10 May 2021
EMA/CVMP/267193/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 13-15 April 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 April 2021 CVMP meeting took place by means of remote participation and decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of a new item, information on publication of the Commission Delegated Regulation (EU) 2021/578 of 29 January 2021, under point 13.

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

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

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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 March 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

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- There were no items for discussion.

2.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions for a new product (EMEA/V/C/005528/0000) for horses. 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 for a new product (EMEA/V/C/005579/0000) for dogs. The Committee noted a peer review report and the comments received from CVMP members.

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 **Daxocox** (EMEA/V/C/005354/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Credelio Plus** (EMEA/V/C/005482/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 type II grouped variation for **Comfortis** (EMEA/V/C/002233/II/0023/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 (subject to a worksharing procedure) for **Purevax RCP FeLV**, **Purevax RCPCh**, **Purevax RCP** and **Purevax RCPCh FeLV** (EMEA/V/C/xxxxx/WS2004), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 (subject to a worksharing procedure) for **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R** (EMEA/V/C/xxxxxx/WS1927), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members 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 for **Purevax Rabies** (EMEA/V/C/002003/II/0015), recommending the variation of the marketing authorisation to implement quality-related change. The Icelandic and Norwegian CVMP members 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 for **Versican Plus Pi/L4**, **Versican Plus Pi/L4R**, **Versican Plus L4**, **Versican Plus DHPPi/L4R** and **Versican Plus DHPPi/L4** (EMEA/V/C/xxxxxx/WS1928/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues to be addressed in writing for a type II grouped variation for **Stelfonta** (EMEA/V/C/005018/II/0004/G) concerning quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Frontpro** (EMEA/V/C/005126/II/0010) to change the product information.
- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **Circovac** and other related nationally authorised products (EMEA/V/C/000114/WS1945/0018) to change the product information.
- The Committee adopted a list of questions for a type IB variation (subject to a worksharing procedure) for **BTVPUR** and other related nationally authorised products (EMEA/V/C/002231/WS2017/0022) concerning quality-related changes.
- The Committee adopted a list of questions and agreed comments on the draft product information for a type II grouped variation for **Porcilis PCV** (EMEA/V/C/000135/II/0014/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II grouped variation for **Veraflox** (EMEA/V/C/000159/II/0024/G) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee adopted the revision of the CVMP opinion (EMA/CVMP/134301/2021) for **Ingelvac CircoFlex** and **Ingelvac MycoFlex** (EMEA/V/C/xxxxxx/WS1920/G.
- The Committee adopted the revision of the MRL table in Annex II of the adopted product information (EMA/CVMP/664676/2020) for **Zactran** (EMEA/V/C/000129/II/0045).
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Emdocam** (EMEA/V/C/002283/X/0012) concerning the extension of the marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Emdocam** (EMEA/V/C/002283/X/0013) concerning the extension of the marketing authorisation.

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

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines** (EMEA/V/A/142), concluding that the benefit-risk balance of the concerned products remains positive and recommending that the marketing authorisations should be varied in order to amend the product information to reflect the agreed risk mitigation measures. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique and draft product information for the referral procedure for **injectable**

veterinary medicinal products containing vitamin A for use in food producing species (EMEA/V/A/141). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the May 2021 meeting of the Committee. The Committee noted a peer review report and the comments made by CVMP members**.**

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 following the Committee's recommendation for **CircoMax Myco** (EMEA/V/C/005184/REC/002).
- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Stelfonta** (EMEA/V/C/005018/REC/003.1), which is now considered completed.
- The Committee endorsed the rapporteur's assessment report on the data submitted following the Committee's recommendation for **Tulinovet** (EMEA/V/C/005076/REC/001), which is now considered completed.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 19.03.2021-15.04.2021:

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2020 – 01.04.2021
Arti-Cell Forte (EMEA/V/C/004727)	29.03.2020 – 28.03.2021
Bluevac BTV (EMEA/V/C/000156)	14.04.2020 – 13.04.2021
Clevor (EMEA/V/C/004417)	13.04.2020 – 12.04.2021
Clomicalm (EMEA/V/C/000039)	01.04.2020 – 31.03.2021
Ecoporc Shiga (EMEA/V/C/002588)	10.04.2020 – 09.04.2021
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2020 – 25.03.2021

Product	Period
Incurin (EMEA/V/C/000047)	24.03.2020 – 23.03.2021
Locatim (EMEA/V/C/000041)	29.03.2020 – 28.03.2021
Neocolipor (EMEA/V/C/000035)	14.04.2020 – 13.04.2021
Purevax FeLV (EMEA/V/C/000056)	13.04.2020 – 12.04.2021
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2020 – 05.04.2021
Veraflox (EMEA/V/C/000159)	12.04.2020 – 11.04.2021

