Committee for Medicinal Products for Veterinary Use
Draft agenda of June 2015 meeting

Chair: Anja Holm
Vice-chair: David Murphy
2 June 2015, 09:00 – 4 June 2015, 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 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. 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 2 June 2015 16.00-20.00
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

<table>
<thead>
<tr>
<th>Substance</th>
<th>For adoption:</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA/V/MRL/003200/EXTN/0003 Bovine tissues and milk</td>
<td>CVMP Scientific overview and list of questions</td>
</tr>
</tbody>
</table>

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

<table>
<thead>
<tr>
<th>Product</th>
<th>For adoption:</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA/V/C/003836/0000 New cardiovascular product Dogs</td>
<td>CVMP opinion, CVMP assessment report, product information</td>
</tr>
<tr>
<td>EMEA/V/C/002723/0000 New antiparasitic product Bees</td>
<td>Scientific overview and benefit-risk assessment and list of questions, rapporteurs’ and PIQ comments on product information</td>
</tr>
<tr>
<td>EMEA/V/C/004013/0000 New vaccine Chickens</td>
<td>Scientific overview and benefit-risk assessment and list of questions, rapporteurs’ and PIQ comments on product information</td>
</tr>
</tbody>
</table>

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:</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA/V/C/002723/0000 New antiparasitic product Bees</td>
<td>Scientific overview and benefit-risk assessment and list of questions, rapporteurs’ and PIQ comments on product information</td>
</tr>
<tr>
<td>EMEA/V/C/004013/0000 New vaccine Chickens</td>
<td>Scientific overview and benefit-risk assessment and list of questions, rapporteurs’ and PIQ comments on product information</td>
</tr>
</tbody>
</table>

2.4 Re-examination of CVMP opinions

- No items
2.5 Other issues

<table>
<thead>
<tr>
<th>Product</th>
<th>For discussion:</th>
<th>For information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMEA/V/C/002804/0000 New cardiovascular product Dogs</td>
<td>Joint assessment report on responses to list of outstanding issues, draft CVMP assessment report</td>
<td>Draft product information</td>
</tr>
<tr>
<td>EMEA/V/C/003866/0000 New anti-inflammatory product Horses</td>
<td>Joint assessment report on responses to list of outstanding issues, updated SOBRA</td>
<td></td>
</tr>
</tbody>
</table>

- **For endorsement**: EPAR module 6 scientific discussion for **Sileo** (EMEA/V/C/003764/0000)
- **For endorsement**: EPAR module 6 scientific discussion for **Cerenia** (EMEA/V/C/000106/X/0023)
- **For information**: Withdrawal letter from Pfizer Limited for **ProMeris Duo** (EMEA/V/C/000108)
- **For information**: Withdrawal letter from Pfizer Limited for **ProMeris** (EMEA/V/C/000107)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

<table>
<thead>
<tr>
<th>Product</th>
<th>Rapp</th>
<th>For adoption:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingelvac CircoFLEX EMEA/V/C/000126/II/0019 To update the product information</td>
<td>M. Tollis</td>
<td>CVMP opinion, CVMP assessment report, product information</td>
</tr>
<tr>
<td>Poulvac E.Coli EMEA/V/C/002007/II/0006 To include an additional route of administration</td>
<td>E. Werner</td>
<td>CVMP opinion, CVMP assessment report, product information</td>
</tr>
<tr>
<td>COXEVAC EMEA/V/C/000155/II/0008/G Quality</td>
<td>J.-C. Rouby</td>
<td>CVMP opinion, CVMP assessment report</td>
</tr>
<tr>
<td>BTVPUR AlSap range EMEA/V/C/xxxxx/WS/0669 Quality</td>
<td>M. Tollis</td>
<td>CVMP opinion, CVMP assessment report</td>
</tr>
</tbody>
</table>

3.2 Oral explanations and list of outstanding issues

- No items
3.3 List of questions

- **Advocate**  
  EMEA/V/C/000076/II/0026/G  
  New indication for dogs and change to the local representatives  
  Rapp: M. Nevalainen  
  Co-rapp: M. Azevedo Mendes  
  **For adoption:** CVMP list of questions

- **Ingelvac CircoFLEX**  
  EMEA/V/C/000126/II/0020  
  Quality  
  Rapp: M. Tollis  
  **For adoption:** CVMP list of questions

- **STARTVAC**  
  EMEA/V/C/000130/II/0003/G  
  Quality  
  Rapp: E. Werner  
  **For adoption:** CVMP list of questions

