10 June 2016
EMA/CVMP/406999/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of June 2016 meeting

Chair: to be elected

Vice-chair: David Murphy

14 June 2016, 09:00 – 16 June 2016, 13:00 - Room 3A

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 3A)	Tue 14 June 2016	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/004113/FULL/0001 *Porcine*	***For decision**:* Request to extend the deadline for submission of responses to list of questions
• **Substance** EMEA/V/MRL/004321/FULL/0001 *All food producing species*	***For decision**:* Request to extend the deadline for submission of responses to list of questions

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004202/0000 *New product for psycholeptic use* *Dogs and cats*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion
• **Metacam** EMEA/V/C/000033/X/119 *Extension to add a new route for the 40mg/ml solution for injection* *Cattle and horses*	Rapp: F. Hasslung Wikström Co-rapp: C. Friis ***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/0004201/0000 *New antiparasitic* *Cattle*	***For decision***: Need for oral explanation ***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/004194/0000 *New antiparasitic product* *Cats*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/004293/0000 *New analgesic product* *Cats*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/004222/0000 *New anti-inflammatory product* *Dogs*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/003939/0000 *New dermatological product* *Dogs*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **DRAXXIN** EMEA/V/C/000077/X/0029 *Extension to add a new target species* *Cattle, pigs*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion**:* Request for re-examination from applicant, request for an ad-hoc expert group (AHEG) ***For decision**:* Appointment of rapporteur, co-rapporteur and peer reviewers and confirmation of need of an AHEG and its composition

2.5 Other issues

- ***For endorsement*:** EPAR module scientific discussion for Bravecto (EMEA/V/C/002526/X/0005)
- ***For endorsement*:** EPAR module scientific discussion for Sevocalm (EMEA/V/C/004199/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- No items

3.2 Oral explanations and list of outstanding issues

• **Trifexis** EMEA/V/C/002635/II/0008 *To add a new therapeutic indication*	Rapp: C. Ibrahim Co-rapp: T. Høy ***For adoption**:* List of outstanding issues

3.3 List of questions

• **Activyl Tick Plus** EMEA/V/C/002234/II/0008 *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: List of questions
• **Bravecto** EMEA/V/C/002526/II/0011 *To add wording to the SPC*	Rapp: G. J. Schefferlie ***For adoption:*** List of questions
• **Draxxin** EMEA/V/C/000077/II/0035 *To add wording to the SPC*	Rapp: C. Ibrahim ***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

• **Denagard 45% and associated names** EMEA/V/A/114 *Tiamulin hydrogen fumarate* *SPC harmonisation*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique, draft product information

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** EMEA/V/A/116 *Environmental risk assessment*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

• **Veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** EMEA/V/A/117 *Withdrawal periods*	Rapp: B. Urbain Co-rapp: H. Jukes ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

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

- No items

5.3 Product anniversary list

Product	Period
Equilis West Nile (EMEA/V/C/002241)	06/06/2015 – 05/06/2016
Vectra Felis (EMEA/V/C/002746)	06/06/2015 – 05/06/2016
Nobilis IB 4-91 (EMEA/V/C/000036)	09/06/2015 – 08/06/2016
Porcilis Pesti (EMEA/V/C/000046)	09/06/2015 – 08/06/2016
Sileo (EMEA/V/C/003764)	10/06/2015 – 09/06/2016
MS-H Vaccine (EMEA/V/C/000161)	14/06/2015 – 13/06/2016
Porcilis ColiClos (EMEA/V/C/002011)	14/06/2015 – 13/06/2016
Poulvac E. coli (EMEA/V/C/002007)	15/06/2015 – 14/06/2016

5.4 Renewals

• **Panacur AquaSol** EMEA/V/C/002008/R/0011	Rapp: G. J. Schefferlie Co-rapp: T. Høy ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- ***For adoption:*** CVMP assessment report of the final study results on post-authorisation safety study (PASS) for **Trifexis** (EMEA/V/C/002635)
- ***For decision:*** Letter from the marketing authorisation holder regarding adverse events reported for **Velactis** (EMEA/V/C/003739)

• **Broadline** EMEA/V/C/002700	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-31.12.15
• **Cardalis** EMEA/V/C/002524	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15-31.01.16
• **Emdocam** EMEA/V/C/002283	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16
• **Equisolon** EMEA/V/C/002382	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 13.09.15-12.03.16
• **ERYSENG** EMEA/V/C/002761	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **ERYSENG PARVO** EMEA/V/C/002762	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **Innovax ILT** EMEA/V/C/003869	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 03.07.15-31.01.16
• **Locatim** EMEA/V/C/000041	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.13-31.12.15

