5 December 2016
EMA/CVMP/811922/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 6-8 December 2016 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

6 December 2016, 09:00 – 8 December 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 competing 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 6 Dec 2016	16.30-20.00

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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/004333/FULL/0001 *Bovine species*	***For decision**:* Request to re-schedule the oral explanation
• **Substance** EMEA/V/MRL/004113/FULL/0001 *Porcine species*	***For decision**:* Request to further extend the deadline for submission of responses to list of questions

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **EQUIOXX** EMEA/V/C/000142/X/0015 *Extension to add a new pharmaceutical form* *Horses*	Rapp: J. G. Beechinor Co-rapp: M. Azevedo Mendes ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion
• **Product** EMEA/V/C/004194/0000 *New antiparasitic product* *Cats*	***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion
• **Product** EMEA/V/C/003993/0000 *New vaccine* *Pigs*	***For adoption**:* CVMP opinion, CVMP assessment report ***For information**:* Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004247/0000 New antiparasitic product *Dogs*	***For decision***: Need for oral explanation ***For adoption**:* Scientific overview and list of outstanding issues, comments on product information

• **Product** EMEA/V/C/004099/0000 *New product for a respiratory condition* *Cattle*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/003939/0000 *New product for a dermatological condition* *Dogs*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/002836/0000 *New antiparasitic product* *Honey bees*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004344/0000 *New antiparasitic product* *Chicken*	***For adoption****:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/004222/0000 *New anti-inflammatory product* *Dogs*	***For decision****:* Request from applicant to extend the clock-stop

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Aivlosin** EMEA/V/C/000083/II/0067/G *Quality*	Rapp: H. Jukes ***For adoption***: CVMP opinion, CVMP assessment report
• **Broadline** EMEA/V/C/002700/II/0011 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report, product information

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **ProZinc** EMEA/V/C/002634/II/0010/G *Quality*	Rapp: R. Breathnach ***For adoption**:* List of questions
• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0004/G *Quality*	Rapp: B. Urbain ***For adoption**:* List of questions
• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0005/G *Quality*	Rapp: B. Urbain ***For adoption**:* List of questions
• **Broadline** EMEA/V/C/002700/II/0013 *To add a new therapeutic indication*	Rapp: B. Urbain Co-rapp: C. Munoz Madero ***For adoption***: List of questions
• **BTVPUR** EMEA/V/C/002231/II/0008/G *Quality*	Rapp: C. Munoz Madero ***For adoption***: List of questions

3.4 Re-examination of CVMP opinions

• **Trifexis** EMEA/V/C/002635/II/0008 *To add a new therapeutic indication associated with* Angiostrongylus vasorum *and to extend the treatment duration to infinite treatment*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision***: Appointment of rapporteur, co-rapporteur and peer reviewers; composition of Ad-Hoc Expert Group (AHEG) ***For discussion***: Request for re-examination and involvement of an AHEG from Eli Lilly and Company

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

• **Girolan and its associated name Apralan** EMEA/V/A/122 *Apramycin sulfate* *SPC harmonisation*	Rapp: C. Muñoz Madero Co-rapp: B. Urbain ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report with co-rapporteur's critique and draft product information

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing zinc oxide to be administered orally to food producing species** EMEA/V/A/118 *ERA and antimicrobial resistance*	Rapp: G. J. Schefferlie Co-rapp: J. Weeks ***For decision***: CVMP response to letter from aniMedica GmbH ***For adoption***: CVMP opinion, CVMP assessment report
• **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 further outstanding issues ***For discussion***: Rapporteur's revised 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

• **FORTEKOR PLUS** EMEA/V/C/002804/REC/008,009	Rapp: E.-M. Vestergaard Co-rapp: C. Muñoz Madero ***For adoption***: Rapporteur's assessment report
• **ZOLVIX** EMEA/V/C/000154/REC/012	Rapp: E.-M. Vestergaard Co-rapp: G. J. Schefferlie ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
DRAXXIN (EMEA/V/C/000077)	11/11/2015 – 10/11/2016
Meloxivet (EMEA/V/C/000124)	14/11/2015 – 13/11/2016
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2015 – 15/11/2016
Masivet (EMEA/V/C/000128)	17/11/2015 – 16/11/2016
Meloxoral (EMEA/V/C/000151)	19/11/2015 – 18/11/2016
Easotic (EMEA/V/C/000140)	20/11/2015 – 19/11/2016
Equip WNV (EMEA/V/C/000137)	21/11/2015 – 20/11/2016
Stronghold (EMEA/V/C/000050)	25/11/2015 – 24/11/2016
Oxyglobin (EMEA/V/C/000045)	29/11/2015 – 28/11/2016
Broadline (EMEA/V/C/002700)	04/12/2015 – 03/12/2016
Quadrisol (EMEA/V/C/000032)	04/12/2015 – 03/12/2016
Vectra 3D (EMEA/V/C/002555)	04/12/2015 – 02/12/2016
Contacera (EMEA/V/C/002612)	06/12/2015 – 05/12/2016

