1 December 2017
EMA/CVMP/799382/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2017 meeting

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Draft agenda of December 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

5 December 2017, 09:00 – 7 December 2017, 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 5 Dec 2017	17.00-20.00

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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/004242/0000 *New vaccine* Pigs	***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/002836/0000 *New antiparasitic product* *Honey bees*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004291/0000 *New antiparasitic product* *Cattle*	***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/004329/0000 *New fixed combination product* *Pigs*	***For adoption****:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/002774/0000 *New product for musculo-skeletal disorder* *Horses*	***For decision***: Request from applicant to extend clock-stop

- ***For adoption:*** EPAR module scientific discussion for **Rabitec** (EMEA/V/C/004387/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **ZACTRAN** EMEA/V/C/000129/II/0036 *To add a new therapeutic indication*	Rapp: E.-M. Vestergaard Co-rapp: J. G. Beechinor ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **RESPIPORC FLUpan H1N1** EMEA/V/C/003993/II/0002/G *Quality*	Rapp: M. Blixenkrone-Moller ***For adoption****:* CVMP opinion ***For endorsement****:* Rapporteur's assessment report
• **Easotic** EMEA/V/C/000140/II/0012 *Quality*	Rapp: E.-M. Vestergaard ***For adoption****:* CVMP opinion ***For endorsement****:* Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Metacam** EMEA/V/C/000033/II/0127 *To register an additional target species*	Rapp: F. Hasslung Wikstrom Co-rapp: G. Hahn **ORAL EXPLANATION** ***For discussion****:* MAH's presentation, draft product information
• **Vaxxitek HVT +IBD** EMEA/V/C/000065/WS1209/G *Quality*	Rapp: B. Urbain ***For adoption****:* List of outstanding issues
• **Porcilis ColiClos** EMEA/V/C/002011/II/0007 *Quality*	Rapp: N. Garcia del Blanco ***For adoption****:* List of outstanding issues

3.3 List of questions

• **Pexion** EMEA/V/C/002543/II/0011/G *To add a new therapeutic indication*	Rapp: S. Louet Co-rapp: H. Jukes ***For adoption**:* List of questions
• **Activyl Tick Plus** EMEA/V/C/002234/II/0011 *To change conditions regarding supply and use*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach **For adoption**: List of questions
• **Naxcel** EMEA/V/C/000079/WS1241/0034 *Quality*	Rapp: S. Louet ***For adoption:*** List of questions
• **Vaxxitek HVT + IBD** EMEA/V/C/000065/WS1242/0024 *Quality*	Rapp: B. Urbain ***For adoption:*** 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

- 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

- ***For information***: Updated questions and answers documents for Article 13, Article 33(4), Article 34 and Article 35 referrals for publication on the EMA website

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

• **NEXGARD SPECTRA** EMEA/V/C/3842/REC/010	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Broadline (EMEA/V/C/002700)	04/12/2016 - 03/12/2017
BTVPUR AISap 2-4 (EMEA/V/C/000139)	05/11/2016 – 04/11/2017
Contacera (EMEA/V/C/002612)	06/12/2016 – 05/12/2017
DRAXXIN (EMEA/V/C/000077)	11/11/2016 - 10/11/2017
Easotic (EMEA/V/C/000140)	20/11/2016 - 19/11/2017
Equip WNV (EMEA/V/C/000137)	21/11/2016 - 20/11/2017
Halocur (EMEA/V/C/000040)	29/10/2016 – 28/10/2017
Masivet (EMEA/V/C/000128)	17/11/2016 - 16/11/2017
Meloxivet (EMEA/V/C/000124)	14/11/2016 - 13/11/2017
Meloxoral (EMEA/V/C/000151)	19/11/2016 - 18/11/2017
Oxyglobin (EMEA/V/C/000045)	21/11/2016 - 20/11/2017
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2016 - 15/11/2017
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2016 – 06/11/2017
Quadrisol (EMEA/V/C/000032)	04/12/2016 - 03/12/2017
Simparica (EMEA/V/C/003991)	06/11/2016 – 05/11/2017
Stronghold (EMEA/V/C/000050)	25/11/2016 - 24/11/2017
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06/11/2016 – 05/11/2017
Vectra 3D (EMEA/V/C/002555)	04/12/2016 – 03/12/2017
Virbagen Omega (EMEA/V/C/000061)	06/11/2016 – 05/11/2017
Zolvix (EMEA/V/C/000154)	04/11/2016 – 03/11/2017
Zycortal (EMEA/V/C/003782)	06/11/2016 – 05/11/2017

