21 March 2023
EMA/CVMP/134248/2023
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 14-15 February 2023 meeting

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

Note on access to documents

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

i. Adoption of the Agenda

The Committee adopted the agenda with a minor amendment to 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 14-15 February 2023

The attendance list was completed and competing interests were identified for the February 2023 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 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 January 2023 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions held in advance or in the margins of the present CVMP meeting

Information relating to briefing meetings taking place with applicants/marketing authorisation holders cannot be released at the present time as it is deemed to be commercially confidential.

1. Maximum residue limits

1.1. Opinions

- There were no items for discussion.

1.2. Oral explanations

- There were no items for discussion.

1.3. Lists of outstanding issues

- There were no items for discussion.

1.4. List of questions

- The Committee adopted the scientific overview and list of questions for the extension of MRLs in chickens for a substance, (EMEA/V/MRL/003420/EXTN/0004), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and of peer review reports.

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 **Bovilis Nasalgen-C** (EMEA/V/C/005906/0000), recommending the granting of a marketing authorisation. The product is a vaccine intended for the active immunisation of cattle from the day of birth onwards to reduce

clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus. 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 **Coxevac** (EMEA/V/C/000155/X/0015), recommending the extension of the marketing authorisation to add sheep as a new target species. 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 **Innovax-ILT-IBD** (EMEA/V/C/005905/0000), recommending the granting of a marketing authorisation. The product is a vaccine intended for the active immunisation of one-day-old chicks or 18-19 day-old embryonated chicken eggs to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus and to prevent mortality and to reduce clinical signs and lesions caused by infectious bursal disease (IBD) virus. 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 **Eurican L4** (EMEA/V/C/005944/0000), recommending the granting of a marketing authorisation. The product is a vaccine intended for active immunisation of dogs from 7 weeks of age to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by *Leptospira interrogans* serogroup Canicola serovar Canicola, *Leptospira interrogan*s serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa, and *Leptospira interrogans* serogroup Australis serovar Bratislava. 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 **Prolevare** (EMEA/V/C/006117/0000), recommending the granting of a marketing authorisation. The product is for the treatment of pruritus associated with allergic dermatitis in dogs and for treatment of clinical manifestations of atopic dermatitis in dogs. 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

- 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/006143/0000), for dogs. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new vaccine (EMEA/V/C/006146/0000), 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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product, (EMEA/V/C/006103/0000).
- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product, (EMEA/V/C/005948/0000).

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 (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 **Bravecto Plus** (EMEA/V/C/004440/VRA/0023/G), recommending the variation of the marketing authorisation to add a new therapeutic indication for the prevention of aelurostrongylosis (by preventing the establishment of adult *Aelurostrongylus abstrusus* responsible for clinical disease) and to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.
- The Committee adopted by consensus (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 **Suvaxyn PRRS MLV** (EMEA/V/C/004276/VRA/0006/G), recommending the variation of the marketing authorisation to add nasal use as an additional route of administration and to modify the approved therapeutic indication to include protection against heterologous subtype-1 AUT15-33, subtype-2 BOR57 and subtype-3 Lena strains of the PRRS virus. 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 for **Zeleris** (EMEA/V/C/004099/VRA/0005/G), recommending the variation of the marketing authorisation to add a new therapeutic indication for the treatment of bovine respiratory disease due to *Mycoplasma bovis* associated with pyrexia and to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation. The Committee noted the summary of the opinion for publication.

- The Committee adopted by majority (25 members in favour out of the 27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a variation requiring assessment for **Lotilaner Elanco** (EMEA/V/C/006030/VRA/0001), recommending the variation of the marketing authorisation concerning the change of classification from 'subject to veterinary prescription' to 'not subject to veterinary prescription'. H. Bergendahl, N. Kyvsgaard and M. Leppanen signed a divergent position not supporting the aforementioned 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 grouped variation requiring assessment for **Librela** (EMEA/V/C/005180/VRA/0005/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to update the product information following the outcome of the CVMP assessment on the PSUR. 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 and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Gumbohatch** (EMEA/V/C/004967/VRA/0008/G), recommending the variation of the marketing authorisation to add a mixed, associated use of two vaccines, Gumbohatch and Evanovo, 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 (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 **BTVPUR** (EMEA/V/C/002231/VRA/0026/G), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and to amend SPC and package leaflet sections on adverse events as recommended based on signal detection activities. 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 variation requiring assessment (subject to a worksharing procedure) for **Purevax RCP FeLV/Purevax RCP** (EMEA/V/C/WS2286), 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 variation requiring assessment for **Trocoxil** (EMEA/V/C/000132/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.

