



7 May 2021  
EMA/CVMP/242543/2021 - draft 3  
Committee for Medicinal Products for Veterinary Use (CVMP)

## Committee for Medicinal Products for Veterinary Use

### Draft agenda of May 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

10 May 2021, 09:00 – 12 May 2021, 13:00 - Room 15B and virtual

#### **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

<b>Scientific Advice Working Party</b>	-	-
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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

- **Substance** *For adoption:* Scientific overview and list of questions  
EMA/V/MRL/003652/EXTN/0004  
*Chickens*

### 1.4 Re-examination of CVMP opinions

- No items

### 1.5 Other issues

- **Substance** *For information:* Letter of withdrawal of application  
EMA/V/MRL/003808/MODF/002  
*Fin fish*
- **Substance** *For discussion:* Request from the European  
EMA/V/MRL/004828/EXTN/0002  
*Chickens* Commission for reconsideration of the CVMP opinion

## 2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

### 2.1 Opinions

- **Product** *For adoption:* CVMP opinion, CVMP assessment  
EMA/V/C/005489/0000  
*New product* report, product information  
*Cats* *For information:* Summary of opinion

### 2.2 Oral explanations and list of outstanding issues

- **Product** **ORAL EXPLANATION – Monday, 10 May 2021**  
EMA/V/C/005309/0000  
*New vaccine* *For discussion:* Rapporteurs' assessment of  
*Horses* responses to list of outstanding issues

### 2.3 List of questions

- No items

### 2.4 Re-examination of CVMP opinions

- No items

## 2.5 Other issues

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- **Simparica Trio**  
EMA/V/C/004846/II/0001  
*Quality-related changes*  
Rapp: R. Breathnach  
**For adoption:** CVMP opinion  
**For endorsement:** Rapporteur's assessment report
- **Vectra 3D and Vectra Felis**  
EMA/V/C/xxxxxx/WS2032/G  
*Quality-related changes*  
Rapp: A. Golombiewski  
**For adoption:** CVMP opinion  
**For endorsement:** Rapporteur's assessment report

### 3.2 Oral explanations and list of outstanding issues

- No items

### 3.3 List of questions

- **Improvac**  
EMA/V/C/000136/II/0036  
*To change the product information*  
Rapp: N. C. Kyvsgaard  
Co-rapp: J. Poot  
**For adoption:** List of questions
- **Porcilis PCV ID**  
EMA/V/C/003942/II/0005/G  
*To change the product information*  
Rapp: J. Poot  
**For adoption:** List of questions
- **Poulvac E. coli**  
EMA/V/C/002007/II/0018  
*To change the product information*  
Rapp: E. Werner  
**For adoption:** List of questions
- **ProZinc**  
EMA/V/C/002634/II/0024  
*Quality-related changes*  
Rapp: R. Breathnach  
**For adoption:** List of questions
- **Prevomax**  
EMA/V/C/004331/II/0006/G  
*Quality-related changes*  
Rapp: S. Louet  
**For adoption:** List of questions

### 3.4 Re-examination of CVMP opinions

- No items

### 3.5 Other issues

- No items

## 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

- **Ronaxan and its associated names** (doxycycline)  
EMA/V/A/135  
*Harmonisation of SPC*  
Rapp: F. Hasslung Wikström  
Co-rapp: J. G. Beechinor  
**For decision:** Need for further list of outstanding issues  
**For discussion:** Rapporteur's assessment report including co-rapporteur's critique, draft product information

#### 4.3 Article 35 of Directive 2001/82/EC

- **Injectable veterinary medicinal products containing vitamin A for use in food producing species**  
EMA/V/A/141  
*Withdrawal periods, user safety*  
Rapp: A. Golombiewski  
Co-rapp: B. Urbain  
**For adoption:** CVMP opinion, CVMP assessment report

#### 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

- **Versican Plus DHPPi/L4R**  
EMA/V/C/002759/REC/012.3  
*Recommendation*  
Rapp: E. Werner  
**For endorsement:** Rapporteur's assessment report

- Purevax RC, Purevax RCP and Purevax RCPCh**  
 EMEA/V/C/000091/REC/023  
 EMEA/V/C/000090/REC/023  
 EMEA/V/C/000088/REC/025  
*Recommendation*

Rapp: B. Urbain  
**For endorsement:** Rapporteur's assessment report
- Equilis Prequenza and Equilis Prequenza Te**  
 EMEA/V/C/000094/REC/025  
 EMEA/V/C/000095/REC/029  
*Recommendation*

Rapp: E. Werner  
**For endorsement:** Rapporteur's assessment report
- Rabitec**  
 EMEA/V/C/004387/REC/009  
*Recommendation*

Rapp: E. Werner  
**For endorsement:** Rapporteur's assessment report
- Cytopoint**  
 EMEA/V/C/003939/REC/020  
*Recommendation*

Rapp: R. Breathnach  
**For endorsement:** Rapporteur's assessment report

### 5.3 Product anniversary list

Product	Period
<b>Bravecto Plus</b> (EMEA/V/C/004440)	08.05.2018
<b>Chanhold</b> (EMEA/V/C/004824)	17.04.2019
<b>Credelio</b> (EMEA/V/C/004247)	25.04.2017
<b>Cytopoint</b> (EMEA/V/C/003939)	25.04.2017
<b>Equilis StrepE</b> (EMEA/V/C/000078)	07.05.2004
<b>Evalon</b> (EMEA/V/C/004013)	18.04.2016
<b>Felisecto Plus</b> (EMEA/V/C/005093)	26.04.2019
<b>Forceris</b> (EMEA/V/C/004329)	23.04.2019
<b>Improvac</b> (EMEA/V/C/000136)	11.05.2009
<b>Letifend</b> (EMEA/V/C/003865)	20.04.2016
<b>Meloxidolor</b> (EMEA/V/C/002590)	22.04.2013
<b>Oncept IL-2</b> (EMEA/V/C/002562)	03.05.2013
<b>Procox</b> (EMEA/V/C/002006)	20.04.2011
<b>ReproCyc ParvoFLEX</b> (EMEA/V/C/004858)	26.04.2019
<b>Tulaven</b> (EMEA/V/C/005153)	24.04.2020
<b>Tulissin</b> (EMEA/V/C/005073)	24.04.2020

