/C/006595/0000 – rabbits

Action: For adoption

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

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

2.5. Re-examinations of CVMP opinions

There were no items for discussion.

2.6. Other issues

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

Action: For adoption

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

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Innovax-ND-H5 - avian influenza vaccine (live recombinant) - EMEA/V/C/006362/VRA/0001 – chickens and chicken embryonated eggs

Variation requiring assessment: to fulfil two quality-related 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 CVMP opinion, CVMP assessment report, and the product information.

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

3.1.2. Porcilis ColiClos - E. coli and C. perfringens vaccine (inactivated) - 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 CVMP opinion, 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. Simparica Trio – sarolaner / moxidectin / pyrantel embonate – EMA/VRA/0000240712 – dogs

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: E. Dewaele

Action: For adoption

The Committee adopted the CVMP opinion, 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

There were no items for discussion.

3.3. List of outstanding issues

There were no items for discussion.

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

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

5.2. 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)

6.1.1. Appointment of new AWP members

Action: For endorsement

The Committee endorsed Keith Baptiste and Ayla Hesp as new members of the AWP starting in February and Alexis Viel starting from May onwards.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.3. Efficacy Working Party (EWP-V)

6.3.1. Revision of efficacy guidelines in line with the definitions in Regulation (EU) 2019/6 for antimicrobial resistance, antimicrobial, antibiotic, metaphylaxis and prophylaxis

Action: For adoption

The Committee adopted the revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and the revised guideline on the conduct of efficacy studies for intramammary products for use in cattle together with the respective overviews of comments received on the draft revised guidelines during public consultation.

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 meeting

Action: For information

The Committee received a verbal report on the 3RsWP meeting of 4-5 February 2025 and noted its agenda.

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 meeting held on 28-29 January 2025

Action: For information

The Committee received a verbal report on the PhVWP-V meeting held on 28-29 January 2025 and noted its agenda together with its draft summary record.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held on 2-3 December 2024 and 20-21 January 2025

Action: For information

The Committee received a verbal report on QWP meetings (2-3 December 2024 and 20-21 January 2025). The Committee noted the minutes of the QWP meeting held on 4-5 November 2024; the agenda and minutes of the QWP meeting held in December and the agenda of the QWP meeting held in January.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 7 February 2025

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 7 February 2025 and noted its agenda together with the minutes of the SAWP-V meeting held on 10 January 2025.

6.10. Safety Working Party (SWP-V)

There were no items for discussion.

6.11. Other working party and scientific group issues

6.11.2. European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) Working Group

Action: For information

The Committee received a verbal report on the ESUAvet WG meeting held on 6-7 February 2025 and noted its agenda together with the minutes of the meeting held on 13-14 November 2024.

7. Other scientific matters

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

7.1. MRL issues

7.1.2. Request for inclusion of polyethylene in the list of substances considered as not falling within the scope of Regulation No. 470/2009

Action: For adoption

The Committee adopted the CVMP assessment report and agreed to amend the current entry for polyethylene in the list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009 under the heading of excipients. This decision followed the Committee's review of a request that had been submitted in accordance with the relevant CVMP guidance.

7.1.3 List of substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin

Action: For adoption

The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (EMA/CVMP/519714/2009-Rev. 58).

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.

7.5.1. EMEA/V/VAMF/00010

Action: For adoption

The Committee adopted the VAMF evaluation report and list of questions.

The Committee noted a peer review report.

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

There were no items for discussion.

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

9.1.2. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for dogs as intended for a limited market but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6, as there is no unmet medical need.

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. CVMP/CMDv Informal meeting under the Hungarian Presidency, Budapest, 23-25 October 2024

Action: For adoption

The Committee adopted the minutes of the CVMP and the joint CVMP/CMDv sessions of the Informal meeting held under the Hungarian Presidency in Budapest on 23-25 October 2024.

10.2. Committee Meeting Dates for 2027-2028

Action: For information

The Committee noted the proposed committee meeting dates for the period of 2027-2028.

10.3. Verbal report on Veterinary Domain meeting held on 21 January 2025

Action: For information

The Committee received a verbal report on the Veterinary Domain meeting held on 21 January 2025 and noted its agenda together with the minutes of the meeting held on 22 October 2024.

