10 April 2017
EMA/CVMP/235742/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

10 April 2017, 09:00 – 12 April 2017, 13:00 - Room 3A

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 3A)	Mon 10 Apr 2017	16.30-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/004706/FULL/0001 *Rabbits*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information****:* Summary of opinion

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/004479/FULL/0001 *Porcine*	***For decision***: Need for oral explanation ***For discussion***: Draft CVMP EPMAR

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

Information on certain topics discussed under section 1.5 cannot be released at the present time as it is deemed to be commercially confidential

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004331/0000 *New antiemetic product* *Dogs, cats*	***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/004364/0000 *New vaccine* *Pigs*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004276/0000 *New vaccine* *Pigs*	***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/004440/0000 *New antiparasitic product* *Cats*	***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/004316/0000 *New antiparasitic product* Cats	***For information***: Letter of withdrawal of the marketing authorisation application

- ***For endorsement*:** EPAR module scientific discussion for **Credelio** (EMEA/V/C/004247/0000)
- ***For endorsement*:** EPAR module scientific discussion for an extension for **Zactran** (EMEA/V/C/000129/X/0034)
- ***For endorsement*:** EPAR module scientific discussion for **Cytopoint** (EMEA/V/C/003939/0000)
- ***For endorsement*:** EPAR module scientific discussion for **ZULVAC BTV Ovis** (EMEA/V/C/004185/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Activyl Tick Plus** EMEA/V/C/002234/II/0008 *Addition of a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For adoption**:* Summary of opinion
• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0004/G *To increase the duration of immunity; Quality*	Rapp: B. Urbain ***For adoption**:* CVMP opinion, CVMP assessment report, product information
• **ZULVAC 1+8 Bovis, ZULVAC 8 Ovis, ZULVAC 8 Bovis, ZULVAC 1+8 Ovis, ZULVAC 1 Ovis, ZULVAC SBV and ZULVAC 1 Bovis** EMEA/V/C/xxxxxx/WS1039 *Quality*	Rapp: E.-M. Vestergaard ***For adoption*:** CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0005/G *Quality*	Rapp: B. Urbain ***For adoption**:* List of outstanding issues
• **Pexion** EMEA/V/C/002543/II/0009 *SPC changes*	Rapp: S. Louet Co-rapp: H. Jukes ***For adoption**:* List of outstanding issues

3.3 List of questions

• **ZULVAC 1+8 Ovis, ZULVAC 1+8 Bovis and ZULVAC 1 Bovis** EMEA/V/C/xxxxxx/WS1096 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: List of questions
• **ZULVAC 8 Bovis and ZULVAC 8 Ovis** EMEA/V/C/xxxxxx/WS1097 *Quality*	Rapp: P. Pasquali Co-rapp: I. Malemis ***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

• **Girolan and its associated name Apralan** EMEA/V/A/122 *Apramycin sulfate* *SPC harmonisation*	Rapp: C. Munoz Co-rapp: B. Urbain ***For adoption***: List of outstanding issues ***For discussion***: Rapporteur's assessment including co-rapporteur's critique on MAH's responses to list of outstanding issues, Rapporteur's assessment report including co-rapporteur's critique, draft product information
• **Denagard 45% and associated names** EMEA/V/A/114 *Tiamulin hydrogen fumarate* *SPC harmonisation*	Rapp: E. Werner Co-rapp: C. Munoz ***For adoption***: CVMP opinion, CVMP assessment report, product information

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** EMEA/V/A/116 *Environmental risk assessment*	Rapp: G. Hahn Co-rapp: C. Munoz **ORAL EXPLANATION – Tuesday 11 April 2017** ***For discussion***: Presentations from Zoetis and from Norbrook

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

- 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

• **Stronghold Plus** EMEA/V/C/004194/REC/001 & 002	Rapp: R. Breathnach Co-rapp: P. Hekman ***For adoption***: Rapporteur's assessment report
• **BTVPUR** EMEA/V/C/002231/REC/019	Rapp: C. Munoz Co-rapp: P. Pasquali ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Advocate (EMEA/V/C/000076)	02/04/2016 – 01/04/2017
BTVPUR AlSap 8 (EMEA/V/C/000146)	17/03/2016 – 01/04/2017
Clomicalm (EMEA/V/C/000039)	01/04/2016 – 31/03/2017
ECOPORC SHIGA (EMEA/V/C/002588)	10/04/2016 – 09/04/2017
Eurican Herpes 205 (EMEA/V/C/000059)	26/03/2016 – 25/03/2017
Incurin (EMEA/V/C/000047)	24/03/2016 – 23/03/2017
Locatim (EMEA/V/C/000041)	29/03/2016 – 28/03/2017
Parvoduk (EMEA/V/C/002740)	11/04/2016 – 10/04/2017
Rabigen SAG2 (EMEA/V/C/000043)	06/04/2016 – 05/04/2017
Veraflox (EMEA/V/C/000159)	12/04/2016 – 11/04/2017

