5 October 2018
EMA/CVMP/662126/2018 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

9 October 2018, 09:00 – 11 October 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 9 Oct 18	16.30–18.00

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/004265/0000 *New product for musculo-skeletal disorder* *Horses*	***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/004868/0000 *New antiprotozoal product* *Calves*	***For decision**:* Need for oral explanation ***For adoption**:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004902/0000 *New vaccine* *Chickens*	***For adoption:*** Scientific overview and list of outstanding issues, comments on product information
Zulvac BTV Ovis EMEA/V/C/004185/X/0001 *To add a new target animal species* *Sheep*	Rapp: N. Garcia del Blanco Co-rapp: F. Klein ***For decision**:* Need for oral explanation ***For adoption**:* Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Innovax-ND-IBD** EMEA/V/C/004422/X/0001 *To add a new route of administration* *Chickens*	Rapp: P. Hekman Co-rapp: E. Werner ***For adoption**:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **LONGRANGE** EMEA/V/C/004291/0000 *New antiparasitic product containing eprinomectin for the treatment of certain specified parasites, and for the prevention of reinfections with certain specified parasites* *Cattle*	**ORAL EXPLANATION – Tuesday 9 October 2018** ***For adoption**:* Final CVMP opinion, final CVMP assessment report, product information ***For discussion***: Applicant's presentation, report from the AHEG meeting held on 2 October 2018, presentation from the AHEG's chair ***For information***: Summary of opinion
• **Horse Allo 20** EMEA/V/C/004222/0000 *New product for musculo-skeletal disorder, containing equine adipose-derived mesenchymal stem cells for the treatment of lameness associated to osteoarthritis in adult non-food producing horses* *Horses*	**ORAL EXPLANATION – Tuesday 9 October 2018** ***For adoption**:* Final CVMP opinion, Final CVMP assessment report, product information ***For discussion***: Applicant's presentation, report from the AHEG meeting held on 4-5 October 2018, presentation from the AHEG's chair ***For information***: Summary of opinion

2.5 Other issues

• **Product** EMEA/V/C/004824/0000 *New antiparasitic product* *Cats and dogs*	***For decision**:* Request from applicant to extend clock-stop

- ***For adoption:*** EPAR module scientific discussion for **Inflacam** (EMEA/V/C/ 002497/X/0015)
- ***For adoption:*** EPAR module scientific discussion for **Rheumocam** (EMEA/V/C/000121/X/0022)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **HALAGON** EMEA/V/C/004201/II/0002/G *Quality*	Rapp: C. Muñoz ***For adoption***: CVMP Opinion ***For endorsement***: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Cytopoint** EMEA/V/C/003939/II/0003/G *Quality*	Rapp: R. Breathnach ***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 decision:*** Need for further outstanding issues ***For discussion***: Revised rapporteurs' assessment report following MAHs' responses to the list of outstanding issues
• **Veterinary medicinal products containing paromomycin to be administered parenterally to pigs** EMEA/V/A/129 *Indications, posology, withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from Belgium under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: Draft list of products concerned
• **Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep** EMEA/V/A/130 *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from the Netherlands under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: Draft 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

• **Veterinary medicinal products containing gentamicin for parenteral administration to horses** EMEA/V/A/128 *Quality*	Rapp: M. O'Grady Co-rapp: W. Schlumbohm ***For decision:*** Need for further outstanding issues ***For discussion:*** Revised rapporteurs' assessment report following API manufacturers; responses to list of outstanding issues

4.7 Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

• **ZULVAC SBV** EMEA/V/C/002781/ANX-004.4 *Condition*	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's assessment report on the condition
• **Bravecto Plus** EMEA/V/C/004440/REC/007 *Recommendation*	Rapp: G. J. Schefferlie ***For endorsement****:* Rapporteur's assessment report on the recommendation
• **Fevaxyn Pentofel** EMEA/V/C/000030/REC/027.2 *Recommendation*	Rapp: E.-M. Vestergaard ***For endorsement****:* Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Cerenia (EMEA/V/C/000106)	29/09/2017 – 28/09/2018
COXEVAC (EMEA/V/C/000155)	20/09/2017 – 19/09/2018
ERAVAC (EMEA/V/C/004239)	22/09/2017 – 21/09/2018
Palladia (EMEA/V/C/000150)	23/09/2017 – 22/09/2018

Product	Period
RHINISENG (EMEA/V/C/000160)	16/09/2017 – 15/09/2017
Trifexis (EMEA/V/C/002635)	19/09/2017 – 18/09/2018 (expired)

