21 April 2020
EMA/CVMP/220479/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 17-18 March 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 (27 members attending of those eligible to vote) that, due to the Covid-19 pandemic and as a temporary measure, the March 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 one new item under point 12 regarding the European Commission's Brexit notice to stakeholders for human and veterinary medicines.

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

The attendance list was completed and competing interests were identified for the March 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 were made in presence of a quorum of members i.e. 22 or more members of the 32 members eligible to vote were attending in the room. It was noted that 17 members were needed for an absolute majority.

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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.

iv. Adoption of the minutes of the previous meeting

The minutes of the February 2020 meeting were adopted with no amendments.

v. Topics for rapporteurs' 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 consensus (27 members attending of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending that the current maximum residue limit status for **ketoprofen** in bovine, porcine and *Equidae* (that is, 'no MRL required') remain unchanged (EMEA/V/MRL/003652/MODF/0003). 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.

1.2 Oral explanations and lists of outstanding issues

- The Committee heard a verbal report from the chair of *ad hoc expert group* (AHEG) and discussed the rapporteurs' joint assessment of the responses to the list of questions for the establishment of MRLs in *salmonidae* for a substance (EMEA/V/MRL/004481/FULL/0002). The Committee adopted a list of outstanding issues and noted the peer review reports and comments received from CVMP members.
- The Committee heard a verbal report from the AHEG Chair and discussed the rapporteurs' joint assessment of the responses to the list of questions for the extension of MRLs in porcine for a substance (EMEA/V/MRL/003649/EXTN/0002). The Committee adopted a list of outstanding issues and noted the comments received from CVMP members. The adoption of the opinion foreseen for the July 2020 meeting of the Committee.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the modification of MRLs in fin fish for a substance (EMEA/V/MLR/003802/MODF/0002), following discussion of the rapporteur's assessment report. The Committee noted a peer review report and the comments received from CVMP members.

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 (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the generic product **Lydaxx** (EMEA/V/C/005199/0000), recommending the granting of a marketing authorisation. The product is indicated for the treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of the opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

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 an extension application for **Emdocam** (EMEA/V/C/002283/X/0012), to add a new strength and new target species. The Committee noted 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 an extension application for **Emdocam** (EMEA/V/C/002283/X/0013), to add a new strength and a new pharmaceutical form. The Committee noted 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 product (EMEA/V/C/005325/0000) 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 vaccine for chickens (EMEA/V/C/005347/0000). 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 vaccine for dogs (EMEA/V/C/005251/0000). The Committee noted three peer review reports 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 **Tulaven** (EMEA/V/C/005153/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Tulissin** (EMEA/V/C/005073/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (27 members attending 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 **Equisolon** and **Meloxoral** (EMEA/V/C/xxxx/WS1778), recommending the variation of the marketing authorisation concerning a new pharmacovigilance system. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, and endorsed the rapporteur's assessment report for a type II grouped variation (subject to a worksharing procedure) for **Vectra 3D** and **Vectra Felis** (EMEA/V/C/xxxx/WS1767/G), recommending the variation of the marketing authorisation concerning 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 and agreed comments on the draft product information for a type II variation for **Aivlosin** (EMEA/V/C/000083/II/0078) to add a new indication.
- The Committee adopted a list of outstanding issues and agreed comments on the product information for a type II grouped variation for **Bluevac BTV8** (EMEA/V/C/000156/II/0010/G).
- The Committee adopted a list of outstanding issues for a type II variation (subject to a worksharing procedure) for **Eryseng Parvo**, **Eryseng** and **Rhiniseng** (EMEA/V/C/xxxx/WS1686), concerning quality-related changes.

