Committee for Medicinal Products for Veterinary Use
Draft agenda of February 2018 meeting

Chair: David Murphy
Vice-chair: Helen Jukes
13 February 2018, 09:00 – 15 February 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 ongoing 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, 13 Feb 18  
16:00 – 20:00
1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
  - EMEA/V/MRL/003517/EXTN/0003
  - *Poultry eggs*
  - **For adoption:** CVMP opinion including EPMAR, CVMP assessment report
  - **For information:** Summary of opinion

1.2 Oral explanations and list of outstanding issues

- **Substance**
  - EMEA/V/MRL/003647/EXTN/0002
  - *Porcine*
  - **For decision:** Need for oral explanation

1.3 List of questions

- **Substance**
  - EMEA/V/MRL/004933/FULL/0001
  - *Bovine*
  - **For adoption:** Scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- **Substance**
  - EMEA/V/MRL/003135/MODF/0003
  - *Salmonidae*
  - **For discussion:** Rapporteur’s joint assessment report

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- **Product**
  - EMEA/V/C/004440/0000
  - *New antiparasitic product for cats*
  - **For decision:** Request from applicant for oral explanation at March CVMP
  - **For adoption:** Draft CVMP opinion, CVMP assessment report, product information
  - **For information:** Summary of opinion

- **Product**
  - EMEA/V/C/004417/0000
  - *New product for dogs*
  - **For adoption:** CVMP opinion, CVMP assessment report, product information
  - **For information:** Summary of opinion

2.2 Oral explanations and list of outstanding issues

- **Product**
  - EMEA/V/C/004222/0000
  - *New product for a musculo-skeletal disorder for horses*
  - **For decision:** Need for oral explanation
  - **For adoption:** Scientific overview and list of outstanding issues; comments on product information
• **Product**  
  EMEA/V/C/004265/0000  
  New product for a musculo-skeletal disorder  
  Horses

  **For decision**: Need for oral explanation

  **For adoption**: Scientific overview and list of outstanding issues; comments on product information

• **Credelio**  
  EMEA/V/C/004485/X/0001  
  To add a new strength for a new target species  
  Dogs

  Rapp: R. Breathnach

  Co-rapp: G. Kulcsár

  **For adoption**: Scientific overview and list of outstanding issues; comments on product information

### 2.3 List of questions

• **Zulvac BTV Ovis**  
  EMEA/V/C/004185/X/0001  
  Extension to add a new target animal species  
  Sheep

  Rapp: N. Garcia del Blanco

  Co-rapp: F. Klein

  **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

• **Product**  
  EMEA/V/C/004291/0000  
  New antiparasitic product  
  Cattle

  **For decision**: Request from applicant to extend clock-stop

• **Product**  
  EMEA/V/C/004611/0000  
  New vaccine  
  Sheep and cattle

  **For decision**: Request from applicant to extend clock-stop

• **Product**  
  EMEA/V/C/004375/0000  
  New product for a musculo-skeletal disorder  
  Dogs

  **For information**: Letter of withdrawal of the marketing authorisation application

### 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

#### 3.1 Opinions

• **Metacam**  
  EMEA/V/C/000033/II/0127  
  To register an additional non-food producing target species

  Rapp: F. Hasslung Wikstrom

  Co-rapp: G. Hahn

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

  **For information**: Summary of opinion
<table>
<thead>
<tr>
<th>Product Name</th>
<th>EMEA/V/C/xxxxxx/WS1195</th>
<th>Rapp: B. Urbain</th>
<th>For adoption: CVMP opinion</th>
<th>For endorsement: Rapporteur’s assessment report</th>
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<tbody>
<tr>
<td>Porcilis PCV ID</td>
<td>EMEA/V/C/003942/WS1277(0002)</td>
<td>Rapp: P. Hekman</td>
<td>For adoption: CVMP opinion, CVMP assessment report, product information</td>
<td>For information: Summary of opinion</td>
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<tr>
<td>ERAVAC</td>
<td>EMEA/V/C/004239/II/0003/G</td>
<td>Rapp: C. Muñoz</td>
<td>For adoption: CVMP opinion, CVMP assessment report, product information</td>
<td>For information: Summary of opinion</td>
</tr>
<tr>
<td>Vaxxitek HVT + IBD</td>
<td>EMEA/V/C/000065/WS1209/G</td>
<td>Rapp: B. Urbain</td>
<td>For adoption: CVMP opinion</td>
<td>For endorsement: Rapporteur’s assessment report</td>
</tr>
<tr>
<td>STARTVAC</td>
<td>EMEA/V/C/000130/II/0005</td>
<td>Rapp: E. Werner</td>
<td>For adoption: CVMP opinion, product information</td>
<td>For endorsement: Rapporteur’s assessment report</td>
</tr>
<tr>
<td>Ingelvac CircoFLEX and Ingelvac PCV FLEC</td>
<td>EMEA/V/C/xxxxxx/WS1249/G</td>
<td>Rapp: B. Urbain</td>
<td>For adoption: CVMP opinion</td>
<td>For endorsement: Rapporteur’s assessment report</td>
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<tr>
<td>Vaxxitek HVT + IBD</td>
<td>EMEA/V/C/000065/WS1242</td>
<td>Rapp: B. Urbain</td>
<td>For adoption: CVMP opinion</td>
<td>For endorsement: Rapporteur’s assessment report</td>
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### 3.2 Oral explanations and list of outstanding issues

