18 June 2024
EMA/CVMP/285480/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 21-22 May 2024 meeting

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

Note on access to documents

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

The meeting was held in-person.

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 21-22 May 2024

The attendance list was completed and competing interests were identified for the May 2024 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters discussed (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I).

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

iv. Adoption of the minutes of the previous meeting

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

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

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

1. Maximum residue limits

1.1. Opinions

There were no items for discussion.

1.2. Oral explanations

There were no items for discussion.

1.3. List of outstanding issues

There were no items for discussion.

1.4. List of questions

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. Nobilis Multriva RT+IBm+ND+EDS – avian metapneumovirus, avian infectious bronchitis virus, Newcastle disease virus, and egg drop syndrome virus vaccine (inactivated) - EMEA/V/C/006043/0000 – chickens

Indication: vaccine intended for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus, reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains, reduction of mortality and clinical signs caused by Newcastle disease virus and reduction of egg drop and eggshell defects caused by egg drop syndrome '76 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 recommendation.

Action: For information

The Committee noted the summary of opinion.

2.1.2. Nobilis Multriva RT+IBm+ND+Gm+REOm – avian metapneumovirus, avian infectious bronchitis virus, Newcastle disease virus, avian infectious bursal disease virus and avian reovirus vaccine (inactivated) - EMEA/V/C/005989/0000 – chickens

Indication: vaccine intended for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus, reduction of respiratory signs and egg drop caused by infectious bronchitis virus strains, reduction of mortality and clinical signs caused by Newcastle disease virus and for the passive immunisation of the progeny of the vaccinated chickens to reduce mortality and clinical signs of disease caused by strains of infectious bursal disease virus, and to reduce viraemia and clinical signs of disease caused by avian reovirus

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 recommendation.

Action: For information

The Committee noted the summary of opinion.

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/006234/0000 – cattle, pigs, dogs, cats

Action: For decision

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

Action: For adoption

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

The Committee noted a peer review report.

2.3.2. EMEA/V/C/0006254/0000 - dogs

Action: For adoption

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

The Committee noted peer review reports.

2.3.3. EMEA/V/C/005345/0000 – dogs

Action: For adoption

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

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

2.3.4. EMEA/V/C/006289/0000 – pigs

Action: For decision

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

Action: For adoption

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

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

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

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. Bluevac BTV - Bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3) - EMEA/V/C/000156/VRA/0012/G – cattle, sheep

Variation requiring assessment: to change the multistrain dossier to allow up to two different inactivated bluetongue virus serotypes in the final product (bivalent vaccine) and quality-related changes.

Rapporteur: E. Werner, Co-Rapporteur: F. Marsilio

Action: For adoption

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

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

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

There were no items for discussion.

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

3.4.1. Clomicalm – clomipramine hydrochloride - EMEA/V/C/000039/VRA/0042/G – dogs

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

Rapporteur: A. Golombiewski

Action: For adoption

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

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

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

Rapporteur: S. Louet

Action: For adoption

The Committee adopted a 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

There were no items for discussion.

4.7.1. Referrals and related procedures under Regulation (EU) 2019/6

4.7.1. Article 130(4) recommendation: direct animal healthcare professional communication (DaHPC) and topic-specific communication plan: Kexxtone 32.4 g continuous-release intraruminal device for cattle – monensin – EMA/V/A/150

Scope: benefit-risk balance

Rapporteur: C. Muñoz Madero, Co-rapporteur: J.G. Beechinor

Action: For endorsement

The CVMP adopted a MAH's direct animal healthcare professional communication (DaHPC) following the suspension of the marketing authorisation for Kexxtone due to a quality defect and the related observation of an increased number of deaths occurring in a non-target species (dogs) after accidental exposure, as well as potential lack of efficacy.

5. Post-authorisation issues for marketing authorisations

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

5.1. Pharmacovigilance under Regulation (EU) 2019/6

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

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

There were no items for discussion.

5.5. Other issues

There were no items for discussion.

6. Working parties

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

6.1. Antimicrobials Working Party (AWP)

6.1.1. Election of the Vice-chair of AWP

Action: For election

As no nominations were received, the Committee agreed to extend the deadline for submission of the nominations and the election of the Vice-chair of AWP is expected to take place at the June CVMP meeting.

