3 November 2014
EMA/CVMP/675239/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

# Committee for Medicinal Products for Veterinary Use

## Draft agenda of November 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

4 November 2014, 09:00 – 6 November 2014, 13:00 - Room 2A

**Declaration on conflict of interests**

In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting are asked to declare any conflict of 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 4 Nov 2014 | 16.00-20.00 |

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## 1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

### 1.1 Opinions

| | |
|---|---|
| • **Substance**<br>EMEA/V/MRL/003225/MODF/0002<br>*Bovine* | ***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report |
| • **Substance**<br>EMEA/V/MRL/004039/FULL/0001<br>*All food producing species* | ***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report |
| • **Substance**<br>EMEA/V/MRL/003878/FULL/0001<br>*Chicken* | ***For adoption****:*<br>Draft CVMP opinion,<br>Draft CVMP assessment report |

### 1.2 Oral explanations and list of outstanding issues

- No items

### 1.3 List of questions

| | |
|---|---|
| • **Substance**<br>EMEA/V/MRL/004047/FULL/0001<br>*Caprine species, Equidae, fin fish & rabbits* | ***For adoption***:<br>Draft CVMP scientific overview and list of questions<br>***For discussion***:<br>Revised rapporteur's assessment report; revised rapporteur's scientific overview and list of questions; peer reviewer's report; peer reviewer's report, comment |
| • **Substance**<br>EMEA/V/MRL/003135/MODF/0003<br>*Salmonidae* | ***For discussion****:*<br>Report from a meeting held on 15 October 2014 between EMA/CVMP, ECHA and EFSA |

### 1.4 Re-examination of CVMP opinions

| | |
|---|---|
| • **Substance**<br>EMEA/V/MRL/003044/EXTN/0005<br>*Eggs* | ***For adoption****:*<br>Draft revised CVMP opinion |

### 1.5 Other issues

- No items

## 2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

### 2.1 Opinions

| | |
|---|---|
| • **Product**<br>EMEA/V/C/003842/0000<br>*New antiparasitic product*<br>*Dogs* | ***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report,<br>Draft product information |

## 2.2 Oral explanations and list of outstanding issues

| | |
|---|---|
| • **Metacam**<br>EMEA/V/C/000033/X/0107<br>*Extension to include a new strength*<br>*Cattle and horses* | Rapp: F. Hasslung-Wikström<br><br>Co-rapp: C. Ibrahim<br><br>***For decision****:*<br>Need for an oral explanation<br><br>***For adoption:***<br>Scientific overview and benefit-risk assessment and list of outstanding issues<br><br>***For discussion***:<br>Draft product information |
| • **Product**<br>EMEA/V/C/002781/0000<br>*New viral vaccine*<br>*Sheep, cattle* | **ORAL EXPLANATION**<br><br>***For discussion***:<br>Applicant's presentation; draft product information with rapporteurs' comments; rapporteurs' assessment of the responses to the list of outstanding issues*;* draft CVMP assessment report |
| • **Product**<br>EMEA/V/C/002794/0000)<br>*New haematological product*<br>*Dogs* | **ORAL EXPLANATION**<br><br>***For discussion:***<br>Applicant's presentation; draft product information with co-rapporteur's comments; rapporteurs' assessment of the responses to the list of outstanding issues |
| • **Product**<br>EMEA/V/C/002757/000<br>*New viral vaccine*<br>*Pigs* | ***For discussion***:<br>Scientific overview and benefit-risk assessment updated after responses to second list of outstanding issues; rapporteurs' assessment of the responses to the second list of outstanding issues, draft product information with rapporteurs' comments |

## 2.3 List of questions

- No items

## 2.4 Re-examination of CVMP opinions

- No items

## 2.5 Other issues

- ***For endorsement:***
  Draft EPAR module 6 scientific discussion for **Porcilis PCV M Hyo** (EMEA/V/C/003796/0000)

## 3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

### 3.1 Opinions

| | |
|---|---|
| • **ZULVAC 1 Bovis, ZULVAC 8 Bovis, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 8 Ovis, ZULVAC 1+8 Ovis**<br>EMEA/V/C/XXXXXX/WS/0597<br>*Quality* | Rapp: M. Tollis<br>***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report |
| • **Purevax RCPCh FeLV; Purevax FeLV and Purevax RCP FeLV**<br>(EMEA/V/C/xxxxxx/WS/0608)<br>*Quality* | Rapp: B. Urbain<br>***For adoption****:*<br>Draft CVMP opinion,<br>Draft CVMP assessment report |