• **Melosus** EMEA/V/C/002001	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16
• **NexGard Spectra** EMEA/V/C/003842	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **Nobilis Influenza H5N2** EMEA/V/C/000118	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16
• **Nobivac L4 & Canigen L4** EMEA/V/C/002010 EMEA/V/C/004079	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 03.07.15-31.01.16
• **Nobivac Myxo RHD** EMEA/V/C/002004	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-31.03.16
• **RevitaCam** EMEA/V/C/002379	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.15-29.02.16
• **Versican Plus DHPPi** EMEA/V/C/003679	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **Versican Plus L4** EMEA/V/C/003680	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **Versican Plus Pi/L4** EMEA/V/C/003683	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.01.16
• **ZACTRAN** EMEA/V/C/000129	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.13-31.01.16
• **ZULVAC 1 Bovis** EMEA/V/C/002334	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16
• **ZULVAC SBV** EMEA/V/C/002781	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.15-29.02.15

- ***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***: Draft EU comments on the concept paper on the need to elaborate on the next steps in the global approach to demonstrate bioequivalence
- ***For endorsement***: Draft EU comments on the concept paper for a general combination products guideline
- ***For endorsement***: Draft EU comments on the proposed draft annex for climatic zones III and IV to the VICH GL3(R) on stability: stability testing of new veterinary drug substances and medicinal products
- ***For endorsement***: Draft VICH guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, to be forwarded to the expert working group for sign off at Step 2
- ***For discussion***: Draft VICH guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species
- ***For information***: 33rd VICH Steering Committee meeting to be held on 20-23 June 2016 in Brussels:
  - Draft agenda;
  - Draft minutes of the 32nd VICH Steering Committee;
  - Update from the Secretariat on the VICH GLs which have passed the 5 years of implementation;
  - Progress report from the Electronic standards implementation Expert Working Group;
  - Progress report from VICH Quality Expert Working Group;
  - Progress report from VICH Biologicals Quality Monitoring Expert Working Group;
  - Progress report from VICH Metabolism and Residue Kinetics Expert Working Group;
  - Progress report from VICH Safety Expert Working Group products TF;
  - Progress report from VICH Anthelmintics Expert Working Group;
  - Progress report from VICH Combination products Task Force.

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)

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

- No items

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

- ***For decision:*** Overview of comments received during the public consultation on the draft reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances (EMA/CVMP/448211/2015)

8.3 Antimicrobial resistance

- ***For information:*** Verbal report on the Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) teleconference held on 23 May 2016
- ***For information:*** Publication for consultation of the updated opinion of the Expert Advisory Group on Antibiotic Resistance (AMEG) on the use of colistin products in animals within the European Union; press release link
- ***For information:*** Verbal report on the 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA)

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 report on simulation exercise for incident management plan for medicines for veterinary use

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

- ***For decision:*** Transfer of rapporteurships

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***: Draft agenda of the meeting to be held on 16-17 June 2016, draft minutes of the meeting held on 19-20 May 2016

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision:*** Election of the Chair of CVMP (3-year term) at the June 2016 CVMP meeting; nomination for D. Murphy
- ***For discussion:*** Verbal report from the secretariat on the survey for appointment of rapporteurs for CVMP procedures
- ***For endorsement:*** Revision of procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC
- ***For discussion and adoption***: CVMP/CMDv Presidency meeting to be held on 27-28 June 2016 in the Netherlands; draft agenda
- ***For discussion***: Revised VNeeS format requirements guideline coming into force on 1 July 2016 – revision of Exceptions to VNeeS format-document
- ***For information***: Verbal update on report to Management Board on performance of the Agency's scientific procedures (2015) to be presented on 16 June 2016

- ***For information***: Verbal update on Scientific Co-ordination Board meeting held on 10 June 2016; agenda of the meeting
- ***For information***: Council Decision of 29 May 2016 on the appointment of four Management Board members, including veterinary representative
- ***For information***: Revision of the documents on dossier submission requirements to commence following the June 2016 CVMP plenary

13. LEGISLATION

- ***For information***: Update on development of CVMP recommendations for methodological principles for the risk assessment and risk management recommendations

14. ANY OTHER BUSINESS

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

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
Jun 2016	14-16			21-22	1	29-30		1-2	14		
Jul 2016	12-14						5/6		12		
Sep 2016	6-8		22-23		13-14			19-21	6	22-23	
Oct 2016	4-6			11-12					4		
Nov 2016	8-10				29-30			29-30	8	24-25	
Dec 2016	6-8							1	6		