



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 October 2023
EMA/CVMP/445464/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 5-7 September 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 ongoing 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 05-07.09.2023

The attendance list was completed and competing interests were identified for the September 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. 21 or more members of the



31 members eligible to vote were present in the room. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

Sylvie Louet gave a proxy to Jacqueline Poot for the whole meeting.

Marc Schmidt gave a proxy to Frédéric Klein for the whole meeting.

João Duarte Silva gave a proxy to Cristina Muñoz Madero for the whole meeting.

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 July 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

- The Committee discussed the rapporteur's assessment of the responses to the list of questions for the extension of MRLs to chickens for a substance, (EMA/V/MRL/003420/EXTN/0004), as well as the comments from the EU Reference Laboratory concerning the analytical method. The adoption of the opinion is foreseen for the October 2023 meeting of the Committee.

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 (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Loxitab** (EMA/V/C/006099/0000), recommending the granting of a marketing authorisation. The product is intended for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Poulvac Procerta HVT-IBD** (EMA/V/C/006000/0000), recommending the granting of a marketing authorisation. The product is a vaccine for the active immunisation of one day old chickens and 18-19 day-old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by Marek's disease virus and prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease virus. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Prevexxion RN+HVT** (EMA/V/C/006146/0000), recommending the granting of a marketing authorisation. The product is a vaccine for the active immunisation of one-day-old chicks to prevent mortality and reduce clinical signs and lesions caused by Marek's disease virus (including very virulent Marek's disease virus) in chickens. The Committee noted the summary of the opinion for publication (EMA/CVMP/398578/2023).

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

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Oxmax** (EMA/V/C/005132/0000), recommending the granting of a marketing authorisation. The product is intended as an adjunct therapy in the management of haemorrhagic shock in dogs. The Committee noted the summary of the opinion for publication.

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

- The Committee heard an oral explanation from the applicant concerning an application for a new product (EMA/V/C/005972/0000), in cats. The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the October 2023 CVMP meeting.

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 product (EMA/V/C/006247/0000), for sea bream. 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 product (EMA/V/C/005345/0000), for dogs. The Committee noted peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new product (EMA/V/C/006230/0000), for 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 (EMA/V/C/006260/0000), for cattle. 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 product (EMA/V/C/006235/0000), for dogs. 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 generic product (EMA/V/C/006234/0000), for cattle, pigs, dogs and cats. 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

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 (26 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 **Previcox** (EMA/V/C/000082/VRA/0051), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.

- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Zenalpha** (EMA/V/C/005465/VRA/0005), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 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 **Leucofeligen FeLV/RCP** (EMA/V/C/000143/VRA/0015), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Felpreva** (EMA/V/C/005464/VRA/0005), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Felpreva** (EMA/V/C/005464/VRA/0006), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Stelfonta** (EMA/V/C/005018/VRA/0008/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 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 **Innovax-ND-ILT** (EMA/V/C/005190/VRA/0004), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment (subject to a worksharing procedure) for **Simparica, MiPet Easecto** (EMA/V/C/WS2508/G), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Nobivac DP Plus** (EMA/V/C/005251/VRA/0004), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Porcilis PCV M Hyo** (EMA/V/C/003796/VRA/0019/G), recommending the variation of the marketing authorisation implement quality-related changes.
- The Committee adopted by consensus (26 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 **Evanovo, Gumbohatch** (EMA/V/C/WS2493), recommending the variation of the marketing authorisation to implement quality-related changes.