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For discussion***: Rapporteur's assessment report on the PSUR for the period 01.03.16-31.08.16
• **Easotic** EMEA/V/C/000140	Rapp: E-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.13-31.05.16
• **ECOPORC SHIGA** EMEA/V/C/002588	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.07.16
• **ERYSENG** EMEA/V/C/002761	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **ERYSENG PARVO** EMEA/V/C/002762	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16

• **Innovax-ILT** EMEA/V/C/003869	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **Kexxtone** EMEA/V/C/002235	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.07.16
• **Loxicom** EMEA/V/C/000141	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 11.08.13-10.08.16
• **NEXGARD SPECTRA** EMEA/V/C/003842	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **Porcilis PCV ID** EMEA/V/C/003942	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.16-31.08.16
• **ProZinc** EMEA/V/C/002634	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.07.16
• **Rheumocam** EMEA/V/C/000121	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.07.16
• **Suvaxyn PCV** EMEA/V/C/000149	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.15-31.07.16
• **UpCard** EMEA/V/C/003836	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **Versican Plus Pi** EMEA/V/C/003681	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **Versican Plus Pi/L4R** EMEA/V/C/003682	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **Versican Plus L4** EMEA/V/C/003680	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16

• **ZACTRAN** EMEA/V/C/000129	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **ZULVAC 8 Ovis** EMEA/V/C/000147	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **ZULVAC SBV** EMEA/V/C/002781	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.16-31.08.16

- ***For endorsement***: List of products and calendar for signal detection

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 GL54 Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for implementation at step 7
- ***For endorsement*:** Draft EU comments on draft (2) VICH GL on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV and draft (2)
- ***For endorsement*:** VICH combination products GL: EU comments on draft 2 of the concept paper proposing a new VICH guideline
- ***For endorsement*:** Revision of VICH anthelmintic GLs 7, 11-16, 19-21: draft EU comments on group 2 proposals
- ***For decision:*** Draft VICH GL (A-1, vs 5) on the use of cell cultures for the detection of extraneous agents in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines; compilation of comments to EU proposal for shortened VICH GL on cell culture-based tests for extraneous viruses
- ***For decision:*** Draft VICH GL on general principles for detection of extraneous agents in veterinary vaccines and defining the testing of the seeds and materials of animal origin; draft VICH GL on a list of extraneous agents need to be covered

6.2 Codex Alimentarius

- ***For information***: Feedback from the CCRVDF meeting held on 17-21 October 2016 in Houston, USA

6.3 Other EU bodies and international organisations

- ***For information***: Verbal report from the 2nd EMA/JECFA liaison meeting held on 26 September 2016
- ***For endorsement***: Draft CVMP comments on JECFA draft guidance document for the establishment of acute reference dose (ARfD) for veterinary drug residues in food

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

8.3 Antimicrobial resistance

- ***For adoption:*** Joint EMA/EFSA scientific opinion from the RONAFA Advisory Group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU

- ***For information:*** Verbal report on the EC request for a joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing 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

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

- ***For adoption***: Q&A on information in SPC section 5.1
- ***For adoption*****:** Concept paper on implementation plan for QRD template v.8.1
- ***For adoption*****:** New QRD template for combined labelling and package leaflet, new template for pilot use

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information***: Draft agenda of meeting to be held on 8-9 December 2016, draft minutes of meeting held on 10-11 November 2016

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption****:* Public CVMP work plan for 2017
- ***For adoption:*** HMA/EMA Task Force on timetables: draft best practice guide on measures improving predictability of submissions and adherence to communicated submission deadlines

- ***For adoption:*** Revision of the scientific overview template guidance for immunological products:
  - Part 1 - Introduction
  - Part 2 - Quality
  - Part 3 - Safety
  - Part 4 - Efficacy
  - Part 5 - Benefit-risk assessment
- ***For discussion:*** CVMP operation and procedures: practical guidance document for CVMP members
- ***For discussion:*** Appointment of rapporteurs for CVMP procedures – next steps; verbal report from the break-out session
- ***For information:*** Update of policy on handling of competing interests of scientific committees' members and experts

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

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
Dec 2016	6-8		14-15						6		
Jan 2017	17-19			31-1			24-25	31–2	17		
Feb 2017	14-16	16	28-1		21-22	1-2			14	2-3	
Mar 2017	14-16						21-22		14		
Apr 2017	10-12										26-27