6.2. Environmental Risk Assessment Working Party (ERAWP)

There were no items for discussion.

6.3. Efficacy Working Party (EWP-V)

There were no items for discussion.

6.4. Immunologicals Working Party (IWP)

6.4.1. Verbal report on IWP meeting held on 24-25 April 2024

Action: For information

The Committee noted the agenda of the meeting and the verbal report on the IWP meeting held on 24-25 April 2024 and the minutes of the IWP meeting held on 14-15 November 2023.

6.5. 3Rs Working Party (3RsWP)

There were no items for discussion.

6.6. Novel Therapies & Technologies Working Party (NTWP)

There were no items for discussion.

6.7. Pharmacovigilance Working Party (PhVWP-V)

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

Action: For information

The Committee noted the agenda and the verbal report of the PhVWP-V meeting held on 25 April 2024 and the summary record of the same meeting.

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings

Action: For information

The Committee noted the minutes of the QWP meeting held on 12-13 February 2024, the agenda and minutes of the QWP meeting held on 11-12 March 2024 and a verbal report on both meetings together with the agenda of the QWP meeting held on 15-16 April 2024.

6.8.2. QWP 3-year workplan 2025-2027

Action: For information

The Committee noted the QWP 3-year workplan 2025-2027 for targeted consultation with stakeholders.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 17 May 2024

Action: For information

The Committee noted the agenda and the verbal report on the SAWP-V meeting held on 17 May 2024 together with the minutes of the SAWP-V meeting held on 12 April 2024.

6.10. Safety Working Party (SWP-V)

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

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

8. Co-operation with other EU or International bodies

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

8.1. VICH

8.1.4. Nomination of EU speakers for VICH Conference in November 2024

Action: For endorsement

The Committee endorsed the participation of experts to represent CVMP at the VICH Conference in November 2024.

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

There were no items for discussion.

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

9.3. Regulatory matters

9.3.1. Q&A Paper on Product Classification

Action: For discussion

The Committee discussed the Q&A paper on product classification. Adoption of the document is expected for the June 2024 CVMP meeting.

10. Organisational and strategic matters

10.1. Verbal report on Veterinary Domain meeting held on 8 May 2024

Action: For information

The Committee noted the agenda and the verbal report on the Veterinary Domain meeting held on 8 May 2024 together with the minutes of the 1 February 2024 meeting.

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

Action: For adoption

The Committee adopted the consolidated 3-year work plan for the veterinary domain (2025-2027) for stakeholders' consultation.

10.4. CVMP Interested Parties

Action: For information

The Committee noted the agenda of the CVMP Interested Parties meeting held on 22 May 2024.

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

Action: For discussion

The Committee discussed the draft Scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months. The final report is expected for discussion at the June 2024 CVMP meeting with adoption at the July 2024 CVMP meeting.

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

Action: For information

13. Any other business

13.1. Meeting highlights

Action: For comments

Upon the completion of the May 2024 CVMP meeting, the draft meeting highlights was circulated for members to provide comments within 24 hours.

14. Annex

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

Isemid – torasemide – EMEA/V/C/004345/VRA/0006 – 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 member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Virbagen Omega – feline interferon omega (recombinant) – EMEA/V/C/000061/VRA/0011 – dogs, 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 member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Forceris – toltrazuril / iron(iii) ion - EMEA/V/C/004329/VRA/0007 – pigs (piglets)

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 member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Porcilis AR-T DF – porcine progressive atrophic rhinitis vaccine (inactivated) - EMEA/V/C/000055/VRA/0019 – pigs (sows), pigs (sows, nullipar)

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

Rapporteur: M. Blixenkrone-Møller

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Contacera – meloxicam - EMEA/V/C/002612/VRA/0017 – horses, cattle, pigs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

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.

Vectra 3D – dinotefuran / pyriproxyfen / permethrin – EMEA/V/C/002555/VRA/0025 – dogs

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

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Vectra Felis – dinotefuran / pyriproxyfen – EMEA/V/C/002746/VRA/0020 - cats

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

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Rabitec – rabies vaccine (live, oral) - EMEA/V/C/004387/VRA/0012 – foxes and raccoon dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendation.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

MS-H Vaccine – *Mycoplasma synoviae* (live) - EMEA/V/C/000161/VRA/0020 – chickens

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.

