16 December 2022
EMA/CVMP/924173/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 8-10 November 2022 meeting

Chair: G. J. Schefferlie – Vice-chair: F. Hasslung Wikström

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session

The attendance list was completed and competing interests were identified for the November 2022 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members, i.e. 17 or more members of the 32 members eligible to vote were present. Furthermore, absolute majority requires that 17 members vote in favour of the proposed decision.

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

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

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the October 2022 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

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

- The Committee adopted by consensus (22 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Neoleish** (EMEA/V/C/005538/0000), recommending the granting of a marketing authorisation. The product is a new vaccine intended for the active immunisation of Leishmania-negative dogs from 6 months of age to reduce the risk to develop an active infection and/or clinical disease after contact with *Leishmania infantum*. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee adopted the scientific overview including the list of outstanding issues and agreed comments on the draft product information for an extension application for **Coxevac** (EMEA/V/C/000155/X/0015). The Committee agreed that an oral explanation would not be requested. The Committee noted the comments received from CVMP members.

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/006117/0000), for dogs.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- 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, the CVMP assessment report, and the product information, for a grouped variation requiring assessment for **Rabitec** (EMEA/V/C/004387/VRA/0010/G), recommending the variation of the marketing authorisation to update the safety information in sections 3.5 special precautions for use, 3.7 use during pregnancy, lactation or lay and section 3.9 administration routes and dosage of the SPC and to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (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 **Versican Plus Pi/L4R** (EMEA/V/C/003682/VRA/0018), 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 **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/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 (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 **ProteqFlu** (EMEA/V/C/000073/VRA/0025), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- 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 **ProteqFlu-Te** (EMEA/V/C/000074/VRA/0033), 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 **Apoquel** (EMEA/V/C/002688/VRA/0024), 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 (22 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 **Semintra** (EMEA/V/C/002436/VRA/0016/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and merge the indications of Semintra 4 mg/ml and 10 mg/ml oral solution by re-arrangement of the already approved product information for both strengths, and to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (19 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 **Porcilis PCV M Hyo** and other related nationally authorised products (EMEA/V/C/xxxx/WS2281), 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 (19 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Simparica Trio** (EMEA/V/C/004846/VRA/0011), 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 (19 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Lydaxx** (EMEA/V/C/005199/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 (19 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Lydaxx** (EMEA/V/C/005199/VRA/0004), 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 (19 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Librela** (EMEA/V/C/005180/VRA/0006), 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 (19 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/0034), 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 (19 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Convenia** (EMEA/V/C/000098/VRA/0037), 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 (19 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Simparica Trio** (EMEA/V/C/004846/VRA/0008), 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 (19 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Rhiniseng** (EMEA/V/C/000160/VRA/0012), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- The Committee adopted a list of outstanding issues and agreed comments on the draft product information, for a grouped variation requiring assessment for **Zeleris** (EMEA/V/C/004099/VRA/0005/G), to add a new therapeutic indication and to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of outstanding issues, and agreed comments on the draft product information, for a grouped variation requiring assessment for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/VRA/0006/G), concerning efficacy-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 **Bravecto Plus** (EMEA/V/C/004440/VRA/0023/G), to add a new therapeutic indication, and 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 grouped variation requiring assessment for **Librela** (EMEA/V/C/005180/VRA/0005/G), to align the product information with version 9.0 of the QRD template, and to process changes following assessment of a PSUR.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Innovax-ND-IBD** (EMEA/V/C/004422/VRA/0010), to align the product information with version 9.0 of the QRD template, and process minor editorial changes in the product information.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Trocoxil** (EMEA/V/C/000132/VRA/0021), to align the product information with version 9.0 of the QRD templates, to correct translation errors, and to process minor editorial changes on the package leaflet.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Simparica Trio** (EMEA/V/C/004846/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 grouped variation requiring assessment for **BTVPUR** (EMEA/V/C/002231/VRA/0026/G), to align the product information with version 9.0 of the QRD template, and amend SPC section 3.6 and section 7 of the package leaflet.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Aservo EquiHaler** (EMEA/V/C/004991/VRA/0007/G), to update the package leaflet following the outcome of the CVMP assessment of a PSUR, and 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 of **Purevax RCP** and **Purevax RCP FeLV** for a variation requiring assessment (subject to a worksharing procedure) (EMEA/V/C/xxxx/WS2286), concerning quality-related changes.