### 3.2 Oral explanations and list of outstanding issues

| | |
|---|---|
| • **NexGard**<br>EMEA/V/C/002729/II/0001<br>*To change the SPC and the package leaflet due to new clinical data* | Rapp: P. Hekman<br>Co-rapp: D. Murphy<br>***For discussion****:*<br>Need for an oral explanation<br>***For adoption***:<br>Draft list of outstanding issues |

### 3.3 List of questions

| | |
|---|---|
| • **Acticam**<br>EMEA/V/C/000138/II/0014<br>*Quality* | Rapp: J. G. Beechinor<br>***For adoption****:*<br>Draft 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)*<br>EMEA/V/A/109<br>*Efficacy* | Rapp: *to be appointed*<br>Co-rapp: *to be appointed*<br>***For adoption***:<br>List of questions,<br>Timetable<br>***For discussion and decision***:<br>Notification from Hungary under Article 33(4) of Directive 2001/82/EC; discussion document<br>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

| | |
|---|---|
| • **All veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses**<br>EMEA/V/A/104<br>*Indications, dosage and target animal safety* | Rapp: K. Baptiste<br>Co-rapp: C. Muñoz Madero<br>***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report |
| • **All veterinary medicinal products containing colistin to be administered orally**<br>EMEA/V/A/106<br>*Indications, prudent use warnings* | Rapp: C. Ibrahim<br>Co-rapp: M. Holzhauser-Alberti<br>***For discussion***:<br>Draft CVMP assessment report |

### 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

| | |
|---|---|
| • **Diclofenac**<br>EMEA/V/A/107<br>*Risk to vultures and other necrophagous birds* | Rapp: B. Kolar<br>Co-rapps: C. Rubio Montejano, J. Schefferlie, M. Holzhauser-Alberti<br>**PRESENTATIONS BY STAKEHOLDERS**<br>***For discussion***:<br>Joint rapporteur's assessment report; presentations by stakeholders |

### 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

| | |
|---|---|
| • **COXEVAC**<br>EMEA/V/C/000155/S/0007<br>*Annual reassessment* | Rapp: J.-C. Rouby<br>***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report,<br>Product information |
| • **BLUEVAC BTV8**<br>EMEA/V/C/000156/S/0003<br>*Annual reassessment* | Rapp: E. Werner<br>***For adoption***:<br>Draft CVMP opinion,<br>Draft CVMP assessment report,<br>Product information |
| • **Loxicom**<br>EMEA/V/C/000141 | Rapp: D. Murphy<br>Co-rapp: S. Srčič<br>***For adoption***:<br>Rapporteur's recommendation assessment report |
| • **Suvaxyn PCV**<br>EMEA/V/C/000149 | Rapp: B. Urbain<br>***For endorsement***:<br>Rapporteur's recommendation assessment report |

### 5.3 Product anniversary list

| Product | Period |
|---|---|
| BTVPUR AlSap 2-4 (EMEA/V/C/000139) | 05.11.2013 – 04.11.2014 |
| HALOCUR (EMEA/V/C/000040) | 29.10.2013 – 28.10.2014 |

### 5.4 Renewals

- No items

### 5.5 Pharmacovigilance - PSURs and SARs

| | |
|---|---|
| • **Acticam**<br>EMEA/V/C/000138 | Rapp: J. G. Beechinor<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.07.13-30.06.14 |
| • **BTVPUR AlSap 1**<br>EMEA/V/C/002230 | Rapp: C. Muñoz Madero<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **BTVPUR AlSap 1-8**<br>EMEA/V/C/002231 | Rapp: C. Muñoz Madero<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **Cardalis**<br>EMEA/V/C/002524 | Rapp: H. Jukes<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.02.14-31.07.14 |
| • **Cerenia**<br>EMEA/V/C/000106 | Rapp: C. Friis<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **Contacera**<br>EMEA/V/C/002612 | Rapp: M. Holzhauser-Alberti<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **Equilis Prequenza**<br>EMEA/V/C/000094 | Rapp: E. Werner<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.02.14-31.07.14 |

