6 September 2022
EMA/CVMP/726655/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 12-14 July 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 (EMA/CVMP/613043/2022) with the addition of a new item under agenda point 5.3.

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 12-14 July 2022

The attendance list was completed and competing interests were identified for the July 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. 16 or more members of the 31 members eligible to vote were present. Furthermore, absolute majority requires that 16 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 June 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

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Lotilaner Elanco** (EMEA/V/C/006030/0000), recommending the granting of a marketing authorisation. The product is for the treatment of flea and tick infestations in dogs and cats and for the treatment of demodicosis in dogs; the product can also be used as part of a treatment strategy for the control of flea allergy dermatitis in dogs and cats. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

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

- 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 a marketing authorisation application for a new vaccine (EMEA/V/C/005860/0000), for chickens. The Committee agreed that an oral explanation would not be requested. The Committee noted the peer review reports and 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 (EMEA/V/C/005993/0000), in dogs. 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

- There were no items for discussion.

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

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product, (EMEA/V/C/005902/0000), for dogs.

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report (EMA/CVMP/254676/2022), recommending the variation requiring assessment for **Purevax RCPCh** (EMEA/V/C/000088/VRA/0036), to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (25 members present and eligible to vote) the CVMP opinion and the product information and endorsed the rapporteur's assessment report (EMA/CVMP/254678/2022), recommending the variation requiring assessment for **Purevax RCPCh FeLV** (EMEA/V/C/000085/VRA/0036), to align the product information with version 9.0 of the QRD template. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Letifend** (EMEA/V/C/003865/VRA/0028), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a variation requiring assessment for **Nexgard** (EMEA/V/C/002729/VRA/0036), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a variation requiring assessment for **Prevomax** (EMEA/V/C/004331/VRA/0012), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

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

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report, for a type II variation application for **ProZinc** (EMEA/V/C/002634/II/0025), recommending the variation of the marketing authorisation to implement quality-related changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

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 **Circomax** (EMEA/V/C/005185/VRA/0001/G), to remove from the product information a warning and to align the product information with the latest QRD template, version 9.0.
- The Committee adopted a list of outstanding issues and agreed comments on the draft product information for a grouped variation requiring assessment for **Circomax Myco** (EMEA/V/C/005184/VRA/0002/G), to remove from the product information a warning and to align the product information with the latest QRD template, version 9.0.

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

- The Committee adopted a list of outstanding issues and agreed comments on the draft product information for a type II variation application (subject to a worksharing procedure) for **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R** (EMEA/V/C/xxxx/WS2184), concerning quality-related changes.

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 **Equip WNV** (EMEA/V/C/000137/VRA/0028), 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 **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 questions for a variation requiring assessment for **Clynav** (EMEA/V/C/002390/VRA/0013), concerning quality-related changes.
- The Committee adopted a Rapporteur's assessment report including a list of questions for a variation requiring assessment (subject to a worksharing procedure) for **Poulvac E. coli** (EMEA/V/C/xxxxxx/WS2257), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Zenalpha** (EMEA/V/C/005465/VRA/0003), concerning quality-related changes.
- The Committee adopted a list of questions for a variation requiring assessment for **Lydaxx** (EMEA/V/C/005199/VRA/0003), 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 list of questions and endorsed the rapporteurs' assessment report for the referral procedure for **veterinary medicinal products containing N-methyl pyrrolidone as an excipient** (EMEA/V/A/146). 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

- The Committee adopted by consensus (27 members present and eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing toltrazuril to be administered orally to chickens** (EMEA/V/A/144). The Committee recommended the amendment of the restriction period before the onset of lay in order to ensure consumer safety. The Norwegian CVMP member agreed with the above-mentioned recommendation.

5. Post-authorisation issues for marketing authorisations

Information relating to inspections, supervision and sanctions under section 5 will not be published as it would be undermining the purpose of such inspections

5.1. Pharmacovigilance under Regulation (EU) 2019/6

- The Committee adopted the update of the product information, a Direct animal Healthcare Professional Communication (DaHPC), and a communication plan for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158) as the outcome of signal detection activities.

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

- There were no items for discussion.

5.3. Inspections and controls under Regulation (EU) 2019/6

5.3. Supervision and sanctions under Regulation (EC) No 726/2004

- Status report on PSURs for centrally authorised veterinary medicinal products

5.4. Re-examination of limited markets and exceptional circumstances authorisations under Regulation (EU) 2019/6

- There were no items for discussion.

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

- The Committee discussed the draft concept paper on a guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6. The adoption of the concept paper is foreseen for the September 2022 meeting of the Committee.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the plenary meeting held on 28 June 2022, including the status of ERAWP activities, and noted the agenda of the meeting, together with the minutes from the meeting held on 2–3 March 2022.

6.3. Efficacy Working Party (EWP-V)

- The Committee adopted a concept paper on the revision of the guideline for veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/222080/2022) for a 3-month period of public consultation. This concept paper highlights the changes which are considered necessary to the current guideline, based on regulatory experience, up-to-date scientific knowledge, and currently applicable legislation or terminology.

- The Committee discussed the call for nominations for two experts for the EWP-V and the selection of two EWP-V experts by CVMP was agreed.

