5 December 2023
EMA/556288/2023
Committee for Veterinary Medicinal Products (CVMP)

# Committee for Veterinary Medicinal Products

## Minutes of the 7-9 November 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).

The meeting was held remotely.

### 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 7-9 November 2023

The attendance list was completed and competing interests were identified for the November 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).

#### 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.

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### iii. Adoption of the minutes of the previous meeting

The minutes of the October 2023 meeting were adopted with no amendments.

### iv. 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

- The Committee adopted a corrigendum to the EPMAR relating to the establishment of maximum residue limits for azamethiphos in fin fish (EU/11/185/FVG), to correct the unit of the ADI in section 3.5.

# 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 product (EMEA/V/C/006103/0000), for cattle, dogs, and cats. 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 product (EMEA/V/C/006128/0000), for dogs. 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 product (EMEA/V/C/006124/0000), for dogs. The Committee agreed that an oral explanation would not be requested. The Committee noted a peer review report and the comments received from CVMP members.

## 2.3. 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/006131/0000), for pigs. 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/006289/0000), for pigs. The Committee noted a peer review report and the comments received from CVMP members.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/006230).
- The Committee agreed to the request from the applicant for an additional extension to the clock-stop for a new product (EMEA/V/C/006249).

## 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, for a variation requiring assessment for **Credelio Plus** (EMEA/V/C/05325/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 (26 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Onsior** (EMEA/V/C/000127/VRA/0036), 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 (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 **Vepured** (EMEA/V/C/004364/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 (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 **Mhyosphere PCV ID** (EMEA/V/C/005272/VRA/0004), 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 (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 **Ubac** (EMEA/V/C/004595/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 (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 **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/VRA/0013), 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 (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 **Eryseng** (EMEA/V/C/002761/VRA/0010), 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 (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 **Eryseng Parvo** (EMEA/V/C/002762/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 (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 **Nasym** (EMEA/V/C/004897/VRA/0005), 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 (26 members present and eligible to vote) the CVMP opinion, the product information and endorsed the rapporteur's assessment report, for a variation requiring assessment (subject to a worksharing procedure, EMEA/V/C/WS2478) for **Leucogen** and for **Nobivac LeuFel**, 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 (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 **Rhiniseng** (EMEA/V/C/000160/VRA/0013), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Evant** (EMEA/V/C/004902/VRA/0003), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Meloxoral** (EMEA/V/C/00151/VRA/0017), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Suvaxyn Circo** (EMEA/V/C/004242/VRA/0011), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Vectormune ND, Newflend ND H9** (EMEA/V/C/WS2554), 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 (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 **Startvac** (EMEA/V/C/000130/VRA/0009), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- 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 **Eravac** (EMEA/V/C/004239/VRA/0008), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Equioxx** (EMEA/V/C/00142/VRA/0030), 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 (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 **Evalon** (EMEA/V/C/004013/VRA/0004), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Nobivac Myxo-RHD Plus** (EMEA/V/C/004989/VRA/0002), recommending the variation of the marketing authorisation to align the product information with version 9 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **Simparica Trio, Felisecto Plus, MiPet Easecto, Simparica, Stronghold Plus** (EMEA/V/C/WS2560), 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 (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 **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/VRA/0021), 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 **Rabitec** (EMEA/V/C/004387/VRA/0011), to add a new strength including a new target species, a new composition of the bait and new vaccine container.
- The Committee adopted a rapporteur's assessment report including list of questions for a variation requiring assessment for **Increxxa** (EMEA/V/C/005305/VRA/0006), 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 **OvuGel** (EMEA/V/C/05219/VRA/0001), to align the product information with version 9 of the QRD template.
- The Committee adopted a rapporteur's assessment report including list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Versican Plus DHPPi/L4** (EMEA/V/C/WS2556), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/VRA/0007), 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 **M-SH vaccine** (EMEA/V/C/000161/VRA/0019), 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

- The Committee noted the updated CVMP opinion for the grouped variation for **Fortekor Plus** (EMEA/V/C/002804/VRA/0023/G).

### 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

- There were no items for discussion.

### 4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

- There were no items for discussion.

### 4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

- There were no items for discussion.

