29 September 2017
EMA/CVMP/647713/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

3 October 2017, 09:00 – 5 October 2017, 13:00 - Room 3E

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 3E)	Tue 3 Oct 2017	16.30-19.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMA/V/MRL/003471/EXTN/0002 *Fin fish*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report
• **Substance** EMEA/V/MRL/004321/FULL/0001 *All food producing species*	***For adoption****:* CVMP opinion including EPMAR, CVMP assessment report

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMA/V/MRL/003141/EXTN/0004 *Fin fish*	***For discussion***: Draft rapporteur's EPMAR
• **Substance** EMA/V/MRL/004856/FULL/0001 *Chicken*	***For adoption***: CVMP scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/003596/FULL/0002 *Honey*	***For information****:* Letter of withdrawal of the application
• **Substance** EMEA/V/MRL/003135/MODF/0003 *Salmonidae*	***To note:*** New data from a field study from a MAH

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004387/0000 *New vaccine* *Foxes and raccoon dogs*	**For adoption**: CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004732/0000 *New antiparasitic product* *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/004417/0000 *New product* *Dogs*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on the draft product information
• **Product** EMEA/V/C/004222/0000 *New anti-inflammatory product* *Dogs*	***For discussion****:* Presentation from applicant, rapporteurs' assessment of responses to list of outstanding issues; draft product information

2.3 List of questions

• **Product** EMEA/V/C/004689/0000 *New anti-inflammatory product* *Dogs*	**For adoption**: Scientific overview and list of questions, comments on product information
• **Credelio** EMEA/V/C/004485/X/0001 *To add a new strength for a new target species*	Rapp: R. Breathnach Co-rapp: G. Kulcsár ***For adoption****:* Scientific overview and list of questions, comments on product information
• **Semintra** EMEA/V/C/002436/X/0008 *To add a new strength and a new indication* *Cats*	Rapp: R. Breathnach Co-rapp: C. Munoz ***For adoption****:* Scientific overview and list of questions, comments on product information
• **Rheumocam** EMEA/V/C/000121/X/0022 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For adoption****:* Scientific overview and list of questions, comments on product information
• **Inflacam** EMEA/V/C/002497/X/0015 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For adoption****:* Scientific overview and list of questions, comments on product information questions

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/004375/0000 *New product for musculo-skeletal disorders* *Dogs*	***For decision****:* Request from applicant for extension of clock-stop

- ***For adoption:*** EPAR module scientific discussion for **Exzolt** (EMEA/V/C/004344/0000)
- ***For adoption:*** EPAR module scientific discussion for **Nobivac LeuFel** (EMEA/V/C/004778/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **SevoFlo** EMEA/V/C/000072/II/0020 *To add a new target species*	Rapp: J. G. Beechinor Co-rapp: G. Hahn ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Porcilis PCV M Hyo** EMEA/V/C/003796/II/0006/G *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Imrestor** EMEA/V/C/002763/II/0005 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion, CVMP assessment report
• **Hiprabovis IBR Marker Live** EMEA/V/C/000158/II/0009 *Quality*	Rapp: N. Garcia del Blanco ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Vectormune ND** EMEA/V/C/003829/II/0017 *To add a new target species*	Rapp: F. Klein Co-rapp: E. Werner ***For adoption****:* Rapporteur's assessment report including list of questions ***For discussion****:* draft product information
• **Panacur Aquasol** EMEA/V/C/002008/II/0015 *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: T. Hoy ***For adoption****:* Rapporteur's assessment report including list of questions
• **Onsior** EMEA/V/C/000127/II/0018 *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: E.-M. Vestergaard ***For adoption****:* Rapporteur's assessment report including list of questions

• **Meloxidyl** EMEA/V/C/000115/II/0023/G *Quality*	Rapp: F. Hasslung Wikstrom ***For adoption**:* Rapporteur's assessment report including list of questions
• **Oncept IL2, Parvoduk, ProteqFlu, Proteq West Nile, ProteqFlu Te, Purevax FeLV, Purevax Rabies, Purevax RC, Purevac RCP, Purevax RCP FeLV, Pu8revax RCPCh, Purevax RCPCh FeLV, Vaxxitek HVT+IBD** EMEA/V/C/xxxxxx/WS/1195 *Quality*	Rapp: B. Urbain ***For adoption**:* Rapporteur's assessment report including list of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Metacam** EMEA/V/C/000033/II/0127 *To register an additional target species*	Rapp: F. Hasslung Wikstrom Co-rapp: G. Hahn ***For adoption***: 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

• **Girolan and its associated name Apralan** EMEA/V/A/122 *Apramycin sulfate* *SPC harmonisation*	Rapp: C. Munoz Co-rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report, product information

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** EMEA/V/A/089 - Follow-up assessment *Efficacy (dosing regimen for E. coli)*	Rapp: H. Jukes Co-rapp: C. Munoz ***For decision:*** Request from Bayer Animal Health to provide an oral explanation ***For discussion***: Rapporteur's assessment of the MAHs' responses to list of questions, revised rapporteur's assessment report, rapporteur's presentation

