16 January 2024
EMA/67783/2024
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 16-17 January 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 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 the addition of a new item, Bravecto (EMA/V/C/002526/VRA/0059), under point 3.6.

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 January 2024

The attendance list was completed and competing interests were identified for the January 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 for discussion (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 December 2023 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. Lists 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

- There were no items for discussion.

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

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information, for a marketing authorisation application for a new vaccine (EMEA/V/C/006222/0000), for cattle. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

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

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product (EMEA/V/C/006311/0000), for dogs. The Committee noted peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/006309/0000), for salmon. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/006296/0000), for chickens. The Committee noted peer review report and the comments received from CVMP members.

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

- There were no items for discussion.

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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/006142/0000).

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for grouped variations requiring assessment for **Metacam** (EMEA/V/C/000033/VRA/0151/G), recommending the variation of the marketing authorisation to modify the indication for use in cats for Metacam 5 mg/ml solution for injection for dogs and cats, and to amend the product information for Metacam 5 mg/ml solution for injection for dogs and cats, Metacam 2 mg/ml solution for injection for cats, and Metacam 0.5 mg/ml oral suspension for cats and guinea pigs with regard to the follow-up oral treatment after initial administration by injection in cats. The Committee noted the summary of the opinion for publication.
    - The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment (subject to a worksharing procedure) for **Fevaxyn Pentofel/Suvaxyn CSF Marker/Suvaxyn PRRS MLV** (EMEA/V/C/WS2477), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Rexxolide** (EMEA/V/C/005384/VRA/0005), recommending the implementation of quality-related changes.

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

- The Committee adopted a list of questions and agreed comments on the draft product information for grouped variations requiring assessment for **Bluevac BTV** (EMEA/V/C/000156/VRA/0012/G), to change the multistrain dossier to allow up to two different inactivated bluetongue virus serotypes in the final product (bivalent vaccine) and to implement other quality-related changes.

- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Halocur** (EMEA/V/C/000040/VRA/0019), to align the product information with version 9.0 of the QRD template and to implement the ATCvet code change for halofuginone.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Tulaven** (EMEA/V/005153/VRA/00080), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Coxatab** (EMEA/V/C/005816/0001/G), concerning quality-related changes.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Rabitec** (EMEA/V/C/004387/VRA/0012), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Nobilis IB Primo QX** (EMEA/V/C/002802/VRA/0011) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Suiseng Diff/A** (EMEA/V/C/005596/VRA/0003) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Respiporc FLUpan H1N1** (EMEA/V/003993/VRA/0017) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/VRA/0016/G), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Purevax RCP FeLV** (EMEA/V/C/000089/VRA/0035) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Coliprotec F4/F18** (EMEA/V/C/004225/VRA/0011), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Purevax RCP** (EMEA/V/C/000090/VRA/0035) to align the product information with version 9.0 of the QRD template.

3.5. Re-examination 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

- The committee adopted a revised CVMP assessment report for a variation requiring assessment for Bravecto (EMA/V/C/002526/VRA/0059) to add a new pharmaceutical form, 150 mg/ml powder and solvent for suspension for injection, for dogs.

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.

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

- The Committee adopted by consensus the CVMP follow-up assessment report for the referral procedure of the conditions on the marketing authorisations for **veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses** (EMEA/V/A/116). The Committee concluded that no further information on risks to the environment of moxidectin was identified during this follow-up assessment which would lead to a change in the CVMP conclusions from the initial phase of the referral procedure on the positive benefit-risk balance of the concerned products. Therefore, the CVMP recommended the maintenance of the marketing authorisations (no changes) for the above mentioned veterinary medicinal products. The Norwegian CVMP member agreed with the above-mentioned recommendation.

5. Post-authorisation issues for marketing authorisations

Information relating to certain pharmacovigilance topics, and 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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Prevexxion RN+HVT+IBD** (EMEA/V/C/005057/REC/008) which is considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Clevor** (EMEA/V/C/004417/REC/009) which is considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Nobivac DP Plus** (EMEA/V/C/005251/REC/006) which is considered fulfilled.