### 4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the procedure for **Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs** (EMEA/V/A/149). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the December 2023 CVMP meeting. The Committee noted peer review reports and the comments made by CVMP members.

### 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 discussed the rapporteur's assessment report including the co-rapporteur's critique 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). The adoption of the CVMP assessment report is foreseen for the December 2023 CVMP meeting. The Committee noted peer review reports.

## 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 adopted the rapporteur's assessment report on the data submitted in response to the Committee's recommendation on the post-authorisation surveillance study (PASS) for **HorStem** (EMEA/V/C/004265/REC/011). The results of the PASS were based on a relatively low number of animals but nevertheless the safety and efficacy findings were not inconsistent with the data evaluated during the initial marketing authorisation application. The MAH is consequently requested to amend the product information for HorStem and more specifically the Annex II, section D, to remove the reference to the risk management plan, which was agreed to be finalised.
- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's condition for **Yurvac RHD** (EMEA/V/C/005992/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

- 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 discussed the overview of comments received on the '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' following the close of the public consultation. The CVMP agreed that AWP should now start the work on the Reflection Paper.
- The Committee discussed the draft AWP Work plan 2024. The adoption of the document is foreseen for the January 2024 meeting of the Committee.

### 6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 11–12 October 2023, and noted the agenda of the meeting together with the minutes from the ERAWP plenary meeting held on 21–22 June 2023.
- The Committee discussed amendments made to the question and answers document on the "Implementation of the CVMP guideline on environmental impact assessment for VMPs in support of VICH GLs 6 and 38". The adoption of the document is foreseen for the December meeting of the Committee.
- The Committee adopted the revised 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.

- The Committee discussed the draft ERAWP work plan for 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.
- The Committee was informed of the upcoming election of the vice-chair of ERAWP and noted the call for nominations.

### 6.3. Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 10-11 October 2023, and noted the agenda of the meeting, together with the minutes of the meeting held on 7 June 2023.
- The Committee discussed the revised guideline on the conduct of pharmacokinetic studies in target animal species (EMA/CVMP/EWP/133/1999-Rev.1) and the overview of comments received following the close of the public consultation. The adoption of the final guideline is foreseen for the December 2023 CVMP meeting.

### 6.4. Immunologicals Working Party (IWP)

- The Committee noted the draft agenda of the IWP interested parties meeting to be held on 16 November 2023.

### 6.5. Working Party on the application of the 3Rs (3RsWP)

- The Committee adopted the concept paper on the revision of the "Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches" (EMA/CHMP/CVMP/JEG-3Rs/450091/2012).
- The Committee noted the members of the non-clinical (NC) and new approach methodologies (NAMS) European Specialised Expert Community (ESEC) endorsed by CHMP/PROM at its October and November 2023 plenary meetings, and the agenda of the NC and NAMs ESEC kick-off meeting held on 18 October 2023.

### 6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee noted the progress status of the concept paper for the development of a guideline on safety of nanomedicines for veterinary applications.

### 6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 25 October 2023, and noted the agenda of the meeting, together with the summary record from the PhVWP-V meeting held on 26-27 September 2023.
- The Committee discussed the draft PhVWP-V work plan 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.

### 6.8. Quality Working Party (QWP)

- The Committee adopted the addendum to the guideline on the use of near infrared spectroscopy (NIRS), for a 6-week period of public consultation. The addendum has been developed to define changes that would be considered within the scope of the NIRS procedure and therefore maintained under GMP only, and those changes that would be considered outside of the scope of the procedure and therefore subject to a variation application.

### 6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 6 November 2023, and noted the agenda of the meeting, together with the final minutes of the SAWP-V meeting held on 2 October 2023.
- The Committee adopted the scientific advice report on the development of a veterinary medicinal product for turkeys.
- The Committee discussed the draft SAWP-V work plan 2024. The adoption of the work plan is foreseen for the January 2024 meeting of the Committee.
- The Committee was informed of the upcoming election for new members of SAWP-V, and noted the call for nominations.

### 6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

### 6.11. Other working party and scientific group issues

- The Committee received a verbal report from the ESUAvet WG co-chair on the meeting held on 29 September 2023, and noted the agenda of the meeting, together with the final minutes of the ESUAvet WG meeting held on 19 June 2023.
- The Committee discussed the revised ESUAvet work plan 2023/2024. The adoption of the revised work plan is foreseen for the January 2024 meeting of the Committee.

