4 May 2015
EMA/CVMP/287758/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of May 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

5 May 2015, 09:00 – 7 May 2015, 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 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 2A)	Tue 5 May 2015	16.00-20.00 (TBC)

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003135/MODF/0003 *Salmonidae*	***For adoption***: CVMP opinion ***For discussion***: Rapporteurs' revised EPMAR ***For information***: Summary of opinion
• **Substance** EMEA/V/MRL/003923/FULL/0001 *Honey*	***For adoption***: CVMP opinion, CVMP assessment report ***For information***: Summary of opinion, comments from EFSA

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

• **Substance** EMEA/V/MRL/003915/FULL/0001 *Bovine species*	***For adoption****:* CVMP opinion, CVMP assessment report ***For discussion***: Rapporteurs' revised EPMAR ***For information***: Summary of opinion

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/003869/0000 *New viral vaccine* Chickens	***For adoption****:* CVMP opinion, CVMP assessment report product information ***For information***: Summary of opinion

• **Product** EMEA/V/C/004079/0000 *New bacterial vaccine* Dogs	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/002763/0000 *Treatment of mastitis* Cattle	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information, co-rapporteur's comments
• **Product** EMEA/V/C/003829/0000 *New live viral vaccine* Chickens	***For decision*****:** Need for oral explanation ***For adoption****:* Scientific overview and benefit-risk assessment and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/003942/0000 *New viral 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

• **Poulvac E. coli** EMEA/V/C/002007/X/0008 *Extension to include a new target species* Chickens	Rapp: E. Werner Co-rapp: A-M. Brady ***For adoption****:* Scientific overview and benefit-risk assessment and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **Lodipressin** EMEA/V/C/003786/0000 *New cardiovascular product* Cats	Rapp: C. Ibrahim Co-rapp: H. Jukes ***For adoption***: Final CVMP opinion, Final CVMP assessment report

2.5 Other issues

• **ZACTRAN** EMEA/V/C/000129/X/0027 *Extension to include a new food producing species* Cattle	Rapp: C. Friis Co-rapp: J. G. Beechinor ***For decision**:* Request from the applicant for an extension to the clock stop
• **DRAXXIN** EMEA/V/C/000077/X/0029 *Extension to include a new target species to add to the solution for injection range* Cattle, Pigs	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For decision**:* Request from the applicant for an extension to the clock stop

- ***For endorsement*:** EPAR module 6 scientific discussion for **Rheumocam** (EMEA/V/C/000121/X/0015)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Nobivac L4** EMEA/V/C/002010/II/0003 *To include a mixed use claim*	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

• **RESPIPORC FLU3** EMEA/V/C/000153/II/0010 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP list of questions
• **Gripovac 3** EMEA/V/C/000157/II/0008 *Quality*	Rapp: E.-M. Vestergaard ***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

• **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** *(zinc oxide)* EMEA/V/A/108 *ERA*	Rapp: P. Hekman Co-rapp: H. Jukes ***For adoption***: CVMP opinion, CVMP assessment report, divergent position
• **Coglapix vakcina A.U.V. suspension for injection for pigs** *(Actinobacillus pleuropneumoniae strains serotype 1 and 2)* EMEA/V/A/109 *Efficacy*	Rapp: M. Tollis Co-rapp: G. Kulcsár **ORAL EXPLANATION – Wednesday 6 May** ***For discussion***: Presentation from CEVA-Phylaxia Veterinary Biologicals Co. Ltd., updated rapporteur's assessment report, updated co-rapporteur's assessment report

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 a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** EMEA/V/A/110 *Indications, dosage and withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from Belgium under Article 35 of Directive 2001/82/EC; appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

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

Information on certain referrals related issues cannot be released at the present time as it is deemed to be confidential

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

• **Nobivac Myxo-RHD** EMEA/V/C/002004 REC 011	Rapp: E. Werner Co-rapp: M. Tollis ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

The following 13 items are for silent endorsement

Product	**Period**
BLUEVAC BTV8 (EMEA/V/C/000156)	14/04/2014 – 13/04/2015
CERTIFECT (EMEA/V/C/002002)	06/05/2014 – 05/05/2015
Equilis StrepE (EMEA/V/C/000078)	07/05/2014 – 06/05/2015
Meloxidolor (EMEA/V/C/002590)	22/04/2014 – 21/04/2015
Neocolipor (EMEA/V/C/000035)	14/04/2014 – 13/04/2015
Oncept IL-2 (EMEA/V/C/002562)	03/05/2014 – 02/05/2015
Parvoduk (EMEA/V/C/002740)	11/04/2014 – 10/04/2015
Procox (EMEA/V/C/002006)	20/04/2014 – 19/04/2015
Purevax FeLV (EMEA/V/C/000056)	13/04/2014 – 12/04/2015
Veraflox (EMEA/V/C/000159)	12/04/2014 – 11/04/2015
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2014 – 06/05/2015
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2014 – 06/05/2015
Zuprevo (EMEA/V/C/002009)	06/05/2014 – 05/05/2015

