9 February 2015
EMA/CVMP/89183/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

10 February 2015, 09:00 – 12 February 2015, 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 10 Feb 2015	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003307/EXTN/0003 *Extension to poultry*	**Background note**: N/a ***For adoption**:* CVMP opinion, CVMP assessment report ***For information***: summary opinion

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003923/FULL/0001 *Honey*	***For decision***: Need for an oral explanation ***For discussion***: Rapporteurs' assessment of the responses to the list of questions, rapporteur's EPMAR, peer reviewer's reports, comments

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

• **Substance** EMEA/V/MRL/003915/FULL/0001 *Bovine species*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision:*** Appointment of new rapporteurs ***For discussion**:* Request for re-examination from the applicant

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Metacam** EMEA/V/C/000033/X/0107 *Extension to include a new strength* *Cattle and horses*	***For adoption***: CVMP opinion, CVMP assessment report, product information

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/003764/0000 *Product for psycholeptic use* *Dogs*	***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/003924/0000 *New viral and bacterial vaccine* *Pigs*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on draft product information

2.4 Re-examination of CVMP opinions

• **Product** EMEA/V/C/003786/0000 *New cardiovascular product* *Cats*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision**:* Request for re-examination – appointment of rapporteur, co-rapporteur and peer reviewers and confirmation of need for an Ad Hoc Expert Group ***For discussion**:* Request for re-examination from applicant

2.5 Other issues

• **Product** EMEA/V/C/003782 *New corticosteroid product* *Dogs*	***For decision***: Letter from applicant requesting an extension to the clock stop
• **Product** EMEA/V/C/002804 *New cardiovascular product* *Dogs*	***For information:*** Letter from applicant requesting an extension to the clock stop

- ***For endorsement:*** EPAR module 6 scientific discussion for **Bovela** (EMEA/V/C/003703/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **ZULVAC SBV** (EMEA/V/C/002781/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **Stronghold** (EMEA/V/C/000050/X/0051/G)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Suvaxyn PCV** EMEA/V/C/000149/II/0017/G *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report

• **NexGard** EMEA/V/C/002729/II/0001 *To change the SPC and the package leaflet*	Rapp: P. Hekman Co-rapp: D. Murphy ***For adoption***: CVMP opinion, CVMP assessment report
• **Zuprevo** EMEA/V/C/002009/II/0006/G *To add a new therapeutic indication and to delete a precautionary statement*	Rapp: C. Ibrahim Co-rapp: E. Lander Persson ***For adoption:*** CVMP opinion, CVMP assessment report
• **Novem; Metacam** EMEA/V/C/xxxxxx/WS/0667 *Quality*	Rapp: F. Hasslung Wikström ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Nobivac L4** EMEA/V/C/002010/II/0003 *To change the SPC and the package leaflet*	Rapp: B. Urbain ***For adoption****:* List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **DRAXXIN** EMEA/V/C/0000077/II/0031 *To add a new indication*	Rapp: C. Ibrahim Co-rapp: C. Munoz ***For discussion****:* Request from Zoetis Belgium SA to extend the clock-stop period
• **Trifexis** EMEA/V/C/002635/IB/0006 *To change the SPC and the package leaflet*	Rapp: C. Ibrahim ***For discussion****:* Rapporteur's assessment report

4 REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

• **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** *(zinc oxide)* EMEA/V/A/108 *ERA*	Rapp: P. Hekman Co-rapp: H. Jukes ***For decision***: Need for outstanding issues ***For decision***: Applicant's request to provide an oral explanation ***For discussion***: Rapporteur's assessment report, co-rapporteur's assessment report

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

• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For discussion***: Rapporteur's assessment report

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

• **Porcilis ColiClos** EMEA/V/C/002011/ANX002, REC012 *Condition listed in Annex II*	Rapp: A.-M. Brady Co-rapp: E. Werner ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

The following 14 items are for silent endorsement

Product	**Period**
Bravecto (EMEA/V/C/002526)	11/02/2014 – 10/02/2015
Comfortis (EMEA/V/C/002233)	11/02/2014 – 10/02/2015
Dicural (EMEA/VC/000031)	16/01/2014 – 15/01/2015
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2014 – 04/02/2015
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2014 – 26/01/2015
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2014 – 12/02/2015
Kexxtone (EMEA/V/C/002235)	28/01/2014 – 27/01/2015
Loxicom (EMEA/V/C/000141)	10/02/2014 – 09/02/2015
NexGard (EMEA/V/C/002729)	11/02/2014 – 10/02/2015
Nobilis OR inac (EMEA/V/C/000062)	24/01/2014 – 23/01/2015
PIRSUE (EMEA/V/C/000054)	29/01/2014 – 28/01/2015
STARTVAC (EMEA/V/C/000130)	11/02/2014 – 10/02/2015
Slentrol (EMEA/V/C/000116) – MA withdrawn	13/04/2014 – 15/01/2015
TruScient (EMEA/V/C/002000) – MA withdrawn	14/12/2014 – 15/01/2015