3.3 Lists of questions

- There were no items for discussion.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- 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 **Betamox LA 150 mg/ml suspension for injection and its associated names, and generic products thereof** (EMEA/V/A/132). The Committee adopted a list of outstanding issues for the marketing authorisation holders, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the July 2020 meeting of the Committee. The Committee noted three peer review reports and the comments received from CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Stresnil 40 mg/ml solution for injection for pigs and**

associated names, and generic products thereof (EMEA/V/A/138). The Committee adopted a list of outstanding issues for the marketing authorisation holder, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the July 2020 meeting of the Committee. The Committee noted a peer review report 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 Art. 45 of Regulation (EC) No. 726/2004 for **Suvaxyn PRRS MLV** (EU/2/17/215/001-003). The Committee adopted a list of outstanding issues for the marketing authorisation holder, and the revised timetable for the procedure. The adoption of the CVMP opinion and assessment report is foreseen for the May 2020 meeting of the Committee. The Committee noted two peer review reports and the comments received from CVMP members.

The following documents were circulated for information:

- Ketabel 100 mg/ml solution for injection and associated names – Article 33(4) referral (EMEA/V/A/133) - Questions and answers for publication.
- Veterinary medicinal products containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs – Article 35 referral (EMEA/V/A/131) - Questions and answers for publication.
- Referrals tracking table.

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 concerning two quality-related recommendations for **Fortekor Plus** (EMEA/V/C/002804/REC/016 and EMEA/V/C/002804/REC/017).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a quality-related recommendation for **Nobilis IB Primo QX** (EMEA/V/C/002802/REC/013).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 21.02.2020 – 18.03.2020:

Product	Period
CaniLeish (EMEA/V/C/002232)	14.03.2019 – 13.03.2020
Coliprotec F4 (EMEA/V/C/003797)	16.03.2019 – 15.03.2020
Econor (EMEA/V/C/000042)	12.03.2019 – 11.03.2020
Equisolon (EMEA/V/C/002382)	12.03.2019 – 11.03.2020
Fungitraxx (EMEA/V/C/002722)	12.03.2019 – 11.03.2020
Melosus (EMEA/V/C/002001)	21.02.2019 – 20.02.2020
Novem (EMEA/V/C/000086)	02.03.2019 – 01.03.2020
Pexion (EMEA/V/C/002543)	25.02.2019 – 24.02.2020
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	01.03.2019 – 29.02.2020
ProteqFlu (EMEA/V/C/000073)	06.03.2019 – 05.03.2020
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2019 – 05.03.2020
Purevax RC (EMEA/V/C/000091)	23.02.2019 – 22.02.2020
Purevax RCP (EMEA/V/C/000090)	23.02.2019 – 22.02.2020
Purevax RCP FeLV (EMEA/V/C/000089)	23.02.2020 – 22.02.2020
Purevax RCPCh (EMEA/V/C/000088)	23.02.2019 – 22.02.2020
Purevax RCPCh FeLV (EMEA/V/C/000085)	23.02.2019 – 22.02.2020
Zulvac 1+8 Bovis (EMEA/V/C/002473)	08.03.2019 – 07.03.2020
Zulvac 1+8 Ovis (EMEA/V/C/002251)	14.03.2019 – 13.03.2020

5.4 Renewals

- The Committee adopted by consensus (27 members attending of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Porcilis PCV ID** (EMEA/V/C/003942/R/0004), and recommended that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **UpCard** (EMEA/V/C/003836/R/0004).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee endorsed the rapporteur's assessment report on the PSUR for the period 01.04.2019-30.09.2019 for **Galliprant** (EMEA/V/C/004222) and recommended amendments to the product information.
- 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
Cytopoint (EMEA/V/C/003939)	01.05.2019-31.10.2019
Evalon (EMEA/V/C/004013)	01.11.2018-31.10.2019
Exzolt (EMEA/V/C/004344)	01.03.2019-31.08.2019
Vaxxitek HVT+IBD (EMEA/V/C/000065)	01.09.2016-31.08.2019

- 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 Committee received an update on the impact of COVID-19 on 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 following EU comments relating to the revision of the VICH anthelmintic guidelines:
  - Arithmetic and Geometric Means (dose confirmation studies);
  - VICH GL7 (general) on Age of Field Isolates and Laboratory Strains;
  - VICH GL7 on Adequacy of Infection and Statistical Justification;
  - VICH GL12, GL13, GL14, GL15, GL19, and GL20 on adequacy of infection/Helminth numbers;
  - VICH GL12 (bovine), GL13 (ovine), GL14 (caprine) and GL15 (equine) on Faecal egg count reduction test;
  - VICH GL16 (porcine) on claims for *Ascaris suum* L3 larvae;
  - VICH GL19-20 (cats, dogs) on persistent efficacy.
- The Committee endorsed a discussion document in the form of a draft concept paper proposing development of further guidance around medicated premixes.

