2 May 2014
EMA/CVMP/268458/2014
Committee for Medicinal Products for Veterinary Use

Committee for Medicinal Products for Veterinary Use (CVMP)

Draft agenda of May 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

6 May 2014, 09:00 – 8 May 2014, 13:00

Room 4A

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).

1. Adoption of the Agenda
2. CVMP delegates list of intended participation and identified conflicts of interests
3. Declaration of contacts between members and companies with regard to points on the agenda
4. Adoption of the minutes of the previous meeting
5. Confirmation of topics for rapporteur's meetings and breakout sessions

• **Scientific Advice Working Party** *(Room 4A)*	Tues. 6 May 2014	16:00-17:30
• **CVMP Interested Parties meeting** *(Room 4C)*	Wed. 7 May 2014	17:00-19:00

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A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

• **Substance** EMEA/V/MRL/002860/FULL/0002 *Equidae*	***For adoption***: Draft CVMP opinion including the EPMAR; Draft CVMP assessment report ***For discussion***: Rapporteur's revised assessment report; rapporteur's EPMAR

A.1.2 Recommendations for extrapolation of established MRLs

- No items

A.1.3 Re-examination of CVMP opinions

- No items

A.2 COMMUNITY MARKETING AUTHORISATIONS

A.2.1 Opinions on applications

• **Product** EMEA/V/C/003681/0000 *New viral vaccine* (dogs)	***For adoption***: Draft CVMP opinion, Draft CVMP assessment report, Draft product information
• **Product** EMEA/V/C/003679/0000 *New viral vaccine* (dogs)	***For adoption***: Draft CVMP opinion, Draft CVMP assessment report, Draft product information
• **Product** EMEA/V/C/002762/000 *New viral and bacterial vaccine* (pigs)	***For adoption***: Draft CVMP opinion, Draft CVMP assessment report, Draft product information
• **Product** EMEA/V/C/002761/000 *New bacterial vaccine* (pigs)	***For adoption***: Draft CVMP opinion, Draft CVMP assessment report, Draft product information
• **DRAXXIN** EMEA/V/C/000077/X/0026 *Extension: new strength* (pigs)	Rapp: C. Ibrahim Co-Rapp: C. Muñoz Madero ***For adoption***: Draft CVMP opinion, Draft CVMP assessment report, Draft product information

A.2.2 Variations to Community marketing authorisations

• **Profender** EMEA/V/C/000097/II/0024 *To change the legal status of Profender spot-on solution for cats from prescription to non-prescription*	Rapp: R. Breathnach **ORAL EXPLANATION - 7 May 2014, 15:30** ***For discussion***: Applicant's presentation
• **STARTVAC** EMEA/V/C/000130/II/0002 *Quality*	Rapp: E. Werner ***For adoption***: Draft list of questions
• **Cerenia** EMEA/V/C/000106/II/0022 *To extend the use of Cerenia tablets*	Rapp: C. Friis ***For adoption***: Draft CVMP opinion, Draft CVMP assessment report
• **Fevaxyn Pentofel** EMEA/V/C/000030/WS/0489/G (039) *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: Draft list of questions
• **ProteqFlu** EMEA/V/C/000073/II/0014 *Strain substitution*	Rapp: J. C. Rouby Co-rapp: E. Werner ***For adoption***: Draft list of outstanding issues
• **ProteqFlu-Te** EMEA/V/C/000074/II/0017 *Strain substitution*	Rapp: J. C. Rouby Co-rapp: E. Werner ***For adoption***: Draft list of outstanding issues
• **Equip WNV** EMEA/V/C/000137/II/0018/G) *Quality*	Rapp: J. C. Rouby ***For adoption***: Draft list of questions
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0002) *Change in SPC*	Rapp: A.-M. Brady ***For adoption***: Draft list of questions
• **Metacam** EMEA/V/C/000033/II/0108/G *Quality*	Rapp: F. Hasslung Wikström ***For adoption***: Draft CVMP opinion, Draft CVMP assessment report

• **Vectra 3D** EMEA/V/C/002555/WS/0532 (002) *Change in the existing pharmacovigilance system*	Rapp: C. Ibrahim ***For adoption***: Draft CVMP opinion, Draft CVMP assessment report

A.2.3 Re-examination of CVMP opinions

- No items

A.2.4 Lists of questions

• **Metacam** EMEA/V/C/000033/X/0107 *Extension: new strength* *(cattle, horses)*	Rapp: F. Hasslung Wikström Co-rapp: C. Ibrahim ***For adoption***: Scientific overview and benefit-risk assessment and list of questions, rapporteurs' and PIQ comments on product information

