



21 May 2024
EMA/CVMP/239662/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 16-18 April 2024 meeting

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

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to ongoing 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 remotely.

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 16-18 April 2024

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

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the March 2024 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

There were no items for discussion.

1.2. Oral explanations

There were no items for discussion.

1.3. List of outstanding issues

There were no items for discussion.

1.4. List of questions

1.4.1. Substance (ketoprofen) – EMEA/V/MRL/003652/MODF/0005 – bovine, porcine, equidae

Action: For adoption

The Committee adopted the scientific overview and list of questions concluding the first phase of a review of its previous opinion on maximum residue limits for ketoprofen.

The Committee also adopted a call for scientific data for use in CVMP assessment work of ketoprofen, to be shared with interested parties such as pharmaceutical industry, learned societies, governmental institutions as well as EU and EEA-EFTA Member States.

The CVMP is seeking to obtain any relevant data, not already reported in CVMP's initial summary report, that may be available to address concerns relating to residue concentrations in tissues that may exceed the ADI.

CVMP noted a peer review report and the comments from the CVMP members.

1.5. Re-examination of CVMP opinions on maximum residue limits

There were no items for discussion.

1.6. Other issues

There were no items for discussion.

2. Marketing authorisations

2.1. Opinions under Regulation (EU) 2019/6

2.1.1. [Respivac TRT – turkey rhinotracheitis virus, live - EMEA/V/C/006160/0000 – turkeys](#)

Indication: active immunisation of chickens to reduce the detrimental effect caused by virulent avian metapneumovirus on the ciliary activity, which may be manifested in respiratory clinical signs.

Action: For adoption

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

Action: To note

The Committee noted the summary of opinion.

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

2.1.2. [Innovax-ND-H5 – Newcastle disease, avian influenza and Marek's disease vaccine \(live recombinant\) - EMEA/V/C/006362/0000 – chickens](#)

Indication: for active immunisation of one-day-old chicks or 18–19 day-old embryonated chicken eggs to reduce mortality, clinical signs and virus excretion due to infection with highly pathogenic Avian Influenza (HPAI) virus of the H5 type.

Action: For adoption

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

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

Action: To note

The Committee noted the summary of opinion.

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

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/005993/0000 – dogs](#)

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 and list of outstanding issues and the comments on the product information.

The Committee noted a peer review report.

[2.3.2. EMEA/V/C/006118/0000 – chickens](#)

Action: For decision

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

Action: For adoption

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

The Committee noted a peer review report.

[2.3.3. EMEA/V/C/006260/0000 - cattle](#)

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 the comments from the CVMP members.

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

[2.4.1. EMEA/V/C/006389/0000 – dogs, cats](#)

Action: For adoption

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

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

[2.4.2. EMEA/V/C/006332/0000 – dogs](#)

Action: For adoption

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

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

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

There were no items for discussion.

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

There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

3.1.1. *Coxevac – Coxiella burnetii* vaccine - EMEA/V/C/000155/VRA/0016/G – cattle, goats, sheep

Variation requiring assessment: quality-related changes.

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.2. 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. Suvaxyn PRRS MLV – porcine respiratory and reproductive syndrome virus vaccine (live) - EMEA/V/C/004276/VRA/0011/G – pigs

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

Action: For adoption

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

3.5. Re-examinations of CVMP opinions on variations requiring assessment under Regulation (EU) 2019/6

There were no items for discussion.

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

There were no items for discussion.

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

There were no items for discussion.

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

There were no items for discussion.

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

There were no items for discussion.

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

There were no items for discussion.

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

4.5.1. Kexxtone 32.4 g continuous-release intraruminal device for cattle – monensin – EMA/V/A/150

Scope: Benefit-risk balance

Action: Oral explanation

An oral explanation was held on 16 April 2024.

Action: For discussion

The Committee discussed the rapporteur's assessment report.

The Committee considered the request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 due to concerns related to deficiencies in the quality of Kexxtone, leading to a potential lack of efficacy in cattle and to reported adverse events in the non-target species dogs. The Committee noted the comments from CVMP members.