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.2020-30.09.2020 for **Galliprant** (EMEA/V/C/004222) 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 01.08.2017-31.07.2020 for **Kexxtone** (EMEA/V/C/002235) with a recommendation to amend section 4.5 'Special precautions for use (Other precautions)' of the SPC and the corresponding section of the package leaflet.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.2020-30.09.2020 for **Simparica Trio** (EMEA/V/C/004846) 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 endorsed the following rapporteur's assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Baycox Iron (EMEA/V/C/004794)	01.06.2020-30.11.2020
Evalon (EMEA/V/C/004013)	01.11.2019-31.10.2020
Gumbohatch (EMEA/V/C/004967)	01.06.2020-30.11.2020
Oncept IL-2 (EMEA/V/C/002562)	01.12.2017-31.11.2020
Palladia (EMEA/V/C/000150)	01.12.2017-30.11.2020
SevoFlo (EMEA/V/C/000072)	01.12.2019-30.11.2020
Suvaxyn Circo MH RTU (EMEA/V/C/003924)	01.12.2019-30.11.2020
Zeleris (EMEA/V/C/004099)	01.12.2019-30.11.2020

- 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 FDA proposals on the revision of VICH Guidelines on efficacy of anthelmintics, namely on VICH Guideline 7 regarding adequacy of infection (general) and Guideline 20 regarding adequacy of infection for heartworm in cats.
- The Committee discussed the EU comments on the draft VICH Good Manufacturing Practice guide for active pharmaceutical ingredients.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- There were no items for discussion.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

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 received a verbal report from the SAWP-V chair on the meeting held on 12 April 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 23-24 March 2021 and noted the agenda of the meeting. The Committee also noted the minutes from the meeting held on 30 November – 1 December 2020.
- The Committee adopted a concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics (EMA/CVMP/EWP/165592/2021) to be released for a one-month period of public consultation.

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 23-24 March 2021 and noted the agenda and the draft summary record of the meeting.
- The Committee adopted the EudraVigilance access policy for medicines for veterinary use (EMA/113700/2008) and noted an overview of comments received (EMA/164806/2021), following the close of the public consultation.

7.9 Novel Therapies & Technologies Working Party (NTWP)

- 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

- The Committee elected C. Bergman as chair of the SWP-V for a 3-year term.
- The Committee elected J. Poot as chair of the NTWP for a 3-year term. The Committee also endorsed the recommendation of the selection committee and appointed a new panel of members under the mandate, objectives and rules of procedure for the NTWP: S. Casado; F. Hasslung Wikström; F. Klein; M. Leitner; A. Pfalzgraff; S. Rieke; J.-C. Rouby; D. Śladowski.

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 15 March 2021.

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

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- There were no items for discussion.

8.4 Pharmacovigilance

- The Committee noted the recent Dutch media publications on antiparasitic compounds detected in human hair (fipronil, permethrin).

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.

- There were no items for discussion.

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 noted the draft minutes of the 18-19 March 2021 meeting as well as the draft agenda of the meeting held on 15-16 April 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Veterinary Domain on the meeting held on 9 April 2021 and noted the agenda of the meeting and the minutes of the meeting held on 15 January 2021.

13. LEGISLATION

- 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.
- The Committee was informed on the publication of the Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals.

14. ANY OTHER BUSINESS

- Upon the completion of the April 2021 CVMP meeting, the draft news highlights were circulated for members to provide any 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 April 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 the company KRKA	4.3 – Art. 35 referral: 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 the company Bayer	4.3 – Art. 35 referral: Vitamin A injectables
RO	Lollita Taban	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	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
IT	Antonio Battisti	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.			
CZ	Eva Pomezná	Full involvement	
DE	Anja Merle Pfalzgraff	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Nadine Matzmohr	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Norbert Möller	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Yasemin Süzer	Full involvement	
DK	Henrik Duelund Pedersen	Full involvement	
DK	Kathrine Just Andersen	Full involvement	
DK	Mette T. Madsen	Full involvement	
DK	Mikkel Calum	Full involvement	
DK	Susanne Havn Aamand	Full involvement	
DK	Yen Pham	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
FR	Gerard Moulin	Full involvement	
FR	Housam Eidi	Full involvement	
FR	Nathalie Bridoux	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
IE	Sarah Hanley	Full involvement	
NL	Erik den Hertog	Full involvement	
SE	Andreea Barbu	Full involvement	
SE	Catarina Eriksson	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Lennart Åkerblom	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Niels Peter Lönn	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	---
AWP	Christine Schwarz
CMDv	---
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	Stefan Scheid

Observer from the European Commission	
Present	

Observers from Swissmedic	
Present	

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