3 October 2014
EMA/CVMP/610787/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

7 October 2014, 09:00 – 9 October 2014, 13:00 - Room 3E

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 3E)	Tue 7 October 2014	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003298/MODF/0004 *Bovine milk*	***For adoption***: Draft CVMP opinion including EPMAR Draft CVMP assessment report ***For information***: Rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report; EU-RL report

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003915/FULL/0001 *Bovine*	***For decision****:* Need for an oral explanation ***For discussion***: Rapporteurs' joint assessment of the responses to the list of questions; rapporteur's EPMAR; rapporteur's updated assessment report; comments; peer reviewer's report; peer reviewer's report; EU-RL report
• **Substance** EMEA/V/MRL/003878/FULL/0001 *Chicken*	***For decision***: Need for an oral explanation ***For discussion***: Rapporteur's assessment of the responses to the list of questions; rapporteur's EPMAR; peer reviewer's report; peer reviewer's report; EU-RL report

1.3 List of questions

• **Substance** EMEA/V/MRL/004039/FULL/0001 *All food producing species*	***For discussion***: Rapporteur's assessment report including the critique from the co-rapporteur; rapporteur's EPMAR, peer reviewer's report; peer reviewer's report; comments from EFSA on rapporteur's assessment report
• **Substance** EMEA/V/MRL/003225/MODF/0002 *Bovine*	***For discussion***: Rapporteur's assessment report; rapporteur's EPMAR; comments; peer reviewer's report; peer reviewer's report

1.4 Re-examination of CVMP opinions

• **Substance**	***For discussion:*** Request from the Commission for the review of the drafting of the CVMP opinion for a substance; detailed comments on the CVMP opinion

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMA/V/C/0003703/0000 *New viral vaccine* *Cattle*	***For adoption***: CVMP opinion; CVMP assessment report; Product information

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/003786/0000 *New cardiovascular product* *Cats*	***For decision****:* Need for an oral explanation ***For adoption****:* Updated scientific overview and benefit-risk assessment and list of outstanding issues; Draft product information
• **Product** EMEA/V/C/002757/000 *New viral vaccine* *Pigs*	**ORAL EXPLANATION – Tuesday 7 October, 14.30** ***For discussion***: Applicant's presentation; draft product information with rapporteurs' comments; rapporteurs' assessment of the responses to the list of outstanding issues; updated scientific overview of benefit-risk assessment after responses to list of outstanding issues
• **Product** EMEA/V/C/003842/0000 *New antiparasitic product* *Dogs*	***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues; Product information

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/0003684/0000 *New vector vaccine* *Dogs*	***For endorsement:*** Draft withdrawal EPAR

- ***For endorsement:*** EPAR module 6 scientific discussion for **Nobilis IB Primo QX** (EMEA/V/C/002802/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **ZACTRAN** EMEA/V/C/002009/II/026/G *Quality*	Rapp: C. Friis ***For adoption**:* Draft CVMP opinion; Draft CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Zuprevo** EMEA/V/C/002009/II/006/G *To add a new indication and delete a precautionary statement*	Rapp: C. Ibrahim Co-rapp: E. Lander Persson ***For discussion:*** Need for an oral explanation ***For adoption**:* Draft list of outstanding issues
• **Easotic** EMEA/V/C/000140/II/0006/G *Quality*	Rapp: C. Friis ***For adoption***: Draft list of outstanding issues

3.3 List of questions

• **ZULVAC 1 Bovis, ZULVAC 8 Bovis, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 8 Ovis, ZULVAC 1+8 Ovis** EMEA/V/C/XXXXXX/WS/0597 *Quality*	Rapp: M. Tollis ***For adoption***: Draft list of questions
• **Suvaxyn PCV** EMEA/V/C/000149/II/0017/G *Quality*	Rapp: B. Urbain ***For adoption**:* Draft list of questions
• **ERYSENG PARVO** EMEA/V/C/002762/WS/0618 *To update the product information with mixing instructions*	Rapp: D. Murphy ***For adoption**:* Draft list of questions
• **Purevax RCPCh; Purevax RCP; Purevax RC; Purevax RCPCh FeLV; Purevax RCP FeLV** (EMEA/V/C/xxxxxx/WS/0606) *To extend the duration of immunity*	Rapp: B. Urbain ***For adoption**:* Draft list of questions
• **LEUCOFELIGEN FeLV/RCP, LEUCOGEN** EMEA/V/C/XXXXXX/WS/0639 *To update the product information*	Rapp: E. Werner ***For adoption***: 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

• **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** *(zinc oxide)* EMEA/V/A/108 *ERA*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: List of questions*;* Timetable ***For discussion and decision***: Notification from the United Kingdom under Article 33(4) of Directive 2001/82/EC; discussion document; 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** *(gentamicin)* EMEA/V/A/104 *Indications, dosage and target animal safety*	Rapp: K. Baptiste Co-rapp: C. Muñoz Madero ***For discussion***: Rapporteur's assessment report with co-rapporteur's critique following 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

• **Resflor injectable solution for cattle** (*florfenicol and flunixins*) EMEA/V/A/101 *Efficacy*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti ***For adoption***: CVMP opinion; CVMP assessment report; Divergent position

