31 October 2019
EMA/CVMP/592201/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of November 2019 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

5 November 2019, 09:00 – 7 November 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)	Tuesday, 5 November 2019	16:30-20:00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/005072/FULL/0001 *Cattle, pigs*	***For decision:*** Need for oral explanation ***For adoption****:* List of outstanding issues

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/005018/0000 *New product* *Dogs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/004991/0000 *New product* *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/005077/0000 *New vaccine* *Chickens*	***For decision:*** Need for an oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/005073/0000 *New product* *Cattle, pigs, sheep*	***For decision:*** Need for an oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/005719/0000 *New product* *Cats*	***For adoption**:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/005076/0000 *New product* *Cattle, pigs, sheep*	***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

• **Product** EMEA/V/C/005132/0000 *New product* *Dogs*	***For decision**:* Request from applicant to extend the clock-stop

- ***For endorsement:*** EPAR scientific discussion for **Gumbohatch** (EMEA/V/C/004967/0000)
- ***For endorsement:*** EPAR scientific discussion for **Nobivac Myxo-RHD PLUS** (EMEA/V/C/004989/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Poulvac E. Coli** EMEA/V/C/002007/II/0016/G *Quality-related changes*	Rapp: E. Werner ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Vectormune ND** EMEA/V/C/WS1597/G *Quality-related changes*	Rapp: F. Klein ***For adoption*:** CVMP opinion, product information ***For endorsement*:** Rapporteur's assessment report
• **ProZinc** EMEA/V/C/002634/II/0019/G *Quality-related changes*	Rapp: R. Breathnach ***For adoption:*** CVMP opinion, product information ***For endorsement**:* Rapporteur's assessment report
• **Exzolt** EMEA/V/C/004344/II/0007/G *Quality-related changes*	Rapp: P. Heckman ***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

• **Bravecto Plus** EMEA/V/C/004440/II/0006 *To modify the therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption:*** List of questions
• **Rabitec** EMEA/V/C/004387/II/0002 *To extend the duration of immunity*	Rapp: E. Werner Co-rapp: K. Kivilahti-Mantyla ***For adoption:*** List of questions
• **Aivlosin** EMEA/V/C/000083/II/0078 *To add a new indication*	Rapp: F. Hasslung Wikström Co-Rapp: G. Hahn ***For adoption:*** List of questions
• **Innovax-ND-IBD** EMEA/V/C/004422/II/0003 *To add a new indication*	Rapp: J. Poot ***For adoption*:** List of questions
• **Evicto** EMEA/V/C/004973/II/0001 *Quality-related changes*	Rapp: J. G. Beechinor ***For adoption:*** List of questions

3.4 Re-examination of CVMP opinions

• **Velactis** EMEA/V/C/003739/II/0004 *Update of product information and submission of new data to demonstrate the safe use of the product*	Rapp: R. Breathnach Co-rapp: C. Muñoz Madero ***For adoption**:* List of questions to AHEG ***For endorsement**:* Final list of AHEG members ***For discussion***: Draft rapporteurs' assessment report for the re-examination of the CVMP opinion

3.5 Other issues

- No items

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

• **Ketabel 100 mg/ml solution for injection and associated names** EMEA/V/A/133 *Adequacy of withdrawal periods*	Rapp: G. Hahn Co-rapp: S. Louet ***For decision***: Applicant's request for oral explanation ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

4.2 Article 34 of Directive 2001/82/EC

• **Ronaxan and its associated names** EMEA/V/A/135 *Harmonisation of SPC*	Rapp: F. Hasslung Wikström Co-rapp: J. G. Beechinor ***For decision***: Request from Boehringer Ingelheim Santé Animale for an extension of the clock-stop ***For adoption:*** Revised timetable

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing tylosin base (as simple active substance) presented as solutions for injection for intramuscular use in pigs** EMEA/V/A/131 *Adequacy of withdrawalperiods*	Rapp: S. Louet Co-rapp: L. Nepejchalová ***For discussion***: Revised rapporteur's assessment report including co-rapporteur's critique
• **Veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered to pigs** EMEA/V/A/137 *Efficacy-related questions*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from Belgium under Article 35 of Directive 2001/82/EC

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

• **Vaxxitek HVT+IBD** EMEA/V/C/000065/REC/026 *Recommendation regarding quality*	Rapp: B. Urbain Co-rapp: J. Poot ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Halocur (EMEA/V/C/000040)	29/10/2018 – 28/10/2019
Nobivac LeuFel (EMEA/V/C/004778)	06/11/2018 – 05/11/2019
Porcilis PCV M Hyo (EMEA/V/C/003796)	07/11/2018 – 06/11/2019
Simparica (EMEA/V/C/003991)	06/11/2018 – 05/11/2019
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06/11/2018 – 05/11/2019
Virbagen Omega (EMEA/V/C/000061)	06/11/2018 – 05/11/2019
Zolvix (EMEA/V/C/000154)	04/11/2018 – 03/11/2019
Zycortal (EMEA/V/C/003782)	06/11/2018 – 05/11/2019

