17 July 2018
EMA/CVMP/435798/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of July 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

17 July 2018, 09:00 – 19 July 2018, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of competing 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 CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP 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. Intended participation and competing 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 17 July 2018	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMA/V/MRL/004856/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/005010/FULL/0001 *Equidae*	***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

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004824/0000 *New antiparasitic product* *Cats and dogs*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004345/0000 *New cardiovascular product* *Dogs*	***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/004858/0000 *New vaccine* *Pigs*	***For adoption****:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **Horse Allo 20** EMEA/V/C/004222/0000 *New product for musculo-skeletal disorder, containing equine adipose-derived mesenchymal stem cells for the treatment of lameness associated to osteoarthritis in adult non-food producing horses* *Horses*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision**:* Appointment of rapporteur, co-rapporteur and peer reviewers ***For discussion***: Request for re-examination from applicant
• **LongRange** EMEA/V/C/004291/0000 *New antiparasitic product containing eprinomectin for the treatment of certain specified parasites, and for the prevention of reinfections with certain specified parasites* *Cattle*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision**:* Appointment of rapporteur, co-rapporteur and peer reviewers ***For discussion***: Request for re-examination from applicant

2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **UBAC** (EMEA/V/C/004595/0000)
- ***For adoption:*** Withdrawal EPAR module scientific discussion for **HopGuard Gold** (EMEA/V/C/002836/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Inflacam and Rheumocam** EMEA/V/C/xxxxxx/WS1301 *Quality*	Rapp: S. Louet ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **Palladia** EMEA/V/C/000150/II/0012/G *Quality*	Rapp: F. Hasslung Wikström ***For adoption***: CVMP opinion **For endorsement**: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Versican Plus DHPPi and Versican Plus Pi** EMEA/V/C/xxxxxx/WS1397 *Quality*	Rapp: E. Werner ***For adoption***: CVMP list of questions, product information for Versican Plus DHPPi and for Versican Plus Pi

• **Versican Plus DHPPi L4R, Versican Plus DHPPi L4, Versican Plus L4, Versican Plus Pi L4R and Versican Plus Pi L4** EMEA/V/C/xxxxxx/WS1398 *Quality*	Rapp: E. Werner ***For adoption***: CVMP list of questions, comments on product information: for Versican Plus DHPPi L4R, Versican Plus DHPPi L4, Versican Plus L4, Versican Plus Pi L4R and for Versican Plus Pi L4

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Clomicalm** EMEA/V/C/000039/II/0027 *Quality*	Rapp: G. Hahn ***For decision****:* Request for extension of clock stop

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

- No items

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

• **Diethanolamine** EMEA/V/A/127 *To consider the risk for the consumer resulting from the use of diethanolamine as an excipient in VMPs for food producing species*	Rapp: B. Urbain Co-rapp: G. Hahn ***For adoption:*** CVMP opinion, CVMP assessment report

• **Veterinary medicinal products containing gentamicin for parenteral administration to horses** EMEA/V/A/128 *Quality*	Rapp: M. O'Grady Co-rapp: W. Schlumbohm ***For discussion:*** Rapporteurs' assessment report including co-rapporteur's critique

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

• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/REC/009 *Recommendation*	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the recommendation
• **Prac-tic** EMEA/V/C/000103/REC/024 *Recommendation*	Rapp: C. Muñoz ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2017 – 14/07/2018
Canigen L4 (EMEA/V/C/004079)	03/07/2017 – 02/07/2018
CLYNAV (EMEA/V/C/002390)	27/06/2017 – 26/06/2018
Equilis Prequenza (EMEA/V/C/000094)	08/07/2017 – 07/07/2018
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2017 – 07/07/2018
Equilis Te (EMEA/V/C/000093)	08/07/2017 – 07/07/2018
EQUIOXX (EMEA/V/C/000142)	25/06/2017 – 24/06/2018
ERYSENG (EMEA/V/C/002761)	04/07/2017 – 03/07/2018
ERYSENG PARVO (EMEA/V/C/002762)	08/07/2017 – 07/07/2018
Innovax-ILT (EMEA/V/C/003869)	03/07/2017 – 02/07/2018
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25/06/2017 – 24/06/2018
Melovem (EMEA/V/C/000152)	07/07/2017 – 06/07/2018
Nobivac L4 (EMEA/V/C/002010)	16/07/2017 – 15/07/2018

