12 January 2018
EMA/CVMP/1779/2018 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Draft agenda of January 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

16 January 2018, 09:00 – 18 January 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 (room 2A)** | Tue, 16 Jan 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

| | |
|---|---|
| • **Substance**<br>EMEA/V/MRL/003135/MODF/0003<br>*Salmonidae* | **ORAL EXPLANATION – Tuesday 16 January 2018**<br>***For discussion***: Presentation from applicant, rapporteurs' assessment of the responses to the LoOI, responses to the list of outstanding issues |

### 1.3 List of questions

- No items

### 1.4 Re-examination of CVMP opinions

- No items

### 1.5 Other issues

| | |
|---|---|
| • **Substance**<br>EMEA/V/MRL/004828/FULL/0001<br>*Rabbits* | ***For decision****:* Request to extend the deadline for submission of responses to list of questions |

## 2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

### 2.1 Opinions

- No items

### 2.2 Oral explanations and list of outstanding issues

| | |
|---|---|
| • **Product**<br>EMEA/V/C/004375/0000<br>*New product for a musculo-skeletal disorder*<br>*Dogs* | **ORAL EXPLANATION – Tuesday 16 January 2018**<br>***For discussion****:* Presentation from applicant, rapporteurs' assessment of responses to list of outstanding issues, draft product information |
| • **Product**<br>EMEA/V/C/004417/0000<br>*New product acting on the nervous system*<br>*Dogs* | **ORAL EXPLANATION – Wednesday 17 January 2018**<br>***For discussion***: Presentation from applicant, rapporteurs' assessment of responses to list of outstanding issues, draft product information |

| | |
|---|---|
| • **Semintra**<br>EMEA/V/C/002436/X/0008<br>*To add a new strength and a new indication*<br>*Cats* | Rapp: R. Breathnach<br>Co-rapp: C. Muñoz<br>***For decision***: Need for oral explanation<br>***For adoption****:* Scientific overview and list of outstanding issues, comments on product information |

### 2.3 List of questions

| | |
|---|---|
| • **Product**<br>EMEA/V/C/004824/0000<br>*New antiparasitic product*<br>*Cats and dogs* | ***For adoption****:* Scientific overview and list of questions, comments on product information |

### 2.4 Re-examination of CVMP opinions

- No items

### 2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **Galliprant** (EMEA/V/C/004222/0000)
- ***For adoption:*** EPAR module scientific discussion for **Suvaxyn Circo** (EMEA/V/C/004242/0000)

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

| | |
|---|---|
| • **Vectormune ND**<br>EMEA/V/C/003829/II/0007<br>*To add a new category target species* | Rapp: F. Klein<br>Co-rapp: E. Werner<br>***For adoption***: CVMP opinion, CVMP assessment report, product information<br>***For information***: Summary of opinion |
| • **Panacur AquaSol**<br>EMEA/V/C/002008/II/0015<br>*To add a new therapeutic indication* | Rapp: G. J. Schefferlie<br>Co-rapp: T. Høy<br>***For adoption****:* CVMP opinion, CVMP assessment report, product information<br>***For information***: Summary of opinion |
| • **Advocate**<br>EMEA/V/C/000076/II/0039/G<br>*To add new therapeutic indications*<br>*Additional changes in the product information* | Rapp: M. Nevalainen<br>Co-rapp: M. Azevedo Mendes<br>***For adoption***: CVMP opinion, CVMP assessment report, product information<br>***For information***: Summary of opinion |

| | |
|---|---|
| • **Meloxidyl**<br>EMEA/V/C/000115/II/0023/G<br>*Quality* | Rapp: F. Hasslung Wikstrom<br>***For adoption**:* CVMP opinion, product information<br>***For endorsement**:* Rapporteur's assessment report |
| • **Suvaxyn PCV**<br>EMEA/V/C/000149/II/0025<br>*Quality* | Rapp: B. Urbain<br>***For adoption***: CVMP opinion<br>***For endorsement***: Rapporteur's assessment report |
| • **Procox**<br>EMEA/V/C/002006/WS1244/0023/G<br>*Quality* | Rapp: E. Lander Persson<br>***For adoption***: CVMP opinion<br>***For endorsement***: Rapporteur's assessment report |

### 3.2 Oral explanations and list of outstanding issues

| | |
|---|---|
| • **Onsior**<br>EMEA/V/C/000127/II/0018/G<br>*To add a new therapeutic indication and to modify the SPC* | Rapp: G. J. Schefferlie<br>Co-rapp: E.-M. Vestergaard<br>***For adoption**:* List of outstanding issues |

