8 December 2014
EMA/CVMP/763244/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

9 December 2014, 09:00 – 11 December 2014, 13:00 - Room 3A

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 3A)	Tue 9 December	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003225/MODF/0002 *All food producing species*	***For information***: CVMP opinion, CVMP assessment report

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/003135/MODF/0003 *Salmonidae*	***For discussion***: Initial discussion after the response to list of questions

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/002757/000 *New viral vaccine* *Pigs*	**For adoption:** CVMP opinion, CVMP assessment report, product information
• **Product** EMEA/V/C/002781/0000 *New viral vaccine* *Sheep, cattle*	***For adoption***: CVMP opinion, CVMP assessment report, CVMP product information

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/003786/0000 *New cardiovascular product* *Cats*	**ORAL EXPLANATION – Tuesday 9 December, 14.30** ***For discussion***: Applicant's presentation; rapporteurs' assessment of the responses to the list of outstanding issues; draft product information with rapporteurs' comments

• **Stronghold** EMEA/V/C/000050/X/051/G *Extension to include new strengths* *Cats, dogs*	Rapp: H. Jukes Co-rapp: I. Malemis ***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and benefit-risk assessment and list of outstanding issues; comments on product information
• **Rheumocam** EMEA/V/C/000121/X/0015 *Extension to include a new strength* *Horses*	Rapp: M. Holzhauser-Alberti Co-rapp: E.-M. Vestergaard ***For decision***: Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues; list of outstanding issues on the ASMF-restricted part; comments on product information
• **Product** EMEA/V/C/002804/0000 *New cardiovascular product* *Dogs*	***For decision:*** Need for oral explanation ***For adoption***: Scientific overview and benefit-risk assessment and list of outstanding issues; comments on product information; joint rapporteurs' assessment on the applicant's and restricted parts of the ASMF
• **Product** EMEA/V/C/003797/0000) *New bacterial vaccine* *Pigs*	***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

• **DRAXXIN** EMEA/V/C/000077/X/0029 *Extension to include a new target species* *Sheep*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For adoption***: Scientific overview and benefit-risk assessment and list of questions; comments on draft product information
• **Product** EMEA/V/C/003942/0000 *New viral 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

- No items

2.5 Other issues

• **Product** EMEA/V/C/002794/0000) *New haematological product* *Dogs*	***For information***: Letter of withdrawal of the marketing authorisation application

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Purevax RCPCh; Purevax RCP; Purevax RC; Purevax RCPCh FeLV; Purevax RCP FeLV** EMEA/V/C/xxxxxx/WS/0606 *To extend the duration of immunity (DOI)*	Rapp: B. Urbain ***For adoption***: CVMP opinion CVMP assessment report
• **Easotic** EMEA/V/C/000140/II/0006/G *Quality*	Rapp: C. Friis ***For adoption***: CVMP opinion CVMP assessment report
• **Equip WNV** EMEA/V/C/000137/II/0018/G *Quality*	Rapp: J.-C. Rouby ***For adoption***: CVMP opinion CVMP assessment report
• **LEUCOFELIGEN FeLV/RCP, LEUCOGEN** EMEA/V/C/xxxxxx/WS/0639 *To update the product information*	Rapp: E. Werner ***For adoption***: CVMP opinion CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Broadline** EMEA/V/C/002700/II/0001 *New indications* *Cats*	Rapp: B. Urbain Co-rapp: C. Munoz ***For discussion****:* Need for an oral explanation ***For adoption****:* CVMP list of outstanding issues
• **Zuprevo** EMEA/V/C/002009/II/0006/G *Addition of a new indication and deletion of a precautionary statement* *Pigs*	Rapp: C. Ibrahim Co-rapp: E. Lander Persson **ORAL EXPLANATION – Wednesday 10 December, 11.30** ***For discussion****:* Applicant's presentation; draft product information

3.3 List of questions

• **Poulvac E.coli** EMEA/V/C/002007/II/0006 *Quality*	Rapp: E. Werner ***For adoption***: CVMP list of questions
• **Nobilis IB 4-91** EMEA/V/C/0000036/WS/0607 *To add a claim for the mixed-use of Nobilis IB 4-91 and Nobilis IB Ma5*	Rapp: A.-M. Brady ***For adoption***: CVMP 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

- No items

4.3 Article 35 of Directive 2001/82/EC

• **All veterinary medicinal products containing colistin to be administered orally** EMEA/V/A/106 *Indications, prudent use warnings*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti ***For adoption***: CVMP opinion CVMP assessment report

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***: Response from the EC to the CVMP request for advice

• **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 adoption*:** CVMP opinion CVMP 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

• **Bovela** EMEA/V/C/003703/ANX001	Rapp: F. Klein Co-rapp: C. Muñoz Madero ***For endorsement***: Rapporteur's condition assessment report
• **Cortavance** EMEA/V/C/000110/REC017	Rapp: C. Friis Co-rapp: C. Muñoz Madero ***For adoption***: Rapporteur's recommendation assessment report
• **Equilis Te** EMEA/V/C/000093/REC012	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: Rapporteur's recommendation assessment report
• **Porcilis AR-T DF** EMEA/V/C/000055/REC022	Rapp: E.-M. Vestergaard Co-rapp: E. Werner ***For endorsement***: Rapporteur's recommendation assessment report

