Committee for Medicinal Products for Veterinary Use
Draft agenda of January 2016 meeting

Chair: Anja Holm
Vice-chair: David Murphy
19 January 2016, 09:00 – 21 January 2016, 13:00 - Room 2A

Declaration of interests
In accordance with the Agency’s revised policy and procedure on the handling of declarations of
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 Scientific
Committee members and, where relevant, experts attending the plenary meeting, as announced by
the Scientific Committee 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. CVMP delegates list of intended participation and identified conflicts of 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 19 Jan 2016  
16.00-20.00
1. **ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS**

1.1 **Opinions**
- No items

1.2 **Oral explanations and list of outstanding issues**

<table>
<thead>
<tr>
<th>Substance</th>
<th>For decision: Need for oral explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA/V/MRL/003200/EXTN/0003 Bovine tissues and milk</td>
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1.3 **List of questions**

<table>
<thead>
<tr>
<th>Substance</th>
<th>For adoption: CVMP Scientific overview and list of questions</th>
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<tbody>
<tr>
<td>EMEA/V/MRL/003639/MOD/0002 Equidae</td>
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<td>EMEA/V/MRL/004113/FULL/0001 Porcine</td>
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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**
- No items

2.3 **List of questions**

<table>
<thead>
<tr>
<th>Product</th>
<th>For adoption: Scientific overview and benefit-risk assessment and list of questions, comments on product information</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA/V/C/004239/0000 New viral vaccine Rabbits</td>
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<tr>
<td>EMEA/V/C/004202/0000 New product for psycholeptic use Dogs and cats</td>
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</tbody>
</table>
2.4 Re-examination of CVMP opinions

- **Bravecto**
  EMEA/V/C/002526/X/0005
  Extension to add a new pharmaceutical form (spot-on solution) for dogs and for a new target species (cats)
  
  **Rapp:** to be appointed
  **Co-rapp:** to be appointed

  **For decision:** Appointment of rapporteur, co-rapporteur and peer reviewers and confirmation of need of an ad-hoc expert group (AHEG) and its composition

  **For discussion:** Request for re-examination from applicant, request for an ad-hoc expert group (AHEG)

2.5 Other issues

- **For endorsement:** EPAR module scientific discussion for Velactis (EMEA/V/C/003739)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Nobilis IB4-91**
  EMEA/V/C/000036/II/0021/G
  Quality
  
  **Rapp:** A-M. Brady

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

- **Panacur AquaSol**
  EMEA/V/C/002008/II/0010
  Quality
  
  **Rapp:** G. J. Schefferlie

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

3.2 Oral explanations and list of outstanding issues

- **Draxxin**
  EMEA/V/C/000077/II/0031
  New indication
  
  **Rapp:** C. Ibrahim
  **Co-rapp:** C. Munoz Madero

  **ORAL EXPLANATION–Wednesday 20 January 2016, 2:30**

  **For discussion:** Applicant’s presentation, draft product information

3.3 List of questions

- No items

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

• No items

4.3 Article 35 of Directive 2001/82/EC

- All veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs
  EMEA/V/A/117
  Withdrawal periods
  Rapp: to be appointed
  Co-rapp: to be appointed
  For discussion and decision: Notification from Belgium under Article 35 of Directive 2001/82/EC
  Appointment of rapporteur, co-rapporteur and peer reviewers
  For information: List of products concerned

- All veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry
  EMEA/V/A/110
  Indications, dosage and withdrawal periods
  Rapp: B. Urbain
  Co-rapp: K. Baptiste
  For decision: Request from Zoetis for a 1-month delay for the submission of responses to the list of questions

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

• 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

- **Suprelorin**  
  EMEA/V/C/000109/REC/022  
  Recommendation  
  Rapp: E.-M. Vestergaard  
  Co-rapp: M. Mendes

<table>
<thead>
<tr>
<th>For adoption:</th>
<th>Rappor...</th>
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<tbody>
<tr>
<td>Rapporteur’s assessment report on the recommendation</td>
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5.3 Product anniversary list

