13 April 2021
EMA/CVMP/212369/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 16-18 March 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 March 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 March 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 February 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

- The Committee adopted by majority (24 members in favour out of the 26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to poultry for **bambermycin** (EMEA/V/MRL/004828/EXTN/0002). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. E. Werner and L. Nepejchalová signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of the opinion for publication.

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 establishment of MRLs in *Equidae* for a substance, (EMEA/V/MRL/005739/FULL/0001), following discussion of the rapporteur's assessment, including the critique from the co-rapporteur and of two peer review reports.

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

- The Committee heard an oral explanation from Eco Animal Health Europe concerning an extension application for **Aivlosin** (EMEA/V/C/000083/X/0081) to add chickens as a new target species to Aivlosin 42.5 mg premix for medicated feeding stuff for pigs. Following the oral explanation the marketing authorisation holder took the decision to withdraw the extension application.

- The Committee adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/005489/0000). The Committee noted three peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of outstanding issues for a marketing authorisation application for a new vaccine (EMEA/V/C/005309/0000). The Committee agreed to invite the applicant for an oral explanation in May 2021. The Committee noted three peer review reports.

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 **Vectormune FP ILT** (EMEA/V/C/005482/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Nobivac DP Plus** (EMEA/V/C/005251/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Enteroporc Coli AC** (EMEA/V/C/005149/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Enteroporc Coli** (EMEA/V/C/005148/0000) concerning the granting of the initial marketing authorisation.

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 for **Cortavance** (EMEA/V/C/000110/II/0015), recommending the variation of the marketing authorisation to add a new therapeutic indication for alleviation of clinical signs associated with atopic dermatitis in dogs. 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.
- The Committee adopted by consensus (25 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 (subject to a worksharing procedure) for **Ingelvac CircoFlex** and **Ingelvac MycoFlex** (EMEA/V/C/xxxxxx/WS1920/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 (25 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type IB variation (subject to a worksharing procedure) for **Suvaxyn Circo+MH RTU** and **Suvaxyn Circo**

(EMEA/V/C/xxxxxx/WS2010), 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 (25 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **MS-H Vaccine** (EMEA/V/C/000161/II/0017/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

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0047) to add a new therapeutic indication.
- The Committee adopted a list of questions for a type II variation for **Suvaxyn CSF Marker** (EMEA/V/C/002757/II/0009) to amend the therapeutic indication.
- The Committee adopted a list of questions for a type II variation (subject to a worksharing procedure) for **Ingelvac CircoFLEX** and **Ingelvac PRRSFLEX** (EMEA/V/C/xxxxxx/WS1921), to amend the product information.
- The Committee adopted a list of questions for a type II grouped variation (subject to a worksharing procedure) for **Eryseng** and **Eryseng Parvo** (EMEA/V/C/xxxxx/WS1986/G) concerning quality-related changes.
- The Committee adopted a list of questions for a type II variation for **Apoquel** (EMEA/V/C/002688/II/0020) concerning quality-related changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for an extension to the clock-stop for a type II grouped variation for **VarroMed** (EMEA/V/C/002723/II/0003/G) concerning quality-related changes.

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 discussed the revised rapporteur's assessment report including the co-rapporteur's critique following the responses to the list of outstanding issues for the referral procedure for **modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines** (EMEA/V/A/142). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the April 2021 meeting of the

Committee. The Committee noted a peer review report and the comments made by CVMP members**.**

- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique 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 there is no need for a further list of outstanding issues, but further discussions on the revised assessment report will take place at the April 2021 CVMP meeting and the Committee agreed to extend the timetable for this procedure. The adoption of the CVMP opinion and assessment report is foreseen for the May 2021 meeting of the Committee. The Committee noted two peer review reports 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 adopted the rapporteur's assessment report on the data submitted in response to the Committee's recommendations for **Ubac** (EMEA/V/C/004595/REC/002-003-004).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 18.02.2021 – 18.03.2021:

Product	Period
CaniLeish (EMEA/V/C/002232)	14/03/2020 – 13/03/2021
Coliprotec F4 (EMEA/V/C/003797)	16/03/2020 – 15/03/2021
Econor (EMEA/V/C/000042)	12/03/2020 – 11/-2/2021
Equisolon (EMEA/V/C/002382)	12/03/2020 – 11/03/2021
Fungitraxx (EMEA/V/C/002722)	12/03/2020 – 11/03/2021
Melosus (EMEA/V/C/002001)	21/02/2020 – 20/02/2021
Novem (EMEA/V/C/000086)	02/03/2020 – 01/02/2021