- The Committee adopted by consensus (26 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 **Clynav** (EMA/V/C/002390/VRA/0016), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- The Committee adopted by consensus (26 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 **Solensia** (EMA/V/C/005179/VRA/0006), recommending the variation of the marketing authorisation to implement the outcome of the MAH's signal management process to add anaphylaxis as an adverse event in cats with frequency "very rare".
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report and the product information, for a variation requiring assessment for **NexGard Spectra** (EMA/V/C/003842/VRA/0036), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a variation requiring assessment for **ProZinc** (EMA/V/C/002634/VRA/0027), recommending the variation of the marketing authorisation to implement quality-related changes.
- The Committee adopted by consensus (26 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 **Felisecto Plus** (EMA/V/C/005093/VRA/0007), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- The Committee adopted by consensus (26 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 **Stronghold Plus** (EMA/V/C/004194/VRA/0011), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template.
- 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 Spectra** (EMA/V/C/003842/VRA/0035/G), to lower the minimum bodyweight of target animals from 2 kg to 1.35 kg and to align the product information with version 9.0 of the QRD template.
- The Committee adopted by consensus (26 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+HVT+IBD** (EMA/V/C/005057/VRA/0008), recommending the variation of the marketing authorisation to implement quality-related changes.

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

- The Committee adopted a list of outstanding issues for a variation requiring assessment for **Equioxx** (EMA/V/C/00142/VRA/0030), concerning quality-related changes.

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 grouped variation requiring assessment for **Tulinovet** (EMA/V/C/005076/VRA/0005/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 **Suvaxyn Circo+MH RTU** (EMA/V/C/003924/VRA/0021), 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 Circo** (EMA/V/C/004242/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 **Meloxoral** (EMA/V/C/000151/VRA/0017), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Evalon** (EMA/V/C/004013/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 **Evant** (EMA/V/C/004902/VRA/0003), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Rhiniseng** (EMA/V/C/000160/VRA/0013), 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 **Nobivac Myxo-RHD Plus** (EMA/V/C/004989/VRA/0002), 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 **Credelio Plus** (EMA/V/C/005325/VRA/0006), 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 **Eryseng** (EMA/V/C/002761/VRA/0010), 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 **Eryseng Parvo** (EMA/V/C/002762/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 **Hibrabovis IBR Marker Live** (EMA/V/C/000158/VRA/0013), 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 **Eravac** (EMA/V/C/004239/VRA/0008), 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 **Nasym** (EMA/V/C/004897/VRA/0005), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a rapporteur's assessment report including list of questions for a grouped variation requiring assessment for **Felpreva** (EMA/V/C/005464/VRA/0004/G), concerning quality-related changes.
- The Committee adopted a rapporteur's assessment report including list of questions for a variation requiring assessment for **Contacera** (EMA/V/C/002612/VRA/0016), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for Nobivac LeuFel and for Leucogen for a variation requiring assessment (subject to a worksharing procedure) for **Nobivac LeuFel, Leucogen** (EMA/V/C/WS2478), 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 **Startvac** (EMA/V/C/000130/VRA/0009), 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 **Vepured** (EMA/V/C/004364/VRA/0006), 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 **Mhyosphere PCV ID** (EMA/V/C/005272/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 **Ubac** (EMA/V/C/004595/0007), to align the product information with version 9.0 of the QRD template.

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 adopted by majority (21 members in favour out of the 24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection** (EMA/V/A/145), recommending changes to the indications, the dosage regimen, the warnings on the effective use of the products, as well as to the withdrawal periods. The Committee concluded that the benefit-risk balance of veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection remains favourable and that those marketing authorisations should be amended. A. Golombiewski, L. Nepechalová and M. Leppänen signed divergent positions not supporting the aforementioned recommendations.

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

- 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

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendations for **Reconcile** (EMA/V/C/000133/REC/021) which is considered fulfilled.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendations for **Circomax** (EMA/V/C/005185/REC/001) which is considered fulfilled.
- The Committee endorsed the post-authorisation recommendation and the rapporteur's assessment report for **Mometamax Ultra** (EMA/V/C/004987/REC/001) which is 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

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 CVMP re-elected, unanimously, D. Bouchard as Vice-Chair of the AWP for further a three-year mandate.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

6.3. Efficacy Working Party (EWP-V)

- The CVMP re-elected, unanimously, C. Muñoz Madero as Chair of the EWP for a further three-year mandate.

6.4. Immunologicals Working Party (IWP)

- There were no items for discussion.

