17 January 2023
EMA/CVMP/30338/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 6-8 December 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 the addition of a new item under point 3.1.

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 December 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.

iv. Adoption of the minutes of the previous meeting

The minutes of the November 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

- There were no items for discussion.

2. Marketing authorisations and extensions

2.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

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

- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for **Brucellin Aquilon** (EMEA/V/C/005577/0000), recommending the granting of a marketing authorisation. The product is for *in vivo* diagnosis of *Brucella* infected pigs (skin test) to discriminate false positive results by *Brucella* serological tests. 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

- 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/005948/0000) for cats. 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 product (EMEA/V/C/006099/0000) for dogs. The Committee noted 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/006000/0000), for chickens. The Committee noted a peer review report and the comments received from CVMP members.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

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 (29 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for a variation requiring assessment (subject to a worksharing procedure) for **Porcilis PCV ID** (EMEA/V/C/WS2294), recommending the variation of the marketing authorisation to update the product information to include new associated use combinations of Porcilis PCV ID, Porcilis Lawsonia ID, Porcilis M Hyo ID ONCE and Porcilis PRRS. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for a grouped variation requiring assessment for **Simparica Trio** (EMEA/V/C/004846/VRA/0009/G), recommending the variation of the marketing authorisation to add three new therapeutic indications: for the

treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*), for the treatment of demodicosis (caused by *Demodex canis*), and for the prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection). The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion), the CVMP assessment report, and the product information for a variation requiring assessment for **Credelio Plus** (EMEA/V/C/005325/VRA/0005), recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of demodicosis (caused by *Demodex canis*). The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, the CVMP assessment report, and the product information for a grouped variation requiring assessment (subject to a worksharing procedure) (EMEA/V/C/WS2280/G), for **NexGard** and for **Nexgard Spectra**, recommending the variation of the marketing authorisation to add two new therapeutic indications for the treatment of tick infestations with *Hyalomma marginatum* and for the treatment of ear mite infestations (caused by *Otodectes cynotis*), and to amend the product information to allow the use of the product in breeding, pregnant and lactating female dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (28 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 **Prevomax** (EMEA/V/C/004331/VRA/0013), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to implement pharmacovigilance-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 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 **Purevax RC**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV**, **BTVPUR**, **Eurican Herpes 205**, **Purevax RCPCh** and **Purevax RCP** (EMEA/V/C/WS2329), 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 (28 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 **Suvaxyn CSF Marker**, **Fevaxyn Pentofel** and **Suvaxyn PRRS MLV** (EMEA/V/C/WS2349), 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 (28 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 **Panacur Aquasol** (EMEA/V/C/WS2355), 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 (28 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for

Solensia (EMEA/V/C/005179/VRA/0005), 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 (28 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Mirataz** (EMEA/V/C/004733/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 (28 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 **Imoxat** (EMEA/V/C/005597/VRA/0001/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 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 **Procox** (EMEA/V/C/002006/VRA/0034/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Procox** (EMEA/V/C/002006/VRA/0033/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped variation requiring assessment for **Bluevac BTV** (EMEA/V/C/000156/VRA/0011/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Locatim** (EMEA/V/C/000041/VRA/0023), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (24 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Improvac** (EMEA/V/C/000136/VRA/0042), 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

- There were no items for discussion.

3.3. List of outstanding issues under Commission Regulation (EC) No 1234/2008

- There were no items for discussion.

3.4. List of questions under Regulation (EU) 2019/6

- The Committee adopted a list of questions for a variation requiring assessment for **Bravecto** (EMEA/V/C/002526/VRA/0057), 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 **Nobilis Influenza H5N2** (EMEA/V/C/000118/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 **Zolvix** (EMEA/V/C/000154/VRA/0030) 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 **Versican Plus Pi** (EMEA/V/C/003681/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 **Versican Plus L4** (EMEA/V/C/003680/VRA/0012) 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 **Versican Plus Pi/L4** (EMEA/V/C/003683/VRA/015) 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 **Lotilaner Elanco** (EMEA/V/C/006030/VRA/0001).
- The Committee adopted a list of questions and agreed comments on the draft product information, for a grouped variation requiring assessment for **Gumbohatch** (EMEA/V/C/004967/VRA/0008/G).
- The Committee adopted a list of questions and agreed comments on the draft product information, for a variation requiring assessment for **Evanovo** (EMEA/V/C/005819/VRA/0001) 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 **Galliprant** (EMEA/V/C/004222/VRA/0018) 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 **Procox** (EMEA/V/C/002006/VRA/0032) to align the product information with version 9.0 of the QRD template.
- The Committee adopted a list of questions for a variation requiring assessment for **Halocur** (EMEA/V/C/000040/VRA/018/G), 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

- 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 the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection** (EMEA/V/A/145). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing and the revised timetable for the procedure. The Committee noted the peer review reports and the comments made by CVMP members.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing N-methyl pyrrolidone as an excipient** (EMEA/V/A/146). The Committee recommended the addition of user and/or target animal safety warnings to the product information of some veterinary medicinal products concerned by this referral. The Norwegian CVMP member agreed with the above-mentioned recommendation.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

- There were no items for discussion.