### 3.3 List of questions

| | |
|---|---|
| • **Porcilis PCV M Hyo**<br>EMEA/V/C/003796/II/0007<br>*To modify the approved therapeutic indication* | Rapp: E. Werner<br>Co-rapp: K. Lehmann<br>***For adoption**:* List of questions |
| • **Vectormune ND**<br>EMEA/V/C/003829/II/0009/G<br>*Quality* | Rapp: F. Klein<br>***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

| | |
|---|---|
| • **Girolan and its associated name Apralan**<br>EMEA/V/A/122 (re-examination)<br>*Apramycin sulfate*<br>*SPC harmonisation* | Rapp: J. G. Beechinor<br>Co-rapp: W. Schlumbohm<br>***For discussion***: Rapporteur's assessment report including co-rapporteur's critique |

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

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|---|---|
| • **Veterinary medicinal products containing enrofloxacin to be administered viadrinking water to chickens and/or turkeys**<br>EMEA/V/A/089 - Follow-up assessment<br>*Efficacy (dosing regimen for E. coli)* | Rapp: H. Jukes<br>Co-rapp: C. Munoz<br>**ORAL EXPLANATION – Wednesday 17 January 2018**<br>***For discussion***: Comments on Bayer's presentation<br>***For discussion***: Presentation from Bayer Animal Health GmbH |

### 4.4 Article 78 of Directive 2001/82/EC

- No items

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

| | |
|---|---|
| • **Seresto**<br>EMEA/V/A/125<br>*Imidacloprid and flumethrin*<br>*Efficacy* | Rapp: H. Jukes<br>Co-rapp: G. Hahn<br>***For decision***: Need for outstanding issues<br>***For discussion***: Rapporteur's assessment report and co-rapporteur's assessment report |

### 4.6 Article 30(3) of Regulation 726/2004

- No items

### 4.7 Other issues

- No items

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

### 5.1 General issues

*Information on certain topics discussed under section 5.1 cannot be released at the present time as it is deemed to be confidential*

### 5.2 Post-authorisation measures and annual reassessments

| | |
|---|---|
| • **Econor**<br>EMEA/V/C/000042/REC/038<br>*Recommendation* | Rapp: H. Jukes<br>***For endorsement***: Rapporteur's assessment report on the recommendation |
| • **Clynav**<br>EMEA/V/C/002390/REC/001<br>*Recommendation* | Rapp: N. Garcia del Blanco<br>***For endorsement***: Rapporteur's assessment report on the recommendation |

### 5.3 Product anniversary list

| Product | Period |
|---|---|

| Product | Period |
|---|---|
| Acticam (EMEA/V/C/000138) | 09/12/2016 – 08/12/2017 |
| Activyl Tick Plus (EMEA/V/C/002234) | 09/01/2017 – 08/01/2018 |
| Bovela (EMEA/V/C/003703) | 22/12/2016 – 21/12/2017 |
| BTVPUR (EMEA/V/C/002231) | 17/12/2016 – 16/12/2017 |
| BTVPUR AlSap 1 (EMEA/V/C/002230) | 17/12/2016 – 16/12/2017 |
| Cepedex (EMEA/V/C/004376) | 13/12/2016 – 12/12/2017 |
| Coliprotec F4/F18 (EMEA/V/C/004225) | 09/01/2017 - 08/01/2018 |
| CORTAVANCE (EMEA/V/C/000110) | 09/01/2017 – 08/01/2018 |
| Gripovac 3 (EMEA/V/C/000157) | 14/01/2017 – 13/01/2018 |
| Halagon ( EMEA/V/C/004201) | 13/12/2016 - 12/12/2017 |
| Imrestor (EMEA/V/C/002763) | 09/12/2016 – 08/12/2017 |
| Inflacam (EMEA/V/C/002497) | 09/12/2016 – 08/12/2017 |
| MELOXIDYL (EMEA/V/C/000115) | 15/01/2017 – 14/01/2018 |
| Metacam (EMEA/V/C/000033) | 07/01/2017 – 06/01/2018 |
| NEXGARD SPECTRA (EMEA/V/C/003842) | 15/01/2017 – 14/01/2018 |
| Onsior (EMEA/V/C/000127) | 16/12/2016 – 15/12/2017 |
| Panacur AquaSol (EMEA/V/C/002008) | 09/12/2016 – 08/12/2017 |
| Porcilis PCV (EMEA/V/C/000135) | 12/01/2017 – 11/01/2018 |
| Prac-tic (EMEA/V/C/000103) | 18/12/2016 – 17/12/2017 |
| RESPIPORC FLU3 (EMEA/V/C/000153) | 14/01/2017 – 13/01/2018 |
| Rheumocam (EMEA/V/C/000121) | 10/01/2017 – 09/01/2018 |
| SevoFlo (EMEA/V/C/000072) | 11/12/2016 – 10/12/2017 |
| Ypozane (EMEA/V/C/000112) | 11/01/2017 – 10/01/2018 |
| ZULVAC 8 Bovis (EMEA/V/C/000145) | 15/01/2017 – 14/01/2018 |
| ZULVAC 8 Ovis (EMEA/V/C/000147) | 15/01/2017 – 14/01/2018 |

