11 February 2025
EMA/CVMP/54921/2025
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 14-15 January 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 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 14-15 January 2025

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

Toomas Tiirats gave a proxy to Zanda Auce for the whole meeting.
Ricardo Carapeto García gave a proxy to Cristina Muñoz Madero for Wednesday, 15 January.

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

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

There were no contacts declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the December 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

1.3.1. Substance – EMA/V/MRL/004380/EXTN/0002 - *salmonidae* and other fin fish

Action: For decision

The Committee agreed that there is no need for oral explanation

Action: For discussion

The Committee discussed the scientific overview and noted a peer review report.

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. Bluevac-3 – Bluetongue virus vaccine (inactivated) - EMEA/V/C/006575/0000 – cattle, sheep

Indication: new vaccine for the active immunisation of sheep to reduce the viraemia, mortality and clinical signs caused by the serotype 3 of the bluetongue virus, and for active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.

Action: For adoption

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

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

Action: For endorsement

The Committee endorsed the summary of opinion and noted a peer review report and the comments from five CVMP members.

2.1.2. Syvazul BTV3 – Bluetongue virus vaccine (inactivated) - EMEA/V/C/006623/0000 – sheep

Indication: new vaccine for the active immunisation of sheep to reduce viraemia, mortality, clinical signs and lesions caused by bluetongue virus serotype 3.

Action: For adoption

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

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

Action: For endorsement

The Committee endorsed the summary of opinion and noted two peer review reports and the comments from four CVMP members.

2.1.3. Nobilis Multriva REOm – avian reovirus vaccine, inactivated - EMEA/V/C/006501/0000 – chickens

Indication: a new vaccine for the active immunisation of chickens for passive immunisation of the progeny of the vaccinated chickens to reduce viraemia and clinical signs of disease caused by avian reovirus (ARV) genotypes 1 and 4.

Action: For adoption

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

Action: For endorsement

The Committee endorsed the summary of opinion and noted two peer review reports.

2.2. Oral explanations

There were no items for discussion.

2.3. List of outstanding issues

There were no items for discussion.

2.4. List of questions

2.4.1. EMEA/V/C/006180/0000 – horses

Action: For adoption

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

The Committed noted three peer review reports.

2.4.2. EMEA/V/C/006589/0000 – chickens

Action: For adoption

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

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

2.5. Re-examinations of CVMP opinions

There were no items for discussion.

2.6. Other issues

There were no items for discussion.

3. Variations to marketing authorisations

3.1. Opinions

There were no items for discussion.

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

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

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one.

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

Action: For adoption

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

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

Variation requiring assessment: quality-related changes.

Rapporteur: S. Louet

Action: For adoption

The Committee adopted the list of questions.

3.4.3. Veraflox – pradofloxacin - EMA/VRA/0000236570 – dogs and cats

Variation requiring assessment: to align the product information with version 9.0 of the QRD template and the EMA Guideline on the SPC for antimicrobial medicinal products (EMA/CVMP/383441/2005-Rev.1 Corr) and to update the MIC data available in the SPC.

Rapporteur: A. Golombiewski

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

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

There were no items for discussion.

4.2. Union interest referral under Article 82 based on Article 129(3)

There were no items for discussion.

4.3. Procedure under Article 70(11) 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) on a CMDv review procedure

There were no items for discussion.

4.5. Request from the European Commission under Article 130(4) 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)

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 under Regulation (EU) 2019/6

There were no items for discussion.

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

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

5.1. Pharmacovigilance

There were no items for discussion.

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

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. Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals

Action: For adoption

The Committee adopted the guideline on AMR risk assessment (EMA/CVMP/AWP/706442/2013) and the overview of comments on the guideline (EMA/CVMP/AWP/702252/2018). The guideline will come into effect on 1 August 2025.

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Upcoming election for chair of ERAWP

Action: For information

The Committee noted the call for nominations for the upcoming election for chair of ERAWP.

6.3. Efficacy Working Party (EWP-V)

6.3.1. Guideline on data requirements for veterinary medicinal products for zootechnical purposes

Action: For adoption

The Committee adopted the revised guideline on data requirements for veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/37280/2023) and the overview of comments received on the draft guideline during public consultation (EMA/CVMP/EWP/259888/2024). The revision will come into effect on 1 August 2025.

6.4. Immunologicals Working Party (IWP)

There were no items for discussion.

