12 March 2021
EMA/CVMP/133239/2021 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Draft agenda of March 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

16 March, 09:00 – 18 March 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, 15 March 2021 | 10:00 – 13:00 CET |

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## 1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

### 1.1 Opinions

- **Substance**
  EMEA/V/MRL/004828/EXTN/0002
  *Chickens*

  ***For adoption:*** CVMP opinion including EPMAR, CVMP assessment report

  ***For information:***
  Summary of opinion

### 1.2 Oral explanations and list of outstanding issues

- No items

### 1.3 List of questions

- **Substance**
  EMEA/V/MRL/005739/FULL/0001
  *Equidae*

  ***For adoption:*** Scientific overview and list of questions

### 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

- **Aivlosin**
  EMEA/V/C/000083/X/0081
  *To add a new target species*

  Rapp: C. Bergman

  Co-rapp: A. Golombiewski

  **ORAL EXPLANATION – Tuesday, 16 March 2021**

  ***For discussion:***
  Rapporteurs' assessment of responses to list of outstanding issues

- **Product**
  EMEA/V/C/005489/0000
  *New product*
  *Cats*

  ***For decision:*** Need for an oral explanation

  ***For adoption:*** CVMP scientific overview and list of outstanding issues

- **Product**
  EMEA/V/C/005309/0000
  *New vaccine*
  *Horses*

  ***For decision:*** Need for an oral explanation

  ***For adoption:*** Scientific overview and list of outstanding issues

### 2.3 List of questions

- No items

### 2.4 Re-examination of CVMP opinions

- No items

### 2.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Vectormune FP ILT** (EMEA/V/C/005482/0000)
- ***For endorsement:*** EPAR scientific discussion for **Nobivac DP Plus** (EMEA/V/C/005251/0000)
- ***For endorsement:*** EPAR scientific discussion for **Enteroporc Coli AC** (EMEA/V/C/005149/0000)
- ***For endorsement:*** EPAR scientific discussion for **Enteroporc Coli** (EMEA/V/C/005148/0000)

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- **Cortavance**
  EMEA/V/C/000110/II/0015
  *To add a new therapeutic indication*

  Rapp: N. C. Kyvsgaard

  Co-rapp: C. Muñoz Madero

  ***For adoption:*** CVMP opinion, CVMP assessment report, product information

  ***For information:*** Summary of opinion

- **Ingelvac CircoFlex** and **Ingelvac MycoFlex**
  EMEA/V/C/xxxxxx/WS1920/G
  *Quality-related changes*

  Rapp: P. Pasquali

  ***For adoption:*** CVMP opinion, product information

  ***For endorsement:*** Rapporteur's assessment report

- **Suvaxyn Circo+MH RTU** and **Suvaxyn Circo**
  EMEA/V/C/xxxxxx/WS2010
  *Quality-related changes*

  Rapp: F. Klein

  ***For adoption:*** CVMP opinion

  ***For endorsement:*** Rapporteur's assessment report

- **MS-H Vaccine**
  EMEA/V/C/000161/II/0017/G
  *Quality-related changes*

  Rapp: B. Urbain

  ***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

- **Bravecto**
  EMEA/V/C/002526/II/0047
  *To add a new therapeutic indication*

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

  ***For adoption:*** List of questions

- **Suvaxyn CSF Marker**
  EMEA/V/C/002757/II/0009
  *To amend the therapeutic indication*

  Rapp: M. Blixenkrone-Møller

  Co-rapp: B. Urbain

  ***For adoption:*** List of questions

- **Ingelvac CircoFLEX** and **Ingelvac PRRSFLEX**
  EMEA/V/C/xxxxxx/WS1921
  *To change the product information*

  Rapp: P. Pasquali

  ***For adoption:*** List of questions

- **Eryseng** and **Eryseng Parvo**
  EMEA/V/C/xxxxx/WS1986/G
  *Quality-related changes*

  Rapp: J. G. Beechinor

  ***For adoption:*** List of questions

- **Apoquel**
  EMEA/V/C/002688/II/0020
  *Quality-related changes*

  Rapp: J. G. Beechinor

  ***For adoption:*** List of questions

### 3.4 Re-examination of CVMP opinions

- No items

### 3.5 Other issues

- **VarroMed**
  EMEA/V/C/002723/II/0003/G
  *Quality-related changes*

  Rapp: K. Štraus

  Co-rapp: A. Golombiewski

  ***For adoption:*** Request from the applicant for an extension of the clock stop

## 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 decision:*** Need for further outstanding issues

  ***For discussion***: Revised rapporteur's assessment report including co-rapporteur's critique following the responses to the list of outstanding issues

- **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 decision:*** Need for further outstanding issues

  ***For discussion:*** Revised rapporteur's assessment report including co-rapporteur's critique following the responses to the list of outstanding issues