5.4 Renewals

• **Loxicom** EMEA/V/C/000141/R/0031	Rapp: J. G. Beechinor Co-rapp: M. Turk ***For adoption***: List of outstanding issues
• **NexGard** EMEA/V/C/002729/R/0023	Rapp: P. Hekman Co-rapp: J. G. Beechinor ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Bravecto** EMEA/V/C/2526/R/0028	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Bravecto** EMEA/V/C002526 *See also 8.4 – US FDA alert to veterinarians and pet owners*	Rapp: G. J. Schefferlie ***For endorsement***: Rapporteur assessment report for the period 01.09.17-28.02.18
• **Bovela** EMEA/V/C003703	Rapp: F. Klein ***For endorsement***: Rapporteur VPhS evaluation for the period 01.07.17-30.06.18
• **BLUEVAC BTV8** EMEA/V/C/000156	Rapp: E. Werner ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.07.17-30.06.18
• **BTVPUR Alsap1** EMEA/V/C/002230	Rapp: C. Muñoz ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.01.17-31.05.18
• **BTVPUR Alsap8** EMEA/V/C/000146	Rapp: P. Pasquali ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.04.17-31.05.18
• **DRAXXIN** EMEA/V/C000042	Rapp: G. Hahn ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.12.17-31.05.18

• **EQUIP WNV** EMEA/V/C/000137	Rapp: J.-C. Rouby ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.17-31.05.18
• **Meloxivet** EMEA/V/C/000124	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.15-31.05.18
• **Meloxoral** EMEA/V/C/000151	Rapp: H. Jukes ***For endorsement***: Rapporteur assessment report on the PSUR for the period 20.05.15-19.05.18
• **Porcilis AR-T-DF** EMEA/V/C/000055	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur assessment report for the PSUR on the period 01.06.15-31.05.18
• **Porcilis PCV M Hyo** EMEA/V/C/003796	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.06.17-31.05.18
• **RESPIPORC FluPan H1N1** EMEA/V/C/003993	Rapp: M. Blixenkrone-Møller ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.12.17-31.05.18
• **SevoFlo** EMEA/V/C/000072	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.12.17-31.05.18
• **Suvaxyn Circo MH RTU** EMEA/V/C/003925	Rapp: B. Urbain ***For endorsement***: Rapporteur assessment report on the PSUR for the period 01.12.17-31.05.18

- ***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:*** Draft EU comments on latest proposals in relation to the revision of VICH anthelmintics guidelines – comments on: Age of Isolates; Field studies for swine (GL16); Field studies for poultry (GL21); Helminth numbers, for submission to the VICH Expert Working Group
- ***For endorsement:*** Draft EU comments on draft 2 of the VICH GL on fixed combination products, for submission to the VICH Expert Working Group
- ***For endorsement:*** Comments on draft training slides on VICH quality guidelines GL3, GL4, GL5 and GL8, for submission to the VICH Steering Committee

- ***For endorsement:*** Draft revised GL on Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use (LABST), for submission to the VICH Expert Working Group

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For discussion***: EFSA public consultation relating to diflubenzuron for use as a pesticide active substance (link)

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 endorsement***: Revised templates for MRL scientific overview and list of questions and MRL assessment report

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 update on the development of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) scientific advice; agenda of the meeting

8.4 Pharmacovigilance

- ***For information***: United States Food and Drug Administration (FDA) alert to veterinarians and pet owners about potential neurologic adverse reactions in dogs and cats receiving flea and tick treatment from the isoxazoline class of drugs and fact sheet for pet owners and veterinarians

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

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 July and September 2018, minutes of the meeting held on 13-14 September 2018; draft agenda of meeting to be held on 11-12 October 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision:*** Appointment of CVMP co-opted members at the December 2018 CVMP meeting; identification of expertise necessary to accomplish the mandate and appointment of co-opted members, CVMP list of expertise 2018
- ***For information:*** Informal Presidency CVMP-CMDv meeting (to be held during the Austrian presidency) on 25-26 October 2018 in Helsinki, Finland; draft agenda
- ***For information***: Update on the EMA working group on operational preparedness for veterinary medicines - impact on the supply of medicines and cut-off dates for post-authorisation procedures
- ***To note:*** CVMP meeting dates for 2019-2021

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	EWP	IWP	PhVWP	SAWP
Sep 2018	11-13	13	18-19	18-19	25 *Adobe*	25-26	11
Oct 2018	9-11						9
Nov 2018	6-8					20-21	6
Dec 2018	4-6						4
Jan 2019	22-24					29-30	22
Feb 2019	19-21						19