5 November 2018
EMA/CVMP/770637/2018 - draft 2
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Draft agenda of November meeting

Chair: David Murphy

Vice-chair: Helen Jukes

6 November 2018, 09:00 – 8 November 2018, 13:00 - Room 2A

**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** | Tue 6 Nov 2018 | 16.30-20.00 |

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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**<br>EMEA/V/MRL/005009/FULL/0001<br>*Porcine* | ***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

| | |
|---|---|
| • **Product**<br>EMEA/V/C/004611/0000<br>*New vaccine*<br>*Sheep and cattle* | ***For adoption:*** CVMP opinion, CVMP assessment report, product information<br>***For information:*** Summary of opinion |
| • **Product**<br>EMEA/V/C/004345/0000<br>*New cardiovascular product*<br>*Dogs* | ***For adoption:*** CVMP opinion, CVMP assessment report, product information<br>***For information:*** Summary of opinion |

### 2.2 Oral explanations and list of outstanding issues

- No items

### 2.3 List of questions

- No items

### 2.4 Re-examination of CVMP opinions

| | |
|---|---|
| • **HorStem**<br>EMEA/V/C/004265/0000<br>*New product for musculo-skeletal disorder - equine umbilical cord mesenchymal stem cells for the treatment of ostheoarthritis*<br>*Horses* | Rapp: *to be appointed*<br>Co-rapp: *to be appointed*<br>***For decision:*** Appointment of rapporteur, co-rapporteur and peer reviewers<br>***For discussion:*** Request for re-examination from applicant |

### 2.5 Other issues

*Information on certain topics discussed under section 2.5 cannot be released at the present time as it is deemed to be confidential*

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

| | |
|---|---|
| • **AFTOVAXPUR DOE**<br>EMEA/V/C/002292/II/0009<br>*To change the onset of immunity* | Rapp: N. Garcia del Blanco<br>Co-Rapp: P. Pasquali<br>***For adoption:*** CVMP opinion, CVMP assessment report, product information<br>***For information:*** Summary of opinion |

### 3.2 Oral explanations and list of outstanding issues

- No items

### 3.3 List of questions

| | |
|---|---|
| • **ProZinc**<br>EMEA/V/C/002634/II/0016<br>*Quality* | Rapp: R. Breathnach<br>***For adoption:*** List of questions |

### 3.4 Re-examination of CVMP opinions

- No items

### 3.5 Other issues

| | |
|---|---|
| • **OSURNIA**<br>EMEA/V/C/003753/II/0008<br>*Quality* | Rapp: S. Louet<br>***For information:*** Request for extension of 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

| | |
|---|---|
| • **Veterinary medicinal products containing gentamicin for parenteral administration to horses**<br>EMEA/V/A/128<br>*Quality* | Rapp: M. O'Grady<br>Co-rapp: W. Schlumbohm<br>***For adoption:*** CVMP opinion, CVMP assessment report |

### 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*

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

### 5.1 General issues

- No items

### 5.2 Post-authorisation measures and annual reassessments

| | |
|---|---|
| • **Vaxxitek HVT + IBD**<br>EMEA/V/C/000065/REC/026 | Rapp: B. Urbain<br>***For adoption***: Assessment report |

### 5.3 Product anniversary list

| **Product** | **Period** |
|---|---|
| **BTVPUR AlSap 2-4** (EMEA/V/C/000139) | 05/11/2017 – 04/11/2018 |
| **Halocur** (EMEA/V/C/000040) | 29/10/2017 – 28/10/2018 |
| **Nobivac LeuFel** (EMEA/V/C/004778) | 06/11/2017 – 05/11/2018 |
| **Porcilis PCV M Hyo** (EMEA/V/C/003796) | 07/11/2017 – 06/11/2018 |
| **Simparica** (EMEA/V/C/003991) | 06/11/2017 – 05/11/2018 |

| Product | Period |
|---|---|
| **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924) | 06/11/2017 – 05/11/2018 |
| **Virbagen Omega** (EMEA/V/C/000061) | 06/11/2017 – 05/11/2018 |
| **ZOLVIX** (EMEA/V/C/000154) | 04/11/2017 – 03/11/2018 |
| **Zycortal** (EMEA/V/C/003782) | 06/11/2017 – 05/11/2018 |

### 5.4 Renewals

| | |
|---|---|
| • **Loxicom**<br>EMEA/V/C/000141/R/0006 | Rapp: J. G. Beechinor<br>Co-rapp: M. Turk<br>***For adoption:*** CVMP opinion, CVMP assessment report, product information |
| • **Parvoduk**<br>EMEA/V/C/002740/R/0006 | Rapp: F. Klein<br>Co-rapp: G. Kulcsár<br>***For adoption:*** CVMP opinion, CVMP assessment report, product information |
| • **Bravecto**<br>EMEA/V/C/2526/R/0028 | Rapp: *to be appointed*<br>Co-rapp: *to be appointed*<br>***For discussion:*** MAH's request for re-examination |