- The Committee adopted a list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Halocur** (EMEA/V/C/000040/VRA/0017) concerning quality-related changes.
- The Committee adopted the rapporteur's assessment report including a list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Versican Plus Pi/L4R**, **Versican Plus Pi/L4**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R**, and **Versican Plus L4** (EMEA/V/C/xxxx/WS2330), concerning quality-related changes.
- The Committee adopted the rapporteur's assessment report including a list of questions for a grouped variation requiring assessment (subject to a worksharing procedure) for **Vectormune FP ILT** and **Vectormune FP ILT + AE** (EMEA/V/C/xxxx/WS2316/G), concerning quality-related changes.
- The Committee adopted a list of questions, for a grouped variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/VRA/0005/G), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/VRA/0007), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Mhyosphere PCV ID** (EMEA/V/C/005272/VRA/0002), concerning quality-related changes.

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

- There were no items for discussion.

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

- There were no items for discussion.

3.5. Re-examination of CVMP opinions on variations under Regulation (EU) 726/2004

- There were no items for discussion.

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

- The Committee was informed of the formal notification from Ceva Sante Animal of their decision to withdraw the application for a variation requiring assessment for **Rabitec** (EMEA/V/C/004387/VRA/0009), concerning quality-related changes. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

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 rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing *N*-methyl pyrrolidone as an excipient** (EMEA/V/A/146). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the December 2022 meeting of the Committee. The Committee noted peer review reports and the comments made by CVMP members.

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 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 adopted a recommendation for changes to the product information for **Solensia** (EMEA/V/C/005197) as the outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Equilis Prequenza Te** (EMEA/V/C/000095) as the outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Equilis Prequenza** (EMEA/V/C/000094) as the outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Equilis Te** (EMEA/V/C/000093) as the outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Nobivac DP Plus** (EMEA/V/C/005251) as the outcome of signal management.

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 post-authorisation recommendation for **CircoMax Myco** (EMEA/V/C/005184) which is 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

- There were no items for discussion.

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 confirmed the appointment of Maria-Eleni Flippitzi as new member of the Antimicrobial Working Party.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the plenary meeting held on 19–20 October 2022 and noted the agenda of the meeting together with the minutes of the ERAWP plenary meeting held on 28 June 2022.
- The Committee discussed the reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs. Comments from CVMP members were requested by 18 November 2022. The adoption of the document is foreseen for the December 2022 CVMP plenary meeting.
- The Committee discussed the call for nominations for two experts for the ERAWP, and the selection of two new ERAWP experts was agreed by the CVMP.
- The Committee discussed the draft ERAWP work plan for 2023. The document is foreseen to be adopted at the December 2022 meeting of the Committee.

6.3. Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 18-19 October 2022, and noted the agenda of the meeting together with the minutes from the meeting held on 17-18 May 2022
- The Committee discussed the draft concept paper on a guideline on efficacy and target animal safety data requirements and potential claims for alternatives to antimicrobials. The adoption of the concept paper is foreseen for the January 2023 meeting of the Committee.
- The Committee discussed the draft questions and answers on the 'Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products'. The adoption of the Q&A is foreseen for the December 2022 meeting of the Committee.

6.4. Immunologicals Working Party (IWP)

- The Committee received an update on the IWP interested parties meeting to be held on 24 November 2022.

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

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee adopted the draft guideline on the development and data requirements of potency tests for cell-based therapy products and the relation to clinical efficacy (EMA/CVMP/NTWP/179287/2022) for a 3-month period of public consultation.
- The Committee discussed the guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy. The adoption of the guideline is foreseen for the January 2023 meeting of the Committee.
- The Committee received an updated on the results from the survey on scientific advice for innovative products.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 26 October 2022 and noted the agenda of the meeting.

6.8. Quality Working Party (QWP)

- The Committee discussed the concept paper on a guideline on risk management requirements for elemental impurities in veterinary medicinal products, including immunological veterinary medicinal products. The adoption of the concept paper is foreseen for the December 2022 meeting of the Committee.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 7 November 2022 and noted the agenda of the meeting together with the minutes of the SAWP-V meeting held on 30 September 2022 (EMA/CVMP/SAWP/816570/2022).

6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

6.11. Other working party and scientific group issues

- The Committee endorsed M. Hoefnagel as chair of the Quality Innovation Group for a 3-year term.
- The Committee adopted the mandate, objectives and rules of procedure for the European Sales and Use of Veterinary Antimicrobials Working Group (ESUVA WG) to replace the ESVAC network. The document will be shared with HMA for endorsement and launch of call for nominations.

7. Other scientific matters

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

7.1. MRL issues

- The Committee agreed to include **hydrogenated castor oil** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.56).