6.5. 3Rs Working Party (3RsWP)

6.5.1. Reflection paper on the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs

Action: For adoption

The Committee adopted a draft revised reflection paper on the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/3Rs/1094/2025), to be released for 4-months of public consultation. This revision of the reflection paper is to align with Regulation (EU) 2019/6 but also proposes relevant updates to scientific guidelines and regulatory provisions, which have 3Rs implications.

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 18 December 2024

The Committee received a verbal report on the PhVWP-V meeting held on 18 December 2024 and noted its agenda and draft summary record.

6.8. Quality Working Party (QWP)

There were no items for discussion.

6.9 Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 10 January 2025

Action: For information

The Committee received a verbal report on the SAWP-V meeting held on 10 January 2025 and noted its agenda together with the minutes of the SAWP-V meeting held on 4 December 2024.

6.11 Other working party and scientific group issues

There were no items for discussion.

7. Other scientific matters

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

7.1. MRL issues

7.1.1. EC request for MRL classification of chemical-unlike biological substances considered as not requiring an MRL evaluation according to Regulation (EU) 2018/782

Action: For adoption

The Committee adopted a scientific advice concluding that the following chemical-unlike biological substances: bovine casein hydrolysate (bCNH), probiotic components including bacteria and yeasts, recombinant bovine IL-8 (His-tag), stem cells, and varroa destructor calmodulin gene-specific double-stranded interfering RNA EP15 (naked unmodified dsRNA) do not pose a risk to public health and that, consequently, they can be included in Table 1 of the Annex to Regulation (EU) No. 37/2010 with a 'No MRL required' classification.

7.2. Environmental risk assessment

There were no items for discussion.

7.3. Antimicrobial resistance

7.3.2 Fifth Joint Interagency Antimicrobial Consumption and Resistance Analysis Report (JIACRA 5)

Action: For information

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

9.1.1. Request for classification

Action: For classification

The Committee classified the veterinary medicinal product for broiler chickens 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 not intended for a limited market and not 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

There were no items for discussion.

11. CMDv

11.1 Verbal report from the CMDv Chair on the meetings held on 14-15 November and 12-13 December 2024

Presenter: L. le Letty

Action: For information

The Committee received an oral report from the CMDv Chair on the meetings held on 14-15 November and 12-13 December 2024.

The Committee noted the draft agenda of the CMDv meeting to be held on 22-23 January 2025, the agenda of the CMDv meeting held on 12-13 December 2024, the minutes of the CMDv meetings held on 17-18 October and 14-15 November 2024, the minutes of the CMDv-Interested Parties meeting held on 20 September 2024 and the CMDv report for Release July-September 2024.

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 on the work progress and noted the minutes of the meeting held on 25 November 2024, the minutes of the meeting held on 6 December 2024 together with the agenda of the meeting held on 18 December 2024.

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights link

14. Annex

2. Marketing authorisations

2.6. Other issues

EMEA/V/C/006300/0000 – cats

Action: For decision

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

3. Variations to marketing authorisations

3.1. Opinions

WS2769 – Porcilis AR-T DF – Porcilis ColiClos – Porcilis Porcoli Diluvac Forte –- pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion.

Action: For endorsement

The Committee endorsed the Rapporteur's assessment report.

EMEA/V/C/WS2767 – Nobivac Bb + MRP, DCP, NAP – cattle, cattle and pigs

Variation requiring assessment: quality related changes.

Rapporteur: E. Werner

Action: For adoption

The Committee adopted the CVMP opinion and the Annex B.

Action: For endorsement

The Committee endorsed the rapporteur's assessment report.

3.4. List of questions

Vectormune ND – Newcastle disease and Marek's disease vaccine (live recombinant) - EMEA/V/C/003829/VRA/0019 – chickens

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

Rapporteur: F. Klein

Action: For adoption

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

Quadrisol – vedaprofen - EMEA/V/C/000032/VRA/0040 – horses

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 list of questions and the comments on the product information.

Sevohale – sevoflurane - EMA/VRA/0000236258 – dogs and cats

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

Rapporteur: J. G. Beechinor

Action: For adoption

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

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

Variation requiring assessment: quality related changes.

Rapporteur: A. Golombiewski

Action: For adoption

The Committee adopted the list of questions.

