16 February 2021
EMA/CVMP/99479/2021
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 19-20 January 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 January 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 January 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 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 December 2020 meeting were adopted with minor amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for the modification of MRLs in fin fish (EMEA/V/MLR/003802/MODF/0002).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- There were no items for discussion.

2.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

2.3 Lists of questions

- 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 agreed to the request from the applicant for an extension to the clock-stop for a new product (EMEA/V/C/005132/0000).

- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Librela** (EMEA/V/C/005180/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Innovax -ND-ILT** (EMEA/V/C/005190/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **PREVEXXION RN+HVT+IBD** (EMEA/V/C/005057/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **PREVEXXION RN** (EMEA/V/C/005058/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **Rexxolide** (EMEA/V/C/005384/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the European public assessment report (EPAR) 'scientific discussion' for **NexGard Combo** (EMEA/V/C/005094/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Exzolt** (EMEA/V/C/004344/II/0011), recommending the variation of the marketing authorisation to amend section 5.1 of the SPC regarding the effect of the product on mite-induced stress and animal welfare. 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 the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Nobilis IB Primo QX** (EMEA/V/C/002802/II/0009/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the product information, and endorsed the rapporteur's assessment report for a type II grouped variation for **Nobilis IB 4-91** (EMEA/V/C/000036/II/0027/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the product information, and endorsed the rapporteur's assessment report for a type II variation for **Eravac** (EMEA/V/C/004239/II/0006), 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 (24 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II variation for **Gumbohatch** (EMEA/V/C/004967/II/0004), recommending the variation of the marketing authorisation to

implement quality-related changes. The Icelandic CVMP member 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 **Melosus** (EMEA/V/C/002001/II/0012), 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 **Meloxoral** (EMEA/V/C/000151/II/0011), 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 grouped variation for **Cytopoint** (EMEA/V/C/003939/II/0011/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and endorsed the rapporteur's assessment report for a type II grouped variation for **VarroMed** (EMEA/V/C/002723/II/0004/G), recommending the variation of the marketing authorisation to implement quality-related changes. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted a list of outstanding issues to be addressed in writing for a type II variation for **Cortavance** (EMEA/V/C/000110/II/0015) to add a new therapeutic indication.

3.3 Lists of questions

- The Committee adopted a list of questions for a type II variation for **Porcilis ColiClos** (EMEA/V/C/002011/II/0012) 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 variation for **Simparica Trio** (EMEA/V/C/004846/II/0001) 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

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique and the draft product information for the referral procedure for **Ronaxan and its associated names** (EMEA/V/A/135). The Committee adopted a list of outstanding issues for the

marketing authorisation holder to address in writing and the revised timetable for the procedure. The Committee noted a peer review report and the comments made by CVMP members**.**

4.3 Article 35 of Directive 2001/82/EC

- The Committee endorsed the composition of the *Ad Hoc* Expert Group (AHEG) and adopted a list of questions to the AHEG for the referral procedure for **Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines** (EMEA/V/A/142).

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 11.12.2020 – 21.01.2021:

Product	Period
Bovela (EMEA/V/C/003703)	22.12.2019 – 21.12.2020
BTVPUR (EMEA/V/C/002231)	17.12.2019 – 16.12.2020
Cepedex (EMEA/V/C/004376)	13.12.2019 – 12.12.2020
Halagon (EMEA/V/C/004201)	13.12.2019 – 12.12.2020
Onsior (EMEA/V/C/000127)	16.12.2019 – 16.12.2020
Prac-tic (EMEA/V/C/000103)	18.12.2019 – 17.12.2020
SevoFlo (EMEA/V/C/000072)	11.12.2019 – 10.12.2020
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2020 – 08.01.2021
Coliprotec F4/F18 (EMEA/V/C/004225)	09.01.2020 – 08.01.2021
Cortavance (EMEA/V/C/000110)	09.01.2020 – 08.01.2021

Galliprant (EMEA/V/C/004222)	09.01.2020 – 08.01.2021
Isemid (EMEA/V/C/004345)	09.01.2020 – 08.01.2021
Meloxidyl (EMEA/V/C/000115)	15.01.2020 – 14.01.2021
Metacam (EMEA/V/C/000033)	07.01.2020 – 06.01.2021
NexGard Spectra (EMEA/V/C/003842)	15.01.2020 – 14.01.2021
Porcilis PCV (EMEA/V/C/000135)	12.01.2020 – 11.01.2021
Respiporc FLU3 (EMEA/V/C/000153)	14.01.2020 – 13.01.2021
Rheumocam (EMEA/V/C/000121)	10.01.2020 – 09.01.2021
Stelfonta (EMEA/V/C/005018)	15.01.2020 – 14.01.2021
Syvazul BTV (EMEA/V/C/004611)	09.01.2020 – 08.01.2021
Ypozane (EMEA/V/C/000112)	11.01.2020 – 10.01.2021
Zulvac 8 Ovis (EMEA/V/C/000147)	15.01.2020 – 14.01.2021

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of the marketing authorisation for **Sevohale** (EMEA/V/C/004199/R/0007).

