7 December 2021
EMA/CVMP/728802/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 3-4 November 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 November 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, under agenda point 12, of a verbal report from the chair of the Veterinary Domain on the meeting held on 25 October 2021.

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

The attendance list was completed and competing interests were identified for the November 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 October 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

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions (EMA/CVMP/479718/2021) for the establishment of MRLs in equidae for a substance, (EMEA/V/MRL/005739/FULL/0001), and adopted the CVMP scientific overview including the list of outstanding issues and the assessment report. The Committee noted peer review reports.

1.3 Lists of questions

- The Committee discussed the rapporteur's assessment report for the extension of MRLs in chicken eggs for a substance, (EMEA/V/MRL/003363/EXTN/0004), and agreed that a list of questions was not necessary. The Committee noted peer review reports and the comments received from CVMP members. The adoption of the opinion is foreseen for the December 2021 meeting of the Committee.

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

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **CircoMax** (EMEA/V/C/005185/0000), recommending the granting of a marketing authorisation. The product is a new porcine circovirus vaccine (inactivated recombinant) for the active immunisation of pigs against porcine circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, faecal shedding and the lesions in lymphoid tissues associated with PCV2 infection. The Norwegian CVMP member 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 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 product (EMEA/V/C/005528/0000) in horses. The Committee noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/005816/0000) in 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 Withdrawal European public assessment report (WEPAR) 'scientific discussion' for **Aivlosin** (EMEA/V/C/000083/X/0081) concerning an extension of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Felpreva** (EMEA/V/C/005464/0000) concerning the granting of the initial marketing authorisation.
- The Committee noted the formal notification from Prevtec Microbia GmbH to withdraw the marketing authorisation for **Coliprotec F4** (EMEA/V/C/003797) for commercial reasons.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information, for a type II variation application for **Respiproc FLUpan H1N1** (EMEA/V/C/003993/II/0013), recommending the variation of the marketing authorisation to implement safety-related changes, specifically the amendment of the product information to allow the use during pregnancy and lactation. 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 II variation application (subject to a work sharing procedure) for **Vaxxitek HVT+IBD and Bovela** (EMEA/V/C/00xxxx/WS1869), 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 II variation application for **Credelio** (EMEA/V/C/004247/II/0018), 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, for a grouped type IB variation application (subject to a work sharing procedure) for **Oncept IL-2** (EMEA/V/C/002562/WS2129/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 (24 members present of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report, for a type II variation application for **Halagon** (EMEA/V/C/004201/II/0007), 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

- The Committee heard an oral explanation from the marketing authorisation holder Zoetis Belgium S.A, concerning a type II variation application for **Improvac** (EMEA/V/C/000136/II/0036). The Committee also discussed the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the December 2021 CVMP meeting.
- The Committee adopted a list of outstanding issues and endorsed the rapporteur's assessment report, for a grouped type II variation application for **Veraflox** (EMEA/V/C/000159/II/0024/G), concerning quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation application for **Cepedex** (EMEA/V/C/004376/II/0006), concerning quality-related changes.
- The Committee adopted a list of questions, for a grouped type II variation application for **Rabitec** (EMEA/V/C/004387/II/0007/G), concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Circovac** (EMEA/V/C/WS1945) concerning the variation 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

- There were no items for discussion.

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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 08.10.2021 – 05.11.2021:

Product	Period
Halocur (EMEA/V/C/000040)	29.10.2020 – 28.10.2021
Zolvix (EMEA/V/C/000154)	04.11.2020 – 03.11.2021

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 10.11.2020 – 31.05.2021 for **Librela** (EMEA/V/C/005180) with a recommendation to amend the product information.
- 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
Credelio Plus (EMEA/V/C/005325)	14.04.2021 – 30.06.2021
Equilis West Nile (EMEA/V/C/002241)	01.07.2020 – 30.06.2021
HorStem (EMEA/V/C/004265)	01.01.2021 – 30.06.2021
Meloxoral (EMEA/V/C/000151)	20.05.2018– 31.05.2021
Mirataz (EMEA/V/C/004733)	01.01.2021 – 30.06.2021
Nobivac Myxo RHD Plus (EMEA/V/C/004989)	01.12.2020 – 31.05.2021
Prac-Tic (EMEA/V/C/000103)	01.07.2018 – 30.06.2021
Vectra Felis (EMEA/V/C/002746)	01.01.2021 – 30.06.2021

- 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 discussed the intended scope of the draft VICH guideline on target animal safety evaluation for veterinary monoclonal antibody products, noting feedback received from an Expert Working Group meeting held on 27 October 2021. The Committee noted that a second meeting of the Expert Working Group is planned in order to finalise the discussions.
- The Committee discussed possible VICH guidelines for review and endorsed the proposed positions which will be communicated to the VICH Steering Committee at its upcoming meeting.
- The Committee received a report from an EU expert, on a meeting of the Bioequivalence Expert Working Group held on 27 September 2021.
- The Committee noted the draft agenda for the VICH Steering Committee meeting to be held on 15 and 17-19 November, along with the draft agenda for the VICH Outreach Forum (VOF) meeting to be held on 16 November, and progress reports from the bioequivalence expert working group, the quality expert working group, the biologicals expert working group, the pharmacovigilance expert working group, the metabolism and residue kinetics expert working group and the medicated premixes expert working group.