5.4 Renewals

• **Ecoporc SHIGA** EMEA/V/C/002588/R/0006	Rapp: N. Garcia del Blanco Co-rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Canigen L4 & Nobivac L4** EMEA/V/C/004079	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.17-31.07.17
• **LEUCOFELIGEN FeLV RCP** EMEA/V/C/000143	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.14-30.06.17
• **Suvaxyn PCV** EMEA/V/C/000149	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16 - 31.07.17
• **Versican Plus DHPPI** EMEA/V/C/003679	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.17-31.07.17
• **Versican Plus Pi** EMEA/V/C/003681	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.17-31.07.17
• **CORTAVANCE** EMEA/V/C/000110	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.14 - 31.07.17
• **Gripovac 3** EMEA/V/C/000157	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.08.14-31.07.17
• **Innovax-ILT** EMEA/V/C/003869	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.01.17-31.07.17
• **MELOXIDYL** EMEA/V/C/000115	Rapp: F. Hasslung Wikström ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.14-31.07.17
• **OSURNIA** EMEA/V/C/003753	Rapp: S. Louet ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.02.17-31.07.17

• **PIRSUE** EMEA/V/C/000054	Rapp: G. Hahn ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.14 - 31.07.17
• **RESPIPORC FLU3** EMEA/V/C/000153	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.08.14-31.07.17
• **Sedadex** EMEA/V/C/004202	Rapp: C. Muñoz Madero ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 13.02.17 - 12.08.17
• **Sileo** EMEA/V/C/003764	Rapp: F. Hasslung Wikström ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.01.17-30.06.17
• **UpCard** EMEA/V/C/003836	Rapp: H. Jukes ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.02.17-31.07.17
• **ZACTRAN** EMEA/V/C/000129	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.02.17-31.07.17

- ***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***: Revision of VICH anthelmintic guidelines:
  - VICH GL07 Rev.1 - General requirements - draft EU comments
  - VICH GL12 Rev.1 - Bovines - draft EU comments
  - VICH GL13 Rev.1 - Ovines - draft EU comments
  - VICH GL14 Rev.1 - Caprines - draft EU comments
  - VICH GL15 Rev.1 - Equines - draft EU comments
  - VICH GL16 Rev.1 - Porcine - draft EU comments
  - VICH GL19 Rev.1 - Canine - draft EU comments
  - VICH GL20 Rev.1 - Feline - draft EU comments
  - VICH GL21 Rev.1 - Poultry - draft EU comments
- ***For endorsement***: New draft VICH guideline on fixed combinations:
  - VICH Combination products – discussion document - draft EU comments
  - VICH Combination products - merger GL – draft EU comments

- ***For endorsement***: Draft training materials for VICH guideline 52 on bioequivalence: blood level bioequivalence study - draft EU comments
- ***For endorsement***: Draft (IV) annex to VICH GL3(R) guideline on stability studies for climatic zones III and IV; compilation of comments on draft III with EU responses
- ***For endorsement***: Draft guideline on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, revised following comments from the BQM EWG; compilation of comments from EWG with EU responses
- ***For endorsement***: VICH GL57 Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species, sign off at step 3
- ***For discussion***: JMAFF proposal for advancing the work on extraneous viruses in veterinary vaccines
- ***For discussion***: JMAFF concept paper proposing development of a guideline on safety evaluation of biotechnology-derived/biological products
- ***To note***: Feedback from 35th VICH Steering Committee meeting and 9th Outreach Forum meeting; mission report

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

- 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

- ***For information***: Verbal report on progress of the pilot project on dose optimisation in the context of SPC harmonisation of established veterinary antibiotics (PPHOVA) and on the second meeting held on 10 November 2017; draft minutes

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

- ***For information:*** Revised incident management plan for medicines for veterinary use- Rev.2

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

- ***For adoption:*** QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP)

- ***For adoption:*** Quick Response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures

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

- ***For information***: Verbal update from the chair of the CMDv on the meeting held on 8-9 November 2017, draft minutes of the meeting; draft agenda of the meeting to be held on 7-8 December 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: Draft CVMP work plan 2018
- ***For information***: User manual on CxMP/EMA external representation; presentation
- ***For information:*** Verbal update on the EMA working group on operational preparedness for veterinary medicines
- ***To note:*** Presidency CVMP/CMDv meeting to be held on 7-8 May 2018 in Madrid, Spain (on behalf of the Bulgarian presidency)

13. LEGISLATION

Information on certain topics discussed under section 13 cannot be released at the present time as it is deemed to be confidential

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
Dec 2017	5-7	6							5	-1	
Jan 2018	16-18			30-31			23-24		16		
Feb 2018	13-15	15	20-21		20-21	28-		27-	13	1-2	
Mar 2018	13-15					-1	20-21	-1	13		
Apr 2018	17-19								17		