Post meeting note: On 23 April 2024, the Committee adopted, via written procedure, the CVMP Opinion and the CVMP Assessment Report concluding that, under the current circumstances, the benefit-risk balance was no longer positive, and recommending suspension of the marketing authorisation from the market.

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.

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.

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)

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 18-19 March 2024

Action: For information

The Committee received a verbal report and noted the agenda of the meeting held on 18–19 March 2024 and the minutes of the meeting held on 11–12 October 2023.

6.2.2. Environmental Risk Assessment ESEC

Action: For adoption

The Committee adopted the mandate, objectives and rules of procedure and noted the call for nominations.

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 discussion

The Committee discussed the draft revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances and the draft revised guideline on the conduct of efficacy studies for intramammary products for use in cattle. The adoption of the draft revised guidelines for public consultation is foreseen for the June 2024 CVMP meeting.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion.

6.5. 3Rs Working Party (3RsWP)

There were no items for discussion.

6.6. Novel Therapies & Technologies Working Party (NTWP)

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

Action: For adoption

The Committee adopted the draft concept paper for the development of a guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations (EMA/CVMP/NTWP/143787/2023) for release for a 3-month period of public consultation.

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on the PhVWP-V meeting held on 26-27 March 2024

Action: For information

The Committee noted the agenda, the draft summary record and the verbal report on the PhVWP-V meeting held on 26-27 March 2024.

6.8. Quality Working Party (QWP)

6.8.1. Draft guideline on stability testing for variations for veterinary medicinal products (VMPs)

Action: For adoption

The Committee adopted the draft guideline on stability testing for variations for VMPs (EMA/CVMP/QWP/515653/2023) for release for public consultation.

6.8.2. Addendum to the guideline on the use of near infrared spectroscopy (NIRS)

Action: For adoption

The Committee adopted the addendum to the guideline on the use of near infrared spectroscopy (NIRS) on defining the scope of an NIRS procedure after public consultation (EMA/101685/2024) and noted the overview of comments (EMA/101673/2024).

6.8.3. Q&A on nitrosamines limits on CEPs

Action: For adoption

The Committee adopted the Q&A document on nitrosamines limits on CEPs.

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 12 April 2024

Action: For information

The Committee noted the agenda and the verbal report on the SAWP-V meeting held on 12 April 2024 and minutes of the SAWP-V meeting held on 8 March 2024.

6.10. Safety Working Party (SWP-V)

6.10.1. Verbal report on SWP-V meeting held on 21-22 March 2024

Action: For information

The Committee noted the agenda and the verbal report on the SWP-V meeting held on 21-22 March 2024 and minutes of the meeting held on 16 November 2023.

6.10.2. Election of the Chair of the SWP-V

Action: For decision

C. Bergman was unanimously re-elected as chair of the SWP-V for a further 3-year mandate.

6.11. Other working party and scientific group issues

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

Draft Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations

Action: For adoption

The Committee adopted the Manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations (EMA/CVMP/ESUAVET/570091/2023).

6.11.3. Active substance master file working group – update of ASMF worksharing procedure guideline

Action: For adoption

The Committee adopted the revised ASMF worksharing procedure guideline.

7. Other scientific matters

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

7.1. MRL issues

7.2. Environmental risk assessment

There were no items for discussion.

7.3. Antimicrobial resistance

There were no items for discussion.

7.4. Pharmacovigilance

There were no items for discussion.

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

There were no items for discussion.

7.7. Other issues

There were no items for discussion.

8. Co-operation with other EU or International bodies

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

8.1. VICH

8.2. Codex Alimentarius

There were no items for discussion.

8.3. Other EU bodies and international organisations

There were no items for discussion.

9. Procedural and regulatory matters

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

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

9.1.1. Request for classification

Action: For classification

The Committee 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

10. Organisational and strategic matters

10.1. Agenda of the CVMP Interested Parties meeting to be held on 22 May 2024

Action: For discussion

The Committee agreed on the agenda topics for the upcoming meeting following an agenda proposal by the CVMP Interested Parties.

