30 November 2018
EMA/CVMP/812471/2018 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

4 December 2018, 09:00 – 6 December, 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 4 Dec 2018	16.30-20.00 (TBC)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/005010/FULL/0001 *Horses*	***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

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004868/0000 *New antiprotozoal product* *Calves*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For discussion:*** Summary of opinion
• **Product** EMEA/V/C/004902/0000 *New vaccine* *Chickens*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Zulvac BTV Ovis** EMEA/V/C/004185/X/0001 *To add a new species* *Sheep*	***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/004858/0000 *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/004735/0000 *New product* *Dogs*	***For adoption**:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004846/0000 *New antiparasitic product* *Dogs*	***For adoption:*** Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004973/0000 *New product* *Cats and Dogs*	***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 endorsement:*** Final list of AHEG members

2.5 Other issues

Information on certain topics discussed under section 2.5 cannot be released at the present time as it is deemed to be confidential

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Aivlosin** EMEA/V/C/000083/II/0072 *Changes to the SPC*	Rapp: H. Jukes ***For adoption*:** CVMP opinion, CVMP assessment report and product information
• **Aivlosin** *EMEA/V/C/000083/II/0074/G* *Quality*	Rapp: H. Jukes ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **BRAVECTO** EMEA/V/C/002526/II/0030/G *Quality*	Rapp: G. J. Schefferlie ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **BRAVECTO PLUS** EMEA/V/C/004440/II/0002/G *Quality*	Rapp: G. J. Schefferlie ***For adoption:*** CVMP opinion ***For endorsement*:** Rapporteur's assessment report

• **OSURNIA** EMEA/V/C/003753/II/0009/G *Quality*	Rapp: S. Louet ***For adoption***: CVMP Opinion ***For endorsement***: Rapporteur's assessment report
• **Ecoporc SHIGA**, **RESPIPORC FLU3**, **RESPIPORC FLUpan H1N1** and **NAP** EMEA/V/C/xxxxxx/WS1484 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion ***For endorsement****:* Rapporteur's assessment report
• **HALAGON** EMEA/V/C/004201/II/0002/G *Quality*	Rapp: C. Muñoz ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **GALLIPRANT** EMEA/V/C/004222/II/0001 *Quality*	Rapp: K. Baptiste ***For adoption****:* CVMP Opinion ***For endorsement****:* Rapporteur's assessment report
• **Canigen L4** and **Nobivac L4** EMEA/V/C/xxxx/WS1439/G *Quality*	Rapp: B. Urbain ***For adoption****:* CVMP opinion ***For endorsement****:* Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Clomicalm** EMEA/V/C/000039/II/0027 *Quality*	Rapp: G. Hahn ***For adoption****:* CVMP list of outstanding issues

3.3 List of questions

• **Vectra 3D** EMEA/V/C/002555/II/0011 *Change in the legal status* *Dogs*	Rapp: G. Hahn Co-rapp: F. Hasslung Wikström **For adoption**: List of questions
• **COLIPROTEC F4/F18** EMEA/V/C/004225/II/0005 *To add a new therapeutic indication* *Pigs*	Rapp: H. Jukes Co-rapp: E. Augustynowicz ***For adoption****:* List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

Information on certain topics discussed under section 3.5 cannot be released at the present time as it is deemed to be confidential

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

- No items

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 endorsement***: CHMP/CVMP letter to EDQM

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
Bovilis Blue-8 (EMEA/V/C/004776)	21/11/2017 – 20/11/2018
Broadline (EMEA/V/C/002700)	04/12/2017 – 03/12/2018
Contacera (EMEA/V/C/002612)	06/12/2017 – 05/12/2018
DRAXXIN (EMEA/V/C/000077)	11/11/2017 – 10/11/2018

