30 September 2016
EMA/CVMP/649396/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2016 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

4 October 2016, 09:00 – 6 October 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 4 Oct 2016	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/004380/FULL/0001 *Chickens*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information:*** Summary of opinion

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/004481/FULL/0001 *Salmonidae*	***For adoption****:* CVMP scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/002723/0000 *New antiparasitic product* *Honey bees*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/0004201/0000 *New antiparasitic product* *Cattle*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004376/0000 *New product for psycholeptic use* *Dogs and cats*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **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****:* Scientific overview and list of outstanding issues, comments on product information

• **Product** EMEA/V/C/004185/0000 *New vaccine* *Sheep*	***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/004265/0000 *New product for musculo-skeletal disorder* *Horses*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004276/0000 *New vaccine* *Pigs*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004364/0000 *New vaccine* *Pigs*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Zactran** EMEA/V/C/000129/X/0034 *Extension to add a new species* *Cattle, pigs*	Rapp: C. Friis Co-rapp: J. G. Beechinor **For adoption:** Scientific overview and list of questions, draft product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/004293/0000 *New analgesic product* *Cats*	***For information***: Letter of withdrawal of the marketing authorisation application
Product EMEA/V/C/003939/0000 *New dermatological poduct* *Dogs*	***For decision***: Comments from rapporteur on batch release certificate and official release

- ***For information*****:** Additional corrections in Part 4 – Efficacy of EPAR module scientific discussion for **ERAVAC** (EMEA/V/C/004239/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Virbagen Omega and CaniLeish** EMEA/V/C/xxxxxx/WS/0929/G *Quality*	Rapp: J.-C. Rouby ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Trifexis** EMEA/V/C/002635/II/0008 *To add new therapeutic indication*	Rapp: C. Ibrahim Co-rapp: T. Høy **ORAL EXPLANATION – Wednesday, 5 October 2016, 11.30** ***For discussion**:* Applicant's presentation, draft product information
• **Bravecto** EMEA/V/C/002526/II/0011 *To add wording to the SPC*	Rapp: G. J. Schefferlie ***For adoption:*** List of outstanding issues

3.3 List of questions

• **COXEVAC** EMEA/V/C/000155/II/0011 *Quality*	Rapp: J.-C. Rouby ***For adoption**:* List of questions
• **NEXGARD SPECTRA** EMEA/V/C/003842/II/0008 *To add new therapeutic indication*	Rapp: J. G. Beechinor Co-rapp: S. Srčič ***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

• **Lincocin and its associated names** EMEA/V/A/123 *Lincomycin* *SPC harmonisation*	Rapp: C. Muñoz Madero Co-rapp: H. Jukes ***For decision***: Request from MAH for a 3-month delay for the submission of responses to the list of questions

4.3 Article 35 of Directive 2001/82/EC

• **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 further outstanding issues ***For discussion***: Rapporteur's assessment report with co-rapporteur's critique on MAHs' responses to list of outstanding issues; revised rapporteur's assessment report with co-rapporteur's critique
• **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:*** Need for further outstanding issues and request for clock-stop ***For decision:*** Request from aniMedica to provide an oral explanation ***For discussion***: Updated rapporteur's assessment report with co-rapporteur's critique following MAHs' responses to list of outstanding issues

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

• **EVALON** EMEA/V/C/004013/ANX/001.1 *Condition*	Rapp: N. Garcia del Blanco Co-rapp: B. Zemann ***For adoption***: Rapporteurs' assessment report

5.3 Product anniversary list

Product	**Period**
Aivlosin (EMEA/V/C/000083)	09/09/2015 – 08/09/2016
Trocoxil (EMEA/V/C/000132)	09/09/2015 – 08/09/2016
Nobivac Bb (EMEA/V/C/000068)	10/09/2015 – 09/09/2016
APOQUEL (EMEA/V/C/002688)	12/09/2015 – 10/09/2016
Previcox (EMEA/V/C/000082)	13/09/2015 – 12/09/2016
Recocam (EMEA/V/C/002247)	13/09/2015 – 12/09/2016
RHINISENG (EMEA/V/C/000160)	16/09/2015 – 15/09/2016
Trifexis (EMEA/V/C/002635)	19/09/2015 – 18/09/2016
Palladia (EMEA/V/C/000150)	23/09/2015 – 22/09/2016
Cerenia (EMEA/V/C/000106)	29/09/2015 – 28/09/2016
COXEVAC (EMEA/V/C/000155)	30/09/2015 – 29/09/2016
Recuvyra (EMEA/V/C/002239)	06/10/2015 – 05/10/2016