| | |
|---|---|
| • **Equilis Prequenza Te**<br>EMEA/V/C/000095 | Rapp: E. Werner<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.02.14-31.07.14 |
| • **Hiprabovis IBR Marker Live**<br>EMEA/V/C/000158 | Rapp: A.-M. Brady<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.08.13-31.07.14 |
| • **Inflacam**<br>EMEA/V/C/002497 | Rapp: M. Holzhauser-Alberti<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **LEUCOFELIGEN FeLV/RCP**<br>EMEA/V/C/000143 | Rapp: E. Werner<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.07.13-30.06.14 |
| • **MELOXIDYL**<br>EMEA/V/C/000115 | Rapp: F. Hasslung-Wikström<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.08.11-31.07.14 |
| • **Panacur AquaSol**<br>EMEA/V/C/002008 | Rapp: J. Schefferlie<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **Porcilis ColiClos**<br>EMEA/V/C/002011 | Rapp: A.-M. Brady<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **Poulvac E. coli**<br>EMEA/V/C/002007 | Rapp: E. Werner<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |
| • **Prac-tic**<br>EMEA/V/C/000103 | Rapp: C. Muñoz Madero<br>***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-30.06.14 |
| • **ProZinc**<br>EMEA/V/C/002634 | Rapp: R. Breathnach<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.02.14-31.07.14 |

| | |
|---|---|
| • **Trifexis**<br>EMEA/V/C/002635 | Rapp: C. Ibrahim<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 05.01.14-04.07.14 |
| • **TruScient**<br>EMEA/V/C/002000 | Rapp: R. Breathnach<br>***For adoption***:<br>CVMP assessment report on the PSUR for the period 01.01.14-30.06.14 |

- ***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 Expert working group on metabolism and residue kinetics: draft revision of VICH GL48 on Marker residue depletion studies for formal adoption for sign-off by EU members of Steering Committee at step 6; VICH GL49 on Method used in Residue Depletion Studies for formal adoption for sign-off by EU members of Steering Committee at step 6
- ***For endorsement***: VICH Task Force on the revision of anthelmintic guidelines: EU comments on topic 4 (dose determination)
- ***For endorsement***: VICH Expert working group on electronic exchange of documents: draft guideline on electronic file formats (EFF) at step 5
- ***For information***: Corrected version of Draft 3 of VICH Guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use; overview of comments received on draft VICH Guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use – corrected version
- ***For adoption***: VICH GL23(R) on Safety: genotoxicity testing for formal adoption for publication and implementation at step 7

### 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

- ***To note***: Australian Pesticides and Veterinary Medicines Authority (APVMA): draft report on regulatory considerations for nanopesticides and veterinary nanomedicines; information leaflet on nanotechnology regulation symposium
- ***For information***: Update on the draft EFSA CONTAM Opinion on Reference Points for Action for chloramphenicol

## 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 (ADVENT) 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 discussion***: Document relating to the need for MRL applications for biological substances already present in food

### 8.2 Environmental risk assessment

- No items

### 8.3 Antimicrobial resistance

- ***For information***: Overview of comments received on answers to the request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals

### 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*

- 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 adoption:*** Concept paper for the revision of the MUMS guidelines
- ***For adoption:*** Guidance for MUMS classification, policy, and comments from IFAH Europe

## 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 6-7 November 2014; minutes of the meeting held on 9-10 October 2014; CMDv October 2014 report to CVMP

## 12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** CVMP implementation of multinational assessment teams: Appointment and responsibilities of rapporteur and co-rapporteur for procedures regarding veterinary medicinal products – revised draft; table to declare potential interest in participating in a multinational assessment team and the expertise available per National Competent Authority
- ***For information:*** Draft minutes of the CVMP Interested Parties Meeting, held on 7th May 2014
- ***For information:*** Update on revised EMA policy on conflicts of interest

## 13. LEGISLATION

- No items

## 14. ANY OTHER BUSINESS

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

## ANNEX

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

| | CVMP | AWP | ERAWP | EWP | IWP | PhVWP | QWP | SAWP | SWP |
|---|---|---|---|---|---|---|---|---|---|
| **November** | 4-6 | 18-19 | | 25-26 | | 18-19 | | 4 | 27-28 |
| **December** | 9-11 | | | | | | 3-5 | 9 | |
| **Jan 2015** | 13-15 | 20-21 | | | | 27-28 | | 13 | |
| **Feb 2015** | 10-12 | | | 3-4 | | | | 10 | 19-20 |