- 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 **Procox** (EMEA/V/C/002006/VRA/0032), 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 (28 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a variation requiring assessment for **Suvaxyn PRRS MLV** (EMEA/V/C/004276/VRA/0007), 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 **Librela** (EMEA/V/C/005180/VRA/0004/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (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 **Innovax-ND-IBD** (EMEA/V/C/004422/VRA/0010), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template and process minor editorial changes in the product information. 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 **Naxcel** (EMEA/V/C/000079/VRA/0042), 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 **Suprelorin** (EMEA/V/C/000109/VRA/0039), 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 **Equip WNV** (EMEA/V/C/000137/VRA/0029), 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 **Equip WNV** (EMEA/V/C/000137/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 (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 **Versican Plus Pi/L4R**; **Versican Plus Pi/L4**; **Versican Plus DHPPi/L4**; **Versican Plus DHPPi/L4R**; **Versican Plus L4** (EMEA/V/C/WS2330),

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 (subject to a worksharing procedure) for **Vectormune FP ILT**; **Vectormune FP ILT + AE** (EMEA/V/C/WS2316/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 variation requiring assessment for **Galliprant** (EMEA/V/C/004222/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 (28 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Halocur** (EMEA/V/C/000040/VRA/0017), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a grouped variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/VRA/0005/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation.
- The Committee adopted by consensus (28 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Mhyosphere PCV ID** (EMEA/V/C/005272/VRA/0002), 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 variation requiring assessment for **Zolvix** (EMEA/V/C/000154/VRA/0030), 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 (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 **Simparica Trio** (EMEA/V/C/004846/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 (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 **Evanovo** (EMEA/V/C/005819/VRA/0001), recommending the variation of the marketing authorisation to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation.

- The Committee adopted by consensus (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 **Aservo EquiHaler** (EMEA/V/C/004991/VRA/0007/G), recommending the variation of the marketing authorisation to update the package leaflet following the outcome of the CVMP assessment of the PSUR and 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

- The Committee adopted a list of outstanding issues and agreed comments on the draft product information for **Melovem** (EMEA/V/C/00152/VRA/0015), concerning quality-related changes.

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

- There were no items for discussion.

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

- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Cerenia** (EMEA/V/C/000106/VRA/0043), 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 (subject to a worksharing procedure) for **Suiseng Diff/A** and other related nationally authorised products (EMEA/V/C/WS2395).
- The Committee adopted a list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Vaxxitek HVT+IBD**, **Prevexxion RN+HVT+IBD**, **Prevexxion RN** (EMEA/V/C/WS2386).
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Proteq West Nile** (EMEA/V/C/002005/VRA/0018/G), to align the product information with version 9.0 of the QRD template and to update the product information in line with the outcome of signal detection activities.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Contacera** (EMEA/V/C/002612/VRA/0015), to align the product information with version 9.0 of the QRD template.
- The Committee adopted a Rapporteur's assessment report including list of questions for a variation requiring assessment for **Syvazul BTV** (EMEA/V/C/004611/VRA/0006), concerning quality-related changes.

- The Committee adopted a list of questions for a grouped variation requiring assessment (subject to a worksharing procedure) for **Purevax RC, Purevax RCP FeLV, Purevax RCPCh FeLV, Purevax RCPCh, Purevax RCP** (EMEA/V/C/WS2376/G), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a grouped variation requiring assessment for **Kriptazen** (EMEA/V/C/004868/VRA/0007/G), concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a variation requiring assessment for **Onsior** (EMEA/V/C/000127/VRA/0035), 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) No 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) No 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

- 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 33(4) of Directive 2001/82/EC

- 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 **Catophos 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats** (EMEA/V/A/147), concluding that the objections raised by Germany during the decentralised procedure should not prevent the granting of a marketing authorisation for the above-mentioned veterinary medicinal product. 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 CVMP assessment report for the referral procedure for **Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats** (EMEA/V/A/148), concluding that the objections raised by Germany during the decentralised procedure should not prevent the granting of a marketing authorisation for the above-mentioned veterinary medicinal product. The Norwegian CVMP members agreed with the above-mentioned recommendation.

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

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 endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Mirataz** (EMEA/V/C/004733/REC/007), which is now considered fulfilled.

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 agreed that the AWP should now start work on developing the proposed guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6, following the close of the public consultation period for the concept paper (EMA/CVMP/AWP/201064/2022).

6.2. Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

6.3. Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 7 February 2023, and noted the agenda of the meeting, together with the minutes from the meeting held on 18-19 October 2022.

6.4. Immunologicals Working Party (IWP)

- The Committee adopted the draft guideline on plasmid DNA vaccines for veterinary use (EMA/CVMP/IWP/365817/2022) for a 4 - month-period public consultation.

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

- The Committee received a verbal report on the upcoming annual stakeholder meeting of the 3RsWP, and noted the draft agenda of the meeting.