10.4. CVMP/CMDv Informal meeting under the Danish Presidency, Copenhagen, 24-26 September 2025

Action: For information

The Committee was informed that the CVMP/CMDv Informal meeting under the Danish Presidency would be held on 24-26 September 2025.

11. CMDv

There were no items for discussion.

12. Legislation

12.1. Verbal report on the work progress of the expert group for the scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with Article 114(1)

Action: For information

The Committee received a verbal report from the expert group's chair.

The Committee noted the minutes of the expert group meetings held on 18 December 2024 and on 22 January 2025 and the agenda of the meeting held on 29 January 2025.

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

Action: For adoption

The Committee adopted the review of the additional evidence provided for a substance with regards to the scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products. The recommendation adopted by the Committee in July 2024 was not modified.

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights link

14. Annex

2. Marketing authorisations and extensions

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

EMEA/V/C/006499/0000 – dogs

Action: For decision

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

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

Action: For information

The Committee noted the product information administrative correction following the omission of Annex II at opinion stage.

3. Variations to marketing authorisations

3.1. Opinions

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

Variation requiring assessment: to add a 100-dose presentation with a volume of 0.5 ml per dose/ quality-related changes.

Rapporteur: E. Werner

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.

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

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

Rapporteur: N.C. Kyvsgaard

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Strangvac – *Streptococcus equi* vaccine (recombinant proteins) – EMEA/V/C/005309/VRA/0008/G – horses

Variation requiring assessment: quality-related changes.

Rapporteur: M. Blixenkrone-Møller

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.

Hydrocortisone aceponate Ecuphar – hydrocortisone aceponate - EMA/VRA/0000166782 – dogs

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

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

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

Bluevac BTV – bluetongue virus vaccine (inactivated) - EMEA/V/C/000156/VRA/0013 – cattle, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

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.

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 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.

Clevor – ropinirole - EMA/VRA/0000227231 – 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.

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

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

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

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

Rapporteur: H. Bremer

Action: For adoption

The Committee adopted the 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.

Ingelvac CircoFLEX vaccine – porcine circovirus vaccine (inactivated) - EMEA/V/C/000126/VRA/0040 – pigs

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

Rapporteur: F. Marsilio

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.

Prozinc – insulin human – EMEA/V/C/002634/VRA/0030 – 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.

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

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

Rapporteur: A. 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.

ReproCyc ParvoFLEX – porcine parvovirosis vaccine (inactivated) - EMEA/V/C/004858/VRA/0007 – pigs

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

Rapporteur: F. Hasslung Wikström

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.

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

Newflend ND H9 – Newcastle disease and avian influenza vaccine (live, recombinant) - EMEA/V/C/005860/VRA/0003 – chickens

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

Rapporteur: J. Poot

Action: For adoption

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

Zycortal – desoxycortone pivalate - EMA/VRA/0000240475 – dogs

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

Rapporteur: H. Bergendahl

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

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

Scientific report on the 'Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.' was published on 30 January 2025.

Action: For information

The Committee noted that the scientific report on the 'Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.' had been published on 30 January 2025.

One Health: EU agencies unite to tackle azole fungicide resistance in Aspergillus fungi - link

9. Procedural and regulatory matters

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

9.3. Regulatory matters

Invented names

11. CMDv

Report from the Chair of CMDv

Action: To note

The Committee noted the draft agenda of the CMDv meeting to be held on 19-20 February 2025; the agenda of the CMDv meeting held on 22-23 January 2025; the minutes of the CMDv meeting held on 12-13 December 2024; and the CMDv report for release October-November 2024.

