5 September 2023
EMA/CVMP/400608/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 11-13 July 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 11-13 July 2023

The attendance list was completed and competing interests were identified for the July 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 eligible to vote were present. Furthermore, absolute majority requires that 16 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 June 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 and extensions

2.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Yurvac RHD** (EMEA/V/C/005992/0000), recommending the granting of a marketing authorisation. The product is a vaccine intended for the active immunisation of rabbits from 30 days of age onwards to reduce mortality of rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV) and variant strains (RHDV2), including highly virulent strains. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

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/005628/0000), for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted peer review comments 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 product (EMEA/V/C/006249/0000), for dogs and cats. 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/006147/0000), for horses.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/006288/0000), for chickens. The Committee noted peer review reports 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 to extend the clock-stop for a new vaccine (EMEA/V/C/006118/0000), for chickens.

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 (24 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 **Zuprevo** (EMEA/V/C/002009/VRA/0017/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to implement the outcome of a veterinary signal management procedure. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a variation requiring assessment for **Tessie** (EMEA/V/C/005427/VRA/0001), recommending the variation of the marketing authorisation to amend the product information with regard to the interactions with other medicinal products. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 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 **Ypozane** (EMEA/V/C/000112/VRA/0006), 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 (24 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 **Palladia** (EMEA/V/C/000150/VRA/0019), 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 (24 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information, for a grouped variation requiring assessment for **NexGard Combo** (EMEA/V/C/005094/VRA/0007/G), recommending the variation of the marketing authorisation to add two new therapeutic indications for persistent tick killing activity against *Ixodes hexagonus* and for persistent tick killing activity against *Rhipicephalus sanguineus*, 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 noted the summary of the opinion for publication.
- The Committee adopted by consensus (24 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 **RenuTend** (EMEA/V/C/005428/VRA/0001), 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 (24 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 **Panacur AquaSol** (EMEA/V/C/002008/VRA/0023), 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 (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Enteroporc Coli AC** (EMEA/V/C/005149/VRA/0005/G), 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 (24 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 **Apoquel** (EMEA/V/C/002688/VRA/0026), recommending the variation of the marketing authorisation implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Felpreva** (EMEA/V/C/005464/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 (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Kexxtone** (EMEA/V/C/002235/VRA/0017), 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 (24 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 **Zactran** (EMEA/V/C/000129/VRA/0048), 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 (24 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 **Porcilis PCV** (EMEA/V/C/000135/VRA/0015), 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 (24 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Tulaven** (EMEA/V/C/005153/VRA/0007/G), 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 (24 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 **Dexdomitor** (EMEA/V/C/000070/VRA/0045), 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 (24 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 **CircoMax Myco** (EMEA/V/C/005184/VRA/0004/G), 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 (24 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 **Cimalgex** (EMEA/V/C/000162/VRA/0009), recommending the variation of the marketing authorisation to implement the outcome of the MAH's signal management process. 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 for a grouped variation requiring assessment for **Fortekor Plus** (EMEA/V/C/002804/VRA/0023/G), concerning quality-related changes.
- The Committee adopted a list of questions for a grouped variation requiring assessment for **Porcilis PCV M Hyo** (EMEA/V/C/002526/VRA/0019/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 **Leucofeligen FeLV/RCP** (EMEA/V/C/000143/VRA/0015), 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 **Previcox** (EMEA/V/C/000082/VRA/0051), 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 **Innovax-ND-ILT** (EMEA/V/C/005190/VRA/0004), 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 **Suvaxyn CSF Marker** (EMEA/V/C/002757/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 **Tulinovet** (EMEA/V/C/005076/VRA/0006), 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 (subject to a worksharing procedure) for **Evanovo** and **Gumbohatch**, 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) 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 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 adoption of the opinion is expected for the September 2023 CVMP meeting.

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

- There were no items for discussion.

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

- The Committee discussed the Veterinary Signal Management activities performed by the National Competent Authorities and the Agency 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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendations for **Neoleish** (EMEA/V/C/005538/REC/001) and (EMEA/V/C/005538/REC/002) which are now considered fulfilled.

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 adopted the draft concept paper for the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals (EMA/CVMP/AWP/933451/2022) for release for a 3-month period of public consultation.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 21–22 June 2023, and noted the agenda of the meeting, together with the minutes from the ERAWP plenary meeting held on 29–30 March 2023.
- The Committee discussed the revised draft reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs (EMA/CVMP/ERA/31905/2021), and the overview of comments received (EMA/CVMP/ERA/156388/2023) following the close of the public consultation.

6.3. Efficacy Working Party (EWP-V)

- The Committee adopted a concept paper on the revision of the guideline for the demonstration of efficacy of ectoparasiticides (EMA/CVMP/EWP/56030/2023) for release for a 3-month period of public consultation.

6.4. Immunologicals Working Party (IWP)

- The Committee adopted a revised 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 (EMA/CVMP/IWP/530940/2021) following the close of the public consultation. The revised guideline will come into effect on 13 January 2024.

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

- The Committee was informed of the endorsement of experts as members of the Non-clinical (NC) and New Approach Methodologies (NAMs) European Specialised Expert Community (ESEC) by CHMP/PROM following nomination by the NcWP.
- The Committee noted the minutes of the 3RsWP meeting held on 11 May 2023 together with the agenda of the 3RsWP meeting held on 19 June 2023.
- The Committee adopted a letter to marketing authorisation holders of botulinum neurotoxin-containing products, requesting information on animal use in LD_{50} batch release testing.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee received a verbal report from the NTWP chair on the meeting held on 15-16 June 2023, and noted the agenda of the meeting, together with the minutes from the meeting held on 26 April 2023.
- The Committee discussed the draft concept paper for the development of a guideline on safety of nanomedicines for veterinary applications. The adoption of the document, for release for public consultation, is expected for the September 2023 meeting of the Committee.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meetings held on 14 June 2023 and 4-5 July 2023, and noted the agenda and summary record of the 14 June 2023 meeting, and the draft agenda of the meeting held on 4-5 July 2023.
- The Committee was informed of a focus group meeting for veterinarians or other healthcare professionals on facilitating pharmacovigilance reporting of medicinal products used in poultry to be held on 11 October 2023, and noted the draft agenda of the meeting.

