18 May 2020
EMA/CVMP/271198/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 21-23 April 2020 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).

The Committee agreed by consensus that, due to the COVID-19 pandemic, the April 2020 CVMP meeting takes place by means of remote participation and decision making.

i. Adoption of the Agenda

The Committee adopted the agenda with the addition of two new items, under point 1.5 regarding the establishment of MRLs for a substance in pigs (EMEA/V/MRL/005009/FULL/0001) and under point 12 regarding the establishment of a single point of contact (SPOC) system within each National Competent Authority (NCA) in order to facilitate the exchange of information between NCAs and EMA in case of anticipated delays with assessments for centrally authorised veterinary medicinal products due to COVID-19 pandemic.

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

The attendance list was completed and competing interests were identified for the April 2020 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

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were made in presence of a quorum of members i.e. 17 or more members of the 32 members eligible to vote attended.. It was noted that 17 members were needed for an absolute majority.

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 2020 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 the MRL for a substance (EMEA/V/MRL/004828/EXTN/0002) 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

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 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/005094/0000). The Committee noted a peer review report and the comments received from CVMP members.
- 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 vaccine (EMEA/V/C/005148/0000). The Committee noted two peer review reports and the comments received from CVMP members.

- 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/005719/0000). The Committee noted three peer review reports 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 new product (EMEA/V/C/005427/0000) for dogs. The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including a list of questions and agreed comments on the draft product information for a new generic product (EMEA/V/C/005384/0000) for cattle, pigs and sheep. 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 agreed to the request from the applicant for an extension to the clock-stop for a new vaccine (EMEA/V/C/005149/0000).
- The Committee agreed to the request from the applicant to further extend the clock-stop for a new product (EMEA/V/C/005132/0000).
- The Committee was informed of the formal notification from Emdoka bvba of their decision to withdraw the application for a new marketing authorisation for the generic product **Tulatrixx** (EMEA/V/C/005364/0000) for cattle, pigs and sheep. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in the withdrawal assessment report.
- The Committee endorsed the EPAR 'scientific discussion' for **Lydaxx** (EMEA/V/C/005199/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 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 a type II variation for **Bravecto** (EMEA/V/C/002526/II/0042), recommending the variation of the marketing authorisation to lower the minimum age of target animals. 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 **Meloxidyl** (EMEA/V/C/000115/II/0031), 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 **Imrestor** (EMEA/V/C/002763/II/0014), 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 heard an oral explanation from Eco Animal Health concerning a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0078), to add a new indication. The Committee also discussed the rapporteurs' assessment of the responses to the list of outstanding issues and the rapporteurs' comments on the product information. The adoption of the opinion is foreseen for the May 2020 CVMP meeting.
- The Committee adopted a list of outstanding issues for a type II grouped variation for **UpCard** (EMEA/V/C/003836/II/0005/G) concerning the implementation of quality-related changes.

3.3 Lists of questions

- The Committee adopted a list of questions and agreed comments on the draft product information for a type II variation for **Cytopoint** (EMEA/V/C/003939/II/0009), to add a new therapeutic indication.
- The Committee adopted a list of questions and agreed comments on the draft product information for a type II variation for **Nobilis Primo IB QX** (EMEA/V/C/002802/II/0008), to present new data on the safe use of the vaccine.

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 **Bluevac BTV** (EMEA/V/C/000156/II/0010/G), to convert the BLUEVAC BTV8 dossier into a multi-strain dossier.

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 rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered to pigs** (EMEA/V/A/137). The Committee adopted a list of outstanding issues for the marketing authorisation holders to address in writing, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the September 2020 meeting of the Committee. The Committee noted two peer review reports and the comments received from 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

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the procedure under Article 45 of Regulation (EC) No 726/2004 for **Suvaxyn PRRS MLV** (EU/2/17/215/001-003). The Committee agreed that no outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the May 2020 meeting of the Committee. The Committee noted a comment received from a CVMP member**.**

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 concerning a condition for **Cytopoint** (EMEA/V/C/003939/ANX/002).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 19.03.2020 – 23.04.2020:

Product	**Period**
Advocate (EMEA/V/C/000076)	02.04.2019 – 01.04.2020
Arti-Cell Forte (EMEA/V/C/004727)	29.03.2019 – 28.03.2020
Bluevac BTV8 (EMEA/V/C/000156)	14.04.2019 – 13.04.2020
Chanhold (EMEA/V/C/004824)	17.04.2019 – 16.04.2020
Clevor (EMEA/V/C/004417)	13.04.2019 – 12.04.2020
Clomicalm (EMEA/V/C/000039)	01.04.2019 – 31.03.2020
Ecoporc Shiga (EMEA/V/C/002588)	10.04.2019 – 09.04.2020
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2019 – 25.03.2020
Evalon (EMEA/V/C/004013)	18.04.2019 – 17.04.2020
Forceris (EMEA/V/C/004329)	23.04.2019 – 22.04.2020
Incurin (EMEA/V/C/000047)	24.03.2019 – 23.03.2020
Letifend (EMEA/V/C/003865)	20.04.2019 – 19.04.2020
Locatim (EMEA/V/C/000041)	29.03.2019 – 28.03.2020
Meloxidolor (EMEA/V/C/002590)	22.04.2019 – 21.04.2020

Product	Period
Neocolipor (EMEA/V/C/000035)	14.04.2019 – 13.04.2020
Procox (EMEA/V/C/002006)	20.04.2019 – 19.04.2020
Purevax FeLV (EMEA/V/C/000056)	13.04.2019 – 12.04.2020
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2019 – 05.04.2020
Veraflox (EMEA/V/C/000159)	12.04.2019 – 11.04.2020

5.4 Renewals

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Novaquin** (EMEA/V/C/003866/R/0005), and recommended that the authorisation should now be indefinite.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **UpCard** (EMEA/V/C/003836/R/0004), and recommended that the authorisation should now be indefinite.
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Vectormune ND** (EMEA/V/C/003829/R/0013).

