14 June 2019
EMA/CVMP/339821/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 18-20 June 2019 meeting

Chair: D. Murphy

Vice-chair: H. Jukes

18 June 2019, 09:00 – 20 June 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)	Tue 18 June 2019	16:30-20:00 (TBC)

Temporary visiting address Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
For deliveries refer to www.ema.europa.eu/how-to-find-us
Send us a question via www.ema.europa.eu/contacts **Telephone** +31(0)88 781 6000 An agency of the European Union

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/005009/FULL/0001 *Porcine*	***For decision:*** Need for oral explanation ***For adoption:*** List of outstanding issues

1.3 List of questions

• **Substance** EMEA/V/MRL/003652/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/004991/0000 *New product* *Horses*	***For decision****:* Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004967/0000 *New vaccine* *Chickens*	***For decision:*** Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For adoption:*** Refusal EPAR scientific discussion (REPAR) for **Horse Allo 20** (EMEA/V/C/00222/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Advocate** EMEA/V/C/000076/II/0041/G *To add new therapeutic indications and to amend the product information relating to an existing indication*	Rapp: T.-M. Muhonen Co-rapp: J. P. Duarte Da Silva ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Suvaxyn Circo, Suvaxyn Circo+MH RTU** EMEA/V/C/xxxxxx/WS1606 *Quality*	Rapp: F. Klein ***For adoption***: CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **Suprelorin** EMEA/V/C/00109/II/0022 *Quality*	Rapp: N. C. Kyvsgaard ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Inflacam and Rheumocam** EMEA/V/C/xxxxxx/WS1618 *To amend the product information in line with the reference product*	Rapp: S. Louet ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Meloxidyl** EMEA/V/C/000115/II/0029 *Quality*	Rapp: F. Hasslung Wikström ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Posatex** EMEA/V/C/000122/II/0027/G *Quality*	Rapp: S. Louet ***For adoption***: List of outstanding issues

3.3 List of questions

• **BLUEVAC BTV8** EMEA/V/C/000156/II/0010/G *To convert the BLUEVAC BTV8 dossier into a multi-strain dossier*	Rapp: E. Werner Co-rapp: P. Pasquali ***For adoption:*** List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Coliprotec F4/F18** EMEA/V/C/004225/II/0005 *To add a new therapeutic indication*	Rapp: R. Cooney Co-Rapp: E. Augustynowicz ***For information:*** Withdrawal letter from the 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

• **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 adoption:*** CVMP opinion, CVMP assessment report
• **Veterinary medicinal products containing containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs** EMEA/V/A/131 *Withdrawal periods*	Rapp: S. Louet Co-rapp: L. Nepejchalová ***For adoption:*** List of outstanding issues, revised timetable ***For discussion:*** Rapporteur's assessment report including co-rapporteur's critique
• **Veterinary medicinal products containing paromomycin to be administered parenterally to pigs** EMEA/V/A/129 *Indications, posology, withdrawal periods*	Rapp: B. Urbain Co-rapp: S. Louet ***For discussion:*** Rapporteur's assessment report to MAH's response to LoOI, revised rapporteurs' assessment report

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

• **Equilis West Nile** EMEA/V/C/002241/REC/014 *Recommendation*	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Convenia (EMEA/V/C/000098)	19.06.2018 – 18.06.2019
Dany's BienenWohl (EMEA/V/C/004667)	14.06.2018 – 13.05.2019
Equilis West Nile (EMEA/V/C/002241)	06.06.2018 – 05.05.2019
Ingelvac PCV FLEX (EMEA/V/C/004645)	24.05.2018 – 23.05.2019
LEUCOGEN (EMEA/V/C/000144)	17.06.2018 – 16.06.2019
MS-H Vaccine (EMEA/V/C/000161)	14.06.2018 – 13.06.2019
Nobilis IB 4-91 (EMEA/V/C/000036)	09.06.2018 – 08.06.2019
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2018 – 14.06.2019
Porcilis Pesti (EMEA/V/C/000046)	09.06.2018 – 08.06.2019
Poulvac E. coli (EMEA/V/C/002007)	15.06.2018 – 14.06.2019
Prevomax (EMEA/V/C/004331)	19.06.2018 – 18.06.2019
Sileo (EMEA/V/C/003764)	10.06.2018 – 09.06.2019
Spironolactone Ceva (EMEA/V/C/000105)	20.06.2018 – 19.06.2019
Vectra Felis (EMEA/V/C/002746)	06.06.2018 – 05.06.2019