### 5.4 Renewals

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|---|---|
| • **Equilis West Nile**<br>EMEA/V/C/002241/R/0005 | Rapp: E. Werner<br>Co-rapp: G. Kulcsar<br>***For adoption***: CVMP opinion, CVMP assessment report, product information |

| | |
|---|---|
| • **Oncept IL-2**<br>EMEA/V/C/002562/R/0006 | Rapp: J.-C. Rouby<br>Co-rapp: N. Garcia del Blanco<br>***For adoption***: CVMP opinion, CVMP assessment report, product information |

### 5.5 Pharmacovigilance - PSURs and SARs

| | |
|---|---|
| • **Bravecto**<br>EMEA/V/C/002526 | Rapp: G. J. Schefferlie<br>***For discussion and endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.17-31.08.17 |
| • **Vectra 3D**<br>EMEA/V/C/002555 | Rapp: G. Hahn<br>***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.07.16-30.06.17 |
| • **Coliprotec F4/F18**<br>EMEA/V/C/004225 | Rapp: N. Garcia del Blanco<br>***For endorsement***: Rapporteur's evaluation of the PSUR for the period 09.01.17-21.07.17 |
| • **Kexxtone**<br>EMEA/V/C/002235 | Rapp: C. Munoz<br>***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.07.17 |
| • **NEXGARD SPECTRA**<br>EMEA/V/C/003842 | Rapp: J. G. Beechinor<br>***For endorsement***: Rapporteur's evaluation of the PSUR for the period 01.02.17-31.07.17 |
| • **Porcilis PCV ID**<br>EMEA/V/C/003942 | Rapp: P. Hekman<br>***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.17-31.08.17 |
| • **ProZinc**<br>EMEA/V/C/002634 | Rapp: R. Breathnach<br>***For endorsement***: Rapporteur's evaluation of the PSUR for the period 01.08.16 - 31.07.17 |
| • **Semintra**<br>EMEA/V/C/002436 | Rapp: R. Breathnach<br>***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.17-31.08.17 |
| • **Stronghold Plus**<br>EMEA/V/C/004194 | Rapp: R. Breathnach<br>***For endorsement***: Rapporteur's assessment report on the PSUR for the period 09.02.17 - 31.08.17 |

- ***For information***: Communication from the FDA to the MAH regarding product
- ***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 adoption***: VICH GL57 Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species, sign off at step 4
- ***For endorsement***: EU comments on the revised concept paper proposing development of a guideline on safety evaluation of biotechnology-derived/biological products; comments
- ***For endorsement***: EU comments on Japanese proposal for advancing the work on extraneous viruses in veterinary vaccines
- ***For endorsement***: Draft VICH GL 56 on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, updated following public consultation; overview of comments
- ***For discussion***: Draft concept paper for a VICH guideline providing guidance on the establishment and running of a basic pharmacovigilance system
- ***For discussion***: EU comments on draft concept paper for revision of VICH GL22 on Studies to evaluate the safety of residues of veterinary drugs in human food: reproduction testing
- ***For information***: Report from 35$^{th}$ VICH Steering Committee meeting and 9$^{th}$ Outreach Forum meeting held in Tokyo on 13-16 November 2017

### 6.2 Codex Alimentarius

*Information on certain topics discussed under section 6.2 cannot be released at the present time as it is deemed to be confidential*

### 6.3 Other EU bodies and international organisations

*Information on certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be confidential*

## 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 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

### 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 adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 removing 'diethanolamine' from the list

### 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*

- ***For adoption:*** CVMP response to European Commission public consultation on pharmaceuticals in the environment

### 8.3 Antimicrobial resistance

- ***For information:*** Verbal report on the meeting of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) held on 14 December 2017; agenda and draft minutes
- ***For information:*** Second OIE Annual report on antimicrobial agents intended for use in animals (link)

### 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*

- No items

## 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 endorsement:*** Report on "Analysis of field efficacy data submitted in support of marketing authorisation applications for veterinary vaccines in EU centralised procedures"

## 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***: Draft minutes of the meeting held on 7-8 December 2017; draft agenda of the meeting to be held on 18-19 January 2018

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

*Information on certain topics discussed under section 12 cannot be released at the present time as it is deemed to be confidential*

## 13. LEGISLATION

*Information on certain topics discussed under section 13 cannot be released at the present time as it is deemed to be confidential*

## 14. ANY OTHER BUSINESS

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

## ANNEX

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

| | CVMP | ADVENT | AWP | ERAWP | EWP | IWP | PhVWP | QWP | SAWP | SWP | J3Rs WG |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Jan 2018** | 16-18 | | | 30-31 | | | 23-24 | | 16 | | |
| **Feb 2018** | 13-15 | 15 | 20-21 | | 20-21 | 28- | | 27- | 13 | 1-2 | |
| **Mar 2018** | 13-15 | | | | | -1 | 20-21 | -1 | 13 | | |
| **Apr 2018** | 17-19 | | | | | | | | 17 | | |
| **May 2018** | 23-25* | 25 | 29-30 | | 29-30 | | 29-30 | | 23 | 17-18 | |

*Wed to Fri