15 June 2021
EMA/CVMP/339658/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 10-12 May 2021 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/127362/2006).

Due to the COVID-19 pandemic, the May 2021 CVMP meeting took place by means of remote participation and decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the May 2021 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.

No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the April 2021 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the extension of MRLs to chickens for a substance (EMEA/V/MRL/003652/EXTN/0004) following discussion of the rapporteur's assessment report. The Committee noted two peer review reports and the comments received from CVMP members.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for the modification of MRLs in fin fish for a substance (EMEA/V/MRL/003808/MODF/0002).
- The Committee noted the request from the European Commission for reconsideration of the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to poultry for **bambermycin** adopted at the March 2021 meeting (EMEA/V/MRL/004828/EXTN/0002).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 **Bonqat** (EMEA/V/C/005489/0000), recommending the granting of a marketing authorisation. The product, containing pregabalin as active substance, is indicated for the alleviation of acute anxiety in cats. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee heard an oral explanation from the applicant concerning an application for a new vaccine (EMEA/V/C/005309/0000) for horses. The Committee also discussed the draft product information and the rapporteurs' preliminary assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the June 2021 CVMP meeting.

2.3 Lists of questions

- There were no items for discussion.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Ultifend ND IBD** (EMEA/V/C/005347/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Solensia** (EMEA/V/C/005719/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Simparica Trio** (EMEA/V/C/004846/II/0001), 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 (24 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type IB grouped variation (subject to a worksharing procedure) for **Vectra 3D** and **Vectra Felis** (EMEA/V/C/xxxxxx/WS2032/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.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Improvac** (EMEA/V/C/000136/II/0036) to change the product information.
- The Committee adopted a list of questions for a type II grouped variation for **Porcilis PCV ID** (EMEA/V/C/003942/II/0005/G) to change the product information.
- The Committee adopted a list of questions for a type II variation for **Poulvac E. coli** (EMEA/V/C/002007/II/0018) to change the SPC.
- The Committee adopted a list of questions for a type II variation for **ProZinc** (EMEA/V/C/002634/II/0024) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Prevomax** (EMEA/V/C/004331/II/0006/G) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique following the assessment of the marketing authorisation holder's responses to the list of outstanding issues and the comments on the draft product information for the referral procedure for **Ronaxan and its associated names** (EMEA/V/A/135). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the June 2021 meeting of the Committee. The Committee noted the comments made by CVMP members.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **injectable veterinary medicinal products containing vitamin A for use in food producing species** (EMEA/V/A/141). The Committee recommended regulatory measures and risk mitigation measures to assure consumer and user safety, including the amendment of withdrawal periods for milk, meat and offal for food producing species. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee endorsed the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Versican Plus DHPPi/L4R** (EMEA/V/C/002759/REC/012.3).
- The Committee adopted the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Purevax RC**, **Purevax RCP** and **Purevax RCPCh** (EMEA/V/C/000091/REC/023, EMEA/V/C/000090/REC/023 and EMEA/V/C/000088/REC/025).
- The Committee adopted the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Equilis Prequenza** and **Equilis Prequenza Te** (EMEA/V/C/000094/REC/025 and EMEA/V/C/000095/REC/029), which is now considered completed.
- The Committee adopted the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Rabitec** (EMEA/V/C/004387/REC/009), which is now considered completed.
- The Committee adopted the rapporteur's assessment report on the data submitted in response to the Committee's recommendation for **Cytopoint** (EMEA/V/C/003939/REC/020).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 16.04.2021 – 12.05.2021:

Product	**Period**
Bravecto Plus (EMEA/V/C/004440)	08.05.2018
Chanhold (EMEA/V/C/004824)	17.04.2019
Credelio (EMEA/V/C/004247)	25.04.2017
Cytopoint (EMEA/V/C/003939)	25.04.2017
Equilis StrepE (EMEA/V/C/000078)	07.05.2004
Evalon (EMEA/V/C/004013)	18.04.2016
Felisecto Plus (EMEA/V/C/005093)	26.04.2019
Forceris (EMEA/V/C/004329)	23.04.2019
Improvac (EMEA/V/C/000136)	11.05.2009
Letifend (EMEA/V/C/003865)	20.04.2016
Meloxidolor (EMEA/V/C/002590)	22.04.2013
Oncept IL-2 (EMEA/V/C/002562)	03.05.2013
Procox (EMEA/V/C/002006)	20.04.2011
ReproCyc ParvoFLEX (EMEA/V/C/004858)	26.04.2019
Tulaven (EMEA/V/C/005153)	24.04.2020
Tulissin (EMEA/V/C/005073)	24.04.2020

Product	Period
Vectormune FP ILT + AE (EMEA/V/C/005077)	24.04.2020
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07.05.2014
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07.05.2014
Zulvac BTV (EMEA/V/C/004185)	25.04.2017
Zuprevo (EMEA/V/C/002009)	06.05.2011