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

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

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)

- The Committee elected D. Bouchard the Chair of the AWP for a 3-year mandate.
- The Committee adopted the AWP work plan for 2024 (EMA/CVMP/AWP/381708/2023).

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the ERAWP work plan for 2024 (EMA/CVMP/ERA/435515/2023).

6.3. Efficacy Working Party (EWP-V)

- The Committee adopted the draft revised guideline on data requirements for veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/37280/2023) for release for a 4-month period of public consultation.
- The Committee adopted the EWP-V work plan for 2024 (EMA/CVMP/EWP/431047/2023).

6.4. Immunologicals Working Party (IWP)

- The Committee adopted the IWP-V work plan for 2024 (EMA/CVMP/IWP/444036/2023).

- The Committee adopted the guideline on plasmid DNA vaccines for veterinary use and the overview of comments received during public consultation. This guideline has been developed to provide advice to manufacturers seeking marketing authorisation for nucleic acid vaccines for use in animals when the vaccine consists of (a) bacterial or a synthetic DNA plasmid(s). It applies to DNA vaccines – consisting of plasmid DNA non-amplifiable in eukaryotic cells. The comments received during the consultation procedure were taken into account in the revision of the guideline. The new guideline will come into effect in July 2024.
- The Committee adopted the revised guideline on live recombinant vector vaccines for veterinary use for release for a 4-month period of public consultation.

6.5. Joint CVMP/CHMP Working Party on the application of the 3Rs (J3RsWP)

- The Committee adopted the Non-Clinical Domain workplan for 2024, including priorities for the 3RsWP.
- The Committee noted the Non-Clinical and New Approach Methodologies ESEC nominations endorsed/to be endorsed by CHMP at its December 2023/January 2024 plenary meeting, respectively.
- The Committee adopted the final composition of the Batch Release Testing Operational Experts Group (BRT OEG).
- The Committee was informed of the on-going revision of the reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/3Rs/164002/2016).

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee adopted the NTWP work plan for 2024.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 19 December 2023, and noted the agenda of the meeting.
- The Committee adopted the PhVWP-V work plan for 2024 (EMA/CVMP/PhVWP/281676/2023).

6.8. Quality Working Party (QWP)

- The Committee adopted the revised question and answer document on assessment of quality of finished products containing known active substances.
- The Committee adopted the question and answer document on how to use a CEP in the context of a Marketing Authorisation Application (MAA) or a Marketing Authorisation Variation (MAV).
- The Committee adopted the QWP work plan for 2024 - 2026.
- The Committee discussed the draft guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water (EMA/CVMP/QWP/592906/2022) and the overview of comments received during the public consultation.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 12 January 2024 and noted the agenda of the meeting.
- The Committee adopted the SAWP-V work plan for 2024 (EMA/CVMP/SAWP/427324/2023).

- The Committee adopted the scientific advice report on further development of an existing veterinary medicinal product for dogs.
- The Committee adopted the scientific advice report on the development of a new veterinary medicinal product for cats.

6.10. Safety Working Party (SWP-V)

- The Committee adopted the guideline on determination of the need for an MRL evaluation for chemical-unlike biological substances and the overview of comments received during public consultation.
- The Committee adopted the SWP-V work plan for 2024 (EMA/CVMP/SWP/425226/2023).
- The Committee noted the overview of comments received on the concept paper on the revision of the guideline on user safety of topically administered veterinary medicinal products. The CVMP agreed that the working party can start the work on the revision of the guideline.

6.11. Other working party and scientific group issues

- The Committee adopted the revised ESUAvet WG work plan for 2023/2024.

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

- 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

- There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

- 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

- The Committee adopted the revised VICH GL22(R) guideline "Reproduction: Studies to evaluate the safety of residues of veterinary drug in human food: reproduction studies" for sign off at step 3.
- The Committee endorsed the EU comments on the summary of comments received at step 4 of the VICH process on the revised VICH GLs 7, 12, 13, 14, 15, 16, 19, 20, 21 on efficacy of anthelmintics, following the end of the public consultation.

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

- The Committee considered the request for limited market classification for a veterinary medicinal product for cats. The Committee classified the product 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

- The Committee agreed to the transfer of all (co-)rapporteurships and peer review responsibilities from B. Urbain to E. Dewaele and F. Klein.