5.3 Product anniversary list

Product	**Period**
Acticam (EMEA/V/C/000138)	09.12.2013 – 08.12.2014
Broadline (EMEA/V/C/002700)	04.12.2013 – 03.12.2014
Contacera (EMEA/V/C/002612)	06.12.2013 – 05.12.2014

DRAXXIN (EMEA/V/C/000077)	11.11.2013 – 10.11.2014
Easotic (EMEA/V/C/000140)	20.11.2013 – 19.11.2014
Equip WNV (EMEA/V/C/000137)	21.11.2013 – 20.11.2014
Inflacam (EMEA/V/C/002497)	09.12.2013 – 08.12.2014
Masivet (EMEA/V/C/000128)	17.11.2013 – 16.11.2014
Meloxivet (EMEA/V/C/000124)	14.11.2013 – 13.11.2014
Meloxoral (EMEA/V/C/000151)	19.11.2013 – 18.11.2014
Oxyglobin (EMEA/V/C/000045)	29.11.2013 – 28.11.2014
Panacur AquaSol (EMEA/V/C/002008)	09.12.2013 – 08.12.2014
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2013 – 15.11.2014
Quadrisol (EMEA/V/C/000032)	04.12.2013 – 03.12.2014
SevoFlo (EMEA/V/C/000072)	11.12.2013 – 10.12.2014
Stronghold (EMEA/V/C/000050)	25.11.2013 – 24.11.2014
Vectra 3D (EMEA/V/C/002555)	04.12.2013 – 03.12.2014

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- ***For decision:*** Revised timetable for PSUR assessments foreseen for completion at the February 2015 CVMP meeting

• **Pexion** EMEA/V/C/002543	Rapp: M. Holzhauser-Alberti ***For decision***: Request from the MAH for re-consideration of CVMP outcome of the 2nd PSUR assessment
• **Activyl Tick Plus** EMEA/V/C/002234	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14
• **BROADLINE** EMEA/V/C/002700	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 04.12.13-30.06.14
• **CORTAVANCE** EMEA/V/C/000162	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.11-31.07.14

• **ECOPORC SHIGA** EMEA/V/C/002535	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14
• **Gripovac 3** EMEA/V/C/000157	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.07.14
• **Nobivac L4** EMEA/V/C/002010	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14
• **PIRSUE** EMEA/V/C/000054	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.11-31.07.14
• **Reconcile** EMEA/V/C/000133	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.07.14
• **RESPIPORC FLU3** EMEA/V/C/000153	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.07.14
• **Rheumocam** EMEA/V/C/000121	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-31.08.14
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14

• **ZULVAC 8 Ovis** EMEA/V/C/000147	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.07.14

- ***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 Task Force on the revision of anthelmintic guidelines: EU comments on discussion paper on topic 4 and EU comments on discussion paper
- ***For adoption***: EU comments on the revised draft VICH guideline summarising discussions on topics 1, 2 and 3 on marker residue depletion studies to establish product withdrawal periods in aquatic species - residue depletion in fish groups
- ***For endorsement:*** Revised draft guideline on study design recommendations for residue depletion studies in honey for establishing MRLs and withdrawal periods
- ***For adoption***: VICH Expert Working Group on Quality - Task Force on revision of (Stability) GL3: EU comments on revised draft concept paper from Task Force leader

6.2 Codex Alimentarius

- ***For endorsement:*** Draft Codex MRLs and the use of the Estimated Daily Intake (EDI); Revised CVMP comments for consideration at 22nd CCRVDF meeting
- ***For endorsement:*** Draft EU comments relating to provisions on establishment of MRLs for honey; report from 21st CCRVDF meeting

6.3 Other EU bodies and international organisations

- ***For information:*** Update on the Joint EMA/HMA workshop on requirements for authorisation of vaccines in the EU

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

- ***For adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009

8.2 Environmental risk assessment

- No items

8.3 Antimicrobial resistance

- ***For adoption***: Final answers to the request from the Commission for scientific advice on the impact on public health and animal health of the use of antibiotics in animals to Question 2 (ranking of antibiotics), Question 3 (new antibiotics) and Question 4 (risk mitigation options), and overview of comments after second consultation

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 on certain topics discussed under section 9 cannot be released at the present time as it is deemed to be confidential

- ***For discussion***: Availability of veterinary medicinal products for aquatic animals

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***: Agenda of the meeting to be held on 11-12 December 2014; minutes of the meeting held on 6-7 November 2014; presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement***: CVMP implementation of multinational assessment teams: appointments and responsibilities of rapporteur and co-rapporteur for procedure regarding veterinary medicinal products – revised draft; table to declare potential interest in participating in a multinational assessment team and the expertise available per National Competent Authority
- ***For discussion***: Guidance on principles to prepare CVMP assessment reports; template for scientific overview and benefit-risk assessment, including list of questions, for veterinary pharmaceutical products
- ***For discussion:*** Draft programme for the 2015 EMA/IFAH-Europe Info Day, to be held in London on 12-13 March 2015
- ***For discussion and endorsement:*** Draft minutes of the informal CVMP meeting, and the joint CVMP/CMDv meeting, held on 22-23 June in Rome, Italy
- ***For information***: Verbal report on the Strategic Planning Group meeting to be held on 10 December 2014 and draft agenda; draft minutes of the meeting held on 10 September 2014

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
December	9-11						3-5	9	
Jan 2015	13-15	20-21	27-28			27-28		13	
Feb 2015	10-12			3-4				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		5	21-22
June 2015	2-4		16-17		17-18	30-1 Jul		2	
July 2015	7-9							7	