9 April 2021
EMA/CVMP/191262/2021 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

13 April 2021, 09:00 – 15 April 2021, 13:00 – Virtual and room 15B

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of competing interests, participants in this meeting are 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 will take 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 meeting.

Disclaimers

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).

i. Adoption of the agenda

ii. Intended participation and competing interests

iii. Declaration of contacts between members and companies with regard to points on the agenda

iv. Adoption of the minutes of the previous meeting

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (virtual)	Monday, 12 April 2021	10:00-13:00 CEST

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

- **Product**
  EMEA/V/C/005528/0000
  New product
  Horses

  For adoption: CVMP scientific overview and list of questions

- **Product**
  EMEA/V/C/005579/0000
  New product
  Dogs

  For adoption: CVMP scientific overview and list of questions

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Daxocox** (EMEA/V/C/005354/0000)
- ***For endorsement:*** EPAR scientific discussion for **Credelio Plus** (EMEA/V/C/005482/0000)
- ***For endorsement:*** EPAR scientific discussion for **Ultifend ND IBD** (EMEA/V/C/005347/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Comfortis**
  EMEA/V/C/002233/II/0023/G
  Quality-related changes

  Rapp: A. Golombiewski

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Purevax RCP FeLV, Purevax RCPCh, Purevax RCP** and **Purevax RCPCh FeLV**
  EMEA/V/C/xxxxx/WS2004
  Quality-related changes

  Rapp: B. Urbain

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Versican Plus Pi/L4R** and **Versican Plus DHPPi/L4R**
  EMEA/V/C/xxxxxx/WS1927
  Quality-related changes

  Rapp: E. Werner

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Purevax Rabies**
  EMEA/V/C/002003/II/0015
  Quality-related changes

  Rapp: B. Urbain

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Versican Plus Pi/L4, Versican Plus Pi/L4R, Versican Plus L4, Versican Plus DHPPi/L4R** and **Versican Plus DHPPi/L4**
  EMEA/V/C/xxxxxx/WS1928/G
  Quality related changes

  Rapp: E. Werner

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- **Stelfonta**
  EMEA/V/C/005018/II/0004/G
  Quality-related changes

  Rapp: K. Boerkamp

  For adoption: List of outstanding issues

3.3 List of questions

- **Frontpro**
  EMEA/V/C/005126/II/0010
  To change the product information

  Rapp: K. Boerkamp

  Co-rapp: J. G. Beechinor

  For adoption: List of questions

- **Circovac**
  EMEA/V/C/000114/WS1945/0018
  To change the product information

  Rapp: P. Pasquali

  For adoption: List of questions

- **BTVPUR**
  EMEA/V/C/002231/WS2017/0022
  Quality-related changes

  Rapp: C. Muñoz Madero

  For adoption: List of questions

- **Porcilis PCV**
  EMEA/V/C/000135/II/0014/G
  Quality-related changes
  Rapp: P. Pasquali
  For adoption: List of questions

- **Veraflox**
  EMEA/V/C/000159/II/0024/G
  Quality-related changes
  Rapp: A. Golombiewski
  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Emdocam** (EMEA/V/C/002283/X/0012)
- ***For endorsement:*** EPAR scientific discussion for **Emdocam** (EMEA/V/C/002283/X/0013)

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- No items

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

- **Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines**
  EMEA/V/A/142
  Animal health
  Rapp: E. Werner
  Co-rapp: F. Klein
  For adoption: CVMP opinion, CVMP assessment report

- **Injectable veterinary medicinal products containing vitamin A for use in food producing species**
  EMEA/V/A/141
  Withdrawal periods, user safety
  Rapp: A. Golombiewski
  Co-rapp: B. Urbain
  For discussion: Revised rapporteur's assessment report, draft product information

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

- No items

4.6 Article 30(3) of Regulation 726/2004

- No items

4.7 Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

- No items

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

- **CircoMax Myco**
  EMEA/V/C/005184/REC/002
  Recommendation
  Rapp: N. C. Kyvsgaard
  For adoption: Rapporteur's assessment report

- **Stelfonta**
  EMEA/V/C/005018/REC/003.1
  Recommendation
  Rapp: K. Boerkamp
  For adoption: Rapporteur's assessment report