6.2 Codex Alimentarius

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

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 16 March 2020 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)

- There were no items for discussion.

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- The Committee noted the draft Antimicrobial Working Party (AWP) work plan for 2020. Comments from CVMP members are invited by 13 April 2020.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee adopted the public bulletin on veterinary pharmacovigilance for 2019 summarizing the Agency's activities regarding pharmacovigilance for veterinary medicinal products during the past year.

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 document was circulated for information:

- Minutes of the SAWP-V meeting held on 18 February 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.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee discussed the preparation of the CVMP strategy on antimicrobials 2021-2025.

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.

- The Committee received an update on the supply chain and availability challenges due to SARS-CoV-2/COVID-19 (link).

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 20-21 February 2020 meeting and the draft agenda of the meeting to be held on 19 March 2020.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report on the European Medicines Regulatory Network Strategy to 2025.
- The Committee received a verbal report on the European Commission's Brexit notice for human and veterinary medicines (link).
- The Committee noted the draft agenda of the upcoming informal presidency CVMP-CMDv meeting to be held during the Croatian EU Presidency on 4-5 June 2020 at Maisons-Alfort, France. The adoption of the draft agenda is foreseen for the April 2020 meeting of the Committee.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the March 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 March 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 Iliev 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	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Involvement only in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading /co-ordinating role or formally appointed peer reviewer for:	4.3 Betamox LA and generics
HU	Gábor Kulcsár	Full involvement	
IT	Paolo Pasquali	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement only in discussions i.e. no part in final deliberations and voting, and cannot act as rapporteur, other leading /co-ordinating role or formally appointed peer reviewer for:	4.3 Betamox LA and generics
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	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
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	Katariina Kivilahti-Mantyla	Full involvement	
FR	Christine Miras	Full involvement	
HU	Melinda Nemes-Terenyi	Full involvement	
IE	Paul McNeill	Full involvement	
RO	Gabriela Tuchila	Full involvement	
SE	Carina Bergman	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 Vernerová	Full involvement	
CZ	Eva Pomezná	Full involvement	
CZ	Josef Suchý	Full involvement	
CZ	Lucie Pokcludová	Full involvement	
CZ	Radka Smítalová	Full involvement	
CZ	Vilma Dosedlová	Full involvement	
DE	Anke Finnah	Full involvement	
DE	Daniela Külbs	Full involvement	
DE	Daniela Loos	Full involvement	
DE	Heike Gyra	Full involvement	
DE	Henriette Rau	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Jan Brosda	Full involvement	
DE	Judith Romberg	Full involvement	
DE	Kathrin Schmidt	Full involvement	
DE	Nikola Lange	Full involvement	
DE	Roland Frötschl	Full involvement	
DE	Rolf Beckmann	Full involvement	
DE	Roswitha Merkel	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Sandra Bertulat	Full involvement	
DE	Sarah Adler-Flindt	Full involvement	
DE	Svenja Rieke	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Yasemin Süzer	Full involvement	
DK	Anne Malene Nissen	Full involvement	
ES	Carles Cristòfol Adell	Full involvement	
FR	Frank Le Curieux	Full involvement	
FR	Nathalie Bridoux	Full involvement	
SE	Catarina Eriksson	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Lennart Åkerblom	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	---
AWP	---
CMDv	---
ERAWP	Ricardo Carapeto García
EWP-V	Cristina Muñoz Madero
IWP	Esther Werner
J3Rs WG	---
PhVWP-V	---
QWP	Mary O'Grady *(Vet vice chair)*
SAWP-V	Frida Hasslung Wikström
SWP-V	Stefan Scheid

Observer from the European Commission	
Remotely	

Observers from Swissmedic	
Remotely	

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