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 documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.
- Published EFSA opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed.

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 27 October 2021, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the ERAWP chair on the meeting held on 20 October 2021, and noted the agenda of the meeting, along with the minutes of the meeting held on 30 June–1 July 2021.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the EWP-V chair on the meeting held on 19- 20 October 2021, and noted the agenda of the meeting, and the minutes from the meeting held on 22-23 June 2021.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee appointed an expert as a new member of the immunological working party.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

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:

- Minutes of the SAWP-V meeting held on 4 October 2021.
- Summary record of the PhVWP-V meeting held on 21-22 September 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

- 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.

- 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.

- The Committee agreed to the transfer of all (co-)rapporteurships and peer review responsibilities from H. Bergendahl to A. Askdal Bjelland.

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 agenda of the CMDv meeting to be held on 4-5 November 2021 and the minutes of the meeting held on 7-8 October 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Veterinary Domain on the meeting held on 25 October 2021, and noted the agenda of the meeting.
- The Committee endorsed the revised procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions in accordance with Regulation (EU) 2019/6.
- The Committee discussed the rules on appointment and responsibilities of the CVMP rapporteur, co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6 and peer reviewer .
- The Committee discussed the CVMP draft work plan for 2022.
- The Committee discussed the upcoming appointment of CVMP co-opted members at the December 2021 CVMP meeting, outlined in the document 'Identification of expertise necessary for CVMP to complement its expertise', as the mandates of K. Baptiste and R. Carapeto will expire in December 2021 and January 2022, respectively. The Committee agreed to appoint two co-opted members, retaining the same areas of expertise (i.e. antimicrobials/antimicrobial resistance and environmental risk assessment). A call for nominations will be launched by the secretariat shortly after the November CVMP meeting.
- The Committee was informed of the EMA Veterinary Info Day #2 to be held on 30 November 2021, and noted the draft programme.

13. LEGISLATION

- The Committee adopted the veterinary good pharmacovigilance practice (VGVP) modules on the collection and recording of suspected adverse events for veterinary medicinal products and overview of comments, signal management and overview of comments, veterinary pharmacovigilance communication and overview of comments, pharmacovigilance inspections and overview of comments, pharmacovigilance systems and their pharmacovigilance systems master file and quality management system and overview of comments, and draft glossary and overview of comments.
- The Committee adopted a draft concept paper on the revision of the CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products for a 3-month period of public consultation.
- The Committee endorsed a draft procedural advice document on veterinary vaccine antigen master file (VAMF) certification for a 2-month period of public consultation.

14. ANY OTHER BUSINESS

- Upon the completion of the November 2021 CVMP meeting, the draft news highlights was circulated for members to provide comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the November 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	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	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	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	• 3.1 One item
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 **VICE CHAIR**	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Tita-Maria Muhonen	Full involvement	
FR	Christine Miras	Full involvement	
HU	Melinda Nemes-Terenyi	Full involvement	
IT	Antonio Battisti	Full involvement	
NL	Kim Boerkamp	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Carina Bergman	Full involvement	
SI	Boris Kolar	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.			
ES	Rosario Bullido	Full involvement	
FR	Anne-Marie Jacques	Full involvement	
SE	Andreea Barbu	Full involvement	
SE	Peter Lönn	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Malin Öhlund	Full involvement	
SE	Jenny Larsson	Full involvement	
FI	Kristina Lehmann	Full involvement	
FI	Jukka Pakkanen	Full involvement	
FI	Katariina Kivilahti-Mäntylä	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Zdenka Mašková	Full involvement	
CZ	Dana Halová	Full involvement	
CZ	Petra Müllerová	Full involvement	
CZ	Lucie Pokludová	Full involvement	
DK	Trine Jensen	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DE	Roswitha Merkel	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Anja Pfalzgraff	Full involvement	
DE	Thea Neumann	Full involvement	
DE	Kathrin Dietze	Full involvement	
DE	Svenja Rieke	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Henrik Duelund Pedersen	Full involvement	
DK	Martin Bronislaw Oleksiewicz	Full involvement	
DK	Mette T. Madsen	Full involvement	
FR	Gerard Moulin	Full involvement	
DE	Christopher Janich	Full involvement	
BE	Sandy Vermout	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	Jacqueline Poot
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	Carina Bergman

Observers from Swissmedic	
Present	

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