15 February 2019
EMA/CVMP/97249/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2019 meeting

Chair: D. Murphy

Vice-chair: H. Jukes

19 February 2019, 09:00 – 21 February 2019, 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 19 February 2019	16:30-18:30

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/005010/FULL/0001 *Horses*	***For adoption:*** CVMP opinion including EPMAR, CVMP assessment report ***For information:*** Summary of opinion

1.2 Oral explanations and list of outstanding issues

• **Substance** EMA/V/MRL/004828/FULL/0001 *Rabbits*	***For decision:*** Need for oral explanation ***For adoption:*** List of outstanding issues

1.3 List of questions

• **Substance** EMEA/V/MRL/005072/FULL/0001 *Bovine, porcine*	***For adoption:*** CVMP 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

• **Product** EMEA/V/C/004329/0000 *New product* *Pigs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/004824/0000 *New antiparasitic product* *Cats and dogs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/004858/0000 *New vaccine* *Pigs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/005093/0000 *New product* *Cats*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

• **Product** EMEA/V/C/005018/0000 *New product* *Dogs*	***For adoption:*** Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004989/0000 *New product* *Rabbits*	***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*	**ORAL EXPLANATION – Tuesday 19 February 2019** ***For adoption:*** Final CVMP opinion, final CVMP assessment report, product information ***For information:*** Summary of opinion ***For discussion:*** Report from the AHEG chair on the AHEG meeting held on 7 February 2019; applicant's presentation to CVMP

2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **EVANT** (EMEA/V/C/004868/0000)
- ***For adoption:*** Withdrawal EPAR for **EQUITEND** (EMEA/V/C/002774/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **LETIFEND** EMEA/V/C/003865/II/0012 *Quality*	Rapp: C. Muñoz ***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:*** List of outstanding issues

3.3 List of questions

• **Zycortal** EMEA/V/C/003782/II/0003 *To introduce a new pharmacovigilance system*	Rapp: H. Bergendahl ***For adoption:*** List of questions
• **MS-H Vaccine** EMEA/V/C/000161/II/0012 *To introduce a new pharmacovigilance system*	Rapp: B. Urbain ***For adoption:*** List of questions
• **MS-H Vaccine** EMEA/V/C/000161/II/0013 *Quality*	Rapp: B. Urbain ***For adoption:*** List of questions
• **Porcilis PCV M Hyo** EMEA/V/C/003796/II/0011/G *Quality*	Rapp: E. Werner ***For adoption:*** List of questions
• **Ingelvac CircoFLEX** EMEA/V/C/000126/II/0030/G *Quality*	Rapp: P. Pasquali ***For adoption:*** List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Rhiniseng** EMEA/V/C/000160/II/0009 *Quality*	Rapp: E.-M. Vestergaard ***For information:*** Request from applicant to extend clock-stop for 5 months
• **Suprelorin** EMEA/V/C/00109/II/0022 *Quality*	Rapp: E.-M. Vestergaard ***For information:*** Request from MAH to extend 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

- No items

4.3 Article 35 of Directive 2001/82/EC

• **Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereof** EMEA/V/A/132 *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from Germany under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information:*** List of products concerned
• **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 adoption:*** CVMP opinion, CVMP assessment report
• **Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep** EMEA/V/A/130 *Withdrawal periods*	Rapp: G. J. Schefferlie Co-rapp: S. Louet ***For decision:*** Need for outstanding issues ***For discussion:*** Rapporteur's assessment report including co-rapporteur's critique

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

- No items

5.3 Product anniversary list

Product	Period
Activyl (EMEA/V/C/000163)	18/02/2018 – 17/02/2019
Bravecto (EMEA/V/C/002526)	11/02/2018 – 10/02/2019
Cimalgex (EMEA/V/C/000162)	18/02/2018 – 17/02/2019
Comfortis (EMEA/V/C/002233)	11/02/2018 – 10/02/2019
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2018 – 04/02/2019
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2018 – 26/01/2019
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2018 – 12/02/2019
Kexxtone (EMEA/V/C/002235)	28/01/2018 – 27/01/2019
Loxicom (EMEA/V/C/000141)	10/02/2018 – 09/02/2019
Melosus (EMEA/V/C/002001)	21/02/2018 - 20/02/2019
MiPet Easecto (EMEA/V/C/004732)	31/01/2018 – 30/01/2019
NexGard (EMEA/V/C/002729)	11/02/2018 – 10/02/2019
Oxybee (EMEA/V/C/004296)	01/02/2018 – 31/01/2019
PIRSUE (EMEA/V/C/000054)	29/01/2018 – 28/01/2019
Purevax Rabies (EMEA/V/C/002003)	18/02/2018 – 17/02/2019
Semintra (EMEA/V/C/002436)	13/02/2018 – 12/02/2019
STARTVAC (EMEA/V/C/000130)	11/02/2018 – 10/02/2019
Stronghold Plus (EMEA/V/C/004194)	09/02/2018 – 08/02/2019
Suvaxyn Circo (EMEA/V/C/004242)	07/02/2018 – 06/02/2019
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2018 – 09/02/2019