5.4 Renewals

• **RHINISENG** EMEA/V/C/000160/R/0003	Rapp: E.-M. Vestergaard Co-rapp: J. G. Beechinor ***For adoption***: CVMP opinion, CVMP assessment report, product information

• **COXEVAC** EMEA/V/C/000155/R/0009 Request for re-examination	Rapp: J.-C. Rouby Co-rapp: C. Muñoz Madero ***For decision***: Request for re-examination

5.5 Pharmacovigilance - PSURs and SARs

• **Slentrol** EMEA/V/C/000116	Rapp: E. Lander Persson ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14
• **TruScient** EMEA/V/C/002000	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.14-30.11.14
• **Vectra 3D** EMEA/V/C/002555	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **Broadline** EMEA/V/C/002700	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **BTVPUR Alsap 1** EMEA/V/C/002230	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **BTVPUR Alsap 1-8** EMEA/V/C/002231	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **Cardalis** EMEA/V/C/002524	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **Cerenia** EMEA/V/C/000106	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **Circovac** EMEA/V/C/000114	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.14-31.12.14
• **Contacera** EMEA/V/C/002612	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14

• **Equilis Prequenza** EMEA/V/C/000094	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **Equilis Prequenza Te** EMEA/V/C/000095	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **ERYSENG** EMEA/V/C/0027616	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 04.07.13-31.01.15
• **ERYSENG PARVO** EMEA/V/C/002762	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 04.07.13-31.01.15
• **Melosus** EMEA/V/C/002001	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-28.02.15
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-31.12.14
• **Trifexis** EMEA/V/C/002635	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 05.07.14-04.01.15

- ***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 GL 52: Bioequivalence: blood level bioequivalence study and annex; EU comments
- ***For endorsement***: Revised draft (draft 4) by EU topic leader of VICH draft guideline on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use and overview of comments received on draft 3 of the draft VICH guideline

6.2 Codex Alimentarius

- ***For information***: Verbal report from the 22nd Session of the Codex Committee on residues of veterinary drugs in foods (CCRVDF) held on 27 April – 1 May 2015; agenda of the meeting

6.3 Other EU bodies and international organisations

- ***For decision:*** Nomination of an expert for a new EFSA working group on *Echinococcus multilocularis*
- ***For decision:*** Nomination of a CVMP representative to attend the ECHA/EFSA topical scientific workshop on soil risk assessment, to be held in Helsinki-Finland on 7-8 October 2015
- ***For decision:*** Nomination of a CVMP representative to attend the EFSA's second scientific conference 'Shaping the future of food safety, together' to be held in Milan, Italy on 14-16 October 2015
- ***For discussion:*** Draft EFSA opinion on reference points for action for nitrofurans

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

- 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

Information on certain Antimicrobial resistance related issues cannot be released at the present time as it is deemed to be confidential

- ***For discussion***: CVMP Strategy on Antimicrobials 2016 to 2020
- ***For discussion***: Request from European Commission for a joint EFSA and EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU; report of the virtual meeting between EFSA, EMA and EC held on 15 April

8.4 Pharmacovigilance

- No items

8.5 Other issues

- 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 discussion***: CMDv position paper on in-use shelf-life of tablet fractions
- ***For information***: Agenda of the meeting to be held on 7-8 May 2015; minutes of the meeting held 9-10 April 2015

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: CVMP Interested Parties' meeting to be held on 6 May 2015 - draft agenda
- ***For discussion***: EU Medicines Agencies Network Strategy to 2020
- ***For discussion***: Cooperation and exchanges between CVMP and CMDv
- ***For information***: Financial incentives to vaccines against certain epizootic diseases
- ***For information***: Extension of the data gathering exercise to veterinary procedures
- ***For information***: EMA 20th anniversary programme

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
May 2015	5-7	12-13		19-20		26-27	26–28	5	21-22
June 2015	2-4		16-17		17-18	30 Jun-1 Jul		2	
July 2015	7-9							7	
Sept 2015	8-10	23-24		15-16		22-23	30 Sept-2 Oct	8	24-25
Oct 2015	6-8		13-14		20-21			6	
Nov 2015	4-6					24-25		4	
Dec 2015	8-10	2-3		1-2			1-3	8	3-4