4.6. Request for a scientific opinion under Article 141(1)(c) or 141(1)(e) of Regulation (EU) 2019/6

- There were no items for discussion.

4.7. Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential.

4.7.1. Referrals under Regulation (EU) 2019/6

- There were no items for discussion.

4.7.2. Referrals under Article 35 of Directive 2001/82/EC

- There were no items for discussion.

5. Post-authorisation issues for marketing authorisations

Information relating to certain pharmacovigilance topics, and to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections

5.1. Pharmacovigilance under Regulation (EU) 2019/6

- The Committee adopted a recommendation for changes to the product information for **Bravecto** (EMEA/V/C/002526) as outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Felpreva** (EMEA/V/C/005464) as outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Improvac** (EMEA/V/C/000136) as outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Proteq West Nile** (EMEA/V/C/002005) as outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Procox** (EMEA/V/C/002006) as outcome of signal management.
- The Committee adopted a recommendation for changes to the product information for **Zuprevo** (EMEA/V/C/002009) as 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

- There were no items for discussion.

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

- The Committee adopted the rapporteur's assessment report on the data submitted in response to the Committee's post-authorisation recommendation for **Purevax RC, Purevax RCP and Purevax RCPCh** (EMEA/V/C/005184) which is now considered fulfilled.

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 received a verbal report from the AWP chair on the meeting held on 22-23 November 2022 and noted the agenda of the meeting, together with the minutes of the AWP meeting held on 20-21 September 2022.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the draft reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs (EMA/CVMP/ERA/31905/2021) for a 3-month period of public consultation.

6.3. Efficacy Working Party (EWP-V)

- The Committee adopted a questions and answers document on the 'Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products' (EMA/CVMP/EWP/799840/2022).
- The Committee discussed the draft revised reflection paper on resistance in ectoparasites (EMA/CVMP/EWP/310225/2014) and the overview of comments received following the close of the public consultation.

6.4. Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 21-22 November 2022 and noted the agenda of the meeting, together with the minutes of the meeting held on 28-29 April 2022.

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

- There were no items for discussion.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee discussed the draft guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy. The adoption of the draft guideline is foreseen for the January 2023 meeting of the Committee.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 29-30 November 2022, and noted the agenda of the meeting.
- The Committee was informed of the upcoming election of the vice-chair of the PhVWP-V for 3-year term, renewable once, at the January 2023 CVMP meeting. A call for nominations was circulated by the secretariat.

6.8. Quality Working Party (QWP)

- The Committee adopted the concept paper on a guideline on risk management requirements for elemental impurities in veterinary medicinal products, including immunological veterinary medicinal products (EMA/CVMP/637041/2022) for a 3-month period of public consultation.
- The Committee adopted the following guidelines and one reflection paper to align with Regulation (EU) 2019/6: Guideline on development pharmaceutics for veterinary medicinal products (EMA/CVMP/QWP/684556/2022); Guideline on chemistry of active substance veterinary (EMA/CVMP/QWP/707366/2017); Reflection Paper on definition of New Active Substance status - Veterinary (EMA/CVMP/QWP/3629/2016); Guideline on control of impurities of pharmacopoeial substances (EMA/CVMP/QWP/907965/2022); Guideline on parametric release (EMA/CVMP/QWP/339588/2005); Guideline on declaration of storage conditions (EMA/CVMP/QWP/857608/2022); Guideline on stability of existing active substance and related finished product (EMA/CVMP/QWP/709423/2022); Guideline on additional quality requirements for products intended for incorporation into animal feed (EMA/CVMP/QWP/711629/2022); Guideline on the quality of single-dose spot-on products (EMA/CVMP/QWP/544461/2007); Guideline on quality of modified release oral dosage forms - veterinary (EMA/CVMP/QWP/908160/2022). All revised guidelines and the reflection paper will come into effect immediately after publication.
- The Committee discussed the annex to the guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water (EMEA/CVMP/540/03 Rev 1) and the concomitant use of veterinary medicinal products and biocides.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 5 December 2022, and noted the agenda of the meeting, together with the minutes of the SAWP-V meeting held on 7 November 2022.

6.10. Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 17-18 November 2022, and noted the agenda of the meeting together with the minutes of the meeting held 31 March – 1 April 2022.
- The Committee discussed the question and answer document on the guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products.