5.5 Pharmacovigilance – PSURs and SARs

- 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)	20.05.2019-30.11.2019
Improvac (EMEA/V/C/000136)	01.12.2016-30.11.2019
Respiporc FluPan H1N1 (EMEA/V/C/003993)	01.06.2019-30.11.2019
SevoFlo (EMEA/V/C/00007)	01.06.2019-30.11.2019
Zeleris (EMEA/V/C/004099)	01.06.2019-30.11.2019
Suvaxyn Circo MH RTU (EMEA/V/C/003924)	01.12.2018-30.11.2019

- 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 nomination of an expert to join the VICH Metabolism and Residues Kinetics Expert Working Group.
- The Committee endorsed the nomination of an expert to join the VICH Safety Expert Working Group.
- The Committee noted the need for a new EU expert with quality background to join the VICH Bioequivalence Expert Working Group.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

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 20 April 2020 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)

- The Committee adopted a concept paper for the development of a reflection paper on the environmental risk assessment for parasiticide veterinary medicinal products used in companion animals for a 6-month public consultation.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee appointed three new members of the AWP.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee endorsed the CVMP Pharmacovigilance monthly product information updates.

- The Committee received a verbal report from the PhVWP-V chair on the meeting held on 24 March 2020 and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

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 document was circulated for information:

- Minutes of the SAWP-V meeting held on 16 March 2020.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

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

- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev. 43).

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.

- The Committee agreed to the transfer of all (co-)rapporteurships and peer reviewer responsibilities from T. Høy to A. 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 received a verbal report from the chair of CMDv on the meetings held on 20–21 February and 19 March 2020, and noted the draft minutes of the meeting held on 19 March 2020, as well as the draft agenda of the meeting to be held on 23 April 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The EMA Management Board, at its meeting on 19 March 2020, adopted amendments to the existing Rules of Procedure of EMA's scientific committees and Management Board. These amendments are required to enable those bodies to continue their work in a virtual emergency setting, as well as to ensure the validity of the various output decisions that each committee will adopt in the coming weeks. A change is also introduced in the quorum required for adoption of scientific opinions or recommendations in case of an emergency situation. To add flexibility to the system, irrespective of an emergency situation, the possibility is introduced to give a proxy vote to another member or to the alternate of a member who is present at the relevant meeting of the body concerned. The Committee adopted the revised CVMP Rules of procedure (EMA/MB/47098/2007).
- The Committee discussed the establishment a single point of contact (SPOC) within each NCA in order to facilitate the exchange of information between NCAs and EMA in case of anticipated delays with assessments for centrally authorised veterinary medicinal products due to COVID-19 pandemic. The Committee agreed that the CVMP rapporteurs and co-rapporteurs will be the SPOCs for the NCAs.
- The Committee received a verbal report from the chair of the Strategic Planning Group (SPG) on the meeting held on 20 April 2020 and noted the agenda of the meeting.
- The Committee noted the minutes of the SPG meeting held on 19 February 2020.
- The Committee was informed of the cancellation of the Presidency CVMP/CMDv meeting scheduled for 4-5 June 2020 at Maisons Alfort, France, due to the COVID-19 pandemic.

13. LEGISLATION

- The Committee received verbal reports from the expert group leaders on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the April 2020 CVMP meeting, the draft press release was 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 2020 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	Emil Kozhuharov	Full involvement	
DE	Esther Werner	Full involvement	
DK	Niels Christian Kyvsgaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Tita-Maria Muhonen	Involvement in discussions only and cannot act as rapporteur or peer reviewer for Orion Oyi	• 2.3 One item
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	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for Bayer	• 5.5 Baycox Iron • 7.1 One item • 10.2 One item
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	
BG	Svetoslav Branchev	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Andrea Golombiewski	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
EL	Spyridon Farlopoulos	Full involvement	
FR	Christine Miras	Full involvement	
IE	Paul McNeill	Full involvement	
NL	Jacqueline Poot	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.			
BE	Michel Goret	Full involvement	
CZ	Eva Pomezná	Full involvement	
DE	Andrea Winchenbach	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Christine Schwarz	Full involvement	
DE	Heike Gyra	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Kathrin Schirmann	Full involvement	
DE	Sandra Bertulat	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Sonja Haase	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Wiebke Weiher	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Anne Malene Nissen	Full involvement	
ES	Mercedes Ureña Montilla	Full involvement	
ES	Raul Belmar Liberato	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Gérard Moulin	Full involvement	
FR	Martine Redureau	Full involvement	
FR	Maryline Buggin-Daubie	Full involvement	
FR	Mathilde Harvey	Full involvement	
FR	Meg-Anne Moriceau	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	Nathalie Bridoux	Full involvement	
IE	Susan Reid	Full involvement	
NL	Anita Bottger	Full involvement	
NL	Kim Boerkamp	Full involvement	
NL	Sandra ten Voorde	Full involvement	
NL	Piet-Hein Overhaus	Full involvement	
SE	Fredrik Hultén	Full involvement	
SE	Hanna Bremer	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Malin Öhlund	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
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	
Remotely	

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