11. CMDv

11.1. Verbal report on the CMDv meetings held on 15-16 February 2024 and 14-15 March 2024

Action: To note

The Committee noted the verbal report on the meetings held on 15-16 February 2024 and 14-15 March 2024, the draft agenda of the meeting to be held on 25-26 April 2024 and the draft minutes of the meeting held on 14-15 March 2024.

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: To note

The Committee received a verbal report on the progress made by the expert group developing a scientific advice under Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances that are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months.

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: To note

The Committee received a verbal report from 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).

13. Any other business

13.1. AOB

There were no items for discussion.

13.2. Meeting highlights

Action: To comment

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

14. Annex

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

[EMEA/V/C/006102/0000 – dogs](#)

Action: For endorsement

The Committee endorsed the request from the applicant for an earlier submission of the responses to the list of questions.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

[Neoleish – canine leishmaniasis vaccine \(recombinant DNA plasmid\) - EMEA/V/C/005538/VRA/0001/G – dogs](#)

Variation requiring assessment: quality-related changes and to align the product information with version 9.0 of the QRD template.

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Coxatab – firocoxib – EMEA/V/C/005816/0001 – dogs](#)

Variation requiring assessment: quality-related changes.

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Convenia – ceftiofur – EMEA/V/C/000098/VRA/0038 – cats, dogs](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Evant – Eimeria acervulina, Eimeria maxima, Eimeria mitis, Eimeria praecox, Eimeria tenella \(vaccine live\) – EMEA/V/C/004902/VRA/0004 – chickens](#)

Variation requiring assessment: quality-related changes.

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Simparica Trio – sarolaner / moxidectin / pyrantel embonate - EMEA/V/C/004846/VRA/0015/G – dogs](#)

Variation requiring assessment: quality-related changes.

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Advocate – imidacloprid / moxidectin - EMEA/V/C/000076/VRA/0049 – cats, ferrets, dogs](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Tessie – tasipimidine - EMEA/V/C/005427/VRA/0002 – dogs](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[UpCard – torasemide - EMEA/V/C/003836/VRA/0009 – dogs](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Arti-Cell Forte – allogeneic equine peripheral blood-derived chondrogenic induced mesenchymal stem cells - EMEA/V/C/004727/VRA/0014 – horses](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Cortavance – hydrocortisone aceponate – EMEA/V/C/000110/VRA/0016 – dogs](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[MS-H vaccine - *Mycoplasma synoviae* \(live\) – EMEA/V/C/000161/VRA/0019 – chickens](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Syvazul BTV – Bluetongue virus vaccine \(inactivated\) \(multistrain: 1-2 strains out of a set of 3\) - EMEA/V/C/004611/VRA/0009 – sheep, cattle](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[NexGard – Afoxolaner - EMA/VRA/0000166782 – dogs](#)

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

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

[Prozinc – insulin human - EMEA/V/C/002634/VRA/0028 – cats, dogs](#)

Variation requiring assessment: quality-related changes.

Action: For adoption

The Committee adopted the CVMP opinion and the product information.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

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

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

[Neptra – florfenicol / terbinafine hydrochloride / mometasone furoate - EMEA/V/C/004735/VRA/0009 – dogs](#)

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

Action: For adoption

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

[Leucofeligen FeLV/RCP, Leucogen, Nobivac LeuFel – feline calicivirus vaccine, feline viral rhinotracheitis vaccine, feline infectious enteritis \(feline panleucopenia\) vaccine \(live\), feline leukaemia vaccine \(recombinant protein\), feline leukaemia vaccine \(inactivated\) – WS2580 – cats](#)

Variation requiring assessment: quality-related changes.

Action: For adoption

The Committee adopted the list of questions.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

4. Referrals and related procedures

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.

5. Post-authorisation issues for marketing authorisations

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

[Mhyosphere PCV ID – EMEA/V/C/005272/REC/004](#)

Post-authorisation recommendation

Action: For endorsement

The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation which is now considered fulfilled.

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

6. Working parties

6.5. 3Rs Working Party (3RsWP)

[6.5.1. Minutes of the 3RsWP plenary meeting held on 6–7 February 2024](#)

Action: To note

The Committee noted the minutes of the 3RsWP plenary meeting held on 6–7 February 2024.