5.4 Renewals

• **Versican Plus L4** EMEA/V/C/003680/R/0007	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** CVMP opinion, CVMP assessment report, product information

• **Versican Plus Pi/L4** EMEA/V/C/003683/R/0011	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Versican Plus DHPPi/L4** EMEA/V/C/003678/R/0013	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Versican Plus DHPPi/L4R** EMEA/V/C/002759/R/0014	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Versican Plus Pi/L4R** EMEA/V/C/003682/R/0013	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption:*** List of outstanding issues
• **Suvaxyn PCV** EMEA/V/C/000149/R/0028	Rapp: B. Urbain Co-rapp: E.-M. Vestergaard ***For adoption:*** List of outstanding issues
• **ERYSENG** EMEA/V/C/002761/R/0004	Rapp: J. G. Beechinor Co-rapp: K. Kivilahti-Mantyla ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **ERYSENG PARVO** EMEA/V/C/002762/R/0006	Rapp: J. G. Beechinor Co-rapp: K. Kivilahti-Mantyla ***For adoption:*** CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **ERAVAC** EMEA/V/C/004239	Rapp: C. Muñoz ***For adoption:*** CVMP assessment report on the PSUR for the period 01/04/18-30/09/18
• **Exzolt** EMEA/V/C/004344	Rapp: P. Hekman ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01/03/18-31/08/18

• **FORTEKOR PLUS** EMEA/V/C/002804	Rapp: E.-M. Vestergaard ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01/04/18-30/09/18
• **Galliprant** EMEA/V/C/004222	Rapp: K. Baptiste ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01/04/18-30/09/18
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01/09/18-31/08/18
• **ProteqFlu** EMEA/V/C/000073	Rapp: J.-C. Rouby ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01/10/17-30/09/18
• **ProteqFlu-Te** EMEA/V/C/000074	Rapp: J-C. Rouby ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01/10/17-30/09/18
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01/09/18-31/08/18
• **VarroMed** EMEA/V/C/002723	Rapp: K. Straus ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 03/02/18-02/08/18

- ***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

- No items

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement:*** EU comments on the revision of VICH Anthelmintics guideline: choice of mean in dose confirmation studies - arithmetic versus geometric means
- ***For endorsement:*** Expert Working Group for a general guideline on combination products - nomination of a back-up expert
- ***For discussion:*** Revision of VICH GL23 on genotoxicity testing – updated draft decision tree description, updated draft decision tree diagram
- ***For discussion:*** Draft concept paper proposing development of a guideline on safety evaluation of biotechnology-derived/biological products

- ***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 26-28 February in Cape Town, South Africa

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information***: EFSA Guidance on Communication of Uncertainty in Scientific Assessments: https://www.efsa.europa.eu/en/efsajournal/pub/5520

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

- No items

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 information:*** Report of the 6th session of the Codex Ad Hoc intergovernmental task force on AMR, held on 10–14 December 2018 in Busan, Republic of Korea

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

- No items

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

- ***For information***: Minutes of the meeting held on 24-25 January 2019, draft agenda of the meeting to be held on 21-22 February 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision:*** Election of the vice-chair of the CVMP for a 3-year term (renewable once)
- ***For discussion:*** Proposals for agenda topics for the upcoming informal presidency CVMP/CMDv meeting (to be held during the Romanian presidency) on 6-8 May 2019 at Lake Balaton, Hungary
- ***For information:*** Update on EMA relocation

13. LEGISLATION

- ***For information:*** Update on work progress concerning provision of scientific recommendations on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Feb 2019	19-21								19		
Mar 2019	19-21						26-27		19		
Apr 2019	15-17								15		
May 2019	21-23						28-29		21		
Jun 2019	18-20								18		