5.4 Renewals

• **Coliprotec F4** EMEA/V/C/003797/R/0005	Rapp: E. Augustynowicz Co-rapp: C. Muñoz Madero ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Zulvac SBV** EMEA/V/C/002781/R/0007	Rapp: G. Kulcsár Co-rapp: M. Blixenkrone-Møller ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Simparica & MiPet Easecto** EMEA/V/C/003991	Rapp: J. G. Beechinor ***For discussion/adoption***: CVMP assessment report on the PSUR for the period 01.06.2018-31.05.2019
• **Letifend** EMEA/V/C/003865	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.2018-30.04.2019
• **OSURNIA** EMEA/V/C/003753	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.2018-31.01.2019

• **Zycortal** EMEA/V/C/003782	Rapp: H. Bergendahl ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.2018-31.05.2019
• **Bluevac BTV8** EMEA/V/C/000156	Rapp: E. Werner ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.07.2018-30.06.2019
• **Bovela** EMEA/V/C/003703	Rapp: F. Klein ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.07.2018-30.06.2019
• **Bovilis Blue8** EMEA/V/C/004776	Rapp: E. Werner ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.07.2018-30.06.2019
• **Bravecto Plus** EMEA/V/C/004440	Rapp: G. J. Schefferlie ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.2018-31.05.2019
• **Clynav** EMEA/V/C/002390	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.01.2019-30.06.2019
• **Halagon** EMEA/V/C/004201	Rapp: G. J. Schefferlie ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.01.19.2030.06.2019
• **Inflacam** EMEA/V/C/002497	Rapp: S. Louet ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.07.2016-30.06.2019
• **Porcilis PCV** EMEA/V/C/000135	Rapp: P. Pasquali ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 13.07.2016-12.07.2019
• **Respiporc FluPan H1N1** EMEA/V/C/003993	Rapp: M. Blixenkrone-Møller ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.2018-31.05.2019
• **SevoFlo** EMEA/V/C/000072	Rapp: J. G. Beechinor ***For endorsement***: CVMP assessment report on the PSUR for the period 01.12.2018-31.05.2019
• **Velactis** EMEA/V/C/003739	Rapp: W. Schlumbohm ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.07.2018-30.06.2019

- ***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***: VICH GL58 Stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV for endorsement at step 5 of the VICH process
- ***For adoption:*** VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use for adoption at step 4 at step 5 of the VICH process
- ***For information***: Draft agenda for VICH Steering Committee meeting scheduled to take place on 18–21 November 2019 in Tokyo, Japan and for VICH Outreach Forum meeting to take place on 19-20 November; Progress reports from VICH experts working groups (EWG) on Quality, ESI Pharmacovigilance, Biologicals quality monitoring, Metabolism and residue kinetics, Safety EWG, Anthelmintics EWG, and on Combination products EWG

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information:*** Feedback from the participation as observer to the EFSA BIOHAZ panel working group on the development of a scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance (AMR) through the food chain

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to SAWP-V procedures and 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)

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 adoption:*** 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 information***: Verbal report on the 9th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 31 European countries in 2017

8.4 Pharmacovigilance

- ***For discussion/adoption:*** Draft responses to questions raised at the Bravecto petition hand over

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

- ***For adoption:*** Concept paper for the revision of scientific guidelines on limited market for veterinary medicinal products

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***: Draft minutes of the October 2019 meeting; draft agenda of the meeting to be held on 7-8 November 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For decision****:* Appointment of CVMP co-opted members at the November 2019 meeting, nominations received for: G. J. Schefferlie (**MRLs/Residues**), R. Breathnach (**General Clinical veterinary practice**), and M. O'Grady (**Quality pharmaceuticals**)
- ***For discussion/endorsement***: Informal presidency CVMP/CMDv meeting held during the Finnish presidency on 25-27 September 2019 in Porvoo, Finland; draft minutes and report on draft conclusions and recommendations of the meeting
- ***For discussion***: Draft CVMP work plan 2020
- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) on the meeting to be held on 6 November 2019; draft agenda of the meeting; draft minutes of the October 2019 SPG
- ***For information:*** Update on relocation

13. LEGISLATION

- ***For adoption:*** Mandates for the expert groups to deliver the scientific advices on implementing and delegated acts: list of antimicrobials reserved for the treatment of certain infections in humans, format of the data to be collected on antimicrobial medicinal products used in animals, rules on oral administration
- ***For information:*** Verbal update on work progress of the expert groups concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6
- ***For information:*** Final report on the criteria to designate antimicrobials for human use

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Nov 2019	5-7						10-20		5		
Dec 2019	3-5								3		
Jan 2020	21-23						21-22		21		
Feb 2020	18-19								18		