18 May 2018
EMA/CVMP/287208/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of May 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

23 May 2018, 09:00 – 25 May 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)	Wed 23 May 18	16:00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

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

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004595/0000 *New vaccine* *Cows and heifers*	***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/004291/0000 *New antiparasitic product* *Cattle*	**ORAL EXPLANATION – Thursday 24 May 2018, 11:30** ***For discussion****:* Presentation from applicant, rapporteur's assessment of responses to the list of outstanding issues of the dossier, draft product information

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **Bravecto Plus** (EMEA/V/C/004440/0000)
- ***For adoption:*** EPAR module scientific discussion for **Semintra** (EMEA/V/C/002436/X/0008)
- ***For adoption:*** EPAR module scientific discussion for **Dany's BienenWohl** (EMEA/V/C/004667/0000)

- ***For adoption:*** Withdrawal EPAR module scientific discussion for **Zydax** (EMEA/V/C/004375/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Pexion** EMEA/V/C/002543/II/0011/G *To add a new therapeutic indication and quality changes*	Rapp: S. Louet Co-rapp: H. Jukes ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Exzolt** EMEA/V/C/004344/II/0003/G *Quality*	Rapp: P. Hekman **Background note**: N/a ***For adoption***: CVMP opinion ***For endorsement***: Rapporteurs' assessment report
• **CLYNAV** EMEA/V/C/002390/II/0001/G *Quality*	Rapp: N. Garcia del Blanco ***For adoption****:* CVMP opinion ***For endorsement****:* Rapporteur's assessment report
• **Porcilis PCV M Hyo** EMEA/V/C/003796/II/0007 *To modify the approved therapeutic indication*	Rapp: E. Werner Co-rapp: K. Lehmann ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Versican Plus range** EMEA/V/C/WS1337 *To change the product information Dogs*	Rapp: E. Werner ***For adoption***: CVMP list of questions, product information: Versican Plus DHPPI, Versican Plus DHPPi+L4, Versican Plus DHPPi+L4R, Versican Plus L4, Versican Plus Pi, Versican Plus Pi+L4, Versican Plus Pi+L4R
• **RESPIPORC FLUpan H1N1** EMEA/V/C/003993/II/0004 *Quality*	Rapp: M. Blixenkrone-Møller ***For adoption****:* CVMP list of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Galliprant** EMEA/V/C/004222/II/0001 *Quality*	Rapp: K. Baptiste ***For decision***: Request for extension of clock stop
• **HALAGON** EMEA/V/C/004201/II/0002/G *Quality*	Rapp: C. Muñoz ***For decision***: Request for extension of clock stop
• **NexGard, NEXGARD SPECTRA** EMEA/V/C/WS1338/G *To add three new therapeutic indications*	Rapp: J. G. Beechinor Co-rapp: P. Hekman ***For information:*** 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

- No items

4.7 Other issues

- ***To note***: Request from CP-Pharma GmbH for an extension of the clock stop for the Art. 30(3) procedure for veterinary medicinal products containing gentamicin for parenteral administration to horses (EMEA/V/A/128) and EMA response

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

• **Exzolt** EMEA/V/C/004344/REC/007-008-009 *Recommendation*	Rapp: P. Hekman ***For endorsement***: Rapporteur's assessment report on the recommendation
• **LETIFEND** EMEA/V/C/003865/REC/012 *Recommendation*	Rapp: C. Muñoz ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Credelio (EMEA/V/C/004247)	25/04/2017 – 24/04/2018
CYTOPOINT (EMEA/V/C/003939)	25/04/2017 – 24/04/2018
Equilis StrepE (EMEA/V/C/000078)	07/05/2017 – 06/05/2018
Improvac (EMEA/V/C/000136)	11/05/2017 – 10/05/2018
Ingelvac PCV FLEX (EMEA/V/C/004645)	24/05/2017 – 23/05/2018
LETIFEND (EMEA/V/C/003865)	20/04/2017 – 19/04/2018
Meloxidolor (EMEA/V/C/002590)	22/04/2017 – 21/04/2018
Naxcel (EMEA/V/C/000079)	19/05/2017 – 18/05/2018
Oncept IL-2 (EMEA/V/C/002562)	03/05/2017 – 02/05/2018
Procox (EMEA/V/C/002006)	20/04/2017 – 19/04/2018
RESPIPORC FLUpan H1N1 (EMEA/V/C/003993)	17/05/2017 – 16/05/2018
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2017 – 06/05/2018
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2017 – 06/05/2018
Zeleris (EMEA/V/C/004099)	15/05/2017 – 14/05/2018
Zulvac BTV Ovis (EMEA/V/C/004185)	25/04/2017 – 24/04/2018
Zuprevo (EMEA/V/C/002009)	06/05/2017 – 05/05/2018

