22 January 2019
EMA/CVMP/25963/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2019 meeting

Chair: D. Murphy

Vice-chair: H. Jukes

22 January 2019, 09:00 – 24 January 2019, 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 22 Jan 2019	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

• **Substance** EMEA/V/MRL/003649/EXTN/0002 *Porcine*	***For adoption**:* Scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

• **Innovax-ND-IBD** EMEA/V/C/004422/X/0001 *To add a new route of administration* *Chickens*	Rapp: J. Poot Co-rapp: E. Werner ***For decision:*** Need for oral explanation ***For adoption:*** Revised scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004794/0000 *New product* *Pigs*	***For decision:*** Need for oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on the product information

2.3 List of questions

• **Product** EMEA/V/C/004991/0000 *New product* *Horses*	***For adoption**:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **HorStem** EMEA/V/C/004265/0000 *New product for musculo-skeletal disorder* *Horses*	***For adoption**:* List of questions to AHEG ***For discussion***: Draft rapporteurs' assessment report for the re-examination of the CVMP opinion

2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **Syvazul BTV** (EMEA/V/C/004611/0000)
- ***For adoption:*** EPAR module scientific discussion for **Zulvac BTV** (EMEA/V/C/004185/X/0001)
- ***For adoption:*** EPAR module scientific discussion for **Isemid** (EMEA/V/C/004345/0000)
- ***For adoption:*** EPAR module scientific discussion for **Kriptazen** (EMEA/V/C/004868/0000)
- ***For adoption:*** Refusal EPAR for **LongRange** (EMEA/V/C/004291/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Purevax RC**, **Purevax RCP**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV** and **Purevax RCPCh** (EMEA/V/C/xxx/WS1517) *Quality*	Rapp: B. Urbain ***For adoption:*** CVMP opinion ***For endorsement:*** CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **ProZinc** EMEA/V/C/002634/II/0015 *To add a new target species*	Rapp: R. Breathnach Co-Rapp: S. Louet ***For adoption**:* List of outstanding issues
• **ProZinc** EMEA/V/C/002634/II/0016 *Quality*	Rapp: R. Breathnach ***For adoption*:** List of outstanding issues
• **Cytopoint** EMEA/V/C/003939/II/0003/G *Quality*	Rapp: R. Breathnach ***For adoption:*** List of outstanding issues

3.3 List of questions

• **Bravecto Plus** EMEA/V/C/004440/II/0003 *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption:*** List of questions

• **Suvaxyn PRRS MLV** EMEA/V/C/004276/II/0004/G *Onset of immunity, duration of immunity and changes to the product information*	Rapp: E. Werner Co-rapp: F. Klein ***For adoption:*** List of questions
• **LEUCOFELIGEN FeLV/RCP**, **LEUCOGEN** and **Nobivac LeuFel** EMEA/V/C/xxxxx/WS1483 *To modify indications*	Rapp: E. Werner ***For adoption:*** List of questions
• **Broadline** EMEA/V/C/002700/II/0023 *Quality*	Rapp: B. Urbain ***For adoption****:* List of questions
• **Porcilis PCV M Hyo** EMEA/V/C/003796/WS1467 *To change the product information*	Rapp: E. Werner ***For adoption:*** List of questions
• **Suprelorin** EMEA/V/C/00109/II/0022 *Quality*	Rapp: E.-M. Vestergaard ***For adoption:*** List of questions
• **Rhiniseng** EMEA/V/C/000160/II/0009 *Quality*	Rapp: E.-M. Vestergaard ***For adoption:*** List of questions
• **CLYNAV** EMEA/V/C/002390/II/0004/G *Quality*	Rapp: J. G. Beechinor ***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

• **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: S. Louet Co-rapp: G. J. Schefferlie ***For discussion:*** Revised rapporteur's assessment report including co-rapporteur's critique following MAHs' responses to the second list of outstanding issues
• **Veterinary medicinal products containing tylosin presented as solution for injection to be administered to pigs** EMEA/V/A/131 *Withdrawal periods*	Rapp: *to be nominated* Co-rapp: *to be nominated* ***For discussion and decision:*** Notification from France 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

- 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

• **CLYNAV** EMEA/V/C/002390/REC/001.2 *Recommendation*	Rapp: R. Cooney ***For endorsement***: Rapporteur's assessment report on the recommendation
• **CLYNAV** EMEA/V/C/002390/REC/008 *Recommendation*	Rapp: R. Cooney ***For endorsement***: Rapporteur's assessment report on the recommendation

• **Vaxxitek HVT+IBD** EMEA/V/C/000065/REC/025 *Recommendation*	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the recommendation
• **Vectormune ND** EMEA/V/C/003829/REC/012 *Recommendation*	Rapp: F. Klein ***For endorsement***: Rapporteur's assessment report on the recommendation
• **ZULVAC SBV** EMEA/V/C/002781/ANX/004.5 *Condition*	Rapp: R. Cooney ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Acticam (EMEA/V/C/000138)	09/12/2017 – 08/12/2018
Activyl Tick Plus (EMEA/V/C/002234)	09/01/2018 – 08/01/2019
Bovela (EMEA/V/C/003703)	22/12/2017 – 21/12/2018
BTVPUR (EMEA/V/C/002231)	17/12/2017 – 16/12/2018
Cepedex (EMEA/V/C/004376)	13/12/2017 – 12/12/2018
Coliprotec F4/F18 (EMEA/V/C/004225)	09/01/2018 – 08/01/2019
Contacera (EMEA/V/C/002612)	06/12/2017 – 05/12/2018
CORTAVANCE (EMEA/V/C/000110)	09/01/2018 – 08/01/2019
Galliprant (EMEA/V/C/004222)	09/01/2018 – 08/01/2019
HALAGON (EMEA/V/C/004201)	13/12/2017 – 12/12/2018
Imrestor (EMEA/V/C/002763)	09/12/2017 – 09/12/2018
Inflacam (EMEA/V/C/002497)	09/12/2017 – 08/12/2018
MELOXIDYL (EMEA/V/C/000115)	15/01/2018 – 14/01/2019
Metacam (EMEA/V/C/000033)	07/01/2018 – 06/01/2019
NEXGARD SPECTRA (EMEA/V/C/003842)	15/01/2018 – 14/01/2019
Nobilis OR inac (EMEA/V/C/000062)	24/01/2018 – 23/01/2019
Onsior (EMEA/V/C/000127)	16/12/2017 – 15/12/2018
Panacur AquaSol (EMEA/V/C/002008)	09/12/2017 – 08/12/2018
Porcilis PCV (EMEA/V/C/000135)	12/01/2018 – 11/01/2019