5.4 Renewals

• **Activyl Tick Plus** EMEA/V/C/002234/R/009	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **ZULVAC 1 + 8 Bovis** EMEA/V/C/002473/R/0009	Rapp: E.-M. Vestergaard Co-rapp: I. Malemis ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Advocate** EMEA/V/C/00076	Rapp: M. Nevalainen ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13-30.04.16

• **APOQUEL** EMEA/V/C/002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15-31.05.16
• **BLUEVAC BTV8** EMEA/V/C/000156	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.15-30.06.16
• **CERTIFECT** EMEA/V/C/002002	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.15-31.05.16
• **Comfortis** EMEA/V/C/002233	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-31.12.15
• **EQUIP WNV** EMEA/V/C/000137	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15-31.05.16
• **MS-H Vaccine** EMEA/V/C/000161	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 15.06.15-14.06.16
• **Naxcel** EMEA/V/C/000079	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.13-31.05.16
• **Porcilis PCV M Hyo** EMEA/V/C/003796	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15-31.05.16
• **RevitaCAM** EMEA/V/C/002379	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.16-26.05.16
• **Simparica** EMEA/V/C/003991	Rapp: G. J. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 06.11.15-31.05.16
• **Suvaxyn Circo MH RTU** EMEA/V/C/003924	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 06.11.15-31.05.16
• **Zycortal** EMEA/V/C/003782	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 06.11.15-31.05.16

- ***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 discussion***: Revised draft concept paper for a general guideline on pharmaceutical combination products
- ***For discussion***: Draft guideline on use of cell cultures for detection of extraneous viruses – comments from VICH experts working group members on EU proposal
- ***For discussion and endorsement***: Revision of anthelmintics guidelines – draft EU comments
- ***For decision***: Need for revision of 6 quality VICH guidelines

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information***: Verbal report from the 2nd EMA/JECFA liaison meeting to be held on 26 September 2016
- ***For discussion***: JECFA draft guidance document for the establishment of acute reference dose (ARfD) for veterinary drug residues in food – published for consultation until 31 December 2016

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

- No items

8.3 Antimicrobial resistance

- ***For adoption:*** Revised CVMP strategy on antimicrobials 2016-2020; response to the comments received following the close of the public consultation
- ***For endorsement:*** CVMP/MAHs Pilot project on harmonization of old veterinary antibiotics - draft terms of reference
- ***For discussion:*** Verbal report on the Reduction of the Need for Antimicrobials in Food Producing Animals (RONAFA) meeting held on 20 September 2016; draft joint scientific opinion (EMA/EFSA) of the RONAFA Advisory Group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU
- ***For information:*** Presentation on the update on European Agencies reports on antimicrobial resistance at the Regional Seminar for OIE National Focal Points for Veterinary Products to be held on 11-13 October 2016 in Budapest, Hungary– CVMP representative K. Baptiste

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

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

- ***For information***: Draft agenda of meeting being held on 6-7 October 2016, draft minutes of meeting held on 8-9 September 2016; presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision****:* Appointment of CVMP co-opted members at the October 2016 meeting, nominations received:

  - General clinical veterinary practice

  - MRLs/Residues

  - Quality of pharmaceuticals

- ***For information***: Verbal report from the chair on the Strategic Planning Group (SPG) meeting to be held on 5 October 2016, draft agenda; minutes from the meeting held on 12 July 2016
- ***For information***: Verbal report on the Scientific Co-ordination Board meeting held on 22 September 2016; agenda of the meeting
- ***For information****:* Verbal update - EMA eSubmission Gateway to become mandatory for all veterinary submissions as of 1 January 2017 and plans for common repository for veterinary submissions in the centralised procedure
- ***For information:*** Revision of dossier submission requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Medicinal Products for Veterinary use (CVMP)
- ***To note:*** CVMP meeting dates for 2017

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	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
Oct 2016	4-6	6		11-12		20-21			4		18-19
Nov 2016	8-10				29-30			29–1	8	24-25	
Dec 2016	6-8		14-15						6		
Jan 2017	17-19			31-1			24	31–2	17		
Feb 2017	14-16		28-1		21-22	1-2			14	2-3	