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

- The Committee noted the agenda of the 3RsWP plenary meeting held on 19 June 2023.
- The Committee noted the non-clinical and new approach methodologies ESEC nominations to be endorsed by CHMP at its September 2023 plenary meeting.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee received a verbal report from the NTWP chair on the meeting held on 29 August 2023, and noted the agenda of the meeting, together with the minutes of the meeting held on 15-16 June 2023.
- The Committee discussed the revised draft guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy (EMA/CVMP/NTWP/32862/2022) and the overview of comments received following the close of the public consultation. The adoption of the guideline is foreseen for the October 2023 meeting of the Committee.
- The Committee was informed that the discussion of the draft concept paper for the development of a guideline on safety of nanomedicines for veterinary applications (EMA/CVMP/NTWP/143787/2023) is foreseen for the October 2023 meeting of the Committee.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The CVMP elected, unanimously, J. Mount as Chair of the PhVWP-V for a three-year mandate.
- The Committee received a verbal report on behalf of the PhVWP-V chair on the meeting held on 30 August 2023, and noted the agenda of the meeting.

6.8. Quality Working Party (QWP)

- The Committee discussed the draft concept paper on a guideline on stability testing for variation for veterinary medicinal products.
- The Committee discussed the draft guideline on development and manufacture of synthetic peptides for release for public consultation.
- The Committee noted a request from the European Commission on updated analysis on titanium dioxide.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 1 September 2023, and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting by written procedure on 10 July 2023.
- The Committee adopted the follow-up scientific advice report on a new veterinary medicinal product horses.
- The Committee adopted the follow-up scientific advice report on the development of a veterinary medicinal product for cattle.
- The Committee adopted the follow-up scientific advice report on the development of a veterinary medicinal product for horses.
- The Committee adopted the scientific advice report on the development of a veterinary medicinal product for turkeys.

6.10. Safety Working Party (SWP-V)

- The Committee adopted the concept paper on the revision of the guideline on user safety of topically administered veterinary medicinal products for release for 2-month period of public consultation.

6.11. Other working party and scientific group issues

- The Committee elected Sara Sacristan as CVMP Co-chair of the ESUAVet Working Group for a 3-year term.

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 appointed C. Schwarz, H. Debergh, and R. Carapeto as experts for the azoles TOR7 working group under the joint-agency mandate.
- The Committee noted the overview of comments received on the draft guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators. The adoption of the guideline is foreseen for the October 2023 meeting of the Committee.

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

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 received feedback from virtual meetings of the VICH Safety EWG held on 7 and 8 August 2023 in preparation for a physical meeting of the Expert Working Group, scheduled to take place in Tokyo from 9 to 11 November with the aim of moving forward the ongoing revisions of the VICH guidelines on reproduction toxicity (GL22) and genotoxicity (GL23).

- The Committee endorsed the draft VICH GL60 on GMP for active ingredients used in Veterinary Medicinal Products, for sign-off at Steering Committee level, prior to release for public consultation.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- The Committee noted that the World Organisation for Animal Health has launched a call for experts to join the working group on Antimicrobial Resistance of the World Organisation for Animal Health, in particular from Africa and the Americas. The deadline for nominations is 15 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 the request for limited market classification for the veterinary medicinal product for ornamental birds pet rabbits, rats, mice and reptiles. The Committee classified the product as intended for a limited market according to Article 4(29) and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered the request for limited market classification of 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

10. Organisational and strategic matters

- The Committee noted the minutes of the Veterinary Stakeholder meeting in Uppsala, Sweden, on 10 May 2023.

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 7-8 September together with the minutes of the meeting held on 13-14 July 2023.