Product	Period
Pexion (EMEA/V/C/002543)	25/02/2020 – 24/02/2021
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	29/02/2020 – 28/02/2021
ProteqFlu (EMEA/V/C/000073)	06/03/2020 – 05/03/2021
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2020 – 05/03/2021
Purevax RC (EMEA/V/C/000091)	23/02/2020 – 22/02/2021
Purevax RCP (EMEA/V/C/000090)	23/02/2020 – 22/02/2021
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2020 – 22/02/2021
Purevax RCPCh (EMEA/V/C/000088)	23/02/2020 – 22/02/2021
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2020 – 22/02/2021
Zulvac 1+8 Bovis (EMEA/V/C/002473)	08/03/2020 – 07/03/2021
Zulvac 1+8 Ovis (EMEA/V/C/002251)	14/03/2020 – 13/03/2021

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 01.10.2019-30.09.2020 for **Comfortis** (EMEA/V/C/002233) 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 information or other regulatory actions were required for:

Product	Period
Arti-Cell Forte (EMEA/V/C/004727)	01.04.2020-30.09.2020
Aservo EquiHaler (EMEA/V/C/004991)	28.01.2020-31.07.2020
Clevor (EMEA/V/C/004417)	01.05.2020-31.10.2020
Forceris (EMEA/V/C/004329)	01.05.2020-31.10.2020
Imrestor (EMEA/V/C/002763)	01.10.2019-30.09.2020

- 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 first draft of a VICH dissolution guidance for orally administered products and on the draft terminology document.
- The Committee discussed the revision of VICH guidelines on efficacy of anthelmintics, namely the draft EU comments on FDA proposals on VICH GL7 regarding adequacy of infection (general) and GL20 regarding adequacy of infection for heartworm in cats. The EU comments will be finalised at the April meeting.

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 15 March 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP veterinary vice-chair of the on the meeting held on 1-2 March 2021 and noted the agenda of the meeting. The Committee also noted the minutes of the QWP meeting held on 14-16 December 2020.

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 4 March 2021 and noted the agenda of the meeting. The Committee also noted the minutes from the meeting held on 15-16 October 2020.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the AWP chair on the meeting held on 2-3 March 2021 and noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel therapy groups and related issues

- The Committee adopted the mandate, objectives, and rules of procedure for the CVMP Novel Therapies and Technologies Working Party (NTWP) (EMA/CVMP/NTWP/706123/2020).

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 following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 15 February 2021;
- Agenda of the PhVWP-V meeting to be held on 23-24 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

- 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.

- 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 noted the new pre-submission (eligibility) request form for marketing authorisation applications for the centralised procedure intended to be submitted after 28 January 2022 under Regulation (EU) 2019/6.

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 CMDv on the meetings held on 21-22 January 2021 and 18-19 February 2021 and noted the draft minutes of the meeting held on 18-19 February 2021, as well as the draft agenda of the meeting held on 18-19 March 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee noted the draft programme of the EMA/AnimalhealthEurope Info Day to be held on 25 March 2021.

13. LEGISLATION

- The Committee endorsed the revision of the QRD templates for compliance with Regulation (EU) 2019/6 for publication for a 6-weeks period of public consultation.
- The Committee received a verbal report on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6.

14. ANY OTHER BUSINESS

- Upon the completion of the March 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 March 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	Mina Leppänen	Full involvement	
FR	Sylvie Louet	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	Involvement in discussions only and cannot act as rapporteur or peer review for the company Bayer	4.3 – Art. 35 referral: Vitamin A Injectables
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Judita Hederová	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	Dominiek Maes	Full involvement	
CZ	Eva Pomezná		
CZ	Eva Vernerová		
CZ	Lucie Pokludová		
DE	Anke Finnah		
DE	Christopher Janich		
DE	Daniela Loos		
DE	Heike Gyra		
DE	Ingun Lemke		
DE	Jan Brosda		
DE	Martina Kern		
DE	Nikola Lange		
DE	Roswitha Merkel		
DE	Sandra Bertulat		
DE	Sandra Schack		
DE	Stephan Steuber		
DE	Uta Herbst		
DE	Yasemin Süzer		
DK	Anja Silke Christensen		
DK	Anne Hasle Buur		
DK	Henrik Duelund Pedersen		
DK	Katherine Just Andersen		
DK	Malene Nissen		

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Martin Oleksiewicz		
DK	Susanne Havn Aamand		
ES	Amparo Lopes Rivera		
ES	Aránzazu Gonzalez-Canga		
ES	Rosario Bullido		
ES	Susana Casado		
FI	Jonna Kumpulainen		
FI	Katariina Kivilahti-Mäntylä		
FI	Kristina Lehmann		
FR	Florence Pillet		
FR	Gérard Moulin		
FR	Hicham Ait Lbacha		
FR	Meg-Anne Moriceau		
FR	Nathalie Bridoux		
NO	Ragnhild Mehli		
PL	Marcin Glanda		
SE	Erika Fredriksson		
SE	Fredrik Hultén		
SE	Hanna Bremer		
SE	Jenny Larsson		

CVMP working parties and CMDv	Chair
NTWP	---
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	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