6.6. Novel therapies & Technologies Working Party (NTWP)

- The Committee confirmed the appointment of the CVMP NTWP Operational Expert Group (OEG) on nanomedicines.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 24-25 January 2023, and noted the agenda of the meeting.

6.8. Quality Working Party (QWP)

- The Committee endorsed Dr. B. Hirschlerova as QWP Chair.
- The Committee discussed the draft annex on compatibility studies between veterinary medicinal products and biocidal products of the guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water and noted the comments received from the European Commission. The adoption of the document is foreseen for the March CVMP meeting.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 10 February 2023, and noted the agenda of the meeting, together with the final minutes of the meeting held on 16 January 2023.
- The Committee adopted the scientific advice report on a veterinary medicinal product for dogs.
- The Committee adopted the scientific advice report on a new veterinary medicinal product for dogs.
- The Committee adopted the scientific advice report on a new veterinary medicinal product for horses
- The Committee adopted the scientific advice report on a new veterinary medicinal product for lambs and calves.
- The Committee adopted the follow-up scientific advice report on a new veterinary medicinal product for horses.

6.10. Safety Working Party (SWP-V)

- There were no items for discussion.

6.11. Other working party and scientific group issues

- The CVMP notes the minutes of the ASMF working group meeting held on 18 May 2022, together with the agenda of the meeting held on 20 January 2023.

7. Other scientific matters

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

7.1. MRL issues

- There were no items for discussion.

7.2. Environmental risk assessment

- There were no items for discussion.

7.3. Antimicrobial resistance

- There were no items for discussion.

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

- There were no items for discussion.

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 adopted the VICH guidelines GL35 Pharmacovigilance: electronic standards for transfer of data, and GL42 Pharmacovigilance: data elements for submission of adverse event reports data for publication.
- The Committee endorsed the revised draft VICH guideline GL18(R2) on Impurities: Residual solvents in new VMPs, active substances and excipients, for sign-off by the EWG.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- The Committee noted that further to adoption by CVMP and endorsement by EFSA's Scientific Committee, the final report on Development of a common approach on exposure assessment methodologies for residues from VMPs, feed additives and pesticides residues in food of animal origin has been sent to the European Commission and published on the EMA website (link to news announcement, link to webpage on dietary exposure assessment).
- The Committee was informed of the public discussion on the WHO Medically Important Antimicrobial List, 7th revision (link)

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

- There were no items for discussion.

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 2 February 2023, and noted the agenda of the meeting and the minutes of the meeting held on 27 October 2022.
- The Committee adopted the Veterinary Domain Training Plan for 2023.
- The Committee noted the proposed CVMP meeting dates for 2025-2026.

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 16-17 February 2023 and the minutes of the meeting held on 19-20 January 2023

12. Legislation

- The Committee adopted the expert group composition and work methodology for delivery of the scientific advice under Article 115(5) of Regulation (EU) 2019/6 regarding the list of substances which are essential for the treatment of equine species and mandate to the expert group (EMA/CVMP/6857/2023), following a request from the European Commission on support of the revision of the implementing act for the establishment of a list of substances which are essential for the treatment of equine species.

13. Any other business

13.1. Meeting highlights

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

ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the February 2023 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**G. Johan Schefferlie**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
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	
MT	Stephen Spiteri	Full involvement	
NL	Jacqueline Poot	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Christine Miras	Full involvement	
NL	Kim Boerkamp	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
SK	Katarína Massányiová	Full involvement	
NO	Annelin Aksdal Bjelland	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of 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.			
BE	Els Dewaele	Full involvement	
BE	Michel Goret	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Ladislava Nejezchlebova	Full involvement	
CZ	Dana Halová	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Lucie Pokludová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Birgit Kegel	Full involvement	
DE	Christine Schwarz	Full involvement	
DE	Kristina Lehmann	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Sandra-Maria Wienhold	Full involvement	
DE	Yasemin Süzer	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Rolf Beckmann	Full involvement	
DE	Brigitte Küchler	Full involvement	
DE	Sandra Schack	Full involvement	
DK	Mikkel Kjelkvist Calum	Full involvement	
DK	Yen Ngoc Pham	Full involvement	
DK	Anne Malene Nissen	Full involvement	
ES	Marta Martin Juárez	Full involvement	
ES	Sonia Gil Morales	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
ES	Mercedes Ureña Montilla	Full involvement	
FR	Marie-Hélène Sabinotto	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Anne-Marie Jacques	Full involvement	
FR	Florence Pillet	Full involvement	
FI	Stella Attia	Full involvement	
FI	Jukka Pakkanen	Full involvement	
SE	Catarina Eriksson	Full involvement	
SE	Mats Welin	Full involvement	
BE	Sandy Vermout	Full involvement	
IE	Sarah Hanley	Full involvement	
IE	Sarah Buckley	Full involvement	
IE	Susan Reid	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	---
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