6.8. Quality Working Party (QWP)

- The CVMP elected, unanimously, M.-H. Sabinotto as Veterinary Vice-Chair of the QWP for a three-year mandate.
- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 26-28 June 2023, and noted the agenda of the meeting, together with the minutes of the meeting held on 6-8 March 2023, and the agenda of QWP interested parties meeting held on 27 June 2023.
- The Committee adopted the guideline on excipients in the dossier for application for marketing authorisation for veterinary medicinal products (EMA/CHMP/CVMP/QWP/307647/2023). The current revision consists mainly of administrative changes to align the guideline with Regulation (EU) 2019/6. The revision will come into effect immediately after publication.
- The Committee adopted the question and answer document on stability of tablet fractions (EMA/CVMP/QWP/182164/2023) for veterinary medicinal products.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 10 July 2023 (in the form of a written procedure) and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting held on 9 June 2023.

6.10. Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 22–23 June 2023, and noted the agenda of the meeting, together with the minutes of the meeting held on 30–31 March 2023.

6.11. Other working party and scientific group issues

- The Committee received a verbal report on the ESUAvet WG meeting held on 19 June 2023 and adopted its 2023/2024 workplan.
- The Committee noted that no nominations were received in response to the call for appointment of the CVMP Co-chair of the European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG).

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 received feedback from the chair of the working group on the first meetings of the 'Dose review and adjustment' (ADRA) group, which took place on 22 and 30 June.

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 a draft reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle (EMA/83833/2023) for a 6-month period of public consultation.

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 Committee was informed of a call for nominations to establish a list of experts from which the World Assembly of Delegates will elect members and nominate Presidents and Vice Presidents to the World Organisation for Animal Health (WOAH)'s four Specialist Commissions.
- The Committee was informed that "The pain in animals" workshop (PAW2023) will be held on 26-27 September 2023.

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 for dogs. 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 limited market classification for the veterinary medicinal product for honeybees. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

9.3. Regulatory matters

10. Organisational and strategic matters

- The Committee received a verbal report from the chair of the Veterinary Domain (VetD) on the meeting held on 29 June 2023, and noted the agenda of the meeting and the minutes of the meeting held on 13 April 2023.
- The Committee adopted the draft agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held on 21-22 September 2023 in Málaga, Spain.
- The Committee adopted the minutes of the CVMP Presidency meeting held under the Swedish presidency on 30-31 May 2023 in Uppsala, Sweden.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 16-17 May 2023 and 15-16 June 2023, and noted the draft minutes of the meeting held on 15-16 June 2023 as well as the draft agenda of the meeting due to be held on 13-14 July 2023.

12. Legislation

- The Committee adopted the work methodology and 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), including the composition of the expert group.
- The Committee adopted the work methodology and mandate for a working group and for the elaboration of the approach regarding the application of section I.1.7. of Annex II to Regulation (EU) 2019/6.
- The Committee adopted a 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 (EMA/CVMP/EWP/231668/2022) for release a 6-month period of public consultation.
- The Committee adopted a guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets (EMA/CVMP/QWP/47285/2022) for release a 6-month period of public consultation.
- The Committee discussed the guideline on safety and residue 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. Adoption of the guideline is foreseen for the September 2023 meeting of the Committee.
- The Committee discussed a guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets. Adoption of the guideline is foreseen for the September 2023 meeting of the Committee.

- The Committee discussed a guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6. Adoption of the guideline is foreseen for the September 2023 meeting of the Committee.
- The Committee received a verbal report from the expert group's chair on 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.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the July 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 July 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	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	Full involvement	
SI	Katarina Straus	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	
BG	Nadya Ognyanova Vladimirova	Full involvement	
DE	Esther Werner	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
FI	Tita-Maria Muhonen	Full involvement	2.4 one item 3.1 one item Annex 14 (3.1) one item
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
IT	Antonio Battisti	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.			
DE	Sarah Adler-Flindt	Full involvement	
DE	Monika Hofmann	Full involvement	
DE	Maike Gömmel	Full involvement	
DE	Sandra Schack	Full involvement	
DE	Heike Gyra	Full involvement	
DE	Henriette Rau	Full involvement	
DE	Rolf Beckmann	Full involvement	
DE	Dagmar Sommer	Full involvement	
DE	Judith Romberg	Full involvement	
ES	Maria Dominguez	Full involvement	
AT	Haru Kroneis	Full involvement	
ES	Rosario Bullido	Full involvement	
DE	Svenja Rieke	Full involvement	
ES	Susana Casado	Full involvement	
SE	Gabriel Westman	Full involvement	
DE	Kathrin Schmidt	Full involvement	
FR	Caroline Guittré	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Sandra Wienhold	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Naomi Barak	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Jens Barthel	Full involvement	
DE	Gunther Speichert	Full involvement	
DE	Jens Schönfeld	Full involvement	
FR	Anne-Marie Jacques	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FI	Saila Antila	Full involvement	
AT	Martin Strobl	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
IE	Susan Reid	Full involvement	
ES	María José Ferrer Montesa	Full involvement	
ES	Adrián Fandiño López	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Jitka Chumchalová	Full involvement	
CZ	Jana Fluksová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
DE	Regina Wolf	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
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