5.4 Renewals

• **Reconcile** EMEA/V/C/000133/R/0018	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report, product information

• **APOQUEL** EMEA/V/C/002688/R/0013	Rapp: R. Breathnach Co-rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Suvaxyn Circo MH- RTU** EMEA/V/C/003924	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.17 - 30.11.17
• **BROADLINE** EMEA/V/C/002700	Rapp: B. Urbain ***For endorsement***: Rapporteur evaluation on the PSUR for the period 01.01.17 - 31.12.17
• **Cerenia** EMEA/V/C/000106	Rapp: E-M. Vestergaard ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.17 - 31.12.17
• **Circovac** EMEA/V/C/000114	Rapp: P. Pasquali ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.15 - 31.12.17
• **Contacera** EMEA/V/C/002612	Rapp: S. Louet ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.17 - 31.12.17
• **Innovax IL-T** EMEA/V/C/003869	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.08.17 - 31.01.18
• **Panacur AquaSol** EMEA/V/C/002008	Rapp: J. G. Schefferlie ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.17 - 31.12.17
• **Posatex** EMEA/V/C/000122	Rapp: S. Louet ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.15 - 31.12.17
• **Poulvac E. Coli** EMEA/V/C/002007	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.07.17 - 31.12.17
• **Spironolactone Ceva** EMEA/V/C/000105	Rapp: H. Jukes ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.15 - 31.12.17

• **Vectra Felis** EMEA/V/C/002746	Rapp: G. Hahn ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.01.15 - 31.12.17
• **Velactis** EMEA/V/C/003739	Rapp: W. Schlumbohm ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.07.17 - 31.12.17
• **Zycortal** EMEA/V/C/003782	Rapp: H. Jukes ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.17 - 31.12.17

- ***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 GL56 on residue studies in honey for establishing MRLs and withdrawal periods, for sign off by the EU expert
- ***For endorsement***: Proposal to put the revision of VICH GL18(R) on residual solvents on hold until ongoing revisions of the parallel ICH guideline are complete
- ***For information***: 36th VICH Steering Committee meeting to be held on 25-26 and 28 June 2018 in Bruges (draft agenda) and 10th VICH Outreach Forum meeting to be held on 26-27 June 2018 in Bruges (draft agenda)

6.2 Codex Alimentarius

- ***For information***: Feedback from 24th session of the Codex Committee on Residues of Veterinary Drugs in Food held in Chicago, USA from 23 – 27 April 2018; meeting report and meeting agenda

6.3 Other EU bodies and international organisations

- ***For discussion***: Report on the appropriateness of the existing 'No MRL required' classification of theophylline; presentation
- ***For information:*** ECHA recommendation to include N-methyl-pyrrolidone in the list of substances subject to authorisation

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

- 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

- No items

8.3 Antimicrobial resistance

- ***For information:*** Feedback on the development of the scientific advice prepared by the Antimicrobial Advice Ad Hoc Expert Group (AMEG) and the comments received on the questionnaire on the Early Hazard Characterisation from AnimalhealthEurope and European Group for Generic Veterinary Products (EGGVP)
- ***For information***: European Commission report on measures to tackle antimicrobial resistance through the prudent use of antimicrobials in animals

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

- ***For adoption:*** Revised Terms of Reference for the CVMP ad hoc group on veterinary vaccine availability (CADVVA)

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***: Draft minutes of the meeting held on 19 April 2018; draft agenda of the meeting to be held on 24-25 May 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Understanding the training needs of NCA assessors involved in the work of the CVMP: preliminary priority needs and plans for training 2018 – 2020; presentation
- ***For discussion***: CVMP roles -1st review and points for consideration
- ***For discussion***: CVMP work plan: Priority setting for 2019
- ***For information***: Verbal feedback on the CVMP/CMDv presidency meeting (during the Bulgarian presidency) held on 7-8 May in Madrid, Spain; agenda
- ***For information***: Verbal update on the EMA working group on operational preparedness for veterinary medicines
- ***To note:*** CVMP dates 2019-2021

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
May 2018	23-25*		29-30		29-30		29-30		23	17-18	
Jun 2018	19-21	21		5-6		6-7		5-7	19		
Jul 2018	17-19								17		
Sep 2018	11-13	13	18-19				25-26		11		
Oct 2018					23-24				9		