- **Tulinovet**
  EMEA/V/C/005076/REC/001
  Recommendation
  Rapp: L. Nepejchalová
  For adoption: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Advocate (EMEA/V/C/000076)	02.04.2020 – 01.04.2021
Arti-Cell Forte (EMEA/V/C/004727)	29.03.2020 – 28.03.2021
Bluevac BTV (EMEA/V/C/000156)	14.04.2020 – 13.04.2021
Clevor (EMEA/V/C/004417)	13.04.2020 – 12.04.2021
Clomicalm (EMEA/V/C/000039)	01.04.2020 – 31.03.2021
Ecoporc Shiga (EMEA/V/C/002588)	10.04.2020 – 09.04.2021
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2020 – 25.03.2021
Incurin (EMEA/V/C/000047)	24.03.2020 – 23.03.2021
Locatim (EMEA/V/C/000041)	29.03.2020 – 28.03.2021
Neocolipor (EMEA/V/C/000035)	14.04.2020 – 13.04.2021
Purevax FeLV (EMEA/V/C/000056)	13.04.2020 – 12.04.2021
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2020 – 05.04.2021
Veraflox (EMEA/V/C/000159)	12.04.2020 – 11.04.2021

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- **Galliprant**
  EMEA/V/C/004222
  Rapp: K. Baptiste
  For adoption: CVMP assessment report on the PSUR for the period 01.04.2020-30.09.2020
- **Kexxtone**
  EMEA/V/C/002235
  Rapp: C. Muñoz Madero
  For adoption: CVMP assessment report on the PSUR for the period 01.08.2017-31.07.2020
- **Simparica Trio**
  EMEA/V/C/004846
  Rapp: R. Breathnach
  For adoption: CVMP assessment report on the PSUR for the period 01.04.2020-30.09.2020
- **Baycox Iron**
  EMEA/V/C/004794
  Rapp: G. J. Schefferlie
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2020-30.11.2020
- **Evalon**
  EMEA/V/C/004013
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.11.2019-31.10.2020
- **Gumbohatch**
  EMEA/V/C/004967
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2020-30.11.2020
- **Oncept IL-2**
  EMEA/V/C/002562
  Rapp: C. Miras
  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.12.2017-31.11.2020
- **Palladia**
  EMEA/V/C/000150
  Rapp: F. Hasslung Wikström
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2017-30.11.2020
- **SevoFlo**
  EMEA/V/C/000072
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2019-30.11.2020
- **Suvaxyn Circo MH RTU**
  EMEA/V/C/003924
  Rapp: B. Urbain
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2019-30.11.2020
- **Zeleris**
  EMEA/V/C/004099
  Rapp: A. Golombiewski
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2019-30.11.2020

- ***For endorsement:*** List of products and calendar for signal detection analysis

5.6 Supervision and sanctions

Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement:*** Revision of VICH GLs on efficacy of anthelmintics: EU comments on FDA proposals on VICH GL7 regarding adequacy of infection (general) and GL20 regarding adequacy of infection for heartworm in cats
- ***For discussion:*** Draft VICH Good Manufacturing Practice guide for active pharmaceutical ingredients with EU comments

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information on certain topics discussed under section 7 cannot be released at the present time as it is deemed to be confidential

7.1 Scientific Advice Working Party (SAWP-V)

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel Therapies & Technologies Working Party (NTWP)

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

7.11 Other working party and scientific group issues

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 confidential

8.2 Environmental risk assessment

Information on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential

8.3 Antimicrobial resistance

- No items

8.4 Pharmacovigilance

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

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

- ***To note:*** Draft agenda of the CMDv meeting to be held on 15-16 April 2021; minutes of the 18-19 March 2021 CMDv meeting

12. ORGANISATIONAL AND STRATEGIC MATTERS

13. LEGISLATION

- ***For information:*** Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans
- ***For information:*** Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of

antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(6))

14. ANY OTHER BUSINESS

- ***For comments***: News highlights of the meeting

ANNEX

	CVMP	NTWP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Apr 2021	13-15								12	22-23	-
May 2021	10-12		25-26			26-27	25-26	25-27	7		-
Jun 2021	15-17				1-2				14		-
Jul 2021	13-15						6-7		12		-
Sep 2021	7-9		21-22				21-22	22-24	7		-