14 February 2023
EMA/72724/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 17-18 January 2023 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).

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

The attendance list was completed and competing interests were identified for the January 2023 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). All decisions taken at this meeting were made in presence of a quorum of members, i.e. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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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 2022 meeting were adopted with a minor amendment to point 6.11.

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 and extensions

2.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

2.1. Opinions under Regulation (EC) No 726/2004

- There were no items for discussion.

2.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

2.2. Oral explanations under Regulation (EC) No 726/2004

- There were no items for discussion.

2.3. List of outstanding issues under Regulation (EU) 2019/6

- There were no items for discussion.

2.3. List of outstanding issues under Regulation (EC) No 726/2004

- There were no items for discussion.

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 generic product (EMEA/V/C/006103/0000), for cattle, cats, and dogs. The Committee noted a peer review report and the comments received from CVMP members.

2.4. List of questions under Regulation (EC) No 726/2004

- There were no items for discussion.

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

- There were no items for discussion.

2.5. Re-examination of CVMP opinions under Regulation (EC) No 726/2004

- 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 a 3-month extension to the clock-stop for a new product (EMEA/V/C/005993/0000), for dogs.

2.6. Other issues under Regulation (EC) No 726/2004

- There were no items for discussion.

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 and endorsed the rapporteur's assessment report for a variation requiring assessment for **Purevax RC,** recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 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 **Bovela** (EMEA/V/C/003703/WS2322/0024), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 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 **Advocate** (EMEA/V/C/WS2383), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Nobivac Myxo-RHD Plus** (EMEA/V/C/004989/VRA/0001), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Galliprant** (EMEA/V/C/004222/VRA/0019), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/VRA/0019), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.

3.1. Opinions under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

3.2. Oral explanations under Regulation (EU) 2019/6

- There were no items for discussion.

3.2. Oral explanations under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

3.3. List of outstanding issues under Regulation (EU) 2019/6

- There were no items for discussion.

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

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

- The Committee adopted a CVMP list of questions and agreed comments on the draft product information for a variation requiring assessment for **Porcilis PCV M Hyo** (EMEA/V/C/003796/VRA/0017), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a CVMP list of questions and agreed comments on the draft product information for a variation requiring assessment for **Stronghold** (EMEA/V/C/000050/VRA/0059), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a CVMP list of questions and agreed comments on the draft product information for a variation requiring assessment for **Bravecto** (EMEA/V/C/002526/VRA/0058), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a CVMP list of questions and agreed comments on the draft product information for a variation requiring assessment for **Purevax Rabies** (EMEA/V/C/002003/VRA/0017), to align the product information with version 9.0 of the QRD template.

- The Committee adopted a CVMP list of questions and agreed comments on the draft product information for a variation requiring assessment for **Poulvac E. coli** (EMEA/V/C/002007/VRA/0020), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for a variation requiring assessment for **Prevomax** (EMEA/V/C/04331/VRA/0014), to implement quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Masivet** (EMEA/V/C/00128/VRA/0022), to implement quality-related changes.

3.4. List of questions under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

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

- There were no items for discussion.

3.5. Re-examination of CVMP opinions on variations under Regulation (EC) No 726/2004

- There were no items for discussion.

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

- There were no items for discussion.

3.6. Other issues under Commission Regulation (EC) No 1234/2008

- 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.

4.7.1. Referrals under Regulation (EU) 2019/6

- There were no items for discussion.

4.7.2. Referrals under Article 33(4) of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Catophos 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats** (EMEA/V/A/147). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the February 2023 meeting of the Committee. The Committee noted peer review reports and the comments made by CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats** (EMEA/V/A/148). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the February 2023 meeting of the Committee. The Committee noted peer review reports and the comments made by CVMP members.

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

5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

- There were no items for discussion.

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

5.2. Post-authorisation measures under Regulation (EC) No 726/2004

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Circovac** (EMEA/V/C/000114/REC/026-028) which is now considered fulfilled.

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

5.3. Supervision and sanctions under Regulation (EC) No 726/2004

- 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)

- There were no items for discussion.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee confirmed the appointment of two new members of the Environmental Risk Assessment Working Party: Andreu Rico and Irene de la Casa.

6.3. Efficacy Working Party (EWP-V)

- The Committee adopted a new reflection paper on resistance in ectoparasites (EMA/CVMP/EWP/310225/2014). The comments received during the consultation procedure were taken into account for the revision of the reflection paper. The reflection paper aims to give an overview of the known resistance of ectoparasites to active substances used in veterinary medicinal products with a special focus on Europe, and to provide a review of the current knowledge on resistance mechanisms, detection methods and possible control strategies.

6.4. Immunologicals Working Party (IWP)

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

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee adopted a draft revised guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy (EMA/CVMP/NTWP/32862/2022) for a 4-month period of public consultation. This guideline has been developed to address the regulatory, technical and scientific basis applicable to the quality, safety and efficacy of phage therapy veterinary medicinal products where a variable composition of the final product is expected.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report on the PhVWP-V meeting held on 14 December 2022.
- The Committee elected unanimously J. Mount as Vice-chair of the PhVWP-V for a 3-year term.