- **ZULVAC SBV**  
  EMEA/V/C/002781/II/0002/G  
  To update the product information  
  Rapp: A.-M. Brady  
  **For adoption:** CVMP 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

- **Coglapix vakcina A.U.V. suspension for injection for pigs**  
  (Actinobacillus pleuropneumoniae strains serotype 1 and 2)  
  EMEA/V/A/109  
  Efficacy  
  Rapp: M. Tollis  
  Co-rapp: G. Kulcsár  
  **For adoption:**  
  CVMP opinion, CVMP assessment report

- **Solamocia 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys**  
  (Amoxicillin)  
  EMEA/V/A/112  
  Bioequivalence and prudent use advice  
  Rapp: to be appointed  
  Co-rapp: to be appointed  
  **For adoption:**  
  List of questions, timetable
  
  **For discussion and decision:** Notification from the United Kingdom under Article 33(4) of Directive 2001/82/EC; appointment of rapporteur, co-rapporteur and peer reviewers.

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

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

5.1 General issues

- No Items

5.2 Post-authorisation measures and annual reassessments

<table>
<thead>
<tr>
<th>Product</th>
<th>Period</th>
<th>Rapp: E. Werner</th>
<th>For adoption: Rapporteur’s assessment report</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEUCOFELIGEN FeLV/RCP EMEA/V/C/000143/REC/015</td>
<td></td>
<td>Rapp: E. Werner</td>
<td>Rapporteur’s assessment report</td>
</tr>
<tr>
<td>Coliprotec F4 EMEA/V/C/003797/ANX/001</td>
<td></td>
<td>Rapp: A.-M. Brady</td>
<td>Rapporteur’s assessment report</td>
</tr>
</tbody>
</table>

5.3 Product anniversary list

<table>
<thead>
<tr>
<th>Product</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvac (EMEA/V/C/000136)</td>
<td>11/05/2014 – 10/05/2015</td>
</tr>
<tr>
<td>Naxcel (EMEA/V/C/000079)</td>
<td>19/05/2014 – 18/05/2015</td>
</tr>
</tbody>
</table>

5.4 Renewals

<table>
<thead>
<tr>
<th>Product</th>
<th>Rapp: H. Jukes</th>
<th>Co-rapp: C. Ibrahim</th>
<th>For adoption: List of outstanding issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meloxoral EMEA/V/C/000151/R/0006</td>
<td>Rapp: H. Jukes</td>
<td>Co-rapp: C. Ibrahim</td>
<td>List of outstanding issues</td>
</tr>
<tr>
<td>Product</td>
<td>EMEA/V/C/Number/R/Number</td>
<td>Re-examination report</td>
<td>For adoption:</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------</td>
<td>-----------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>COXEVAC</td>
<td>EMEA/V/C/000155/R/0009</td>
<td>Re-examination</td>
<td>CVMP opinion,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CVMP assessment report, product information</td>
</tr>
<tr>
<td>BTVPUR AlSap 2-4</td>
<td>EMEA/V/C/000139/R/0006</td>
<td>Rapp: M. Tollis</td>
<td>CVMP opinion,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Co-rapp: J.-C Rouby</td>
<td>CVMP assessment report, product information</td>
</tr>
</tbody>
</table>

5.5 Pharmacovigilance - PSURs and SARs

<table>
<thead>
<tr>
<th>Product</th>
<th>EMEA/V/C/Number/R/Number</th>
<th>Rapp:</th>
<th>For adoption:</th>
<th>For adoption report on the PSUR for the period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activyl Tick Plus</td>
<td>EMEA/V/C/002234</td>
<td>G. J. Schefferlie</td>
<td>CVMP assessment report</td>
<td>01.08.14-31.01.15</td>
</tr>
<tr>
<td>ECOPORC SHIGA</td>
<td>EMEA/V/C/002588</td>
<td>A.-M. Brady</td>
<td>CVMP assessment report</td>
<td>01.08.14-31.01.15</td>
</tr>
<tr>
<td>Emdocam</td>
<td>EMEA/V/C/002283</td>
<td>D. Murphy</td>
<td>CVMP assessment report</td>
<td>01.03.14-28.02.15</td>
</tr>
<tr>
<td>Equilis Te</td>
<td>EMEA/V/C/000093</td>
<td>E. Werner</td>
<td>CVMP assessment report</td>
<td>01.02.14-31.01.15</td>
</tr>
<tr>
<td>Kexxtone</td>
<td>EMEA/V/C/002235</td>
<td>C. Munoz Madero</td>
<td>CVMP assessment report</td>
<td>01.08.14-31.01.15</td>
</tr>
<tr>
<td>Nobilis Influenza HSN2</td>
<td>EMEA/V/C/000118</td>
<td>A.-M. Brady</td>
<td>CVMP assessment report</td>
<td>01.03.14-28.02.15</td>
</tr>
<tr>
<td>ProZinc</td>
<td>EMEA/V/C/002634</td>
<td>R. Breathnach</td>
<td>CVMP assessment report</td>
<td>01.08.14-31.01.15</td>
</tr>
</tbody>
</table>
• **Stronghold**  
EMEA/V/C/000050  
Rapp: H. Jukes  
*For adoption*: CVMP assessment report on the PSUR for the period 01.02.12-31.01.15