5.4 Renewals

• **Cardalis** EMEA/V/C/002524/R/0009	Rapp: H. Jukes Co-rapp: C. Munoz ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Aivlosin** EMEA/V/C/000083	Rapp: H. Jukes ***For discussion / adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For discussion / adoption****:* Draft CVMP assessment report on the PSUR for the period 01.03.16-31.08.16
• **Broadline** EMEA/V/C/002700	Rapp: B. Urbain ***For adoption:*** CVMP assessment report on the PSUR for the period 01.07.16-31.12.16
• **BTVPUR AlSap 2-4** EMEA/V/C/000139	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15-30.11.16
• **Contacera** EMEA/V/C/002612	Rapp: S. Louet ***For adoption:*** CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **Draxxin** EMEA/V/C/000077	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-30.11.16
• **Equip WNV** EMEA/V/C/000137	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-30.11.16
• **Improvac** EMEA/V/C/000136	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.13-30.11.16
• **Oncept IL-2** EMEA/V/C/002562	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.15-30.11.16

• **Panacur AquaSol** EMEA/V/C/002008	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **Parvoduk** EMEA/V/C/002740	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.16-30.10.16
• **Porcilis ColiClos** EMEA/V/C/002011	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **Porcilis PCV M Hyo** EMEA/V/C/003796	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-30.11.16
• **Purevax FeLV** EMEA/V/C/000056	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.13-30.10.16
• **Suvaxyn Circo+Mh RTU** EMEA/V/C/003924	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-01.12.16
• **Vectra Felis** EMEA/V/C/002746	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.16-31.12.16
• **Versican Plus DHPPi/L4** EMEA/V/C/003678	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-30.11.16
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-30.11.16
• **Zycortal** EMEA/V/C/003782	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-30.11.16

- ***For endorsement:*** **Metacam** (EMEA/V/C/000072) - recommendation from PhVWP-V to the MAH following surveillance analysis findings
- ***For endorsement:*** **Purevax Rabies** (EMEA/V/C/000072) - recommendation from PhVWP-V to the MAH following surveillance analysis findings
- ***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 information***: Report from 34th VICH Steering Committee meeting and 8th Outreach Forum meeting held in Buenos Aires between 27 February – 2 March 2017

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information:*** Report from the CVMP representative on the EFSA workshop on benchmark dose, held in Brussels, Belgium on 1-2 March 2017; programme of the workshop
- ***For information:*** Verbal report from the 3nd EMA/JECFA liaison meeting held on 7 March 2017; meeting agenda
- ***For information:*** Report from the CVMP representative on the 5th International Fresenius conference on environmental risk assessment of biocides, held in Dusseldorf, Germany on 23-24 March 2017; programme of the conference
- ***For information:*** Participation of CVMP representative at the upcoming EFSA-FEEDAP expert group meeting on ERA guidelines in Parma, Italy on 19-21 April 2017

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

- ***For adoption:*** Revised reflection paper on the authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances; overview of comments received during the public consultation

8.3 Antimicrobial resistance

- ***For information***: Presentation of ESVAC draft guidance on provision of data on antimicrobial use by animal species from national data collection systems; Questions and answers for the guidance on provision of data on antimicrobial use by animal species from national data collection systems

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

- ***For decision:*** Transfer of rapporteurships from E. Werner to G. Hahn

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 agenda of meeting to be held on 11-12 April 2017; draft minutes of meeting held on 16 March 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion / adoption***: CVMP operation and procedures: practical guidance document for CVMP members
- ***For information***: Verbal report from the chair of the Strategic Planning Group (SPG) on the SPG meeting to be held on 11 April 2017, draft agenda; draft minutes from the meeting held on 18 January 2017
- ***For information***: Update on developments following the triggering of Article 50 of the Lisbon Treaty by the UK
- ***For information***: EMA framework of collaboration with academia
- ***For information***: Timing of the CVMP Interested Parties' Meeting 2017
- ***For information***: CVMP chair presentation to EMA Management Board meeting, held on 16 March 2017

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
Apr 2017	10-12*								10		
May 2017	10-12**	12	23-24		30-31		16-17	22-24	10	18-19	
Jun 2017	13-15			20-21		21-22			13		20
Jul 2017	11-13						18-19		11		
Sep 2017	5-7	7	20-21		12-13		26-27	27-29	5	21-22	

**Monday to Wednesday*

***Wednesday to Friday*