9 February 2018
EMA/CVMP/88236/2018 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

13 February 2018, 09:00 – 15 February 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, 13 Feb 18	16:00 – 20:00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003517/EXTN/0003 *Poultry eggs*	***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/003647/EXTN/0002 *Porcine*	***For decision****:* Need for oral explanation

1.3 List of questions

• **Substance** EMEA/V/MRL/004933/FULL/0001 *Bovine*	***For adoption***: Scientific overview and list of questions

1.4 Re-examination of CVMP opinions

• **Substance** EMEA/V/MRL/003135/MODF/0003 *Salmonidae*	***For discussion***: Rapporteur's joint assessment report

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004440/0000 *New antiparasitic product* *Cats*	***For decision***: Request from applicant for oral explanation at March CVMP ***For adoption****:* Draft CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004417/0000 *New 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/004222/0000 *New product for a musculo-skeletal disorder* *Horses*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues; comments on product information

• **Product** EMEA/V/C/004265/0000 *New product for a musculo-skeletal disorder* *Horses*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues; comments on product information
• **Credelio** EMEA/V/C/004485/X/0001 *To add a new strength for a new target species* *Dogs*	Rapp: R. Breathnach Co-rapp: G. Kulcsár ***For adoption****:* Scientific overview and list of outstanding issues; comments on product information

2.3 List of questions

• **Zulvac BTV Ovis** EMEA/V/C/004185/X/0001 *Extension to add a new target animal species* *Sheep*	Rapp: N. Garcia del Blanco Co-rapp: F. Klein ***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/004291/0000 *New antiparasitic product* *Cattle*	***For decision***: Request from applicant to extend clock-stop
• **Product** EMEA/V/C/004611/0000 *New vaccine* *Sheep and cattle*	***For decision***: Request from applicant to extend clock-stop
• **Product** EMEA/V/C/004375/0000 *New product for a musculo-skeletal disorder* *Dogs*	***For information:*** Letter of withdrawal of the marketing authorisation application

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Metacam** EMEA/V/C/000033/II/0127 *To register an additional non-food producing target species*	Rapp: F. Hasslung Wikstrom Co-rapp: G. Hahn ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

• **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/WS1195 *Quality*	Rapp: B. Urbain ***For adoption**:* CVMP opinion ***For endorsement**:* Rapporteur's assessment report
• **Porcilis PCV ID** EMEA/V/C/003942/WS1277(0002) *To change the SPC/leaflet wording concerning a precision regarding administration during associated use*	Rapp: P. Hekman ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **ERAVAC** EMEA/V/C/004239/II/0003/G *To amend the duration of immunity and extension of safety; related changes in the product information*	Rapp: C. Muñoz ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Vaxxitek HVT + IBD** EMEA/V/C/000065/WS1209/G *Quality*	Rapp: B. Urbain ***For adoption**:* CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **STARTVAC** EMEA/V/C/000130/II/0005 *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion, product information ***For endorsement**:* Rapporteur's assessment report
• **Ingelvac CircoFLEX and Ingelvac PCV FLEC** EMEA/V/C/xxxxxx/WS1249/G *Quality*	Rapp: B. Urbain ***For adoption**:* CVMP opinion ***For endorsement**:* Rapporteur's assessment report
• **Vaxxitek HVT + IBD** EMEA/V/C/000065/WS1242 *Quality*	Rapp: B. Urbain ***For adoption**:* CVMP opinion ***For endorsement:*** Rapporteur's assessment report

3.2 Oral explanations and 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

• **BTVPUR** EMEA/V/C/002231/II/0010 To add a new serotype	Rapp: C. Muñoz Co-rapp: P. Pasquali ***For adoption**:* List of questions
• **CLYNAV** EMEA/V/C/002390/II/0001/G *Quality*	Rapp: N. Garcia del Blanco ***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 (re-examination) *Apramycin sulfate* *SPC harmonisation*	Rapp: J. G. Beechinor Co-rapp: W. Schlumbohm ***For adoption***: Final CVMP opinion, final 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. Muñoz ***For adoption***: CVMP follow-up assessment report
• **Veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep** EMEA/V/A/126 *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from the United Kingdom under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

• **Seresto** EMEA/V/A/125 *Imidacloprid and flumethrin* *Efficacy*	Rapp: H. Jukes Co-rapp: G. Hahn ***For adoption***: CVMP opinion, CVMP assessment report