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

• **Coliprotec F4/F18** EMEA/V/C/004225/REC/008	Rapp: N. Garcia del Blanco ***For endorsement:*** Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Aivlosin (EMEA/V/C/000083)	09/09/2016 – 08/09/2017
APOQUEL (EMEA/V/C/002688)	12/09/2016 – 11/09/2017
Cerenia (EMEA/V/C/000106)	29/09/2016 – 28/09/2017
COXEVAC (EMEA/V/C/000155)	30/09/2016 – 29/09/2017
ERAVAC (EMEA/V/C/004239)	22/09/2016 – 21/09/2017
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2016 – 07/09/2017
Nobivac Bb (EMEA/V/C/000068)	10/09/2016 – 09/09/2017
Novaquin (EMEA/V/C/003866)	08/09/2016 – 07/09/2017
Palladia (EMEA/V/C/000150)	23/09/2016 – 22/09/2017
Previcox (EMEA/V/C/000082)	13/09/2016 – 12/09/2017
Recocam (EMEA/V/C/002247)	13/09/2016 – 12/09/2017
RHINISENG (EMEA/V/C/000160)	16/09/2016 – 15/09/2017
Trifexis (EMEA/V/C/002635)	19/09/2016 – 18/09/2017
Trocoxil (EMEA/V/C/000132)	09/09/2016 – 09/09/2017
Vectormune ND (EMEA/V/C/003829)	08/09/2016 – 07/09/2017

5.4 Renewals

• **Semintra** EMEA/V/C/002436/R/0009	Rapp: R. Breathnach Co-rapp: C. Munoz ***For adoption***: List of outstanding issues ***For discussion***: Product information
• **Pexion** EMEA/V/C/002543/R/0010	Rapp: S. Louet Co-rapp: H. Jukes ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Kexxtone** EMEA/V/C/002235/R/0009	Rapp: C. Munoz Co-rapp: J. G. Beechinor ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For discussion***: CVMP assessment report on the PSUR for the period 01.09.16-28.02.17
• **Apoquel** EMEA/V/C/002688	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.16-31.05.17
• **DRAXXIN** EMEA/V/C/000077	Rapp: G. Hahn ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.16-31.05.17
• **Fungitraxx** EMEA/V/C/002722	Rapp: S. Louet ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.10.16-31.03.17
• **Imrestor** EMEA/V/C/002763	Rapp: E-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.10.16-31.03.17
• **Porcilis PCV M Hyo** EMEA/V/C/003865	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.16-31.05.17
• **ProMeris (WD)** EMEA/V/C/000107	Rapp: G. J. Schefferlie ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.06.14-31.05.17

• **ProMeris Duo (WD)** EMEA/V/C/000108	Rapp: G. J. Schefferlie ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.06.14-31.05.17
• **Simparica** EMEA/V/C/003991	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.16-31.05.17
• **Suvaxyn Circo MH RTU** EMEA/V/C/003924	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.16-31.05.17
• **Versican Plus DHPPi L4** EMEA/V/C/003678	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 02.12.16-31.05.17
• **Versican Plus DHPPi L4R** EMEA/V/C/002759	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 02.12.16-31.05.17
• **Zycortal** EMEA/V/C/003782	Rapp: H. Jukes ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.16-31.05.17

- ***For discussion:*** PhVWP-V surveillance findings on **Improvac** (EMEA/V/C/000136)
- ***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***: 35th VICH Steering Committee meeting to be held on 13-17 November 2017 in Tokyo and 9th VICH Outreach Forum meeting to be held on 14-15 November 2017 in Tokyo
- ***For endorsement:*** EU comments on draft VICH GL on stability studies for climatic zones III and IV

6.2 Codex Alimentarius

- ***For endorsement:*** CVMP comments on proposed draft revision of the Code of practice to minimise and contain antimicrobial resistance (CAC/RCP 61-2005), and the proposed draft guidelines for the integrated [monitoring and] surveillance of foodborne antimicrobial resistance CL 2017/82-AMR - *see also 8.3*

6.3 Other EU bodies and international organisations

- ***For information:*** ECHA adopted opinion proposing harmonised classification and labelling for Vitamin D3 (colecalciferol)

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 discussion***: Verbal report on the new AMEG mandate; draft action plan and draft timetable; composition of the AMEG
- ***For endorsement:*** CVMP comments on proposed draft revision of the Code of practice to minimise and contain antimicrobial resistance (CAC/RCP 61-2005), and the proposed draft

guidelines for the integrated [monitoring and] surveillance of foodborne antimicrobial resistance CL 2017/82-AMR - *see also 6.2*

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:*** Feedback from the European Association of Fish Pathologists (EAFP) 18th International Conference on fish and shellfish diseases held on 4-8 September 2017 in Belfast, Northern Ireland; programme

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 discussion:*** Final report of the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, held on 22-23 June 2017

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 co-rapporteurship for Zeleris from L. Markus Cizelj to F. Bozic
- ***For decision:*** Transfer of rapporteurship for Oxybee from G. J. Schefferlie to J. Poot

10.2 Regulatory matters

Information relating to certain topics discussed under section 10.2 cannot be released at the present time as it is deemed to be confidential

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

- ***For information***: Verbal report on the meeting held on 7-8 September 2017, draft minutes of the meeting; draft agenda of meeting to be held on 5-6 October 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information***: Verbal report from the chair of the Strategic Planning Group (SPG) on the meeting to be held on 4 October 2017, draft agenda; draft minutes from the SPG meeting held on 12 July 2017
- ***For information:*** Adopted best practice guide on measures improving predictability of submissions/responses and adherence to communicated submission/responses deadlines, overview of comments

13. LEGISLATION

Information relating to certain legislative issues 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
Oct 2017	3-5			24-25		18-19			3		
Nov 2017	7-9	9	22-23		28-29		21-22	28-30	7	30-1/12	
Dec 2017	5-7								5	30/11-1	
Jan 2018	16-18								16		
Feb 2018	13-15								13		