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
Evant (EMEA/V/C/004902)	01.03.2020-31.08.2020
Pirsue (EMEA/V/C/000054)	01.08.2017-31.07.2020
Respiporc FLU3 (EMEA/V/C/000153)	01.08.2018-31.07.2020
Semintra (EMEA/V/C/002436)	01.09.2019-31.08.2020
Stelfonta (EMEA/V/C/005018)	15.01.2020-31.07.2020
Suvaxyn Circo (EMEA/V/C/004242)	01.03.2020-31.08.2020
Suvaxyn PCV (EMEA/V/C/000149) - WD	01.08.2017-31.07.2020
VarroMed (EMEA/V/C/002723)	03.08.2019-02.08.2020

- 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 regarding the revision of VICH guidelines on efficacy of anthelmintics.
- The Committee endorsed the concept paper proposing development of VICH guidelines to parallel ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System).

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 18 January 2021 and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

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

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the IWP chair on the meeting held on 16-17 December 2020 and noted the agenda and draft minutes of the meeting.
- The Committee adopted a concept paper for the development of a guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances (EMA/CVMP/IWP/630533/2020) for release for a 2-month period of public consultation.
- The Committee adopted a concept paper for the development of a guideline on data requirements for vaccine antigen master files (EMA/674640/2020) for release for a 2-month period of public consultation.

- The Committee adopted a concept paper for the development of a guideline on data requirements for vaccine platform technology master files (EMA/582191/2020) for release for a 2-month period of public consultation.
- The Committee adopted a concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza, bluetongue and foot and mouth disease (EMA/CVMP/IWP/600275/2020) for release for a 2-month period of public consultation.
- The Committee adopted a concept paper on the provision of field efficacy studies in support of marketing authorisation applications for IVMPs and on indications for veterinary vaccines (EMA/CVMP/IWP/671155/2020) for release for a 2-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

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

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 7 December 2020.
- Minutes of the QWP meeting held on 16-18 September 2020.

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

- The Committee adopted the CVMP strategy on antimicrobials for 2021-2025 (EMA/CVMP/179874/2020) and the overview of comments received during the public consultation (EMA/CVMP/517722/2020).

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 responsibilities from:
    - A. Askdal Bjelland to H. Bergendahl;
    - K. Kivilahti-Mantyla to M. Leppänen.

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 5-6 November 2020 and 3-4 December 2020 and noted the draft minutes of the meeting held on 3-4 December 2020 as well as the draft agenda of the meeting to be held on 21-22 January 2021. The Committee also noted the draft agenda of the CMDv-Interested Parties meeting to be held on 22 January 2021.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the CVMP work plan for 2021.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 15 January 2021 and noted the agenda of the meeting and the minutes of the meeting held on 29 October 2021.
- The Committee noted the updated list of acronyms, abbreviations and capitalisations used in CVMP agenda and minutes (EMA/456228/2013-Rev. 1).

13. LEGISLATION

- The Committee noted Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union product database on veterinary medicinal products, and Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment (link).

14. ANY OTHER BUSINESS

- Upon completion of the January 2021 CVMP meeting, the draft news highlights of the meeting (EMA/CVMP/22437/2021) 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 January 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 Branchev	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	Tita-Maria Muhonen	Involvement in discussions only and cannot act as rapporteur or peer reviewer for Orion	**2.5** – One item
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Jacqueline Poot	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
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	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Katariina Kivilahti-Mantyla	Full involvement	
FR	Christine Miras	Full involvement	
HR	Hrvoje Pasavovic	Full involvement	
HU	Melinda Nemes-Terenyi	Full involvement	
IE	Paul McNeill	Full involvement	
LV	Santa Ansonska	Full involvement	
NL	Kim Boerkamp	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.			
	Davide Arcella	Full involvement	
AT	Haru Kroneis	Full involvement	
CZ	Dana Studená	Full involvement	
CZ	Zdenka Mašková	Full involvement	
DE	Christina Bredtmann	Full involvement	
DE	Ingun Lemke	Full involvement	
DE	Stephan Steuber	Full involvement	
DE	Uta Herbst	Full involvement	
DE	Yasemin Süzer	Full involvement	
DK	Anja Silke Christensen	Full involvement	
DK	Anne Hasle Buur	Full involvement	
DK	Malene Nissen	Full involvement	
ES	Rosario Bullido	Full involvement	
FR	Damien Bouchard	Full involvement	
FR	Elisabeth Begon	Full involvement	
NL	Engeline van Duijkeren	Full involvement	
NL	René van Herwijnen	Full involvement	
SE	David Khan	Full involvement	
SE	Jenny Larsson	Full involvement	
SE	Malin Öhlund	Full involvement	

CVMP working parties and CMDv	Chair
NTWP	---
AWP	Christine Schwarz
CMDv	Laetitia Le Letty

CVMP working parties and CMDv	Chair
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