## 7. Other scientific matters

*Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential.*

### 7.1. MRL issues

- The Committee adopted the revised list of biological substances considered as not requiring an MRL evaluation as per Regulation (EU) No. 2018/782 (EMA/CVMP/572629/2019 – Rev.2), to include Varroa destructor calmodulin gene-specific double-stranded interfering RNA EP15.

### 7.2. Environmental risk assessment

- There were no items for discussion.

### 7.3. Antimicrobial resistance

### 7.4. Pharmacovigilance

- There were no items for discussion.

### 7.5. Vaccine antigen master file (VAMF) certification

- There were no items for discussion.

### 7.6. Platform technology master file (PTMF) certification

- There were no items for discussion.

### 7.7. Other issues

## 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 VICH guideline on between strengths bio-waivers for veterinary immediate release solid oral dosage forms, including EU comments, to be forwarded to the VICH Expert Working Group.
- The Committee endorsed the updated draft concept paper on principles for technical guidance for the transition to in vitro methods for batch potency tests in veterinary immunologicals.
- The Committee endorsed an updated draft of VICH GL49 on validation of analytical methods used in residue depletion studies to be forwarded to the expert working group for review.
- The Committee noted the meeting documents for the 42nd VICH Steering Committee meeting to be held on 14-16 November 2023 in Tokyo.

### 8.2. Codex Alimentarius

- There were no items for discussion.

### 8.3. Other EU bodies and international organisations

- There were no items for discussion.

***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 a veterinary medicinal product for cats. 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 the request for limited market classification for a veterinary medicinal product for horses. The Committee classified the product as intended for a limited market and not eligible for authorisation under Article 23 of Regulation (EU) 2019/6.

### 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 26 October 2023, and noted the agenda of the meeting and the minutes of the meeting held on 29 June 2023.
- The Committee discussed the draft CVMP work plan for 2024. The adoption of the document is foreseen for the December 2023 meeting of the Committee.
- The Committee adopted the minutes of the joint CVMP/CMDv Presidency meeting under the Spanish Presidency held on 20 – 21 September 2023 in Malaga, Spain.

## 11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 9-10 November 2023 and minutes of the CMDv meeting held on 5-6 October 2023.

## 12. Legislation

- The Committee discussed scientific advice on the implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the GMP for veterinary medicinal products and active substances used as starting materials. The adoption of the document is foreseen for the December 2023 meeting of the Committee.
- The Committee discussed the draft guideline on the evaluation of the benefit-risk balance of veterinary medicinal products. The adoption of the document is foreseen for the December 2023 meeting of the Committee.
- The Committee received a verbal report on the work progress of the expert group for the scientific advice under Article 114(3) of Regulation (EU) 2019/6 for the establishment of a list of substances which may be used in food-producing aquatic species in accordance with article 114(1).
- The Committee received a verbal report on the work progress of the expert group for the scientific advice on Article 115(5) of Regulation (EU) 2019/6 as regards the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months.
- The Committee received a verbal report on the work progress of the working group for the implementation of Section I.1.7 of Annex II to Regulation (EU) 2019/06.

## 13. Any other business

### 13.1. AOB

- There were no items for discussion.

### 13.2. Meeting highlights

- Upon the completion of the November 2023 CVMP meeting, the draft meeting highlights was circulated for members to provide comments within 24 hours.

# ANNEX I

**List of participants** including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the November 2023 meeting, which was held remotely.

| Country | CVMP Member | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| **CHAIR** | **G. Johan Schefferlie** | **Full involvement** | |
| AT | Petra Falb | Full involvement | |
| BE | 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 | |
| IT | Fulvio Marsilio | 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 | |
| NO | Hanne Bergendahl | Full involvement | |