<table>
<thead>
<tr>
<th>Product Name</th>
<th>EMEA/V/C/002011/II/0007</th>
<th>Rapp: N. Garcia del Blanco</th>
<th>For adoption: List of outstanding issues</th>
</tr>
</thead>
</table>
### 3.3 List of questions

<table>
<thead>
<tr>
<th>Issue</th>
<th>Reference</th>
<th>Summary</th>
<th>Rapp</th>
<th>Co-rapp</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTVPUR</td>
<td>EMEA/V/C/002231/II/0010</td>
<td>To add a new serotype</td>
<td>C. Muñoz</td>
<td>P. Pasquali</td>
</tr>
<tr>
<td>CLYNAV</td>
<td>EMEA/V/C/002390/II/0001/G</td>
<td>Quality</td>
<td>N. Garcia del Blanco</td>
<td></td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Issue</th>
<th>Reference</th>
<th>Summary</th>
<th>Rapp</th>
<th>Co-rapp</th>
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</thead>
<tbody>
<tr>
<td>Girolan and its associated name Apralan</td>
<td>EMEA/V/A/122 (re-examination)</td>
<td>Apramycin sulfate SPC harmonisation</td>
<td>J. G. Beechinor</td>
<td>W. Schlumbohm</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Issue</th>
<th>Reference</th>
<th>Summary</th>
<th>Rapp</th>
<th>Co-rapp</th>
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<tbody>
<tr>
<td>Veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys EMEA/V/A/089 - Follow-up assessment Efficacy (dosing regimen for E. coli)</td>
<td></td>
<td></td>
<td>H. Jukes</td>
<td>C. Muñoz</td>
</tr>
</tbody>
</table>

*For adoption: CVMP follow-up assessment report*

**For discussion and decision:** Notification from the United Kingdom under Article 35 of Directive 2001/82/EC

Appointment of rapporteur, co-rapporteur and peer reviewers

**For information:** List of products concerned
4.4 Article 78 of Directive 2001/82/EC
- No items

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

<table>
<thead>
<tr>
<th>Seresto</th>
<th>EMEA/V/A/125</th>
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<tr>
<td>Imidacloprid and flumethrin</td>
<td></td>
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<tr>
<td>Efficacy</td>
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</tr>
</tbody>
</table>

Rapp: H. Jukes
Co-rapp: G. Hahn

For adoption: CVMP opinion, CVMP 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
- No items

5.2 Post-authorisation measures and annual reassessments
- No items

5.3 Product anniversary list

<table>
<thead>
<tr>
<th>Product</th>
<th>Period</th>
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<tbody>
<tr>
<td>Bravecto (EMEA/V/C/002526)</td>
<td>11/02/2017 – 10/02/2018</td>
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<tr>
<td>Comfortis (EMEA/V/C/002233)</td>
<td>11/02/2017 – 10/02/2018</td>
</tr>
<tr>
<td>Feavaxyn Pentofel (EMEA/V/C/000030)</td>
<td>05/02/2017 – 04/02/2018</td>
</tr>
<tr>
<td>Hiprabovis IBR Marker Live (EMEA/V/C/000158)</td>
<td>27/01/2017 – 26/01/2018</td>
</tr>
<tr>
<td>Ingelvac CircoFLEX (EMEA/V/C/000126)</td>
<td>13/02/2017 – 12/02/2018</td>
</tr>
<tr>
<td>Kexxtone (EMEA/V/C/002235)</td>
<td>28/01/2017 – 27/01/2018</td>
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<tr>
<td>Loxicom (EMEA/V/C/000141)</td>
<td>10/02/2018 – 09/02/2018</td>
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<tr>
<td>NexGard (EMEA/V/C/002729)</td>
<td>11/02/2017 – 10/02/2018</td>
</tr>
<tr>
<td>Nobilis OR inac (EMEA/V/C/000062)</td>
<td>24/01/2017 – 23/01/2018</td>
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<tr>
<td>PIRSUE (EMEA/V/C/000054)</td>
<td>29/01/2017 – 28/01/2018</td>
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<tr>
<td>Semintra (EMEA/V/C/002436)</td>
<td>13/02/2017 – 12/02/2018</td>
</tr>
<tr>
<td>STARTVAC (EMEA/V/C/000130)</td>
<td>11/02/2017 – 10/02/2018</td>
</tr>
<tr>
<td>Product</td>
<td>Date Range</td>
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<tr>
<td>Stronghold Plus (EMEA/V/C/004194)</td>
<td>09/02/2017 – 08/02/2018</td>
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<tr>
<td>Suvaxyn CSF Marker (EMEA/V/C/002757)</td>
<td>10/02/2017 – 09/02/2018</td>
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<tr>
<td>VarroMed (EMEA/V/C/002723)</td>
<td>02/02/2017 – 01/02/2018</td>
</tr>
<tr>
<td>ZULVAC SBV (EMEA/V/C/002781)</td>
<td>06/02/2017 – 05/02/2018</td>
</tr>
</tbody>
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### 5.4 Renewals