<table>
<thead>
<tr>
<th>Product</th>
<th>Period</th>
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<tbody>
<tr>
<td>Activyl Tick Plus (EMEA/V/C/002234)</td>
<td>09/01/2015 – 08/01/2016</td>
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<tr>
<td>Bovela (EMEA/V/C/003703)</td>
<td>22/12/2014 – 21/12/2015</td>
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<tr>
<td>BTVPUR AlSap 1 (EMEA/V/C/002230)</td>
<td>17/12/2014 – 16/12/2015</td>
</tr>
<tr>
<td>BTVPUR AlSap 1-8 (EMEA/V/C/002231)</td>
<td>17/12/2014 – 16/12/2015</td>
</tr>
<tr>
<td>CORTAVANCE (EMEA/V/C/000110)</td>
<td>09/01/2015 – 08/01/2016</td>
</tr>
<tr>
<td>Gripovac 3 (EMEA/V/C/000157)</td>
<td>14/01/2015 – 13/01/2016</td>
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<tr>
<td>MELOXIDYL (EMEA/V/C/000115)</td>
<td>15/01/2015 – 14/01/2016</td>
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<tr>
<td>Metacam (EMEA/V/C/000033)</td>
<td>07/01/2015 – 06/01/2016</td>
</tr>
<tr>
<td>NEXGARD SPECTRA (EMEA/V/C/003842)</td>
<td>15/01/2015 – 14/01/2016</td>
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<tr>
<td>Onsior (EMEA/V/C/000127)</td>
<td>16/12/2014 – 15/12/2015</td>
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<tr>
<td>Porcilis PCV (EMEA/V/C/000135)</td>
<td>12/01/2015 – 11/01/2016</td>
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<tr>
<td>Prac-tic (EMEA/V/C/000103)</td>
<td>18/12/2014 – 17/12/2015</td>
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<tr>
<td>RESPIPORC FLU3 (EMEA/V/C/000153)</td>
<td>14/01/2015 – 13/01/2016</td>
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<tr>
<td>Rheumocam (EMEA/V/C/000121)</td>
<td>10/01/2015 – 09/01/2016</td>
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<tr>
<td>SevoFlo (EMEA/V/C/000072)</td>
<td>11/12/2014 – 10/12/2015</td>
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<tr>
<td>Ypozane (EMEA/V/C/000112)</td>
<td>11/01/2015 – 10/01/2016</td>
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<tr>
<td>ZULVAC 8 Bovis (EMEA/V/C/000145)</td>
<td>15/01/2015 – 14/01/2016</td>
</tr>
<tr>
<td>ZULVAC 8 Ovis (EMEA/V/C/000147)</td>
<td>15/01/2015 – 14/01/2016</td>
</tr>
</tbody>
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5.4 Renewals

- **Zuprevo**  
  EMEA/V/C/002009/R/0010  
  Rapp: C. Ibrahim  
  Co-rapp: E. Lander Persson

<table>
<thead>
<tr>
<th>For adoption:</th>
<th>Rappor...</th>
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</thead>
<tbody>
<tr>
<td>CVMP renewal assessment report, CVMP opinion, product information</td>
<td></td>
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</table>

- **CERTIFECT**  
  EMEA/VC/002002/R/0011  
  Rapp: S. Louet  
  Co-rapp: E. Lander Persson

<table>
<thead>
<tr>
<th>For adoption:</th>
<th>Rappor...</th>
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</thead>
<tbody>
<tr>
<td>CVMP list of outstanding issues</td>
<td></td>
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</tbody>
</table>
5.5 Pharmacovigilance - PSURs and SARs