Product	Period
Prac-tic (EMEA/V/C/000103)	18/12/2017 – 17/12/2018
RESPIPORC FLU3 (EMEA/V/C/000153)	14/01/2018 – 13/01/2019
Rheumocam (EMEA/V/C/000121)	10/01/2018 – 09/01/2019
SevoFlo (EMEA/V/C/000072)	11/12/2017 – 10/12/2018
Ypozane (EMEA/V/C/000112)	11/01/2018 – 10/01/2019
ZULVAC 8 Bovis (EMEA/V/C/000145)	15/01/2018 – 14/01/2019
ZULVAC 8 Ovis (EMEA/V/C/000147)	15/01/2018 – 14/01/2019

5.4 Renewals

• **Versican Plus DHPPi/L4R** EMEA/V/C/002759/R/0014	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption***: List of outstanding issues
• **Versican Plus DHPPi/L4** EMEA/V/C/003678/R/0013	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** List of outstanding issues
• **Versican Plus DHPPi** EMEA/V/C/003679/R/0013	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Versican Plus Pi** EMEA/V/C/003681/R/0011	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Fungitraxx** EMEA/V/C/002722/R/0004	Rapp: S. Louet Co-rapp: K. Straus ***For adoption:*** CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Bovela** EMEA/V/C/003703	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.17-30.06.18

• **NEXGARD SPECTRA** EMEA/V/C/003842	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.17-31.07.18
• **Ingelvac CircoFLEX / Ingelvac PCV FLEX** EMEA/V/C/000126 / EMEA/V/C/004645	Rapp: P. Pasquali and B. Urbain ***For endorsement***: Rapporteur's evaluation on the joint PSUR for the period 01.09.15-31.08.17 and 24.05.18-31.08.18
• **CERTIFECT (WD)** EMEA/V/C/002002	Rapp: S. Louet ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.16-31.08.18
• **Innovax ND IBD** EMEA/V/C/004422	Rapp: P. Hekman ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.03.18-31.08.18
• **Prac-Tic** EMEA/V/C/000103	Rapp: C. Muñoz ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.07.18-30.06.18
• **Sedadex** EMEA/V/C/004202	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 13.02.18-12.08.18
• **Stronghold Plus** EMEA/V/C/004194	Rapp: R. Breathnach ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.03.18-31.08.18
• **Suvaxyn Circo** EMEA/V/C/004242	Rapp: F. Klein ***For endorsement***: Rapporteur assessment report on the PSUR for the period 07.02.18-31.08.18
• **Suvaxyn PRRS MLV** EMEA/V/C/004276	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.03.18-31.08.18; annex
• **ZULVAC SBV** EMEA/V/C/002781	Rapp: R. Cooney ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.09.17-31.08.18

- ***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 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 5
- ***For endorsement:*** Review of VICH anthelmintics guidelines: adequacy of infection – statistical justification - draft EU comments; Use of Faecal Egg Count Reduction Test (FECRT) – draft EU comments
- ***For discussion***: VICH Anthelmintic Expert Working Group - Choice of Mean in Dose Confirmation Studies: post-teleconference notes 2018 on the arithmetic versus geometric means
- ***For information***: Draft agenda of 37th Steering Committee meeting to be held on 24-25 February and 1 March 2019 in Cape Town, South Africa; draft agenda of 11th VICH Outreach Forum meeting to be held on 25-26 February 2019 in Cape Town, South Africa; draft programme of 6th VICH Conference to be held on 27-28 February in Cape Town, South Africa

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For discussion***: Invitation from EFSA to nominate a CVMP 'Hearing Expert' to participate in discussions relating to 4-chloroaniline, the genotoxic metabolite of diflubenzuron
- ***For discussion***: Mission report from OECD/FAO/WHO workshop and JMPR/JECFA meeting on residue definition held in Geneva in December 2018

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

7.11 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

- No items

8.3 Antimicrobial resistance

- ***For adoption***: Draft scientific advice by the Antimicrobial Advice Ad Hoc Expert Group on the categorisation of antimicrobials

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 adoption***: Verbal report from the CMDv chair on the meetings held in October, November and December 2018; minutes of the meeting held on 6-7 December 2018; draft agenda of meeting to be held on 24-25 January 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Upcoming election of the vice-chair of the Committee for Veterinary Use (CVMP) (3-year term, renewable once) at the February 2019 CVMP meeting; call for nominations
- ***To note:*** SPG November 2018 meeting - draft minutes

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

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Jan 2019	22-24						29-30		22		
Feb 2019	19-21								19		
Mar 2019	19-21						26-27		19		
Apr 2019	15-17								15		
May 2019	21-23						28-29		21		