Product	Period
Easotic (EMEA/V/C/000140)	20/11/2017 – 19/11/2018
Equip WNV (EMEA/V/C/000137)	21/11/2017 – 20/11/2018
Masivet (EMEA/V/C/000128)	17/11/2017 – 16/11/2018
Meloxoral (EMEA/V/C/000151)	19/11/2017 – 18/11/2018
Oxyglobin (EMEA/V/C/000045)	29/11/2017 – 28/11/2018
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2017 – 15/11/2018
Quadrisol (EMEA/V/C/000032)	04/12/2017 – 03/12/2018
Rabitec (EMEA/V/C/004387)	01/12/2017 – 30/11/2018
Stronghold (EMEA/V/C/000050)	25/11/2017 – 24/11/2018
Vectra 3D (EMEA/V/C/002555)	04/12/2017 – 03/12/2018

5.4 Renewals

• **Fungitraxx** EMEA/V/C/002722/R0004	Rapp: S. Louet Co-rapp: K. Straus ***For adoption:*** List of questions
• **Vectra Felis** EMEA/V/C/002746/R/0008	Rapp: G. Hahn Co-rapp: F. Hasslung Wikström ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Equisolon** EMEA/V/C/002526/R/0004	Rapp: E.-M. Vestergaard Co-rapp: T. Høy ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Bravecto** EMEA/V/C/002526/R/0028	Rapp: H. Jukes Co-rapp: G. Hahn ***For adoption:*** Final CVMP opinion, final CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **APOQUEL** EMEA/V/C002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.17-31.05.18

• **Credelio** EMEA/V/C004247	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.18-31.07.18
• **Coliprotec F4-F18** EMEA/V/C/004225	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.02.18-31.07.18
• **Hiprabovis IBR Marker Live** EMEA/V/C/000158	Rapp: H. Jukes ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.15-31.07.18
• **Porcilis Porcoli Diluvac Forte** EMEA/V/C/000024	Rapp: J. Poot ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.15-31.07.18
• **Profender** EMEA/V/C/000097	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.15-31.07.18
• **Reconcile** EMEA/V/C/000133	Rapp: S. Louet ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.15-31.07.18
• **Vectra 3D** EMEA/V/C/002555	Rapp: G. Hahn ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.07.17-30.06.18
• **VEPURED** EMEA/V/C/004364	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.18-31.08.18
• **Versican Plus L4** EMEA/V/C003680	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report for the period 01.08.17-31.07.18
• **Versican Plus Pi L4** EMEA/V/C003683	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report for the period 01.08.17-31.07.18
• **Versican Plus Pi L4 R** EMEA/V/C003682	Rapp: E. Werner ***For endorsement***: Rapporteur assessment report for the period 01.06.17-31.05.18
• **ZACTRAN** EMEA/V/C000129	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur evaluation for the period 01.02.18-31.07.18

- ***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***: EU comments on draft VICH GL57 on Marker residue depletion studies to establish product withdrawal periods in aquatic species containing responses to comments received during the public consultation

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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 adoption***: Draft scientific advice by the Antimicrobial Advice Ad Hoc Expert Group on the preliminary risk profiling for new antimicrobials
- ***For discussion***: 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

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 and November 2018, minutes of the meeting held on 8-9 November 2018, draft agenda of meeting to be held on 6-7 December 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: CVMP work plan 2019
- ***For endorsement:*** Draft minutes and recommendations arising from the informal presidency meeting held on 25-26 October 2018 in Helsinki, Finland
- ***For endorsement***: Revised draft guidance on 'Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products'
- ***For decision****:* Appointment of CVMP co-opted members at the December 2018 meeting; nominations received for Antimicrobial resistance and Environmental risk assessment
- ***For discussion/endorsement***: Training priorities for 2019
- ***For information:*** Update on EMA relocation
- ***For information:*** Update on EVVet3 project
- ***For information:*** Presidency meeting to be held in May 2019 in Hungary, under the Romanian presidency
- ***To note*****:** Workshop: advancing regulatory science to 2025 for veterinary medicines – 6 December 2018, EMA, London; agenda

13. LEGISLATION

- ***For information:*** Update from the Commission on planning for preparation of delegated and implementing acts and on the mandates to EMA to provide scientific input to the EC; update on proposed work methodology

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Dec 2018	4-6								4		
Jan 2019	22-24						29-30		22		
Fev 2019	19-21								19		
Mar 2019	19-21						26-27		19		
Apr 2019	15-17								15		