12. Legislation

- The Committee adopted a 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 (EMA/CVMP/SWP/32027/2022) to be released for a 4-month period of public consultation.
- The Committee adopted 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 (EMA/CVMP/IWP/224724/2022) to be released for a 4-month period of public consultation.
- The Committee adopted a guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets (EMA/CVMP/IWP/228730/2022) to be released for a 4-month period of public consultation.
- 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 September 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 September 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 (<i>remotely</i>)	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 (<i>remotely</i>)	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	Paul McNeill	Full involvement	
LU	Marc Schmit (<i>remotely</i>)	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Frida Hasslung Wikström (Vice-Chair)	Full involvement	
SK	Eva Chobotová (<i>remotely</i>)	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach (<i>remotely</i>)	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 (<i>remotely</i>)	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 (<i>remotely</i>)	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller (<i>remotely</i>)	Full involvement	
FR	Christine Miras (<i>remotely</i>)	Full involvement	
NL	Kim Boerkamp (<i>remotely</i>)	Full involvement	
SE	Hanna Bremer	Full involvement	
SI	Boris Kolar	Full involvement	
SK	Katarína Massányiová	Full involvement	
NO	Knud Torjesen (<i>remotely</i>)	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.			
	James Mount (<i>remotely</i>)	Full involvement	
DE	Sandra ten Voorde (<i>remotely</i>)	Full involvement	
ES	Maria Dominguez (<i>remotely</i>)	Full involvement	
BE	Michael Goret (<i>remotely</i>)	Full involvement	
DE	Christina Bredtmann	Full involvement	
AT	Richard Cejka-Scheidl (<i>remotely</i>)	Full involvement	
ES	Susana Casado (<i>remotely</i>)	Full involvement	
DE	Svenja Rieke (<i>remotely</i>)	Full involvement	
DK	Trine Sidonia Jensen (<i>remotely</i>)	Full involvement	
DK	Anja Silke Christensen (<i>remotely</i>)	Full involvement	
DK	Theis Moselund Jensen (<i>remotely</i>)	Full involvement	
DK	Kira Rosenkilde Underbjerg (<i>remotely</i>)	Full involvement	
SE	Jenny Larsson (<i>remotely</i>)	Full involvement	
SE	Malin Ohlund (<i>remotely</i>)	Full involvement	
DK	John Jensen (<i>remotely</i>)	Full involvement	
DE	Anke Finnah (<i>remotely</i>)	Full involvement	
NO	Kari Grave (<i>remotely</i>)	Full involvement	
FR	Anne-Marie Jacques (<i>remotely</i>)	Full involvement	
FR	Thierry Godard (<i>remotely</i>)	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
CZ	Josef Suchý (<i>remotely</i>)	Full involvement	
CZ	Zdenka Mašková (<i>remotely</i>)	Full involvement	
CZ	Dana Halová (<i>remotely</i>)	Full involvement	
CZ	Petra Kubová (<i>remotely</i>)	Full involvement	
CZ	Eva Pomezná (<i>remotely</i>)	Full involvement	
FR	Grégory Verdier (<i>remotely</i>)	Full involvement	
DE	Rolf Beckmann (<i>remotely</i>)	Full involvement	
DE	Sonja Haase (<i>remotely</i>)	Full involvement	
DE	Naomi Barak (<i>remotely</i>)	Full involvement	
DE	Werner Terhalle (<i>remotely</i>)	Full involvement	
DE	Christian Zoschke (<i>remotely</i>)	Full involvement	
DE	Sandra Bertulat (<i>remotely</i>)	Full involvement	
DE	Sandra Wienhold (<i>remotely</i>)	Full involvement	
DE	Jan Brosda (<i>remotely</i>)	Full involvement	
ES	Rocio Fernandez Granda (<i>remotely</i>)	Full involvement	
ES	Jose Ignacio Garcia Blanco (<i>remotely</i>)	Full involvement	
ES	Patricia Vera Luque (<i>remotely</i>)	Full involvement	
ES	Leyre Sánchez Sánchez de Rojas (<i>remotely</i>)	Full involvement	
IE	Sarah Buckley (<i>remotely</i>)	Full involvement	
IE	Sarah Hanley (<i>remotely</i>)	Full involvement	
IE	Gavin Ryan (<i>remotely</i>)	Full involvement	
IE	Alice Stack (<i>remotely</i>)	Full involvement	
IE	Bryan Deane (<i>remotely</i>)	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WP	Sarah Adler-Flindt (<i>veterinary vice chair</i>)
QWP	Marie-Hélène Sabinotto (<i>veterinary vice chair</i>)
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observer from the European Commission	
Present	

Observers from Swissmedic

Present	
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European Medicines Agency support

Meeting run with support from the relevant EMA staff
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