11 July 2023
EMA/CVMP/321089/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 13-15 June 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 a minor amendment to point 12 regarding the participation of R. Breathnach at the Standing Committee on Veterinary Medicinal Products on 26 June 2023.

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 13-15 June 2023

The attendance list was completed and competing interests were identified for the June 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. 16 or more members of the 31 members

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eligible to vote were present. Furthermore, absolute majority requires that 16 members vote in favour of the proposed decision.

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

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

iv. Adoption of the minutes of the previous meeting

The minutes of the May 2023 meeting were adopted with a minor amendment under section 9.2.

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

- 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/006000/0000), for chickens. 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.
- 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/006045/0000), for cattle. The Committee agreed that an oral explanation would not be requested. The Committee noted peer review reports and the comments received from CVMP members.

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 vaccine (EMEA/V/C/006160/0000), for turkeys. 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/006222/0000), for cattle. The Committee noted a peer review report 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/006043/0000), for chickens. 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/005989/0000), for chickens. 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

- There were no items for discussion.

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

- The Committee agreed to the request from the applicant for extension to the clock-stop for a new product (EMEA/V/C/005132/0000), for dogs.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information, for a grouped variation requiring assessment for **Nobilis IB 4-91** (EMEA/V/C/000036/VRA/0029/G), recommending the variation of the marketing authorisation to include information on onset of immunity and duration of immunity to the product information and 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 (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 **Eryseng Parvo** and other related nationally authorised products (EMEA/V/C/002762/WS2446/0014), 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 (25 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/0020), 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 (25 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Simparica Trio**, 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 (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 **Versican Plus DHPPi** (EMEA/V/C/003679/VRA/0015), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. In addition, translation errors and the name of the Marketing Authorisation Holder (from Zoetis Belgium S.A. to Zoetis Belgium) were corrected. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Versican Plus DHPPi/L4** (EMEA/V/C/003678/VRA/0017), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. In addition, translation errors and the name of the Marketing Authorisation Holder (from Zoetis Belgium S.A. to Zoetis Belgium) were corrected. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- 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 grouped variation requiring assessment for **Equilis Te** (EMEA/V/C/000093/VRA/0011/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome signal management activities (EMA/VS/0000110158): to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet). The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 grouped variation requiring assessment for **Equilis Prequenza** (EMEA/V/C/000094/VRA/0016/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities (EMA/VS/0000107212): to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet). The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 grouped variation requiring assessment for **Equilis Prequenza Te** (EMEA/V/C/000095/VRA/0019/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to change the product information to implement the outcome of signal management activities (EMA/VS/0000110126): to add the adverse event 'hypersensitivity reaction' with a very rare frequency in section 3.6 (SPC) and section 7 (Package Leaflet). The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **SevoFlo** (EMEA/V/C/000072/VRA/0026), 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 (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 **Mhyosphere PCV ID** (EMEA/V/C/005272/VRA/0003), 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 (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 **Cytopoint** (EMEA/V/C/003939/VRA/0016), 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 (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 **Prevexxion RN** (EMEA/V/C/005058/VRA/0007), 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 (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 **Easotic** (EMEA/V/C/000140/VRA/0025), 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.

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 list of questions and agreed comments on the draft product information for a variation requiring assessment for **Bravecto** (EMEA/V/C/002526/VRA/0059), to add a new pharmaceutical form.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Stronghold Plus** (EMEA/V/C/004194/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 **Felisecto Plus** (EMEA/V/C/005093/VRA/0007), 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 **Zenalpha** (EMEA/V/C/005465/VRA/0005), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Prozinc** (EMEA/V/C/002634/VRA/0027), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Equioxx** (EMEA/V/C/00142/VRA/0030), concerning 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) 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) 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

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection** (EMEA/V/A/145). The Committee noted peer review reports and the comments made by CVMP members. The Committee agreed that no outstanding issues remained. Adoption of the opinion is foreseen for the July 2023 meeting of Committee.
    - *Post-meeting note:* adoption of the opinion is foreseen for the September 2023 meeting of the Committee.

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 considered the request from the marketing authorisation holder, Chanelle, for a delay in the submission of responses for the follow-up assessment of the referral procedure for **veterinary medicinal products containing moxidectin to be administered orally, topically or subcutaneously to cattle, sheep and horses** (EMEA/V/A/116) and adopted a revised timetable for the procedure.

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.

5.1. 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

- There were no items for discussion.

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

- There were no items for discussion.

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)

- The Committee received a verbal report from the AWP chair on the meeting held on 23-24 May 2023, and noted the agenda of the meeting, together with minutes from the meeting held on 14-15 March 2023.
- The Committee confirmed the appointment of three new AWP members: Aránzazu González-Canga, Dariusz Wasyla and Sandra-Maria Wienhold.
- The Committee adopted a questions and answers document on the guideline on the SPC for Veterinary Medicinal Products (VMPs) containing antimicrobial substances (EMA/CVMP/AWP/933465/2022). The document was drafted in order to provide guidance on the inclusion of clinical breakpoints in the SPC for generic antibiotic VMPs.

- The Committee was informed that the draft reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6 (EMA/CVMP/AWP/387275/2020) is to be removed from the EMA website.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee confirmed the appointment of a new ERAWP member: Philippe Berny.

6.3. Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 7 June 2023, and noted the agenda of the meeting, together with the minutes of the meeting held on 7 February 2023.
- The Committee discussed the concept paper on the revision of the guideline for the demonstration of efficacy of ectoparasiticides.

