15 March 2022
EMA/CVMP/157941/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Minutes of the 15-16 February 2022 meeting

Chair: D. Murphy – Vice-chair: G. J. Schefferlie

Note on access to documents

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

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CVMP plenary session 15-16 February 2022

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

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.

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the January 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

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for establishment of MRLs in Equidae for a substance (EMEA/V/MRL/005739/FULL/0001).

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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Chanaxin** (EMEA/V/C/005606/0000), recommending the granting of a marketing authorisation with an obligation, included in Annex II of the SPC, for the applicant to conduct post-authorisation measures. The product is intended for treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

- The Committee adopted by majority (26 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **RenuTend** (EMEA/V/C/005428/0000), recommending the granting of a marketing authorisation. The product is intended for treatment of tendon and ligament injuries in horses. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste and N. C. Kyvsgaard signed a divergent position not supporting the aforementioned 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

- There were no items for discussion.

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

- 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/005944/0000), for dogs. The Committee noted peer review reports and the comments received from CVMP members.

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 a 3-month extension to the clock-stop for a new product (EMEA/V/C/005579/0000).
- The Committee agreed to the request from the applicant for a further extension to the clock-stop for a new product (EMEA/V/C/005132/0000).

3. Variations to marketing authorisations

3.1. Opinions under Regulation (EU) 2019/6

- There were no items for discussion.

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

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report, for a grouped type II variation application for **Forceris** (EMEA/V/C/004329/II/0004/G), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation application for **Strangvac** (EMEA/V/C/005309/II/0002), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II variation application for **Tulissin** (EMEA/V/C/005073/II/0005), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped type II variation application for **Veraflox** (EMEA/V/C/000159/II/0024/G), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a grouped type IB variation application (subject to a worksharing procedure) for **Metacam** and **Novem** (EMEA/V/C/xxxx/WS2215/G), 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 (26 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type IB variation application (subject to a worksharing procedure) for **Purevax RCPCh FeLV**, **Purevax RCP FeLV**, **Purevax RCP**, **Purevax RC** and **Purevax RCPCh** (EMEA/V/C/xxxx/WS2201), recommending the variation of the marketing authorisation to implement changes in section 4.6 of the SPC that were approved in the 10th PSUR assessment (PSUR covering period 01 March 2018 - 28 February 2021). 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

- There were no items for discussion.

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 grouped type II variation application for **Suprelorin**

(EMEA/V/C/000109/II/0032/G), to add a new therapeutic indication and to add a new target species. The Committee agreed that an oral explanation would not be requested.

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

- There were no items for discussion.

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

- The Committee adopted a list of questions for a grouped type II variation application for **Fortekor Plus** (EMEA/V/C/00280/II/0021/G), concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation application for **Credelio Plus** (EMEA/V/C/005325/II/0004), concerning quality-related changes.
- The Committee adopted a list of questions for a grouped type II variation application (subject to a worksharing procedure) for **Canigen L4** and **Novibac L4** (EMEA/V/C/xxxx/WS2160/G), concerning quality-related changes.

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 considered the notification from Germany for a referral for **veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection**. The Committee agreed to start a referral procedure (EMEA/V/A/145) under Article 82 of Regulation (EU) 2019/6 and appointed A. Golombiewski as rapporteur and K. Baptiste as co-rapporteur, and three CVMP members as peer reviewers for the procedure. The Committee adopted a list of questions to be addressed by relevant MAHs (EMA/CVMP/104859/2022), a list of questions to stakeholders (EMA/CVMP/104860/2022) and the timetable (EMA/CVMP/104861/2022) for the procedure.

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

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

5.1. Pharmacovigilance under Regulation (EU) 2019/6

- There were no items for discussion.

5.1. Pharmacovigilance – PSURs and SARs under Regulation (EC) No 726/2004

- The Committee endorsed the outcome of signal detection activities for **Neptra** (EMEA/V/C/004735) with a recommendation for changes to the SPC.
- The Committee endorsed the outcome of signal detection activities for **Nobivac Myxo-RHD Plus** (EMEA/V/C/004989) with a recommendation for changes to the SPC.
- The Committee endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product information or other regulatory actions were required for:

Product	Period
Arti-Cell Forte (EMEA/V/C/004727)	01.04.2021 – 30.09.2021
Comfortis (EMEA/V/C/002233)	01.10.2020 – 30.09.2021
Daxocox (EMEA/V/C/005354)	20.04.2021 – 31.10.2021
ProteqFlu (EMEA/V/C/000073)	01.10.2018 – 30.09.2021
ProteqFlu-Te (EMEA/V/C/000074)	01.10.2018 – 30.09.2021
Simparica Trio (EMEA/V/C/004846)	01.04.2021 – 30.09.2021

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 **Purevax RCP** (EMEA/V/C/000090/REC/023.1), **Purevax RC** (EMEA/V/C/000091/REC/023.1), and **Purevax RCPCh** (EMEA/V/C/000088/REC/025.1), which is now considered fulfilled.