<table>
<thead>
<tr>
<th>Product</th>
<th>EMEA/V/C/Number</th>
<th>Rapp</th>
<th>For adoption: CVMP assessment report on the PSUR for the period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kexxtone</td>
<td>EMEA/V/C/002235</td>
<td>C. Muñoz Madero</td>
<td>01.02.15 - 31.07.15</td>
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<tr>
<td>Nobivac L4</td>
<td>EMEA/V/C/002010</td>
<td>B. Urbain</td>
<td>CVMP assessment report on the PSUR for period 01.02.15 - 31.07.15</td>
</tr>
<tr>
<td>Profender</td>
<td>EMEA/V/C/000097</td>
<td>R. Breathnach</td>
<td>CVMP assessment report on the PSUR for the period 01.08.12 - 31.07.15</td>
</tr>
<tr>
<td>Zolvix</td>
<td>EMEA/V/C/000154</td>
<td>C. Friis</td>
<td>CVMP assessment report on the PSUR for the period 01.11.09 - 31.07.15 (targeted PSUR)</td>
</tr>
<tr>
<td>Activyl</td>
<td>EMEA/V/C/000163</td>
<td>G. J. Schefferlie</td>
<td>CVMP assessment report on the PSUR for the period 01.09.14 – 30.08.15</td>
</tr>
<tr>
<td>Bovilis BTV8</td>
<td>EMEA/V/C/000148</td>
<td>M. Tollis</td>
<td>CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15</td>
</tr>
<tr>
<td>Bravecto</td>
<td>EMEA/V/C/002526</td>
<td>G. J. Schefferlie</td>
<td>CVMP assessment report on the PSUR for the period 01.03.15 – 31.08.15</td>
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<tr>
<td>Econor</td>
<td>EMEA/V/C/000042</td>
<td>H. Jukes</td>
<td>CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15</td>
</tr>
<tr>
<td>Ingelvac CircoFLEX</td>
<td>EMEA/V/C/000126</td>
<td>M. Tollis</td>
<td>CVMP assessment report on the PSUR for the period 01.09.12 – 31.08.15</td>
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<tr>
<td>NexGard</td>
<td>EMEA/V/C/002729</td>
<td>P. Hekman</td>
<td>CVMP assessment report on the PSUR for the period 01.03.15 – 31.08.15</td>
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<tr>
<td>Nobilis IB4-91</td>
<td>EMEA/V/C/000036</td>
<td>A-M. Brady</td>
<td>CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15</td>
</tr>
</tbody>
</table>
- **Nobilis IB Primo QX**  
  EMEA/V/C/002802  
  Rapp: A-M. Brady  
  *For adoption*: CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15

- **Semintra**  
  EMEA/V/C/002436  
  Rapp: R. Breathnach  
  *For adoption*: CVMP assessment report on the PSUR for the period 01.03.15 – 31.08.15

- **ZULVAC SBV**  
  EMEA/V/C/002781  
  Rapp: A-M. Brady  
  *For adoption*: CVMP assessment report on the PSUR for the period 06.02.15 – 31.08.15

- *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*: GL30 Revision of species and breeds list
- *For discussion*: Revised draft VICH GL54 on general approach to establish an acute reference dose (ARfD); draft overview of comments received during the public consultation

#### 6.2 Codex Alimentarius

- No items

#### 6.3 Other EU bodies and international organisations

- *For information*: Summary and conclusions from the 81st Joint FAO/WHO Expert Committee on Food Additives (Residues of veterinary drugs) held in Rome on 17–26 November 2015

### 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 AHEG on the application of the 3Rs
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

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
• For discussion: Request from the Commission for an update of the 2013 advice on the impact on public health and animal health of the use of antibiotics in animals (colistin)
• For information: Verbal report on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety) meeting held on 15 December 2015

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 contain commercially confidential information

• For information: Verbal update on the first meeting of the ad hoc expert group on RD114 held on 2-3 December 2015; agenda of the meeting

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:** Agenda of the meeting to be held on 21-22 January 2016; minutes of the meeting held on 10-11 December 2015 and Chair’s presentation for November and December 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- **For discussion:** Revision of the scientific overview template guidance for immunological products
- **For discussion:** Draft public CVMP work plan for 2016
- **For discussion:** Information about the round table with stakeholders on the 10-year anniversary of the micro-, small- and medium-sized-enterprise (SME) office
- **For information:** CVMP Interested Parties’ meeting to be held on 20 April 2016: first announcement/invitation and draft minutes of previous meeting, held on 6 May 2015.

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**

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<tr>
<th></th>
<th>CVMP</th>
<th>ADVENT</th>
<th>AWP</th>
<th>ERAWP</th>
<th>EWP</th>
<th>IWP</th>
<th>PHVWP</th>
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<td>16-18</td>
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