- **Meloxidolor**  
  EMEA/V/C/002590/R/0007  
  Rapp: C. Muñoz  
  Co-rapp: M. Turk  
  *For adoption*: List of outstanding issues

- **ProZinc**  
  EMEA/V/C/002634/R/0013  
  Rapp: R. Breathnach  
  Co-rapp: S. Louet  
  *For adoption*: CVMP opinion, CVMP assessment report, product information

### 5.5 Pharmacovigilance - PSURs and SARs

- **Bravecto**  
  EMEA/V/C/002526  
  Rapp: G. J. Schefferlie  
  *For discussion*: Draft revised assessment report on the PSUR for the period 01.03.17 - 31.08.17

- **Versican Plus L4**  
  EMEA/V/C/003680  
  Rapp: E. Werner  
  *For adoption*: CVMP assessment report

- **Versican Plus Pi L4**  
  EMEA/V/C/003683  
  Rapp: E. Werner  
  *For adoption*: CVMP assessment report

- **Versican Plus Pi L4R**  
  EMEA/V/C/003682  
  Rapp: E. Werner  
  *For adoption*: CVMP assessment report

- **Aivlosin**  
  EMEA/V/C/000083  
  Rapp: H. Jukes  
  *For endorsement*: Rapporteur’s assessment report on the PSUR for the period 01.04.17 – 30.09.17

- **Bovela**  
  EMEA/V/C/003703  
  Rapp: F. Klein  
  *For endorsement*: Rapporteur’s evaluation of the PSUR for the period 01.01.17 - 30.06.17

- **Coliprotec F4**  
  EMEA/V/C/003797  
  Rapp: N. Garcia del Blanco  
  *For endorsement*: Rapporteur’s assessment report on the PSUR for the period 01.04.17 – 30.09.17
<table>
<thead>
<tr>
<th>Product</th>
<th>EMA/V/C/ID</th>
<th>Rapp:</th>
<th>Endorsement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Econor</td>
<td>EMEA/V/C/000042</td>
<td>H. Jukes</td>
<td>Rapporteur’s assessment report on the PSUR for the period 01.10.16 – 30.09.17</td>
</tr>
<tr>
<td>Fortekor Plus</td>
<td>EMEA/V/C/002804</td>
<td>E. Vestergaard</td>
<td>Rapporteur’s assessment report on the PSUR for the period 01.04.17 – 30.09.17</td>
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<tr>
<td>Eravac</td>
<td>EMEA/V/C/004239</td>
<td>C. Muñoz</td>
<td>Rapporteur’s evaluation of the PSUR for the period 01.04.17 – 30.09.17</td>
</tr>
<tr>
<td>Eurican Herpes</td>
<td>EMEA/V/C/000059</td>
<td>N. Garcia del Blanco</td>
<td>Rapporteur’s evaluation of the PSUR for the period 01.10.16 – 30.09.17</td>
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<tr>
<td>Proteq Flu</td>
<td>EMEA/V/C/000073</td>
<td>J.-C. Rouby</td>
<td>Rapporteur’s evaluation of the PSUR for the period 01.10.16 - 30.09.17</td>
</tr>
<tr>
<td>Proteq Flu Te</td>
<td>EMEA/V/C/000074</td>
<td>J.-C. Rouby</td>
<td>Rapporteur’s evaluation of the PSUR for the period 01.10.16 - 30.09.17</td>
</tr>
</tbody>
</table>

- **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 JMAFF proposal for advancing the work on extraneous viruses in veterinary vaccines

- **For endorsement**: EU comments on the revised concept paper proposing development of a guideline on safety evaluation of biotechnology-derived/biological products

- **For endorsement**: EU comments on draft concept paper for a VICH guideline providing guidance on the establishment and running of a basic pharmacovigilance system

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

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.

8.3 Antimicrobial resistance

Information on certain topics discussed under section 8.3 cannot be released at the present time as it is deemed to be confidential.
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

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 meetings held in December 2017 and January 2018, draft minutes of the meeting held on 18-19 January 2018; draft agenda of meeting to be held on 15-16 February 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS
• For information: Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 14 February 2018, draft agenda; draft minutes from the SPG meeting held on 8 November 2017
• For information: Verbal update on the EMA working group on operational preparedness for veterinary medicines

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 ITS WORKING PARTIES

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<th>SAWP</th>
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