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

- No items

5.3 Product anniversary list

Product	Period
Bravecto (EMEA/V/C/002526)	11/02/2017 – 10/02/2018
Comfortis (EMEA/V/C/002233)	11/02/2017 – 10/02/2018
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2017 – 04/02/2018
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2017 – 26/01/2018
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2017 – 12/02/2018
Kexxtone (EMEA/V/C/002235)	28/01/2017 – 27/01/2018
Loxicom (EMEA/V/C/000141)	10/02/2018 – 09/02/2018
NexGard (EMEA/V/C/002729)	11/02/2017 – 10/02/2018
Nobilis OR inac (EMEA/V/C/000062)	24/01/2017 – 23/01/2018
PIRSUE (EMEA/V/C/000054)	29/01/2017 – 28/01/2018
Semintra (EMEA/V/C/002436)	13/02/2017 – 12/02/2018
STARTVAC (EMEA/V/C/000130)	11/02/2017 – 10/02/2018

Stronghold Plus (EMEA/V/C/004194)	09/02/2017 – 08/02/2018
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2017 – 09/02/2018
VarroMed (EMEA/V/C/002723)	02/02/2017 – 01/02/2018
ZULVAC SBV (EMEA/V/C/002781)	06/02/2017 – 05/02/2018

5.4 Renewals

• **Meloxidolor** EMEA/V/C/002590/R/0007	Rapp: C. Muñoz Co-rapp: M. Turk ***For adoption***: List of outstanding issues
• **ProZinc** EMEA/V/C/002634/R/0013	Rapp: R. Breathnach Co-rapp: S. Louet ***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***: Draft revised assessment report on the PSUR for the period 01.03.17 - 31.08.17
• **Versican Plus L4** EMEA/V/C/003680	Rapp: E. Werner ***For adoption***: CVMP assessment report
• **Versican Plus Pi L4** EMEA/V/C/003683	Rapp: E. Werner ***For adoption***: CVMP assessment report
• **Versican Plus Pi L4R** EMEA/V/C/003682	Rapp: E. Werner ***For adoption***: CVMP assessment report
• **Aivlosin** EMEA/V/C/000083	Rapp: H. Jukes ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.04.17 – 30.09.17
• **Bovela** EMEA/V/C/003703	Rapp: F. Klein ***For endorsement:*** Rapporteur's evaluation of the PSUR for the period 01.01.17 - 30.06.17
• **Coliprotec F4** EMEA/V/C/003797	Rapp: N. Garcia del Blanco ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.04.17 – 30.09.17

• **Econor** EMEA/V/C/000042	Rapp: H. Jukes ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.10.16 – 30.09.17
• **Fortekor Plus** EMEA/V/C/002804	Rapp: E. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.04.17 – 30.09.17
• **Eravac** EMEA/V/C/004239	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation of the PSUR for the period 01.04.17 – 30.09.17
• **Eurican Herpes** EMEA/V/C/000059	Rapp: N. Garcia del Blanco ***For endorsement*:** Rapporteur's evaluation of the PSUR for the period 01.10.16 - 30.09.17
• **Proteq Flu** EMEA/V/C/000073	Rapp: J.-C. Rouby ***For endorsement***: Rapporteur's evaluation of the PSUR for the period 01.10.16 - 30.09.17
• **Proteq Flu Te** EMEA/V/C/000074	Rapp: J.-C. Rouby ***For endorsement:*** Rapporteur's evaluation of the PSUR for the period 01.10.16 - 30.09.17

- ***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***: EU comments on JMAFF proposal for advancing the work on extraneous viruses in veterinary vaccines
- ***For endorsement***: EU comments on the revised concept paper proposing development of a guideline on safety evaluation of biotechnology-derived/biological products
- ***For endorsement***: EU comments on draft concept paper for a VICH guideline providing guidance on the establishment and running of a basic pharmacovigilance system

6.2 Codex Alimentarius

Information on certain topics discussed under section 6.2 cannot be released at the present time as it is deemed to be confidential

6.3 Other EU bodies and international organisations

Information on certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be confidential

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

- ***For adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009

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

Information on certain topics discussed under section 8.3 cannot be released at the present time as it is deemed to be confidential

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

- No items

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 December 2017 and January 2018, draft minutes of the meeting held on 18-19 January 2018; draft agenda of meeting to be held on 15-16 February 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information***: Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 14 February 2018, draft agenda; draft minutes from the SPG meeting held on 8 November 2017
- ***For information***: Verbal update on the EMA working group on operational preparedness for veterinary medicines

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
Feb 2018	13-15	15	20-21		20-21	28-1		27-1	13	1-2	
Mar 2018	13-15						20-21		13		
Apr 2018	17-19								17		
May 2018	23-25*	25	29-30		29-30		29-30		23	17-18	
June 2018	19-21			5-6		6-7		5-7	19		