[6.5.2. Agenda of the 3RsWP plenary meeting held on 21 March 2024](#)

Action: To note

The Committee noted the agenda of the 3RsWP plenary meeting held on 21 March 2024.

Action: To note

The Committee noted the agenda of [3RsWP annual stakeholders meeting](#) held on 20 March 2024.

7. Other scientific matters

7.7. Other issues

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 April 2024 meeting, which was held virtually.

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	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	
Croatia	Hrvoje Pavasovic	Full involvement	
Czechia	Leona Nepejchalová	Full involvement	
Denmark	Niels Christian Kyvsgaard	Full involvement	
Denmark	Merete Blixenkron-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	
Greece	Spyridon Farlopoulos	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	
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	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	Full involvement	
Sweden	Hanna Bremer	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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
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* Experts were evaluated against the topics they have been invited to talk about.

Austria	Richard Cejka-Scheidl	Full involvement	
Austria	Elvira Zimre-Grabensteiner	Full involvement	
France	Florence Pillet	Full involvement	
France	Tiphaine Moreac-Pesselier	Full involvement	
France	Anne Sagnier	Full involvement	
France	Anne-Marie Jacques	Full involvement	
Denmark	Kirsten Brolin THOMSEN	Full involvement	
Denmark	Kathrine Just ANDERSEN	Full involvement	
Denmark	Susanne Havn AAMAND	Full involvement	
France	Nathalie Bridoux	Full involvement	
Germany	Sandra Bertulat	Full involvement	
Germany	Christine Schwarz	Full involvement	
Germany	Svenja Rieke	Full involvement	
Netherlands	René van Herwijnen	Full involvement	
France	Laurent Fabry	Full involvement	
Spain	Maria Esperanza Herreros Avila	Full involvement	
Spain	Cristina Benito Sastre	Full involvement	
Spain	Maria Jose Ferrer	Full involvement	
Spain	Rosario Bullido	Full involvement	
Spain	Alberto de Prado Lopez	Full involvement	
Spain	Susana Casado	Full involvement	
Spain	Marta Martin Juárez	Full involvement	
Spain	Rocío Fernández Granda	Full involvement	
Spain	Adrian Fandiño Lopez	Full involvement	
Germany	Luela Fröhlich	Full involvement	
Germany	Kathrin Schirmann	Full involvement	
Germany	Daniel Benesh	Full involvement	
Germany	Jan Brosda	Full involvement	
Germany	Anke Finnah	Full involvement	
Germany	Jens Schönfeld	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
Germany	Alina Hoskins	Full involvement	
Germany	Christina Bredtmann	Full involvement	
Germany	Nuria Doñamayor Alonso	Full involvement	
Germany	Andrea Orthmann	Full involvement	
Germany	Antje Gerofke	Full involvement	
Germany	Monika Hofmann	Full involvement	
Germany	Dagmar Sommer	Full involvement	
Germany	Babett Kobe	Full involvement	
Germany	Heike Gyra	Full involvement	
Germany	Ingun Lemke	Full involvement	
Germany	Jana Hundt	Full involvement	
Germany	Rolf Beckmann	Full involvement	
Czech Republic	Eva Pomezna	Full involvement	
Czech Republic	Radka Smítalová	Full involvement	
Czech Republic	Jana Fluksová	Full involvement	
Romania	Vilma Dosedlova	Full involvement	
Czech Republic	Jitka Chumchalova	Full involvement	
Czech Republic	Lucie Pokludová	Full involvement	
Ireland	Alice Stack	Full involvement	
Ireland	Sarah Buckley	Full involvement	
Ireland	Gavin Ryan	Full involvement	
Ireland	Bryan Deane	Full involvement	
Belgium	Sandy Vermout	Full involvement	
Germany	Andrea Winchenbach	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
ESUAVet WG	Sara Sacristan (<i>ESUAVet WG CVMP co-chair</i>)
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
PhVWP-V	James Mount
QWP	Marie-Hélène Sabinotto (<i>veterinary vice chair</i>)
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission

Present

Observers from Swissmedic

Present

European Medicines Agency support

Meeting run with support from the relevant EMA staff