6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 21-23 November 2022, and noted the agenda of the meeting together with the minutes of the QWP meeting held on 19-21 September 2022, the agenda of the joint GMDP IWG/QWP meeting held on 21 September 2022, and the minutes of the joint GMDP IWG/QWP meeting held on 21 September 2022.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V Chair on the meeting held on 16 January 2023, and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting held on 5 December 2022.
- The Committee adopted the scientific advice report on a new veterinary medicinal product for swine The Committee adopted the scientific advice report on a new veterinary medicinal product for dogs.

- The Committee adopted the scientific advice report on a new veterinary medicinal product for cattle.
- The Committee adopted the scientific advice report on a new veterinary medicinal product for cows.

6.10. Safety Working Party (SWP-V)

- The Committee adopted the question and answer document on the Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016) – (EMA/CVMP/SWP/32272/2022).

6.11. Other working party and scientific group issues

- The Committee adopted the work plans for 2023 for the CVMP working parties: IWP (EMA/CVMP/IWP/820589/2022) and SWP-V (EMA/CVMP/SWP/618508/2022).

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

- The Committee agreed to include **2,5-furandione polymer with ethene** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.57).

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

- There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

7.7. Other issues

- The Committee adopted the procedural advice for vaccine platform technology master file (vPTMF) certification (EMA/CVMP/184591/2022) and the overview of comments received during public consultation (EMA/CVMP/695453/2022).

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

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

9. Procedural and regulatory matters

Information relating to 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 a request for a veterinary medicinal product (ATCvet classification: immunologicals), for captive squirrel monkeys. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered a request for a veterinary medicinal product (ATCvet classification: nervous system) for horses. The Committee classified the product as intended for a limited market and not eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered a request for a veterinary medicinal product (ATCvet classification: immunologicals) for horses. 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

- The Committee agreed to the transfer of (co-)rapporteurships and peer review responsibilities from F. Wikström to H. Bremer.
- The Committee agreed to the transfer of (co-)rapporteurships and peer review responsibilities from C. Bergman to H. Bremer.

9.3. Regulatory matters

10. Organisational and strategic matters

- The Committee adopted the minutes of the CVMP Informal meeting under the Czech Presidency, held on 12-13 October 2022 in Prague, Czechia and the minutes from the Joint CVMP/CMDv sessions.
- The Committee was informed of the programme of the upcoming EMA Veterinary Medicines Info Day 2023 to be held on 16-17 February 2023.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 10-11 November 2022 and 8-9 December 2022, and noted the draft minutes of the meeting held on 8-9 December 2022, the draft agenda of the meeting to be held on 19-20 January 2023, as well as the draft agenda of the CMDv-Interested Parties meeting to be held on 20 January 2023.

12. Legislation

- The Committee adopted the guideline on the application of Article 34 of Regulation (EU) 2019/6 (EMA/CVMP/273040/2022) and the overview of comments received during public consultation (EMA/CVMP/855384/2022).

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

Upon the completion of the January 2023 CVMP meeting, the draft news 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 2023 meeting.

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	Bruno Urbain	Full involvement	
BG	Krasimir Zlatkov	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	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	
HU	Gábor Kulcsár	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	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	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Hanna Bremer	Full involvement	
NO	Annelin Aksdal Bjelland	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.			
ES	Sonia Gil Morales	Full involvement	
ES	Ramón Lorenzo Gómez	Full involvement	
ES	Pablo Otero Pazos	Full involvement	
ES	Mercedes Ureña Montilla	Full involvement	
NO	Hans Kristian Østensen	Full involvement	
FR	Hicham Ait Lbacha	Full involvement	
FR	Martine Redureau	Full involvement	
FR	Thierry Godard	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Lise Laborieux	Full involvement	
AT	Richard Cejka-Scheidl	Full involvement	
AT	Jan Joseph	Full involvement	
IE	Sarah Beesley	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
FR	Florence Pillet	Full involvement	
FR	Marie-Hélène Sabinotto	Full involvement	
IE	Gavin Ryan	Full involvement	
ES	Maria Dominguez Nicolas	Full involvement	
BE	Els Dewaele	Full involvement	
DE	Anke Finnah	Full involvement	
FR	Laetitia Le Letty	Full involvement	
DE	Birgit Kegel	Full involvement	
ES	Susana Casado	Full involvement	
BE	Sandy Vermout	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Ladislava Nejezchlebová	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Jens Schönfeld	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Christian Kühne	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Sarah Adler-Flindt	Full involvement	
ES	Luis González Rivas	Full involvement	
BE	Michel Goret	Full involvement	
BE	Simon Degand	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WP	---
PhVWP-V	Els Dewaele
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