A.3 REFERRALS AND RELATED PROCEDURES

A.3.1 Article 33 of Directive 2001/82/EC

- No items

A.3.2 Article 34 of Directive 2001/82/EC

- No items

A.3.3 Article 35 of Directive 2001/82/EC

• **Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications** EMEA/V/A/086 *Indications, dosage and withdrawal periods*	Rapp: C. Ibrahim Co-Rapp: B. Urbain ***For decision***: Request for a clock stop ***For discussion***: Rapporteur's assessments on responses to the list of outstanding issues; revised rapporteurs' joint assessment report
• **All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs** EMEA/V/A/100 *Indications, dosage, antimicrobial resistance*	Rapp: E. Lander Persson Co-rapp: A. Wachnik-Święcicka ***For adoption***: Draft CVMP opinion, Draft CVMP assessment report

A.3.4 Article 39 of Directive 2001/82/EC

- No items

A.3.5 Article 13 of Regulation (EC) No 1234/2008

- No items

A.3.6 Article 78 of Directive 2001/82/EC

- No items

A.3.7 Article 30(3) of Regulation 726/2004

• **Dapsone** EMEA/V/A/075 *Genotoxicity*	Rapp: M. Holzhauser-Alberti Co-rapp: W. Schlumbohm ***For discussion***: Letter by EDQM requesting confirmation of proposed limit
• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-Rapp: C. Muñoz Madero ***For discussion***: Revised rapporteur's assessment report including co-rapporteur's critique

A.3.8 Article 45 of Regulation 726/2004

- No items

A.3.9 Miscellaneous items

- No items

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

• **Product** EMEA/V/C/003684/0000 *New vaccine (dogs)*	***For decision***: Need for oral explanation ***For adoption*:** Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information
• **Product** EMEA/V/C/003753/0000 *New otological product (dogs)*	***For discussion***: Joint rapporteurs' assessment of responses to list of questions; updated product information; updated scientific overview and benefit-risk assessment
• **Product** EMEA/V/C/002390 *New vaccine (Atlantic salmon)*	***For decision***: Request for extension of clock-stop

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 GENERAL ISSUES

- No items

C.2 Post-authorisation measures to CVMP opinions on the granting of Community marketing authorisations and annual reassessments

• **CERTIFECT** EU/2/11/125/001-008	Rapp: M. Holzhauser-Alberti Co-rapp: E. Lander Persson ***For adoption***: Rapporteur's recommendation assessment report
• **Porcilis ColiClos** EU/2/12/141/001-009	Rapp: Anna-Maria Brady Co-rapp: Esther Werner ***For adoption***: Rapporteur's recommendation assessment report

C.3 Product anniversary list

Product	**Period**
BLUEVAC BTV8 (EMEA/V/C/000156)	14.04.2013 – 13.04.2014
CERTIFECT (EMEA/V/C/002002)	06.05.2013 – 05.05.2014
Equilis StrepE (EMEA/V/C/000078)	07.05.2013 – 06.05.2014
Meloxidolor (EMEA/V/C/002590)	22.04.2013 – 21.04.2014
Neocolipor (EMEA/V/C/000035)	14.04.2013 – 13.04.2014
Oncept IL-2 (EMEA/V/C/002562)	03.05.2013 – 02.05.2014
Procox (EMEA/V/C/002006)	20.04.2013 – 19.04.2014
Purevax FeLV (EMEA/V/C/000056)	13.04.2013 – 12.04.2014
Slentrol (EMEA/V/C/000116)	13.04.2013 – 12.04.2014
Veraflox (EMEA/V/C/000159)	12.04.2013 – 11.04.2014
Zuprevo (EMEA/V/C/002009)	06.05.2013 – 05.05.2014

C.4 Renewals of marketing authorisations

- No items

C.5 Pharmacovigilance - PSURs and SARs

• **Draxxin** EMEA/V/C/000077	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.10-30.11.13 ***For discussion***: Comments received
• **BTVPUR AlSap 1** EMEA/V/C/002230	Rapp: C. Munoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **BTVPUR AlSap 1-8** EMEA/V/C/002231	Rapp: C. Munoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Cardalis** EMEA/V/C/002524	Rapp: H. Jukes ***For adoption*** CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Cerenia** EMEA/V/C/000106	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Circovac** EMEA/V/C/000114	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.13-31.12.13
• **Contacera** EMEA/V/C/002612	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Convenia** EMEA/V/C/000098	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.11-31.12.13
• **Ibaflin(WD)** EMEA/V/C/000052	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.11-31.12.13

