12 April 2019
EMA/CVMP/226983/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2019 meeting

Chair: D. Murphy

Vice-chair: H. Jukes

15 April 2019, 09:00 – 17 April 2019, 13:00 - Room 1C

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 1C)	Monday, 15 April 2019	16.30-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMA/V/MRL/004828/FULL/0001 *Rabbits*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information***: Summary of opinion

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/003131/MODF/0003 *Ovine*	***For adoption***: CVMP scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

Information on certain topics discussed under section 1.5 cannot be released at the present time as it is deemed to be confidential

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004733/0000 *New product* *Cats*	***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/005077/0000 *New vaccine* *Chickens*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/005057/0000 *New vaccine* *Chickens*	***For adoption****:* Scientific overview and list of questions, comments on product information

• **Product** EMEA/V/C/005058/0000 *New vaccine* *Chickens*	***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

- ***For adoption:*** EPAR module scientific discussion for **Forceris** (EMEA/V/C/004329/0000)
- ***For adoption:*** EPAR module scientific discussion for **Afoxolaner MERIAL** (EMEA/V/C/005126/0000)
- ***For adoption:*** EPAR module scientific discussion for **ReproCyc ParvoFLEX** (EMEA/V/C/004858/0000)
- ***For adoption:*** EPAR module scientific discussion for extension for **Innovax-ND-IBD** (EMEA/V/C/004422/X/0001)
- ***For adoption:*** EPAR module scientific discussion for **Arti-Cell Forte** (EMEA/V/C/004727/0000)
- ***For adoption:*** EPAR module scientific discussion for **HorStem** (EMEA/V/C/004265/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Suvaxyn PRRS MLV** EMEA/V/C/004276/II/0004/G *To reduce the onset of immunity and other changes to the product information*	Rapp: E. Werner Co-rapp: F. Klein ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Porcilis PCV M Hyo** EMEA/V/C/003796/WS1467/0010 *To change the product information*	Rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **LEUCOGEN, LEUCOFELIGEN FeLV-RCP and Nobivac LeuFeL** EMEA/V/C/xxxx/WS1483 *To modify the indication*	Rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Broadline** EMEA/V/C/002700/II/0023 *Quality*	Rapp: B. Urbain ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Velactis** EMEA/V/C/003739/II/0004 *Quality*	Rapp: W. Schlumbohm Co-rapp: F. Hasslung Wikström ***For decision:*** Need for oral explanation ***For adoption:*** List of outstanding issues

3.3 List of questions

• **Vectra Felis** EMEA/V/C/002746/II/0009 *To change the legal status*	Rapp: G. Hahn Co-rapp: F. Hasslung Wikström ***For adoption:*** List of questions
• **NEXGARD SPECTRA** EMEA/V/C/003842/II/0019 *To add a new therapeutic indication*	Rapp: J. G. Beechinor ***For adoption:*** List of questions
• **NexGard/NEXGARD SPECTRA** EMEA/V/C/WS1559 *To add a new therapeutic indication*	Rapp: J. G. Beechinor ***For adoption***: List of questions
• **Melovem** EMEA/V/C/000152/II/0011/G *Quality*	Rapp: R. Breathnach ***For adoption:*** List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Bravecto** EMEA/V/C/002526/II/0033/G *To add new therapeutic indications*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For decision:*** Request from MAH to extend clock-stop
• **Bravecto** EMEA/V/C/002526/II/0035/G *To update the SPC*	Rapp: G. J. Schefferlie ***For information:*** Withdrawal letter from MAH

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: G. Hahn Co-rapp: P. Hekman ***For decision:*** Request for extension of the clock-stop ***For adoption:*** Revised timetable

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

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

- No items

5.3 Product anniversary list

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2018 – 01.04.2019
BLUEVAC BTV8 (EMEA/V/C/000156)	14.04.2018 – 13.04.2019
Clevor (EMEA/V/C/004417)	13.04.2018 – 12.04.2019
Clomicalm (EMEA/V/C/000039)	01.04.2018 – 31.03.2019
Ecoporc SHIGA (EMEA/V/C/002588)	10.04.2018 – 09.04.2019
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2018 – 25.03.2019
Incurin (EMEA/V/C/000047)	24.03.2018 – 23.03.2019
Locatim (EMEA/V/C/000041)	29.03.2018 – 28.03.2019
Neocolipor (EMEA/V/C/000035)	14.04.2018 – 13.04.2019

Product	Period
Parvoduk (EMEA/V/C/002740)	11.04.2018 – 10.04.2019
Purevax FeLV (EMEA/V/C/000056)	13.04.2018 – 12.04.2019
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2018 – 05.04.2019
Veraflox (EMEA/V/C/000159)	12.04.2018 – 11.04.2019

5.4 Renewals

• **OSURNIA** EMEA/V/C/003753/R/0014	Rapp: S. Louet Co-rapp: F. Hasslung Wikström ***For adoption:*** CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **CYTOPOINT** EMEA/V/C/003939	Rapp: R. Breathnach ***For adoption:*** CVMP assessment report on the PSUR for the period 01.05.2018-31.10.2018
• **RESPIPORC FLUPan H1N1** EMEA/V/C/0003993	Rapp: M. Blixenkrone-Møller ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.06.2018-30.11.2018
• **SevoFlo** EMEA/V/C/000072	Rapp: J. G. Beechinor ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.06.2018-30.11.2018
• **Suvaxyn Circo MH+RTU** EMEA/V/C/003924	Rapp: B. Urbain ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.06.2018-30.11.2018
• **Virbagen Omega** EMEA/V/C/000061	Rapp: J.-C. Rouby ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.12.2015-30.11.2018
• **Zeleris** EMEA/V/C/004099	Rapp: W. Schlumbohm ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.06.2018-30.11.2018

- ***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 fixed combinations guideline: draft EU list of minimum requirements
- ***For endorsement***: VICH GL58 on stability testing in climatic zones III and IV - draft responses to comments received during the public consultation; draft revised guideline
- ***To note:*** Revision of VICH anthelmintic guidelines: topic summary document

6.2 Codex Alimentarius

- No items

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

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 decision:*** Overview of comments received during the public consultation on the "AMEG Scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Preliminary risk profiling for new antimicrobials"
- ***For decision:*** Follow up on comments expected during the ongoing consultation to the answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Categorisation of antimicrobials

8.4 Pharmacovigilance

- No items

8.5 Other issues

Information on certain topics discussed under section 8.5 cannot be released at the present time as it is deemed to be 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

- ***For decision:*** Transfer of (co-)rapporteurships responsibilities from E.-M. Vestergaard to N. C. Kyvsgaard and M. Blixenkrone-Møller

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***: Verbal report from the CMDv chair on the meetings held in January, February and March 2019; minutes of the meeting held on 21-22 March 2019; draft agenda of the meeting to be held on 16-17 April 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: Agenda of the upcoming informal presidency CVMP/CMDv meeting (to be held during the Romanian presidency) on 6-8 May 2019 at Lake Balaton, Hungary
- ***For discussion and decision***: Follow-on actions to the revised guidance on 'Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products'
- ***For information***: Election of the chair of the Committee for Medicinal Products for Veterinary Use (CVMP) at the May 2019 CVMP meeting; call for nominations
- ***For information:*** Brexit preparedness - Extension of the period under 'Article 50'

13. LEGISLATION

- ***For information:*** Verbal update on work progress of the expert groups 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
Apr 2019	15-17								15		
May 2019	21-23						28-29		21		
Jun 2019	18-20								18		
Jul 2019	16-18						9-10		16		
Sep 2019	10-12						24-25		10		