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

Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

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

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- 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)

- Following the close of the public consultation, the Committee received a presentation on the comments received on the concept paper on an update of the CVMP's reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health. As agreed at the October 2021 CVMP meeting, an update of the reflection paper will be drafted.

6.2. Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6 (EMA/CVMP/ERA/622045/2020) and the overview of comments received (EMA/CVMP/ERA/768241/2021) following the close of the public consultation.

6.3. Efficacy Working Party (EWP-V)

- There were no items for discussion.

6.4. Immunologicals Working Party (IWP)

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

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 25-26 January 2022, and noted the agenda of the meeting.

6.8. Quality Working Party (QWP)

- There were no items for discussion. *See agenda point 6.11*

6.9. Scientific Advice Working Party (SAWP-V)

- The Committee received a verbal report from the SAWP-V chair on the meeting held on 14 February 2022, and noted the agenda of the meeting, together with the minutes of the SAWP-V meeting held on 17 January.

6.10. Safety Working Party (SWP-V)

6.11. Other working party and scientific group issues

- The Committee elected Dr C. Schwarz as chair of the AWP for a 3-year term.
- The Committee elected Dr R. Carapeto García as chair of the ERAWP for a 3-year term.

7. Other scientific matters

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

7.1. MRL issues

- The Committee agreed to include benzoic acid, zinc salt (CAS No 553-72-0), neodecanoic acid, calcium salt (CAS No 27253-33-4), and tripropylene glycol (CAS No 24800-44-0) as new entries in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.51).

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

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

- There were no items for discussion.

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

- 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 draft EU comments on the draft VICH guideline on Good Manufacturing Practice for Active Pharmaceutical Ingredients to circulate to the Expert Working Group.

8.2. Codex Alimentarius

- There were no items for discussion.

8.3. Other EU bodies and international organisations

9. Procedural and regulatory matters

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

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

- The Committee endorsed the 12th annual report on Veterinary MUMS / Limited Markets, for adoption by the EMA Management Board on 16-17 March 2022.

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 consolidated 3-year work plan for the Veterinary Domain.

11. CMDv

- The Committee received a verbal report from the chair of CMDv on the meetings held on 9-10 December 2021 and 20-21 January 2022, and noted the agenda of the CMDv meeting to be held on 17-18 February 2022, and the minutes of the CMDv meeting held on 20-21 January 2022.

12. Legislation

- The Committee adopted scientific advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans for the implementing act to Regulation (EU) 2019/6.

- The Committee adopted a draft reflection paper on criteria for determining that an active substance is essential when considered in the context of Article 37(2)(j) of Regulation (EU) 2019/6 (EMA/CVMP/116512/2021) for a 3-month public consultation.
- The Committee adopted procedural advice on extended assessment time of 90 days for initial marketing authorisation applications (EMA/CVMP/612534/2021).
- The Committee discussed article 106(1) of Regulation (EU) 2019/6 in relation to the practical interpretation of the legal text.
- 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)) (EMA/102749/2022).

13. Any other business

13.1. AOB

- There were no items for discussion.

13.2. Meeting highlights

- Upon the completion of the February 2022 CVMP meeting, the draft news highlights were 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 2022 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Petra Falb	Full involvement	
BE	Bruno Urbain	Full involvement	
BG	Svetoslav Valentinov Branchev	Full involvement	
CY	Christodoulos Pipis	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	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	
SI	Katarina Straus	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie **VICE CHAIR**	Full involvement	
Co-opted	Mary O'Grady	Full involvement	
Co-opted	Ricardo Carapeto García	Full involvement	
IS	Peter Zsolt Fekete	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
NL	Kim Boerkamp	Full involvement	
SE	Carina Bergman	Full involvement	
SK	Eva Chobotová	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.			
FR	Gerard Moulin	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DE	Heike Gyra	Full involvement	
DE	Nikola Lange	Full involvement	
NL	Sandra ten Voorde	Full involvement	
FR	Nathalie Bridoux	Full involvement	
SE	Andreea Barbu	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Peter Lönn	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
ES	Patricia Vera	Full involvement	
ES	Mercedes Ureña	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Sandra Wienhold	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Yvonne Mein	Full involvement	
DE	Juliane Schäfer	Full involvement	
DE	Gabriele Schweyen	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Martina Kern	Full involvement	
IE	Sarah Beesley	Full involvement	
IE	Susan Reid	Full involvement	
IE	Sarah Buckley	Full involvement	
SI	Katarina Glogoški	Full involvement	
SI	Luka Kosec	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 WG	---
PhVWP-V	Els Dewaele
QWP	Mary O'Grady *(veterinary vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Carina Bergman

Observers from Swissmedic	
Present	

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