9.3. Regulatory matters

10. Organisational and strategic matters

- The Committee received an update on IRIS for core Regulatory Procedures.
- The Committee noted the draft agenda of the meeting to be held on 18-19 January 2024, the minutes of the meeting held on 7-8 December 2023 as well as the draft CMDv-IP agenda of the meeting to be held on 19 January 2024.

12. Legislation

- The Committee received a verbal report from the experts' group chair 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.

- The Committee received a 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).
- The Committee received a verbal report on the work progress of the working group for the implementation of Section I.1.7 of Annex II to Regulation (EU) 2019/06, which relates to the implementation of the 3Rs principles.
- The Committee noted a draft legal proposal for a regulation establishing a common data platform on chemicals, related to the "One substance, one assessment" initiative of the European Commission.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

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

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 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**	
AT	Petra Falb	Full involvement	
BE	Els Dewaele	Full involvement	
BG	Krasimir Zlatkov	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	Paul McNeill	Full involvement	
IT	Fulvio Marsilio	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	Full involvement	
PT	João Pedro Duarte da Silva*	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Frida Hasslung Wikström (Vice-Chair)	Full involvement	
SK	Eva Chobotová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
Co-opted	Carina Bergman	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Manuela Leitner*	Full involvement	
BE	Frédéric Klein*	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Esther Werner*	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	
LU	Caroline Coner*	Full involvement	
NL	Kim Boerkamp*	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SI	Boris Kolar	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 only evaluated against the topics they have been invited to talk about.			
NO	Ane Kvingedal*	Full involvement	
DK	Anja Silke Christensen*	Full involvement	
DE	Anke Finnah*	Full involvement	
DE	Christina Maria Bredtmann	Full involvement	
FR	Damien Bouchard*	Full involvement	
DE	Daniela Loos*	Full involvement	
NO	Eva Otterstad	Full involvement	
DE	Gerd Maack*	Full involvement	
NO	Gunn Kisen*	Full involvement	
DE	Gunther Speichert*	Full involvement	
DK	Hanne Lomholt Larsen	Full involvement	
DE	Heike Gyra*	Full involvement	
DE	Ingun Lemke*	Full involvement	
DE	Katja Boxberger*	Full involvement	
DE	Kathrin Schirmann*	Full involvement	
DK	Kathrine Just Andersen*	Full involvement	
DK	Kira Rosenkilde Underbjerg*	Full involvement	
DE	Maike Goemmel*	Full involvement	
NO	Ragnhild Mehli	Full involvement	
DE	Sandra Bertulat*	Full involvement	
DE	Sandra Schack*	Full involvement	
NL	Sandra ten Voorde*	Full involvement	
IE	Susan Reid*	Full involvement	
DE	Svenja Rieke*	Full involvement	
DE	Wiebke Weiher*	Full involvement	
IE	Sarah Beesley*	Full involvement	
IE	Sarah Hanley*	Full involvement	
ES	Marta Martin Juárez*	Full involvement	
ES	Rocío Fernández Granda*	Full involvement	
CZ	Zdenka Maskova*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
ES	Jaime Garcia*	Full involvement	
ES	Maria Jose Ferrer*	Full involvement	
ES	Rosario Bullido*	Full involvement	
ES	Maria Esperanza Herreros Avila*	Full involvement	
ES	Cristina Benito*	Full involvement	
ES	Susana Casado*	Full involvement	
ES	Alberto de Prado*	Full involvement	
ES	Carolina Elisa Rodriguez*	Full involvement	
ES	Luis Agote Casado*	Full involvement	
ES	Leyre Sanchez Sanchez de Rojas*	Full involvement	
IE	Tatyana Devine*	Full involvement	
ES	Raúl Belmar Liberato*	Full involvement	
ES	Sonia Gil Morales*	Full involvement	
BE	Sandy Vermout*	Full involvement	
NO	Magnus Backelin*	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Damien Bouchard*
ERAWP	Ricardo Carapeto García
ESUAVet WG	Sara Sacristan *(CVMP co-chair)**
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

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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