6.11. Other working party and scientific group issues

- The Committee discussed the draft IWP work plan for 2023 foreseen to be adopted at the January 2023 meeting of the Committee.
- The Committee discussed the draft SWP-V work plan for 2023 foreseen to be adopted at the January 2023 meeting of the Committee.
- The Committee adopted the work plans for 2023 for the CVMP working parties: SAWP-V (EMA/CVMP/SAWP/827784/2022), QWP (EMA/CHMP/CVMP/QWP/822156/2022), ERAWP (EMA/CVMP/ERA/828487/2022), EWP-V (EMA/CVMP/EWP/817611/2022), AWP (EMA/CVMP/AWP/715896/2022), PhVWP-V (EMA/CVMP/PhVWP/593990/2022), subject to the amendments agreed.
- The Committee adopted the work plan for 2023 for NTWP (EMA/CVMP/ NTWP/701391/2022).

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

- The Committee received a verbal report on new information on the risk to necrophagous birds from the use of NSAIDs in the EU.

7.3. Antimicrobial resistance

- The Committee received feedback on the twelfth ESVAC report: Sales of veterinary antimicrobial agents in 31 European countries in 2021. Trends from 2010 to 2021 (link).

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 EU comments on the VICH GL on target animal safety of veterinary monoclonal antibody products (VMAP), to be forwarded to the VICH expert working group.

- The Committee endorsed the draft EU comments on the VICH GL8 on stability testing for medicated premixes, to be forwarded to the VICH expert working group.
- The Committee endorsed the revised draft of VICH GL18 on residual solvents updated to take account of comments received during the public consultation and the overview of comments received during public consultation including proposed responses (EMA/910424/2022). Both documents will be forwarded to the VICH expert working group.
- The Committee agreed that no further comments are needed on the draft VICH GL on pharmaceutical development. The VICH expert working group will be informed that the EU has no comments.
- The Committee received a verbal report on the VICH Steering Committee and Outreach Forum meetings held 14-17 November 2022.

8.2. Codex Alimentarius

- The Committee endorsed the SWP-V comments on MRL recommendations and general considerations from the 94th meeting of the Joint FAO/WHO Expert Committee on Food Additives and the SWP-V comments on MRL extrapolations to be considered by CCRVDF at the upcoming meeting in February 2023.

8.3. Other EU bodies and international organisations

- The Committee adopted the 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.

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

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 adopted the CVMP work plan for 2023 (EMA/CVMP/617330/2022).
- The Committee received an update on IRIS for core regulatory procedures.

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 8-9 December 2022 and the minutes of the meeting held on 10-11 November 2022.

12. Legislation

- The Committee received a verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6)).

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the December 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 December 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	
BG	Krasimir Zlatkov	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	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	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	
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	
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
NL	Kim Boerkamp	Full involvement	
SI	Boris Kolar	Full involvement	
NO	Annelin Aksdal Bjelland	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	Anke Finnah	Full involvement	
DE	Sandra Wienhold	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
ES	María Dominguez Nicolás	Full involvement	
ES	Ramón Lorenzo Gómez	Full involvement	
ES	Luis Agote Casado	Full involvement	
DE	Norbert Moller	Full involvement	
DE	Anja Christensen	Full involvement	
DK	John Jensen	Full involvement	
DK	Sanne Have	Full involvement	
DK	Trine Jensen	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Dana Halová	Full involvement	
FR	Damien Bouchard	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Eva Pomezná	Full involvement	
SE	Jenny Larsson	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Alina Rößner	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Silke Hickmann	Full involvement	
DE	Gunther Speichert	Full involvement	
DE	Werner Terhalle	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
NL	Alejandro Montón Silva	Full involvement	

Field C

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Sandy Vermout	Full involvement	
AT	Haru Kroneis	Full involvement	
FR	Benoit Courty	Full involvement	
FR	Jean-Christophe Faucon	Full involvement	
ES	Susana Casado	Full involvement	
ES	Verónica Devesa	Full involvement	
SE	James Mount	Full involvement	
NL	Anita Bottger	Full involvement	
DE	Kathrin Schirmann	Full involvement	
DK	Emilie Pouplier	Full involvement	
DE	Nikola Lange	Full involvement	
EFSA	Davide Arcella	Full involvement	
EFSA	Bruno Dujardin	Full involvement	
IE	Gavin Ryan	Full involvement	
IE	Sarah Buckley	Full involvement	
DE	Dagmar Sommer	Full involvement	
DE	Brigitte Küchler	Full involvement	
DE	Yasemin Süzer	Full involvement	
DE	Rolf Beckmann	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Sarah Beesley	Full involvement	
DE	Monika Hofmann	Full involvement	
DE	Birgit Kegel	Full involvement	
DE	Maike Gömmel	Full involvement	
DE	Judith Romberg	Full involvement	
DE	Babett Kobe	Full involvement	
FR	Sandrine Rougier	Full involvement	
DE	Christine Schwarz	Full involvement	
NO	Hans Kristian Ostensen	Full involvement	
FR	Corinne Piquemal	Full involvement	

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

CVMP working parties and CMDv	Chair
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