7.2. Environmental risk assessment

- There were no items for discussion.

7.3. Antimicrobial resistance

- There were no items for discussion.

7.4. Pharmacovigilance

- The CVMP was informed of the revision of the "Incident management plan for medicines for veterinary use" (EMA/711053/2010) to reflect the changes in the management of veterinary pharmacovigilance and organisational changes within the EMA since the previous revision, and to update the legal references (Regulation (EU) 2019/6).

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 discussed the draft procedural advice for vaccine platform technology master file (vPTMF) certification (EMA/CVMP/184591/2022).

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

- The Committee agreed that there is no need for further EU comments on the draft VICH Guideline on GMP for active pharmaceutical ingredients and indicated that it could endorse the document in its current form.
- The Committee endorsed the draft concept paper for a Global Regulatory Dossier Framework for VMP.
- The Committee noted the meeting documents for the VICH Steering Committee, and VICH Outreach Forum meetings to be held on 14-17 November 2022.

8.2. Codex Alimentarius

- The Committee discussed the draft SWP comments on MRL recommendations and general considerations from the 94th JECFA meeting, and the draft SWP comments on MRL extrapolations to be considered by CCRVDF.

8.3. Other EU bodies and international organisations

- The Committee discussed the draft report of the working group on the development of a harmonised approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides in food of animal origin, and the overview of comments received during public consultation. The Committee noted the comments received from the European Commission. The adoption of the report is foreseen for the December 2022 CVMP meeting.

The following documents was circulated for information:

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

9. Procedural and regulatory matters

Information relating to new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

- The Committee considered a request for limited market classification for a veterinary medicinal product (ATCvet classification: Immunologicals) for horses. The Committee classified the product as intended for a limited market and eligible for authorisation under Article 23 of Regulation (EU) 2019/6.
- The Committee considered a request for limited market classification for a veterinary medicinal product (ATCvet classification: Antineoplastic and immunomodulating agents) 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.

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 27 October 2022, and noted the agenda of the meeting and the minutes of the meeting held on 7 July 2022.
- The Committee agreed to resume the CVMP Interested parties meeting and to virtually hold the next meeting on Wednesday, 24 May 2023 from 10.00-12.00 CEST.
- The Committee discussed the draft CVMP Work plan for 2023. The document is foreseen to be adopted at the December 2022 meeting of the Committee.
- The Committee received an update on the 2nd Veterinary Big Data Stakeholder Forum to be held on 23 November 2022.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 8-9 September 2022 and 6-7 October 2022 and noted the draft minutes of the meeting held on 6-7 October 2022 as well as the draft agenda of the meeting held on 10-11 November.

12. Legislation

- The Committee adopted the draft reflection paper on the application of Article 40(5) of Regulation (EU) 2019/6 for certain categories of variations (EMA/CVMP/64911/2021) for a 3-month period of public consultation.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the November 2022 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 November 2022 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Minna Leppänen	Full involvement	
FR	Sylvie Louet	Full involvement	
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	
SK	Eva Chobotová	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
Co-opted	Carina Bergman	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Manuela Leitner	Full involvement	
BE	Frédéric Klein	Full involvement	
BG	Nadya Ognyanova Vladimirova	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Christine Miras	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
NL	Kim Boerkamp	Full involvement	
SK	Katarína Massányiová	Full involvement	

Country	CVMP Expert* remote attendance	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.			
AT	Haru Kroneis	Full involvement	
DE	Sandra-Maria Wienhold	Full involvement	
DE	Regina Wolf	Full involvement	
DE	Sarah Adler Flindt	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Silke Hickmann	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Anja Merle Pfalzgraff	Full involvement	
DE	Maike Gömmel	Full involvement	
DE	Yasemin Süzer	Full involvement	
DE	Jan Brosda	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
DK	Anne Hasle Buur	Full involvement	
ES	Sonia Gil Morales	Full involvement	
ES	Susana Casado	Full involvement	
ES	Rosario Bullido	Full involvement	
ES	Maria José Ferrer Montesa	Full involvement	
ES	Lorena Touriño González	Full involvement	
ES	Alberto de Prado	Full involvement	
FR	Mariette Saléry	Full involvement	
FR	Nathalie Bridoux	Full involvement	
FR	Damien Bouchard	Full involvement	
IE	Alma Moffett	Full involvement	
IE	Sarah Hanley	Full involvement	
NL	René van Herwijnen	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

CVMP working parties and CMDv	Chair
IWP	Esther Werner
J3Rs WP	Sarah Adler-Flindt *(veterinary vice chair)*
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