12. Legislation

ANNEX I

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

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

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Gerrit Johan Schefferlie***	No interests declared	
Austria	Petra Falb	No interests declared	
Austria	Manuela Leitner	No interests declared	
Belgium	Els Dewaele	No interests declared	
Belgium	Frederic Klein	No interests declared	
Bulgaria	Nadya Ognyanova Vladimirova	No interests declared	
Croatia	Frane Božić	No interests declared	
Czechia	Leona Nepejchalová	No interests declared	
Denmark	Niels Christian Kyvsgaard	No interests declared	
Denmark	Merete Blixenkrone-Møller	No interests declared	
Estonia	Toomas Tiirats	No interests declared	
Finland	Minna Leppänen	No interests declared	
France	Sylvie Louet	No interests declared	
France	Christine Miras	No interests declared	
Germany	Andrea Christina Golombiewski	No interests declared	
Germany	Esther Werner	No interests declared	
Hungary	Gábor Kulcsár	No interests declared	
Ireland	Paul McNeill	No interests declared	
Italy	Fulvio Marsilio	No interests declared	
Latvia	Zanda Auce	No interests declared	
Latvia	Renate Kuske	No interests declared	
Luxembourg	Despoina Iatridou	No interests declared	
Luxembourg	Caroline Coner	No interests declared	
Netherlands	Jacqueline Poot	No interests declared	
Netherlands	Kim Boerkamp	No interests declared	
Norway	Hanne Bergendahl	No interests declared	
Poland	Anna Wachnik-Święcicka	No interests declared	
Portugal	João Pedro Duarte Da Silva	No interests declared	
Romania	Gabriela Tuchila	No interests declared	
Slovakia	Eva Chobotová	No interests declared	
Slovenia	Katarina Straus	No interests declared	
Spain	Cristina Muñoz Madero	No interests declared	
Sweden	Frida Hasslung Wikström	No interests declared	
Denmark	Keith Baptiste	No interests declared	
Spain	Ricardo Carapeto García	No interests declared	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
Ireland	Rory Breathnach	No interests declared	
Ireland	Mary O'Grady	No interests declared	
Sweden	Carina Bergman	No interests declared	

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.			
Slovakia	Renata Kovacova	No interests declared	
Sweden	Birger Scholz	No interests declared	
Germany	Sandra-Maria Wienhold	No interests declared	
France	Nathalie Bridoux	No interests declared	
Finland	Saila Antila	No interests declared	
Finland	Jukka Pakkanen	No interests declared	
Finland	John Aspegren	No interests declared	
Ireland	Hannah Pratt	No interests declared	
Ireland	Bryan Deane	No interests declared	
Ireland	Sarah Beesley	No interests declared	
Germany	Judith Romberg	No interests declared	
Germany	Monika Hofmann	No interests declared	
Germany	Dagmar Sommer	No interests declared	
Germany	Daniela Loos	No interests declared	
Germany	Sandra Schack	No interests declared	
Germany	Jana Hundt	No interests declared	
Germany	Wiebke Weiher	No interests declared	
Germany	Sandra-Maria Wienhold	No interests declared	
Germany	Roswitha Merkel	No interests declared	
Germany	Gabriele Schweyen	No interests declared	
Germany	Kerstin Cramer	No interests declared	
Germany	Jan Brosda	No interests declared	
Sweden	Frida Martin	No interests declared	
Czech Republic	Radka Smítalová	No interests declared	
Czech Republic	Jana Fluksová	No interests declared	
Czech Republic	Jitka Chumchalova	No interests declared	
Czech Republic	Vilma Dosedlová	No interests declared	
Denmark	Charlotte Smith Bonde	No interests declared	
Denmark	Trine Sidonia Jensen	No interests declared	
Spain	Veronica Devesa	No interests declared	
Spain	Rosario Bullido	No interests declared	
Spain	Susana Casado	No interests declared	
Spain	Alberto de Prado	No interests declared	
Spain	Luis Agote Casado	No interests declared	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
Spain	Lorena Touriño González	No interests declared	
Spain	Raul Belmar Liberato	No interests declared	
Spain	Jose Ignacio Garcia	No interests declared	
Spain	Cristina Ballesteros	No interests declared	
Germany	Dusan Palic	No interests declared	
Belgium	Sonja Beken	No interests declared	
Belgium	Sandy Vermout	No interests declared	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard
ERAWP	Ricardo Carapeto García
PhVWP-V	James Mount
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
QWP	Marie-Hélène Sabinotto *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman
J3Rs WP	Sarah Adler-Flindt *(veterinary vice chair)*
A representative from the European Commission attended the meeting.	
An observer 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.