### 5.5 Pharmacovigilance - PSURs and SARs

| | |
|---|---|
| • **Bovela**<br>EMEA/V/C003703 | Rapp: F. Klein<br>***For endorsement:*** Rapporteur assessment report evaluation for the period 01.07.17-30.06.18 |
| • **Simparica and MiPet Easecto**<br>EMEA/V/C003991 | Rapp: J. G. Beechinor<br>***For adoption:*** CVMP assessment report for the period 01.12.17-31.05.18 |
| • **Versican Plus DHPPi L4**<br>EMEA/V/C003678 | Rapp: E. Werner<br>***For endorsement:*** Rapporteur assessment report for the period 01.06.17-31.05.18 |
| • **Versican Plus DHPPi L4R**<br>EMEA/V/C002759 | Rapp: E. Werner<br>***For endorsement:*** Rapporteur assessment report for the period 01.06.17-31.05.18 |
| • **Zycortal**<br>EMEA/V/C003782 | Rapp: H. Jukes<br>***For adoption:*** CVMP assessment report for the period 01.01.18-31.05.18 |

| | |
|---|---|
| • **Acticam**<br>EMEA/V/C/000138 | Rapp: J. G. Beechinor<br>***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.07.15-30.06.18 |
| • **EQUIOXX**<br>EMEA/V/C/000142 | Rapp: J. G. Beechinor<br>***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.01.18-30.06.18 |
| • **Fevaxyn Pentofel**<br>EMEA/V/C/000030 | Rapp: E.-M. Vestergaard<br>***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.07.17-30.06.18 |
| • **Halagon**<br>EMEA/V/C/004201 | Rapp: C. Muñoz<br>***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.01.18-30.06.18 |
| • **Rabitec**<br>EMEA/V/C/004387 | Rapp: E. Werner<br>***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.12.17-30.06.18 |
| • **Trifexis**<br>EMEA/V/C/002635 | Rapp: G. Hahn<br>***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 05.01.18-04.07.18 |
| • **Velactis**<br>EMEA/V/C/003739 | Rapp: W. Schlumbohm<br>***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.01.18-30.06.18 |

- ***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:*** Comments on draft training slides on VICH quality guidelines GL10, GL11, GL18, GL45 and GL51 and VICH TABST guidelines GL50(R) and GL55
- ***For endorsement:*** Proposal for limited revision of VICH GL36 on the general approach to establish a microbiological ADI
- ***For discussion:*** Draft VICH GL 57 on marker residue depletion studies to establish product withdrawal periods in aquatic species containing responses to comments received during the public consultation; overview of comments received during public consultation

### 6.2 Codex Alimentarius

- ***For information:*** Proposed draft guideline on integrated surveillance of antimicrobial resistance, request for comments – *see also 8.3*

### 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)

*Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential*

### 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 (ADVENT)

### 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 MRLs issues

*Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential*

- ***For endorsement:*** Revised templates for MRL scientific overview and list of questions and MRL assessment report
- ***For adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009

### 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

- ***For discussion:*** Draft scientific advice by the Antimicrobial Advice Ad Hoc Expert Group on the categorisation of antimicrobials and the preliminary risk profiling for new antimicrobials
- ***For information:*** Verbal report on 8th European Surveillance of Veterinary Antimicrobial Consumption report on sales of veterinary antimicrobial agents in 30 European countries in 2016
- ***For information:*** Verbal report on the "Focus group meeting on dose optimisation of established veterinary antibiotics in the context of summary of product characteristics harmonisation" held on 12 October 2018; agenda and minutes of the meeting
- ***For information:*** Proposed draft guideline on integrated surveillance of antimicrobial resistance, request for comments – *see also 6.2*

### 8.4 Pharmacovigilance

- ***To note:*** United States Food and Drug Administration (FDA) alert to veterinarians and pet owners about potential neurologic adverse reactions in dogs and cats receiving flea and tick treatment from the isoxazoline class of drugs and fact sheet for pet owners and veterinarians

### 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*

- ***For adoption:*** Revision of the policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market and the guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS)/limited market

## 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 decision:*** Transfer of co-rapporteurships from B. Hauser to P. Falb and I. Lindner

### 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:*** Minutes of the meeting held on 11-12 October 2018; draft agenda of meeting to be held on 8-9 November 2018

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** Draft CVMP work plan for 2019
- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 7 November 2018, draft agenda of the meeting; draft minutes from the SPG meeting held on 12 September 2018
- ***For information:*** Update on Brexit-related matters
- ***For information:*** Update on the Regulatory Science Strategy 2020-2025
- ***For information:*** Knowledge sharing package to support UK product portfolio transfer and access instructions
- ***For information:*** Update on EMA relocation

## 13. LEGISLATION

- No items

## 14. ANY OTHER BUSINESS

- ***For comments:*** Press release of the meeting

## ANNEX

### NEXT MEETINGS OF THE CVMP AND ITS WORKING PARTIES

| | CVMP | ADVENT | AWP | EWP | IWP | PhVWP | SAWP |
|---|---|---|---|---|---|---|---|
| **Nov 2018** | 6-8 | | | | | 20-21 | 6 |
| **Dec 2018** | 4-6 | | | | | | 4 |
| **Jan 2019** | 22-24 | | | | | 29-30 | 22 |
| **Feb 2019** | 19-21 | | | | | | 19 |
| **Mar 2019** | 19-21 | | | | | 26-27 | 19 |