<b>Product</b>	<b>Period</b>
<b>Vectormune FP ILT + AE</b> (EMA/V/C/005077)	24.04.2020
<b>Versican Plus DHPPi/L4</b> (EMA/V/C/003678)	07.05.2014
<b>Versican Plus DHPPi/L4R</b> (EMA/V/C/002759)	07.05.2014
<b>Zulvac BTV</b> (EMA/V/C/004185)	25.04.2017
<b>Zuprevo</b> (EMA/V/C/002009)	06.05.2011

#### 5.4 Renewals

- Eravac**  
EMA/V/C/004239/R/0007  
Rapp: C. Muñoz Madero  
Co-rapp: P. Pasquali  
**For adoption:** List of outstanding issues
- Sedadex**  
EMA/V/C/004202/R/0005  
Rapp: C. Muñoz Madero  
Co-rapp: M. Leitner  
**For adoption:** List of outstanding issues

#### 5.5 Pharmacovigilance - PSURs and SARs

- Cytopoint**  
EMA/V/C/003939  
Rapp: R. Breathnach  
**For adoption:** CVMP assessment report on the PSUR for the period 01.11.2019-30.10.2020
- Draxxin**  
EMA/V/C/000077  
Rapp: A. Golombiewski  
**For adoption:** CVMP assessment report on the PSUR for the period 01.12.2019-30.11.2020
- Circovac**  
EMA/V/C/000114  
Rapp: P. Pasquali  
**For endorsement:** Rapporteur assessment report on the PSUR for the period 01.01.2018-31.12.2020
- Clynav**  
EMA/V/C/002390  
Rapp: J. G. Beechinor  
**For endorsement:** Rapporteur assessment report on the PSUR for the period 01.01.2020-31.12.2020
- Mirataz**  
EMA/V/C/004733  
Rapp: S. Louet  
**For endorsement:** Rapporteur assessment report on the PSUR for the period 01.07.2020-31.12.2020

- **Panacur AquaSol**  
EMA/V/C/002008  
Rapp: G. J. Schefferlie  
**For endorsement:** Rapporteur assessment report on the PSUR for the period 01.01.2018-31.12.2020
- **Posatex**  
EMA/V/C/000122  
Rapp: S. Louet  
**For endorsement:** Rapporteur assessment report on the PSUR for the period 01.12.2018-31.12.2020
- **Spironolactone Ceva**  
EMA/V/C/000105  
Rapp: C. Muñoz Madero  
**For endorsement:** Rapporteur assessment report on the PSUR for the period 01.01.2018-31.12.2020
- **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:** EU comments on Draft VICH Good Manufacturing Practice guide for active pharmaceutical ingredients
- **For endorsement:** Draft concept paper proposing development of VICH guidelines to parallel ICH guidelines Q8 (pharmaceutical development), Q9 (quality risk management) and Q10 (pharmaceutical quality system) including EU comments
- **For discussion:** Draft guideline on target animal safety evaluation for veterinary monoclonal antibody products

### 6.2 Codex Alimentarius

- No items

### 6.3 Other EU bodies and international organisations

- **For information:** Report of the meeting of the OIE Working Group on Antimicrobial Resistance, 13-15 October 2020, including refinement of the OIE list of antimicrobials of veterinary importance with respect to their use in poultry

#### **Document for information:**

**6.3:** Consideration of alternative intake calculation models for estimation of consumer exposure to residues - minutes from the enlarged expert group's 2<sup>nd</sup> meeting held on 3 March 2021

## 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*

- No items

### **8.3 Antimicrobial resistance**

- No items

### **8.4 Pharmacovigilance**

- No items

### **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

- **For information:** Verbal report from the CMDv chair on the CMDv meetings held on 18-19 March and 15-16 April 2021; minutes of the 15-16 April 2021 meeting; agenda of the meeting to be held on 11-12 May 2021; draft agenda of the CMDv-Interested Parties meeting to be held on 12 May 2021
- **For information:** Verbal report from the CMDv Legislation WG chair on the CMDv Best Practice Guides for SPC harmonisation required by Regulation (EU) 2019/6; best practice guide for the selection of the products for the SPC harmonisation; best practice guide for the harmonisation procedure of the SPC of the reference products; best practice guide for the harmonisation procedure of the SPC of generic/hybrid veterinary medicinal products

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- **To note:** Veterinary Big Data Stakeholder Forum to be held on 1-2 June 2021; draft agenda and registration ([link](#))

## 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	SAWP	QWP	SWP	ERAWP	EWP	AWP	IWP	PhVWP	NTWP	J3Rs WG
<b>May 2021</b>	10-12		25-27				25-26	26-27	25-26		-
<b>Jun 2021</b>	15-17	14				22-23					-
<b>Jul 2021</b>	13-15	12							6-7		-
<b>Sep 2021</b>	7-9	6	22-24				21-22		21-22		-
<b>Oct 2021</b>	5-7	4				19-20					-