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

| Country | CVMP Alternate | Outcome restriction following evaluation of e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| BG | Nadya Ognyanova Vladimirova | Full involvement | |
| DE | Esther Werner | Full involvement | |
| DK | Merete Blixenkrone-Møller | Full involvement | |
| FR | Christine Miras | Full involvement | |
| NL | Kim Boerkamp | Full involvement | |
| SE | Hanna Bremer | Full involvement | |
| SI | Boris Kolar | Full involvement | |
| NO | Knud Torjesen | 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 | |
| ES | Sara Sacristan Alvarez | Full involvement | |
| BE | Michel Goret | Full involvement | |
| BE | Simon Degand | Full involvement | |
| DE | Dušan Palic | Full involvement | |
| DE | Sonja Beken | Full involvement | |
| DK | Susanne Havn Aamand | Full involvement | |
| DK | Anja Silke Christensen | Full involvement | |
| DK | Malene Nissen | Full involvement | |
| DK | Trine Jensen | Full involvement | |
| DK | Jenny Larsson | Full involvement | |
| FR | Benoit Courty | Full involvement | |
| FR | Jean-Christophe Faucon | Full involvement | |
| FR | Florence Pillet | Full involvement | |
| FR | Béatrice Leroux | Full involvement | |
| FR | Thierry Godard | Full involvement | |
| FR | Damien Bouchard | Full involvement | |
| FR | Martine Redureau | Full involvement | |
| FR | Hicham Ait Lbacha | Full involvement | |
| FI | Jukka Pakkanen | Full involvement | |
| FI | Kristina Lehmann | Full involvement | |
| FI | Katariina Kivilahti-Mäntylä | Full involvement | |
| CZ | Zdenka Mašková | Full involvement | |
| CZ | Lucie Pokludová | Full involvement | |
| CZ | Radka Smítalová | Full involvement | |
| CZ | Jitka Chumchalová | Full involvement | |
| CZ | Eva Pomezná | Full involvement | |
| CZ | Josef Suchý | Full involvement | |
| IE | Sarah Hanley | Full involvement | |

| Country | CVMP Expert* | Outcome restriction following evaluation of the e-DoI for the meeting | Topics on current agenda for which restriction applies |
|---|---|---|---|
| IE | Sarah Buckley | Full involvement | |
| IE | Gavin Ryan | Full involvement | |
| ES | Irene de la Casa | Full involvement | |
| AT | Haru Kroneis | Full involvement | |
| DE | Sandy Vermout | Full involvement | |
| IE | Nick Lee | Full involvement | |
| DE | Christopher Janich | Full involvement | |
| DE | Kathrin Schmidt | Full involvement | |
| DE | Jens Barthel | Full involvement | |
| ES | Maria Amparo Haro Castuera | Full involvement | |
| ES | Sonia Gil Morales | Full involvement | |
| ES | Luis Gonzalez Rivas | Full involvement | |
| ES | Beatriz Corcho Corral | Full involvement | |
| DE | Roswitha Merkel | Full involvement | |
| DE | Christian Kühne | Full involvement | |
| DE | Gunther Speichert | Full involvement | |
| DE | Silke Hickmann | Full involvement | |
| DE | Uta Herbst | Full involvement | |
| DE | Ingun Lemke | Full involvement | |
| DE | Maike Gömmel | Full involvement | |
| DE | Henriette Rau | Full involvement | |
| DE | Daniela Loos | Full involvement | |
| DE | Heike Gyra | Full involvement | |
| ES | Raúl Belmar Liberato | Full involvement | |
| NL | Anita Bottger | Full involvement | |

| CVMP working parties and CMDv | Chair |
|---|---|
| NTWP | Jacqueline Poot |
| AWP | Christine Schwarz |
| CMDv | Laetitia Le Letty |
| ERAWP | Ricardo Carapeto García |
| ESUAVet WG | Barbara Freischem / Sara Sacristan *(co-chairs)* |
| EWP-V | Cristina Muñoz Madero |
| IWP | Esther Werner |
| J3Rs WP | Sarah Adler-Flindt *(veterinary vice chair)* |
| PhVWP-V | James Mount |
| QWP | Marie-Hélène Sabinotto *(veterinary vice chair)* |
| SAWP-V | Frida Hasslung Wikström |
| SWP-V | Carina Bergman |

| Observer from the European Commission | |
|---|---|
| Present | |

| Observers from Swissmedic | |
|---|---|
| Present | |

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