3 September 2021
EMA/497915/2021 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Draft agenda of September 2021 meeting

Chair: D. Murphy
Vice-chair: G. J. Schefferlie

7 September 2021, 09:00 – 9 September 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 July 2021 CVMP meeting and the August 2021 written procedure

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

| | | |
|---|---|---|
| **Scientific Advice Working Party (virtual)** | Monday, 6 September 2021 | 10.00-13.00 CEST |

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

## 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

- **Product**
  EMEA/V/C/005464/0000
  *New product*
  *Cats*

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

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

### 2.2 Oral explanations and list of outstanding issues

- No items

### 2.3 List of questions

- **Product**
  EMEA/V/C/005819/0000
  *New product*
  *Chickens*

  ***For adoption:***
  CVMP scientific overview and list of questions

- **Product**
  EMEA/V/C/005528/0000
  *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 **Fatrovax RHD** (EMEA/V/C/005301/0000)
- ***For endorsement:*** EPAR scientific discussion for **Tessie** (EMEA/V/C/005427/0000)

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

- **Frontpro**
  EMEA/V/C/005126/II/0010
  *To change the legal status*

  Rapp: K. Boerkamp

  Co-rapp: J. G. Beechinor

  Rapp: E. Werner

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

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

- **Poulvac E. coli**
  EMEA/V/C/002007/II/0018
  *To change the product information*

  Rapp: E. Werner

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

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

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

  Rapp: P. Pasquali

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

- **Porcilis PCV ID**
  EMEA/V/C/003942/II/0005/G
  *To change the product information*

  Rapp: J. Poot

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

- **ProZinc**
  EMEA/V/C/002634/II/0024
  *Quality-related changes*

  Rapp: R. Breathnach

  ***For adoption:*** CVMP opinion

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

- **Prevomax**
  EMEA/V/C/004331/II/0006/G
  *Quality-related changes*

  Rapp: S. Louet

  ***For adoption:*** CVMP opinion

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

- **Innovax-ND-IBD**
  EMEA/V/C/004422/II/0007
  *Quality-related changes*

  Rapp: J. Poot

  ***For adoption:*** CVMP opinion

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

- **Innovax-ILT** and **Innovax-ND-IBD**
  EMEA/V/C/xxxxxx/WS2102/G
  *Quality related changes*

  Rapp: E. Werner

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

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

- **Locatim**
  EMEA/V/C/000041/II/0018
  *Quality-related changes*

  Rapp: B. Urbain

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

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

- **Startvac**
  EMEA/V/C/000130/II/0008/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

- **Improvac**
  EMEA/V/C/000136/II/0036
  *To add a new therapeutic indication*

  Rapp: N. C. Kyvsgaard

  Co-rapp: J. Poot

  ***For adoption:*** List of outstanding issues

- **Veraflox**
  EMEA/V/C/000159/II/0024/G
  *Quality-related changes*

  Rapp: A. Golombiewski

  ***For adoption:*** List of outstanding issues

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

### 3.3 List of questions

- **Suprelorin**
  EMEA/V/C/000109/II/0032/G
  *To add a new therapeutic indication and target species*

  Rapp: N. C. Kyvsgaard

  Co-rapp: J. P. Duarte Da Silva

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

- **Bravecto**
  EMEA/V/C/002526/II/0051
  *To add a new therapeutic indication*

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

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

- **Cytopoint**
  EMEA/V/C/003939/II/0014/G
  *Quality-related changes*

  Rapp: R. Breathnach

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

- **Mhyosphere PCV ID**
  EMEA/V/C/005272/II/0001/G
  *Quality-related changes*

  Rapp: E. Werner

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

- **Simparica, Felisecto Plus, Stronghold Plus, MiPet Easecto** and **Simparica Trio**
  EMEA/V/C/xxxxxx/WS2073
  *Quality-related changes*

  Rapp: R. Breathnach

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

### 3.4 Re-examination of CVMP opinions

- No items

### 3.5 Other issues

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

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

  ***For information***: Withdrawal letter from applicant

- **Neocolipor**
  EMEA/V/C/000035/II/0018/G
  *Quality-related changes*

  Rapp: C. Miras

  ***For decision***: 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

- No items

### 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

- No items

### 5.3 Product anniversary list

| **Product** | **Period** |
|---|---|
| **Aivlosin** (EMEA/V/C/000083) | 09.09.2020 – 08.09.2021 |
| **Bovilis** BTV8 (EMEA/V/C/000148) | 06.09.2020 – 05.09.2021 |
| **Cardalis** (EMEA/V/C/002524) | 23.07.2020 – 22.07.2021 |