5.4 Renewals

• **Porcilis PCV M Hyo** EMEA/V/C/003796/R/0012	Rapp: E. Werner Co-rapp: K. Kivilahti-Mantyla ***For adoption:*** List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Trifexis** EMEA/V/C/002700	Rapp: G. Hahn ***For adoption:*** Rapporteur assessment report on the PSUR for the period 05.07.2018-04.01.2019
• **ERYSENG** EMEA/V/C/002761	Rapp: J. G. Beechinor ***For adoption:*** Rapporteur assessment report on the PSUR for the period 01.02.2018-31.01.2019

• **ERYSENG PARVO** EMEA/V/C/002762	Rapp: J. G. Beechinor ***For adoption:*** Rapporteur assessment report on the PSUR for the period 01.02.2018-31.01.2019
• **Innovax ILT** EMEA/V/C/003869	Rapp: E. Werner ***For adoption:*** Rapporteur assessment report on the PSUR for the period 01.02.2018-31.01.2019
• **LEUCOGEN / Nobivac Leufel** EMEA/V/C/000144 EMEA/V/C/004778	Rapp: E. Werner ***For adoption***: Rapporteur assessment report on the PSUR for the period 01.07.2018-31.10.2018
• **Nobilis OR Inac** EMEA/V/C/000062	Rapp: J.-C. Rouby ***For adoption***: Rapporteur assessment report on the PSUR for the period 01.02.2016-31.01.2019
• **ZACTRAN** EMEA/V/C/000127	Rapp: N. C. Kyvsgaard ***For adoption***: Rapporteur evaluation on the PSUR for the period 01.08.2018-31.01.2019
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: P. Pasquali ***For adoption***: Rapporteur assessment report on the PSUR for the period 01.02.2018-31.01.2019

- ***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

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement:*** Revision of VICH anthelmintics guidelines: draft EU comments
- ***For endorsement:*** EU comments on draft concept paper proposing development of guidance on in vitro dissolution testing and biowaivers for in vivo blood bioequivalence determinations; EU experts to join the VICH Expert Working Group
- ***For endorsement:*** Nominations for an expert advisor to support EU expert for revision of VICH GL23 on genotoxicity testing

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

- 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 adoption:*** Revised AMEG scientific advice for public consultation on the preliminary risk profiling (EMA/CVMP/CHMP/682199/2017) and overview of comments (EMA/CVMP/CHMP/201533/2019) received during the public consultation

8.4 Pharmacovigilance

- ***For discussion:*** Letter from the MAH to veterinarians on Bravecto Spot on / Bravecto Plus regarding the use of gloves

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

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

- ***For information:*** Draft minutes of the meeting held on 23-24 May 2019; draft agenda of the meeting to be held on 20-21 June 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 19 June 2019, draft agenda of the meeting; draft minutes from the SPG meeting held on 7 November 2018
- ***For discussion:*** Informal presidency meeting held (during the Romanian presidency) on 6-8 May 2019 at Lake Balaton, Hungary; report on conclusions and recommendations of the meeting
- ***For information:*** Upcoming informal presidency CVMP/CMDv meeting (to be held during the Finnish presidency) on 25-27 September 2019 at Haikko Manor, Finland
- ***For information:*** Update on EMA preparedness

13. LEGISLATION

- ***For discussion:*** Draft scientific recommendation on the list of variations not requiring assessment and annexes; presentation from the group leader; comments received on the recommendation and on annexes
- ***For discussion:*** Draft scientific recommendations on the revision of Annex II of Regulation(EU) 2019/6; comments received
- ***For discussion:*** Draft report from the expert group on specific requirements for collection of data for antimicrobials used in animals
- ***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
Jun 2019	18-20	4							18		
Jul 2019	16-18						9-10		16		
Sep 2019	10-12						24-25		10		
Oct 2019	8-10								8		
Nov 2019	5-7						10-20		5		