• **Suprelorin**  
EMEA/V/C/000109  
Rapp: E.-M. Vestergaard  
*For adoption*: CVMP assessment report on the PSUR for the period 01.02.12-31.01.15

• **Suvaxyn PCV**  
EMEA/V/C/000149  
Rapp: B. Urbain  
*For adoption*: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15

• **Ypozane**  
EMEA/V/C/000112  
Rapp: J. G. Beechinor  
*For adoption*: CVMP assessment report on the PSUR for the period 01.02.12-31.01.15

• **ZULVAC 1 Bovis**  
EMEA/V/C/002334  
Rapp: E.-M. Vestergaard  
*For adoption*: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15

• **ZULVAC 1 Ovis**  
EMEA/V/C/002335  
Rapp: M. Tollis  
*For adoption*: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15

• **ZULVAC 8 Bovis**  
EMEA/V/C/000145  
Rapp: M. Tollis  
*For adoption*: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15

• **ZULVAC 8 Ovis**  
EMEA/V/C/000147  
Rapp: M. Tollis  
*For adoption*: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15

• **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**: Nomination of advisor to support the EU expert in relation to the review of VICH GL23 on genotoxicity testing

• **For endorsement**: VICH Anthelmintic Guidelines Task Force, EU comments on discussion paper

6.2 **Codex Alimentarius**

• No items
6.3 Other EU bodies and international organisations

- For information: Revisiting the International Estimate of Short-Term Intake (IESTI) - Joint EFSA/FAO/WHO Stakeholder Meeting and Scientific Workshop

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

- 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 antimicrobial resistance related issues cannot be released at the present time as it is deemed to be confidential

- **For discussion**: European Commission request for a joint EFSA and 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, mandate

8.4 Pharmacovigilance

- No items

8.5 Other issues

- 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. **COORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES**

- **For information**: Agenda of the meeting to be held on 4-5 June 2015; minutes of the meeting held 7-8 May 2015; presentation

12. **ORGANISATIONAL AND STRATEGIC MATTERS**

  - **For discussion**: Consultation draft of the EU Medicines Agencies Network Strategy to 2020
  - **For discussion**: Experience gained on multinational assessment teams
  - **For information**: Verbal report from the Strategic Planning Group (SPG) to be held on 3 June 2015, draft agenda, draft minutes from the meeting held on 11 March 2015

13. **LEGISLATION**

14. **ANY OTHER BUSINESS**

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

OTHER EVENTS OF INTEREST FOR CVMP OR ITS WORKING PARTIES
Assessor trainings, workshops, focus groups, presidency meetings, etc.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Place</th>
<th>Organiser</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training for assessors:</strong> Quality</td>
<td>25–26 June 2015</td>
<td>EMA</td>
<td>EMA / QWP</td>
</tr>
<tr>
<td><strong>Training for assessors:</strong> Quality Assessment of Drug Substances</td>
<td>12–13 October 2015</td>
<td>Estonia</td>
<td>State Agency of Medicines - Estonia</td>
</tr>
<tr>
<td><strong>Workshop (with industry): Lifecycle Management</strong></td>
<td>28–29 October 2015</td>
<td>EMA</td>
<td>EMA / QWP / BWP / GMDP IWG</td>
</tr>
<tr>
<td><strong>Workshop / Focus group meeting:</strong> VeDDRA</td>
<td>tbd</td>
<td>tbd</td>
<td>EMA / EWP</td>
</tr>
<tr>
<td><strong>Training for assessors:</strong> Benchmark dose approach</td>
<td>2015/ tbd</td>
<td>tbd</td>
<td>EMA / SWP</td>
</tr>
<tr>
<td><strong>Training for assessors:</strong> Microbiological ADI</td>
<td>2015/ tbd</td>
<td>tbd</td>
<td>EMA / SWP</td>
</tr>
</tbody>
</table>