6.4. Immunologicals Working Party (IWP)

- The CVMP re-elected, unanimously, E. Werner as Chair of the IWP for a further three-year mandate starting on 16 July 2023.
- The Committee adopted the draft concept paper for the revision of the guideline on live recombinant vector vaccines for veterinary use (EMEA/CVMP/004/04-FINAL) for release for a 3-month period of public consultation.
- The Committee discussed the draft guideline on requirements for the quality (production and control), safety and efficacy of allergen products for use in horses, dogs and cats (EMA/CVMP/IWP/170689/2016) and the overview of comments received during the consultation. The adoption of the guideline is expected for the July 2023 meeting of the Committee.

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

- The Committee adopted the call for nominations for the Batch Release Testing Operational Experts Group OEG (EMA/234913/2023) as well as the mandate, objectives and rules of procedure for the BRT OEG (EMA/234912/2023).
- The Committee endorsed the list of members of the Non-clinical (NC) and New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC) proposed by CHMP/PROM following nomination by the Non-Clinical Working Party.
- The Committee noted the minutes of the 3RsWP stakeholder and plenary meeting held on 28 February and 1 March 2023, respectively, together with the agenda of the 3RsWP plenary meeting held on 11 May 2023.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee adopted the guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy (EMA/CVMP/NTWP/179287/2022) and the overview of comments received (EMA/CVMP/NTWP/85029/2023) following the close of the public consultation. The new guideline will come into effect in June 2023.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 23-24 May 2023, and noted the agenda of the meeting and its summary record.

- The Committee adopted the revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/10418/2009-Rev.14), list of changes to combined VeDDRA list of clinical terms (EMA/CVMP/PhVWP/218994/2023), guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007), non-current VeDDRA LLT terms and codes (EMA/CVMP/PhVWP/360871/2010).

6.8. Quality Working Party (QWP)

- The Committee adopted the recommendation from the selection panel on members for the new Quality Domain.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 9 June 2023, and noted the agenda of the meeting together with the minutes of the SAWP-V meeting held on 14 April 2023.
- The Committee adopted two scientific advice reports on new veterinary medicinal products for dogs.

6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

6.11. Other working party and scientific group issues

- The Committee noted the agenda of the first ESUAvet meeting to be held on 19 June 2023.
- The Committee agreed to the proposed timetable for the call for nominations for a CVMP ESUAvet co-chair.

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

- The Committee adopted the draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022) for release for 1-month period of public consultation.

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 noted the draft reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle, which scope is predominantly related to human medicinal products.
- The Committee noted a report from the first Quality Innovation Group Listen and Learn Focus Group (LLFG) (link) held on 13 March 2023.

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 endorsed the draft EU comments on the *in vitro* dissolution guideline for immediate release solid oral veterinary dosage forms, to be forwarded to the Expert Working Group.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- The Committee was informed of the EFSA draft opinion on vaccination against highly pathogenic avian influenza (HPAI).

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 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 a request for limited market classification for the veterinary medicinal product 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

9.3. Regulatory matters

- There were no items for discussion.

10. Organisational and strategic matters

- The Committee was informed of the CVMP meeting under the Spanish Presidency, to be held on 21-22 September in Málaga, Spain.

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 15-16 June 2023 and the minutes of the meeting held on 16-17 May 2023, together with the minutes of the CMDv-Interested Parties meeting held on 24 March 2023 (link), and the draft agenda of the CMDv-Interested Parties meeting to be held on 16 June 2023.

12. Legislation

- The Committee adopted scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall be used in accordance with these articles subject to certain conditions (EMA/CVMP/151584/2021), noting the comments received from CVMP members. The Committee endorsed the participation of R. Breathnach at the Standing Committee on Veterinary Medicinal Products on 26 June 2023 to present the adopted scientific advice.
- The Committee received a verbal report from the expert group's Chair on Article 115(5) of Regulation (EU) 2019/6 - implementing measures 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 - and adopted the appointment of two new experts.
- The Committee discussed the guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6. The adoption of the guideline is expected for the July 2023 meeting of the Committee.
- The Committee discussed the guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets. The adoption of the guideline is expected for the July 2023 meeting of the Committee.
- The Committee discussed the work methodology and draft mandate of the expert group for delivery of a 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 also agreed to extend the duration of the call for nominations for experts for the drafting group.

13. Any other business

13.1. AOB

- No items for discussion.

13.2. Meeting highlights

- Upon the completion of the June 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 June 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	
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	
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 (Vice-Chair)	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	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
IT	Antonio Battisti	Full involvement	
LU	Caroline Coner	Full involvement	
LV	Renāte Kušķe	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Hanna Bremer	Full involvement	
SK	Katarína Massányiová	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.			
BE	Boudewijn Catry	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Eva Pomezná	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Rolf Beckmann	Full involvement	
DE	Dagmar Sommer	Full involvement	
DE	Brigitte Küchler	Full involvement	
DE	Henriette Rau	Full involvement	
DE	Judith Romberg	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Monika Hofmann	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Sandra Wienhold	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Naomi Barak	Full involvement	
DE	Maren Osmers	Full involvement	
DE	Julia Stiles	Full involvement	
DE	Christina Bredtmann	Full involvement	
DE	Christopher Janich	Full involvement	
DK	Anne Malene Nissen	Full involvement	
DK	Charlotte Hejl	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Trine Sidonia Jensen	Full involvement	
ES	Rosario Bullido	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
FR	Mariette Saléry	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Nathalie Bridoux	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Bryan Deane	Full involvement	
NO	Hans Kristian Østensen	Full involvement	
SE	Gabriel Westman	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Christine Schwarz
CMDv	Laetitia Le Letty
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WP	Sonja Beken *(veterinary vice chair)*
NTWP	Jacqueline Poot
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