WS2768 - Porcilis ColiClos, Porcilis Porcoli Diluvac Forte, Porcilis AR-T DF - *E. coli* and *C. perfringens* vaccine (inactivated) to provide passive immunity to pigs, Porcine progressive atrophic rhinitis vaccine (inactivated) - pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

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

EMEA/V/C/WS2760 – Forceris, Gleptosil – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: C. Muñoz Madero

Action: For adoption

The Committee adopted the list of questions.

4. Referrals and related procedures

4.7. Other issues

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

6. Working parties

6.5 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

The Committee noted the NC and NAMs ESEC nominations.

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

VICH status of guidelines

Action: For information

The Committee noted the VICH status of guidelines.

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

10. Organisational and strategic matters

ANNEX I

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

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

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie***	**Full involvement**	
Austria	Petra Falb	Full involvement	
Belgium	Els Dewaele	Full involvement	
Croatia	Frane Božić	Full involvement	
Czechia	Leona Nepejchalová	Full involvement	
Denmark	Niels Christian Kyvsgaard	Full involvement	
Finland	Minna Leppänen	Full involvement	
France	Sylvie Louet	Full involvement	
France	Christine Miras	Full involvement	
Germany	Andrea Christina Golombiewski	Full involvement	
Greece	Spyridon Farlopoulos	Full involvement	
Hungary	Gábor Kulcsár	Full involvement	
Ireland	Paul McNeill	Full involvement	
Italy	Fulvio Marsilio	Full involvement	
Latvia	Zanda Auce	Full involvement	
Luxembourg	Caroline Coner	Full involvement	
Netherlands	Jacqueline Poot	Full involvement	
Netherlands	Kim Boerkamp	Full involvement	
Norway	Hanne Bergendahl	Full involvement	
Poland	Ewa Augustynowicz	Full involvement	
Romania	Gabriela Tuchila	Full involvement	
Slovakia	Katarina Massányiová	Full involvement	
Slovenia	Urska Peunik	Full involvement	
Spain	Cristina Muñoz Madero	Full involvement	
Sweden	Frida Hasslung Wikström	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	
Austria	Manuela Leitner*	Full involvement	
Belgium	Frederic Klein*	Full involvement	
Denmark	Merete Blixenkrone-Møller*	Full involvement	
Estonia	Toomas Tiirats*	Full involvement	
Finland	Kristina Lehmann*	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
Germany	Esther Werner*	Full involvement	
Luxembourg	Despoina Iatridou*	Full involvement	
Portugal	João Pedro Duarte Da Silva*	Full involvement	
Slovakia	Eva Chobotová*	Full involvement	
Sweden	Hanna Bremer*	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.			
Belgium	Boudewijn Catry	Full involvement	
Germany	Christine Schwarz	Full involvement	
Germany	Dusan Palic	Full involvement	
Germany	Wiebke Weiher	Full involvement	
Germany	Ingun Lemke	Full involvement	
Germany	Henriette Rau	Full involvement	
Germany	Daniela Loos	Full involvement	
Germany	Monika Hofmann	Full involvement	
Germany	Jana Hundt	Full involvement	
Germany	Heike Gyra	Full involvement	
Sweden	Helena Back	Full involvement	
Sweden	Frida Martin	Full involvement	
Sweden	Jenny Larsson	Full involvement	
Sweden	Catarina Eriksson	Full involvement	
France	Carole Cousin	Full involvement	
France	Anne-Marie Jacques	Full involvement	
France	Nathalie Bridoux	Full involvement	
Germany	Daniel Benesh	Full involvement	
Germany	Martina Kern	Full involvement	
Germany	Svenja Rieke	Full involvement	
Germany	Kerstin Cramer	Full involvement	
Spain	Rosario Bullido	Full involvement	
Spain	Marta Martin	Full involvement	
Spain	Maria Jose Ferrer	Full involvement	
Spain	Adrian Fandiño	Full involvement	
Spain	Susana Casado	Full involvement	
Spain	Ana Isabel Olías	Full involvement	
Spain	Cristina Ballesteros	Full involvement	
Czech Republic	Vilma Dosedlová	Full involvement	
Czech Republic	Radka Smítalová	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
Denmark	Kirsten Thomsen	Full involvement	
Denmark	Charlotte Smith Bonde	Full involvement	
Ireland	Emily Hams	Full involvement	
Ireland	Susan Reid	Full involvement	
Ireland	Sarah Buckley	Full involvement	
Ireland	Alice Stack	Full involvement	

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)**

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

European Medicines Agency support
Meeting run with support from the relevant EMA staff.