6.4. Immunologicals Working Party (IWP)

- There were no items for discussion.

6.5. Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- There were no items for discussion.

6.6. Novel therapies & Technologies Working Party (NTWP)

- There were no items for discussion.

6.7. Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 5-6 July 2022, and noted the agenda of the meeting.
- The Committee adopted the revision of the questions and answers on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL)).

6.8. Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 27-29 June 2022, and noted the agenda of the meeting, together with the minutes of the QWP meeting held on 28 February - 2 March 2022 and the minutes of the QWP-interested parties meeting held on 3-5 May 2022.
- The Committee discussed the draft concept paper on the development of a guideline on synthetic peptides with a view to adopting it at the September 2022 meeting of the Committee.
- The Committee discussed the draft concept paper on the development of a guideline on synthetic oligonucleotides with a view to adopting it at the September 2022 meeting of the Committee.

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee elected S. Louet as Vice-chair of the SAWP-V for a further 3-year term.
- The Committee received a verbal report from the SAWP-V chair on the meeting held on 8 July 2022, and noted the agenda of the meeting, together with the minutes of the SAWP-V meeting held on 13 June 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 adopted the revised proposal from the Quality Domain governance on the provisional mandate, objectives and rules of procedure for the Quality Innovation Group (QIG) and endorsed the list of candidates proposed.

7. Other scientific matters

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

7.1. MRL issues

- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.53).

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 Committee discussed the process description for the EU Veterinary Pilot Signal Management Expert Group (P-SMEG). The adoption of the process is foreseen for the October 2022 CVMP meeting.

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 endorsed the EU comments on the draft guideline on good manufacturing practice guide for active pharmaceutical ingredients used in veterinary medicinal products. The comments will be forwarded to the VICH Expert Working Group.
- The Committee endorsed the EU comments on the draft guideline on pharmaceutical development. The comments will be forwarded to the VICH Expert Working Group
- The Committee endorsed the EU comments on the draft revised guideline on stability testing for medicated premixes and noted the VICH EWG discussion points document with EU comments. The comments will be forwarded to the VICH Expert Working Group.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

- The Committee was informed of the publication of a draft report on the development of a common approach on consumer exposure assessment methodologies for residues from VMPs, feed additives and pesticides residues in food of animal origin (link to news announcement, link to public consultation), further to its adoption by CVMP, endorsement by EFSA Scientific Committee and review by European Commission.

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

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 7 July 2022, and noted the agenda of the meeting and the minutes of the meeting held on 5 May 2022.
- The CVMP elected Dr Carina Bergman as CVMP co-opted member with relevant scientific competence in toxicology and residues for a three-year mandate.
- The Committee endorsed the recommendations of the CVMP/CMDv Presidency meeting, held under the French Presidency on 31 May – 1 June 2022 in Saint Malo, France.

11. CMDv

- The Committee noted the draft agenda of the CMDv meeting to be held on 14-15 July 2022, the minutes of the meeting held on 16-17 June 2022, and the minutes of the CMDv-Interested Parties meeting held on 17 June 2022 (link).

12. Legislation

- The Committee adopted a draft guideline on the application of Article 34 of Regulation (EU) 2019/6 (classification of veterinary medicinal products - prescription status) (EMA/CVMP/273040/2022) for a 3-month period of public consultation. This guideline has been developed to elaborate on the scientific criteria within the various provisions of Article 34 of Regulation (EU) 2019/6 and to provide assessors and stakeholders with clear guidance for its consistent and predictable application.

- The Committee discussed a revised draft reflection paper on Article 37(2)(j) of Regulation (EU) 2019/6, together with the overview of comments received during the public consultation.
- The Committee discussed the guideline on quality data requirements for applications for non-biological products intended for limited markets (applicable to applications submitted under either Article 8 or Article 23).
- The Committee discussed the guideline on safety and residues data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23.
- The Committee discussed the guideline on efficacy and target animal safety data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23.
- The Committee discussed the guideline on quality data requirements for applications for biological products (including IVMPs) intended for limited markets (applicable to applications submitted under either Article 8 or Article 23).
- The Committee discussed the guideline on safety and efficacy data requirements for applications for IVMPs intended for limited markets but not deemed eligible for authorisation under Article 23.
- The Committee received an update on work progress of the expert group providing scientific recommendations on implementing measures under Article 107(6) of Regulation (EU) 2019/6 on a 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.

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the July 2022 CVMP meeting, the draft news highlights was circulated for members to provide comments within 24 hours.

14. ANNEX I

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the July 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	Svetoslav Valentinov Branchev	Full involvement	4.1 one item
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	J. Gabriel Beechinor	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	
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	
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
IE	Paul McNeill	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	Full involvement	
SK	Katarína Massányiová	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.			
AT	Ines Lindner	Full involvement	
DE	Sandra Bertulat	Full involvement	
ES	Beatriz Martinez	Full involvement	
DE	Kathrin Dietze	Full involvement	
ES	Maria Dominguez	Full involvement	
DE	Norbert Möller	Full involvement	
FR	Gérard Moulin	Full involvement	
FR	Jean-Christophe Faucon	Full involvement	
DE	Sandra-Maria Wienhold	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Jan Brosda	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Dana Halová	Full involvement	
CZ	Eva Pomezná	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
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