• **Inflacam** EMEA/V/C/000093	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Masivet** EMEA/V/C/000128	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.12-30.11.13
• **Panacur AquaSol** EMEA/V/C/002008	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Suvaxyn Aujeszky 783+O/W** EMEA/V/C/000038	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.11-31.12.13

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

C.6 Supervision and sanctions

- No items

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- ***For endorsement***: Draft 8 of draft guideline on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD): proposal for EU comments
- ***For endorsement***: Draft 2 of VICH Metabolism and Residue Kinetics guideline on Residue studies in fish: preparation of EU position for discussion of revised draft guideline at next EWG meeting to be held in June 2014 – comments received
- ***For endorsement***: VICH Task Force on Efficacy studies for combination products (TFcomb): Questionnaire to collect data on combination products in regions: draft response from EU
- ***For information***: Draft concept paper for the revision of VICH Stability GL 3(R) to include climatic zones III and IV: EU comments on revised draft summary of discussion and proposal for action plan

D.2 Codex Alimentarius

- No items

D.3 Other EU bodies and international organisations

- ***For discussion***: Focus Group meeting on the requirements for the authorisation of vaccines in the EU

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to contain commercially confidential information

E.2 Pharmacovigilance Working Party (PhVWP)

E.3 Efficacy Working Party (EWP)

E.4 Safety Working Party (SWP)

E.5 Immunologicals Working Party (IWP)

E.6 Quality Working Party (QWP)

E.7 Environmental Risk Assessment Working Party (ERAWP)

E.8 Antimicrobials Working Party (AWP)

E.9 Joint CVMP/CHMP AHEG on the application of the 3Rs

E.10 Other Working Party issues

F. SAFETY OF VETERINARY MEDICINES AND RESIDUES

F.1 Appointment of Rapporteurs, Co-rapporteurs and Peer reviewers for the establishment of new MRLs

Information relating to letters of intent for new MRL applications cannot be released at the present time as it is deemed to contain commercially confidential information

- No items

F.2 Critical issues related to centralised procedures

Information on critical issues related to MRL centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information

- No items

F.3 Other MRL and safety items

Information on pending MRL related issues cannot be released at the present time as it is deemed to contain commercially confidential information

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

F.4 Antimicrobial resistance

- ***For decision***: The Danish Council of Ethics' statement on the use of antibiotics

F.5 Pharmacovigilance

- No items

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

G.1 Eligibility and appointment of Rapporteurs, Co-rapporteurs and Peer reviewers

Information concerning letters of intent and eligibility requests relating to community marketing authorisations cannot be released at the present time as it is deemed to contain commercially confidential information

G.2 Inspections

Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

- No items

G.3 Regulatory issues

Information relating to certain regulatory issues on community marketing authorisations cannot be released at the present time as it is deemed to contain commercially confidential information

- No items

G.4 Miscellaneous items

Information relating to certain miscellaneous items on community marketing authorisations cannot be released at the present time as it is deemed to contain commercially confidential information

- ***For endorsement:*** EPAR module 6 scientific discussion for **Vectra Felis** (EMEA/V/C/002746/0000)

H. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to contain commercially confidential information

- No items

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

- ***For information***: Agenda of the meeting to be held on 7-8 May 2014; minutes of the meeting held on 10-11 April 2014

J. ORGANISATIONAL MATTERS

- ***For discussion***: CVMP Interested Parties' meeting to be held on 7 May 2014 at the EMA; draft agenda and draft minutes of the previous meeting held on 15 May 2013
- ***For endorsement***: Rapporteurs meetings via Adobe Connect: recommendations
- ***For information***: Letter from Guido Rasi to delegates on move to 30 Churchill Place
- ***For information***: An Agency on the move presentation

K. LEGISLATION

- No items

L. ANY OTHER BUSINESS

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

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES 2014

	CVMP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	JEG 3Rs
May	6-8	14-15		13-14		20-21	13-15	6	22-23	
June	3-5		17-18		18-19			3		
July	8-10					1-2 (Poss. Adobe)		8		
September	9-11	24-25		30 Sept - 1 Oct	30 Sept-1 Oct	16-17	17-19	9	3-4	
October	7-9		21-22					7		28-29
November	4-6	18-19		25-26		18-19		4	27-28	
December	9-11						3-5	9		