Product	Period
Posatex (EMEA/V/C/000122)	23/06/2017 – 22/06/2018
ProZinc (EMEA/V/C/002634)	12/07/2017 – 11/07/2018
Reconcile (EMEA/V/C/000133)	08/07/2017 – 07/07/2018
Suprelorin (EMEA/V/C/000109)	10/07/2017 – 09/07/2018
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2017 – 03/07/2018
Versican Plus Pi (EMEA/V/C/003681)	04/07/2017 – 03/07/2018

5.4 Renewals

• **Broadline** EMEA/V/C/2700/R/0020	Rapp: B. Urbain Co-rapp: C. Muñoz ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Easotic** EMEA/V/C/000140	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report
• **OSURNIA** EMEA/V/C/003753	Rapp: S. Louet ***For endorsement***: Rapporteur's assessment report
• **ERYSENG** EMEA/V/C/002761	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.17-31.01.18
• **ERYSENG PARVO** EMEA/V/C/002762	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.17-31.01.18
• **Suvaxyn PRRS MLV** EMEA/V/C/004276	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 24.08.17-28.02.18
• **Canigen L4/Nobivac L4** EMEA/V/C/004079 EMEA/V/C/002010	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.17-31.01.18
• **Coliprotec F4/F18** EMEA/V/C/004225	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.17-31.01.18

• **Equilis Te** EMEA/V/C/000093	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.02.15-31.01.18
• **Imrestor** EMEA/V/C/00273	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.04.17-30.09.17
• **Purevax RCP** EMEA/V/C/000090	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.15-28.02.18
• **Purevax RCPCh** EMEA/V/C/000088	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.15-28.02.18
• **Sedadex** EMEA/V/C/004202	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 13.08.17-12.02.18
• **Stronghold Plus** EMEA/V/C/004194	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.09.17-28.02.18
• **UpCard** EMEA/V/C/003836	Rapp: H. Jukes ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.17 - 31.01.18
• **Ypozane** EMEA/V/C/000112	Rapp: G. J. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.02.15-31.01.18
• **ZACTRAN** EMEA/V/C/000129	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.17-31.01.18

- ***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 adoption:*** VICH GL56 Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, for implementation at step 7

- ***For adoption***: VICH GL58 Stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV, for consultation at Step 4
- ***For information***: Feedback on the 36th VICH Steering Committee meeting held on 25-26 and 28 June 2018, and 10th VICH Outreach Forum meeting held on 26-27 June 2018 in Bruges, Belgium

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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 Working Group on the application of the 3Rs (J3RsWG)

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

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***: Reflection paper on the pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation

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 be commercially confidential

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***: Verbal report from the CMDv chair on the meetings held in April, May and June 2018; draft minutes of the meeting held on 21-22 June 2018; draft agenda of meeting to be held on 19-20 July 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** CVMP work plan for 2019: general areas of activity
- ***For discussion:*** Recommendations arising from the informal presidency meeting held on 7-8 May 2018, in Madrid, Spain; agenda and draft minutes of the meeting
- ***For discussion and decision***: CVMP roles -1st review, points for consideration and outcome of discussion at the May-June 2018 CVMP meetings; recommendations and next steps
- ***For discussion:*** Informal Presidency CVMP-CMDv meeting (to be held during the Austrian presidency) on 25-26 October 2018 in Helsinki, Finland; draft agenda
- ***For information:*** Update on EMA relocation
- ***For information:*** Information on potential issues or procedures that would require CVMP decision via written procedure during August 2018

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- For comments: Press release of the meeting

ANNEX

NEXT MEETINGS OF THE CVMP AND ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Jul 2018	17-19								17		
Sep 2018	11-13	13	18-19				25-26		11		
Oct 2018	9-11				23-24	17-18			9		
Nov 2018	6-8						20-21	27-29	6	29-30	
Dec 2018	4-6		11-12						4		