| Product | Period |
|---|---|
| **Dexdomitor** (EMEA/V/C/0000)70 | 30.08.2020 – 29.08.2021 |
| **Emdocam** (EMEA/V/C/002283) | 18.08.2020 – 17.08.2021 |
| **Evicto** (EMEA/V/C/004973) | 19.07.2020 – 18.07.2021 |
| **Exzolt** (EMEA/V/C/004344) | 18.08.2020 – 17.08.2021 |
| **Fortekor Plus** (EMEA/V/C/002804) | 08.09.2020 – 07.09.2021 |
| **Hydrocortisone aceponate Ecuphar** (EMEA/V/C/004689) | 27.08.2020 – 26.08.2021 |
| **Innovax-ND-IBD** (EMEA/V/C/004422) | 22.08.2020 – 21.08.2021 |
| **Nasym** (EMEA/V/C/004897) | 29.07.2020 – 28.07.2021 |
| **Nobilis IB Primo QX** (EMEA/V/C/002802) | 04.09.2020 – 03.09.2021 |
| **Nobilis Influenza H5N2** (EMEA/V/C/000118) | 01.09.2020 – 31.08.2021 |
| **Nobivac L4** (EMEA/V/C/002010) | 16.07.2020 – 16.05.2021 |
| **Nobivac Myxo-RHD** (EMEA/V/C002004) | 07.09.2020 – 06.09.2021 |
| **Novaquin** (EMEA/V/C/003866) | 08.09.2020 – 07.09.2021 |
| **Osurnia** (EMEA/V/C/003753) | 31.07.2020 – 30.07.2021 |
| **Porcilis PCV ID** (EMEA/V/C/003942) | 28.08.2020 – 27.08.2021 |
| **Prevexxion RN** (EMEA/V/C/005058 | 20.07.2020 – 19.07.2021 |
| **Prevexxion RN+HVT+IBD** (EMEA/V/C/005057 | 20.07.2020 – 19.07.2021 |
| **Profender** (EMEA/V/C/000097) | 27.07.2020 – 26.07.2021 |
| **Proteq West Nile** (EMEA/V/C/002020) | 05.08.2020 – 04.08.2021 |
| **Sedadex** (EMEA/V/C/004202) | 12.08.2020 – 11.08.2021 |
| **Suvaxyn Aujeszky 783 + O/W** (EMEA/V/C/000038) | 07.08.2020 – 06.08.2021 |
| **Suvaxyn PRRS MLV** (EMEA/V/C/004276) | 24.08.2020 – 23.08.2021 |
| **Trocoxil** (EMEA/V/C/000132) | 09.09.2020 – 08.09.2021 |
| **Ubac** (EMEA/V/C/004595) | 26.07.2020 – 25.07.2021 |
| **UpCard** (EMEA/V/C/003836) | 31.07.2020 – 30.07.2021 |
| **Vaxxitek HVT+IBD** (EMEA/V/C/000065) | 09.08.2020 – 08.08.2021 |
| **Vectormune ND** (EMEA/V/C/003829) | 08.09.2020 – 07.09.2021 |
| **Vepured** (EMEA/V/C/004364) | 17.08.2020 – 16.08.2021 |

| Product | Period |
|---|---|
| **Versican Plus L4** (EMEA/V/C/003680) | 31.07.2020 – 30.07.2021 |
| **Versican Plus Pi/L4** (EMEA/V/C/003683) | 31.07.2020 – 30.07.2021 |
| **Versican Plus Pi/L4R** (EMEA/V/C/003682) | 31.07.2020 – 30.07.2021 |
| **Zactran** (EMEA/V/C/000129) | 24.07.2020 – 23.07.2021 |

### 5.4 Renewals

- **Coliprotec F4/F18**
  EMEA/V/C/004225/R/0009

  Rapp: E. Augustynowicz

  Co-rapp: C. Muñoz Madero

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

- **Cepedex**
  EMEA/V/C/004376/R/0007

  Rapp: C. Muñoz Madero

  Co-rapp: M. Leitner

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

### 5.5 Pharmacovigilance - PSURs and SARs

- ***For adoption:*** Recommendation for changes to the SPC for **Vepured** as an outcome of the CAP surveillance

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

  Rapp: C. Muñoz Madero

  ***For endorsement***: rapporteur's assessment report on the PSUR for the period 01.11.2020-30.04.2021

- **Meloxidolor**
  EMEA/V/C/002590

  Rapp: C. Muñoz Madero

  ***For endorsement***: rapporteur's assessment report on the PSUR for the period 23.04.2018-30.04.2021

- **Reprocyc ParvoFLEX**
  EMEA/V/C/004858

  Rapp: F. Hasslung Wikström

  ***For endorsement***: rapporteur's assessment report on the PSUR for the period 01.11.2020-30.04.2021

- ***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

*Information on certain topics discussed under section 6 cannot be released at the present time as it is deemed to be confidential*

### 6.1 VICH

- ***For endorsement***: EU comments on draft VICH GL on good manufacturing practice guide for active pharmaceutical ingredients
- ***For endorsement***: EU comments on draft revision of VICH GL8: Stability testing for medicated premixes
- ***For information***: VICH dissolution guidance for orally administered products, including EU 6.2 Codex Alimentarius

### 6.2 Codex Alimentarius

### 6.3 Other EU bodies and international organisations

## 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*

- 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*

### 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 09-10 September 2021; minutes of the CMDv meeting held on 15-16 July 2021

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

## 13. LEGISLATION

- ***For adoption:*** Overview of comments on guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6
- ***For adoption:*** Overview of comments on guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6

- ***For adoption:*** Overview of comments on guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of Regulation (EU) 2019/6

## 14. ANY OTHER BUSINESS

- ***For comments***: meeting highlights

**ANNEX**

| | CVMP | SAWP | QWP | SWP | ERAWP | EWP | AWP | IWP | PhVWP | NTWP | J3Rs WG |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sep 2021** | 7-9 | 6 | 22-24 | | | | 21-22 | | 21-22 | 16 | - |
| **Oct 2021** | 5-7 | 4 | | | 20-21 | 19-20 | | | | | - |
| **Nov 2021** | 3-5 | 27 Oct | 22-24 | 18-19 | | | 23-24 | 17-18 | 16-17 | 24 | - |
| **Dec 2021** | 7-9 | 6 | | | | | | | | | - |
| **Jan 2022** | 18-20 | 14 | | | | | | | | | |