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Eravac** (EMEA/V/C/004239/R/0007).
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Sedadex** (EMEA/V/C/004202/R/0005).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted a recommendation to amend section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet for **Osurnia** based on the outcome of signal detection activities.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.2019-30.10.2020 for **Cytopoint** (EMEA/V/C/003939) with a recommendation to amend section 4.6 'Adverse reactions (frequency and seriousness)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.12.2019-30.11.2020 for **Draxxin** (EMEA/V/C/000077) with a recommendation to amend section 4.5 'Special precautions for use' of the SPC and the corresponding section of the package leaflet.
- 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
Circovac (EMEA/V/C/000114)	01.01.2018-31.12.2020
Clynav (EMEA/V/C/002390)	01.01.2020-31.12.2020
Mirataz (EMEA/V/C/004733)	01.07.2020-31.12.2020
Panacur AquaSol (EMEA/V/C/002008)	01.01.2018-31.12.2020
Posatex (EMEA/V/C/000122)	01.12.2018-31.12.2020
Spironolactone Ceva (EMEA/V/C/000105)	01.01.2018-31.12.2020

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the EU comments on the draft VICH Good Manufacturing Practice guide for active pharmaceutical ingredients.
- The Committee endorsed the draft concept paper proposing development of VICH guidelines to parallel ICH guidelines Q8 (pharmaceutical development), Q9 (quality risk management) and Q10 (pharmaceutical quality system) including EU comments.
- The Committee discussed the draft guideline on target animal safety evaluation for veterinary monoclonal antibody products. A revised version of the draft guideline will be presented for discussion at the June 2021 CVMP meeting with a view to adopting the draft EU comments at the July 2021 CVMP meeting.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Consideration of alternative intake calculation models for estimation of consumer exposure to residues - minutes from the enlarged expert group's 2nd meeting held on 3 March 2021.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 cannot be released at the present time as it is deemed to be commercially confidential.

7.1 Scientific Advice Working Party (SAWP-V)

- The Committee noted the draft agenda of the May 2021 SAWP-V.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the SWP-V chair on the meeting held on 22 April 2021 and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on on-going ERAWP activities and agreed to the requested extensions of the deadline for the completion of some of the activities.
- The Committee received a verbal report from the ERAWP chair on an EFSA opinion on antimicrobial resistance in the environment.

7.5 Efficacy Working Party (EWP-V)

- The Committee discussed the guideline on the Summary of Product Characteristics (SPC) for veterinary medicinal products containing antimicrobial substances and the overview of comments received. – *see also point 7.6*

7.6 Antimicrobials Working Party (AWP)

- The Committee discussed the guideline on the Summary of Product Characteristics (SPC) for veterinary medicinal products containing antimicrobial substances and the overview of comments received. – *see also point 7.5*

7.7 Immunologicals Working Party (IWP)

- The Committee adopted an Updated 'Reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products' (EMA/CVMP/IWP/251741/2015) for a two-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the revised Pharmacovigilance Working Party mandate to come into force on 28 January 2022.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- No items.

8. OTHER SCIENTIFIC MATTERS

8.1 MRL issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be commercially confidential

- There were no items for discussion.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- There were no items for discussion.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to be commercially confidential.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a verbal report from the chair of the CMDv on the meetings held on 18-19 March and 15-16 April 2021, and noted the draft minutes of the meeting held on 15-16 April 2021 as well as the draft agenda of the meeting held on 11-12 May 2021. The Committee also noted the draft agenda of the CMDv-Interested Parties meeting held on 12 May 2021.
- The Committee received a verbal report from the CMDv Legislation Working Group chair on the CMDv Best Practice Guides for:
  - selection of the products for the SPC harmonisation;
  - harmonisation procedure of the SPC of the reference products;
  - harmonisation procedure of the SPC of generic/hybrid veterinary medicinal products.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee was informed on the Veterinary Big Data Stakeholder Forum to be held on 1-2 June 2021 and noted the draft agenda and the registration process (link).

13. LEGISLATION

- The Committee adopted a joint EMA/CMDv guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations (EMA/CMDv/190673/2021). The document will be sent to the Heads of Medicines Agencies for endorsement and will be published on the Agency's website in due course.
- The Committee received a verbal report on work progress concerning provision of scientific recommendations on implementing acts as required by Regulation (EU) 2019/6 and in line with the mandates received from the European Commission.

14. ANY OTHER BUSINESS

- Upon the completion of the May 2021 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 May 2021 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	Involvement in discussions only and cannot act as rapporteur or peer reviewer for **KRKA**.	4.3 – Vitamin A injectables
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	
MT	Stephen Spiteri	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for **Bayer**.	4.3 – Vitamin A injectables
PT	João Pedro Duarte da Silva	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	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	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Carina Bergman	Full involvement	
SK	Eva Chobotová	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.			
BE	Dries Minne	Full involvement	
BE	Els Dewaele	Full involvement	
BE	Sandy Vermout	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Zdenka Mašková	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Christine Schwarz	Full involvement	
De	Heike Gyra	Full involvement	
De	Kathrin Schirmann	Full involvement	
De	Kathrin Schmidt	Full involvement	
De	Martina Kern	Full involvement	
De	Nikola Lange	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Stefan Scheid	Full involvement	
DK	Anne H. Buur	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DK	Martin Oleksiewicz	Full involvement	
DK	Mette Madsen	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
FI	Kristina Lehmann	Full involvement	
FR	Elisabeth Begon	Full involvement	
FR	Laetitia Le Letty	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Mathilde Harvey	Full involvement	
SE	David Khan	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Malin Öhlund	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

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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