### 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

- **Ubac**
  EMEA/V/C/004595/REC/002-003-004
  *Recommendations*

  Rapp: E. Werner

  Co-rapp: E. Augustynowicz

  ***For endorsement*:** Rapporteur's assessment report

### 5.3 Product anniversary list

| **Product** | **Period** |
|---|---|
| **CaniLeish** (EMEA/V/C/002232) | 14/03/2020 – 13/03/2021 |
| **Coliprotec F4** (EMEA/V/C/003797) | 16/03/2020 – 15/03/2021 |
| **Econor** (EMEA/V/C/000042) | 12/03/2020 – 11/-2/2021 |
| **Equisolon** (EMEA/V/C/002382) | 12/03/2020 – 11/03/2021 |
| **Fungitraxx** (EMEA/V/C/002722) | 12/03/2020 – 11/03/2021 |
| **Melosus** (EMEA/V/C/002001) | 21/02/2020 – 20/02/2021 |

| Product | Period |
|---|---|
| **Novem** (EMEA/V/C/000086) | 02/03/2020 – 01/02/2021 |
| **Pexion** (EMEA/V/C/002543) | 25/02/2020 – 24/02/2021 |
| **Porcilis Porcoli Diluvac Forte** (EMEA/V/C/000024) | 29/02/2020 – 28/02/2021 |
| **ProteqFlu** (EMEA/V/C/000073) | 06/03/2020 – 05/03/2021 |
| **ProteqFlu-Te** (EMEA/V/C/000074) | 06/03/2020 – 05/03/2021 |
| **Purevax RC** (EMEA/V/C/000091) | 23/02/2020 – 22/02/2021 |
| **Purevax RCP** (EMEA/V/C/000090) | 23/02/2020 – 22/02/2021 |
| **Purevax RCP FeLV** (EMEA/V/C/000089) | 23/02/2020 – 22/02/2021 |
| **Purevax RCPCh** (EMEA/V/C/000088) | 23/02/2020 – 22/02/2021 |
| **Purevax RCPCh FeLV** (EMEA/V/C/000085) | 23/02/2020 – 22/02/2021 |
| **Zulvac 1+8 Bovis** (EMEA/V/C/002473) | 08/03/2020 – 07/03/2021 |
| **Zulvac 1+8 Ovis** (EMEA/V/C/002251) | 14/03/2020 – 13/03/2021 |

### 5.4 Renewals

- No items

### 5.5 Pharmacovigilance - PSURs and SARs

- **Comfortis**
  EMEA/V/C/002233

  Rapp: A. Golombiewski

  ***For adoption:*** CVMP assessment report on the PSUR for the period 01.10.2019-30.09.2020

- **Arti-Cell Forte**
  EMEA/V/C/004727

  Rapp: F. Hasslung Wikström

  ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.04.2020-30.09.2020

- **Aservo EquiHaler**
  EMEA/V/C/004991

  Rapp: K. Baptiste

  ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 28.01.2020-31.07.2020

- **Clevor**
  EMEA/V/C/004417

  Rapp: C. Muñoz Madero

  ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.05.2020-31.10.2020

- **Forceris**
  EMEA/V/C/004329

  Rapp: C. Muñoz Madero

  ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.05.2020-31.10.2020

- **Imrestor**
  EMEA/V/C/002763

  Rapp: N. C. Kyvsgaard

  ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.10.2019-30.09.2020

- ***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 first draft of VICH dissolution guidance for orally administered products; EU comments on draft terminology document
- ***For discussion:*** Revision of VICH GLs on efficacy of anthelmintics: draft EU comments on FDA proposals on VICH GL7 and GL20 regarding adequacy of infection for heartworm in cats

### 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 therapy groups and related issues

### 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*

- No items

### 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*

- ***For information:*** New pre-submission (eligibility) request form for marketing authorisation applications for the centralised procedure intended to be submitted after 28 January 2022 under Regulation (EU) 2019/6

### 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 21-22 January and 18-19 February 2021*;* minutes of the 18-19 February 2021 meeting*;* draft agenda of the meeting to be held on 18-19 March 2021

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** EMA/AnimalhealthEurope Info Day to be held on 25 March 2021; draft programme

## 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Mar 2021** | 16-18 | | 2-3 | 4-5 | 23-24 | | 23-24 | 1-3 | 15 | | - |
| **Apr 2021** | 13-15 | | | | | | | | 12/13 | 22/23 | - |
| **May 2021** | 10-12 | | 25-26 | | | 26-27 | 25-26 | 25-27 | 7 | | - |
| **Jun 2021** | 15-17 | | | | 1-2 | | | | 14/15 | | - |
| **Jul 2021** | 13-15 | | | | | | 6-7 | | 12 | | - |