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- ***For information:*** Trifexis - progress update report and cover letter for the post-authorisation study, cover letter

• **Aivlosin** EMEA/V/C/000083	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09.14

• **CaniLeish** EMEA/V/C/002232	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13-30.09.14
• **Comfortis** EMEA/V/C/002233	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09.14
• **Econor** EMEA/V/C/000042	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09.14
• **Meloxidolor** EMEA/V/C/002590	Rapp: C. Munoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 22.04.14-22.10.14
• **Previcox** EMEA/V/C/000082	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.11-30.09.14
• **ProteqFlu** EMEA/V/C/000073	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-30.09.14
• **ProteqFlu-Te** EMEA/V/C/000074	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-30.09.14
• **Recocam** EMEA/V/C/002247	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09.14
• **ZULVAC 1+8 Bovis** EMEA/V/C/002473	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09.14

• **ZULVAC 1+8 Ovis** EMEA/V/C/002251	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.14-30.09-14

- ***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 endorsement:*** VICH Expert Working Group on Electronic File Formats (EFF): VICH guideline 53 on electronic exchange of documents: electronic file formats, to be signed off by the VICH Steering Committee at step 6 for implementation at step 7
- ***For endorsement:*** VICH Task Force on the revision of anthelmintic guidelines: draft EU comments on topics 5 and 6
- ***To note:*** VICH Steering Committee to be held on 23-26 February 2015 in Washington DC, USA; meeting documents:
  - Draft agenda;
  - VICH draft phase IV strategy;
  - Review of VICH GLs at step 9;
  - Report from VICH Quality Expert Working Group;
  - Report from VICH Electronic Standards Implementation Expert Working Group;
  - Report from VICH Biologicals Quality Monitoring Expert Working Group;
  - Report from VICH Safety Expert Working Group;
  - Report from VICH Electronic File Formats Working Group;
  - Revised concept paper for the revision of VICH GL03 (Quality) Stability: Stability Testing of New Veterinary Drug Substances and Medicinal Products; to add climatic zones III and IV and annex;
  - Revised discussion document from industry on the revision of the VICH Pharmacovigilance guidelines;
  - Progress report from VICH Task Force combination products.
- ***For adoption***: VICH guideline 48(R) on studies to evaluate the metabolism and residues kinetics of veterinary drugs in human food-producing animals: market residue depletion studies to establish product withdrawal periods; revision at step 9 – for formal adoption for publication and implementation at step 7
- ***For adoption***: VICH guideline 49(R) on studies to evaluate the metabolism and residues kinetics of veterinary drugs in human food-producing animals: validation of analytical methods used in residue depletion studies; revision at step 9 – for formal adoption for publication and implementation at step 7

6.2 Codex Alimentarius

- No items

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)

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 discussion***: Request for inclusion of substance in the list of substances not falling within the scope of Regulation (EC) No 470/2009;
- ***For discussion***: Request for inclusion of substance in the list of substances 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

- No items

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

- ***For endorsement***: 5th Annual Report Veterinary MUMS/limited market

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

- ***For decision***: Transfer of (co-)rapporteurships from I. Happonen and K. Lehmann to M. Nevalainen

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 12-13 February 2015; minutes of the meeting held 15-16 January 2015; presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision and adoption***: CVMP implementation of multinational assessment teams
- ***For discussion***: Discussion of format and/or timing of future CVMP Interested Parties' meetings
- ***For discussion***: EMA-HMA Road Map 2016-2020; procedure and timelines for CVMP comments
- ***For information***: EMA/IFAH-Europe Info Day 2015 to be held on 12-13 March 2015 at the EMA, draft programme
- ***For information***: Informal CVMP and Joint CVMP/CMDv meetings to be held on 21-22 September 2015 in Luxembourg

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
Feb 2015	10-12			3-4			3–5	10	19-20
Mar. 2015	10-12				26-27	24-25		10	
April 2015	8-10							8	
May 2015	5-7	12-13		19-20		26-27	26–28	5	21-22
June 2015	2-4		16-17		17-18	30 Jun-1 Jul		2	
July 2015	7-9							7	