Circovac – Porcine circovirus vaccine (inactivated) - EMEA/V/C/000114/VRA/0021 – 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 member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Nobivac LoVo L4 – canine Leptospira vaccine - EMEA/V/C/005628/VRA/0001 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Dewaele

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Locatim – immunoglobulins against *Escherichia coli* F5 antigen, Bovine - EMEA/V/C/000041/VRA/0026 – cattle (newborn calves)

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.

Tulissin – tulathromycin - EMEA/V/C/005073/VRA/0010/G – cattle, pigs, sheep

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the CVMP opinion.

The Norwegian member agreed with the above-mentioned recommendations.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

Felpreva – tigolaner, emodepside, praziquantel- EMEA/V/C/005464/VRA/0007 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

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

Variation requiring assessment: quality-related changes.

Rapporteur: R. Carapeto Garcia

Action: For adoption

The Committee adopted the list of questions.

Osurnia – terbinafine / florfenicol/ betamethasone acetate – EMEA/V/C/003753/VRA/0026/G – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the list of questions.

Osurnia – terbinafine / florfenicol / betamethasone acetate - EMEA/V/C/003753/VRA/0027 – 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 agreed comments on the product information.

Nobilis IB Primo QX – avian infectious bronchitis vaccine (live) - EMEA/V/C/002802/VRA/0012/G - chickens

Variation requiring assessment: quality-related changes.

Rapporteur: C. Miras

Action: For adoption

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

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

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

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

Meloxoral - meloxicam- EMA/VRA/0000174596 – dogs, cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the rapporteur's assessment report including the request for supplementary information.

3.6 Other issues under Regulation (EU) 2019/6

Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMEA/V/C/004846/VRA/0015/G – dogs

Rapporteur: R. Breathnach

Action: For endorsement

The Committee endorsed the rapporteur's 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

6.5. 3Rs Working Party (3RsWP)

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

VICH GL23 (R2) Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing

Action: For endorsement

The Committee endorsed the draft VICH GL23 (R2) for sign off at step 3.

9.3. Regulatory matters

Invented names

12. Legislation

Publication in the Official Journal of the EU the DA on oral administration

Commission Delegated Regulation (EU) 2024/1159 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals has been published today in the (https://eur-lex.europa.eu/eli/reg_del/2024/1159/oj)

Action: For information

ANNEX I

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

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

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie**	**Full involvement**	
Austria	Petra Falb	Full involvement	
Austria	Manuela Leitner*	Full involvement	
Belgium	Els Dewaele	Full involvement	
Belgium	Frederic Klein	Full involvement	
Bulgaria	Nadya Ognyanova Vladimirova*	Full involvement	
Croatia	Frane Božić	Full involvement	
Czechia	Leona Nepejchalová	Full involvement	
Denmark	Niels Christian Kyvsgaard	Full involvement	
Denmark	Merete Blixenkrone-Møller*	Full involvement	
Estonia	Toomas Tiirats	Full involvement	
Finland	Minna Leppänen	Full involvement	
Finland	Kristina Lehmann*	Full involvement	
France	Sylvie Louet	Full involvement	
France	Christine Miras*	Full involvement	
Germany	Andrea Christina Golombiewski	Full involvement	
Germany	Esther Werner*	Full involvement	
Hungary	Gabor 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	Anna Wachnik-Święcicka*	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	Katarina Straus*	Full involvement	
Slovenia	Boris Kolar*	Full involvement	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	Full involvement	

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

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were evaluated against the topics they have been invited to talk about.			
France	Laurent Fabry*	Full involvement	
France	Anne-Marie Jacques*	Full involvement	
France	Lise Laborieux*	Full involvement	
France	Nathalie Bridoux*	Full involvement	
Netherlands	Sandra ten Voorde*	Full involvement	
Spain	Ana Isabel Olías Molero*	Full involvement	
Spain	Adrian Fandiño Lopez*	Full involvement	
Germany	Dusan Palic*	Full involvement	
Czech Republic	Josef Suchý*	Full involvement	
Czech Republic	Zdenka Mašková*	Full involvement	
Czech Republic	Eva Pomezna*	Full involvement	
Ireland	Bryan Deane*	Full involvement	
Ireland	Rhona McHugh*	Full involvement	
Ireland	Sarah Beesley*	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*
PhVWP-V	James Mount*
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