4.6 Article 30(3) of Regulation 726/2004

• **Diclofenac** EMEA/V/A/107 *Risk to vultures and other necrophagous birds*	Rapp: B. Kolar Co-rapps: C. Rubio Montejano, J. Schefferlie, M. Holzhauser-Alberti ***For discussion***: Joint rapporteur's assessment report

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
APOQUEL (EMEA/V/C/002688)	12.09.2013 – 11.09.2014
Cerenia (EMEA/V/C/000106)	29.09.2013 – 28.09.2014
COXEVAC (EMEA/V/C/000155)	30.09.2013 – 29.09.2014
Palladia (EMEA/V/C/000150)	23.09.2013 – 22.09.2014
Recocam (EMEA/V/C/002247)	13.09.2013 – 12.09.2014
Recuvyra (EMEA/V/C/002239)	06.10.2013 – 05.10.2014
RHINISENG (EMEA/V/C/000160)	16.09.2013 – 15.09.2014
Trifexis (EMEA/V/C/002635)	19.09.2013 – 18.09.2014

5.4 Renewals

• **Gripovac 3** EMEA/V/C/000157/R/0005	Rapp: E.-M. Vestergaard Co-rapp: B. Urbain ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report

• **RESPIPORC FLU3** EMEA/V/C/000153/R/0006	Rapp: E.-M. Vestergaard Co-rapp: B. Urbain ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report

5.5 Pharmacovigilance - PSURs and SARs

• **Nobivac Myxo-RHD** EMEA/V/C/002004	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13-31.03.14
• **Pexion** EMEA/V/C002543	Rapp: M. Holzhauser-Alberti ***For discussion***: Rapporteur's assessment report on the PSUR for the period 01.09.13-28.02.14
• **ProMeris Duo** EMEA/V/C/000108	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 20.06.11-31.05.14
• **Recuvyra** EMEA/V/C/002239	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.112013-30.04.2014
• **Aivlosin** EMEA/V/C/000083	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13-31.04.14
• **APOQUEL** EMEA/V/C/002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-31.05.14
• **BTVPUR Alsap 2-4** EMEA/V/C/000139	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-31.05.14
• **CERTIFECT** EMEA/V/C/002002	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-31.05.14
• **EQUIOXX & Previcox** EMEA/V/C/000142	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-30.06.14
• **LEUCOGEN** EMEA/V/C/000144	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-30.06.14

• **MS-H Vaccine** EMEA/V/C/000161	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 15.12.13-14.06.14
• **Oncept IL-2** EMEA/V/C/002562	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-31.05.14
• **ProMeris** EMEA/V/C/000107	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 20.06.11-35.05.14
• **Vectra 3D** EMEA/V/C/002555	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 04.12.13-30.06.14

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

5.6 Supervision and sanctions

- ***For adoption***: Aivlosin (EMEA/V/C/000083) Eco Animal Health Ltd. PhV Inspection request
- ***For adoption***: Recocam (EMEA/V/C/002247) Cross Vetpharm Group Ltd. PhV Inspection request

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement***: Revised draft by EU topic leader of VICH Guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: residue studies in honey, for circulation to VICH expert working group
- ***For endorsement***: Draft EU comments on revised draft VICH guideline GL52 on Bioequivalence following public consultation
- ***For endorsement***: Revised draft (draft 3) by EU topic leader of VICH Guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use and overview of comments received in VICH regions on the draft guideline for circulation to VICH expert working group
- ***For discussion***: VICH survey on the need for VICH Guidelines for biotechnological/biological veterinary medicinal products: draft EU response and analysis and recommendations; comments received

6.2 Codex Alimentarius

- ***For information***: Codex Committee on residues of veterinary drugs in food electronic working group report on Countries' needs for MRLs
- ***For information***: Provisional agenda for the 22nd session of the Codex Committee on residues of veterinary drugs in food to be held in Costa Rica from 27 April to 1 May 2015
- ***For information***: Proposed draft MRLs for consideration at the 22nd session of the CCRVDF

6.3 Other EU bodies and international organisations

- ***For decision***: Joint EMA/HMA workshop on the requirements for the authorisation of vaccines in the EU – Background and draft agenda
- ***To note***: EFSA/WHO meeting on the threshold of toxicological concern (TTC) on 2 December 2014 – see http://www.efsa.europa.eu/en/events/event/141202.htm

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting 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

- ***For endorsement:*** Revised draft template for EPMARs
- ***For decision:*** Request to include a substance, in the list of substances not following within the scope of Regulation (EC) No 470/2009

8.2 Environmental risk assessment

- No items

8.3 Antimicrobial resistance

- ***For information***: Verbal report on the ESVAC 4th annual report: Sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2012

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

- No items

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

- ***For discussion***: Questions from CMDv to CVMP for consideration by the Efficacy Working Party
- ***For information***: Agenda of the meeting to be held on 9-10 October 2014; minutes of the meeting held on 11-12 September 2014; presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion****:* CVMP implementation of multinational assessment teams: presentation
- ***For information****:* Annual report on the performance of the Agency's scientific procedures key performance indicators (KPIs) for medicinal products for human and veterinary use

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
October	7-9		21-22	30 Sep-1 Oct	30 Sep-1 Oct			7	
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