EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2019
EMA/CVMP/399992/2019
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 16-18 July 2019 meeting

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Committee for Medicinal Products for Veterinary Use

Draft agenda of 16-18 July 2019 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

16 July 2019, 09:00 – 18 July 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 1B)	Tuesday 16 July 2019	16:30-20:00

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- **Substance**
  EMEA/V/MRL/005009/FULL/0001
  Porcine

  For decision: Clock stop extension request

- **Substance**
  EMEA/V/MRL/005072/FULL/0001
  Bovine, porcine

  For decision Clock stop extension request

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- **Product**
  EMEA/V/C/004846/0000
  New product
  Dogs

  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/004735/0000
  New product
  Dogs

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

- **Product**
  EMEA/V/C/005018/0000
  New product
  Dogs

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

- **Product**
  EMEA/V/C/004989/0000
  New vaccine
  Rabbits

  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/005132/0000
  New product
  Dogs

  For adoption: Scientific overview and list of questions, comments on product information

- **Product**
  EMEA/V/C/005199/0000
  New product
  Cattle, pigs, sheep

  For adoption: Scientific overview and list of questions, comments on product information

- **Product**
  EMEA/V/C/005153/0000
  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

- ***For adoption:*** EPAR scientific discussion for **Evicto** (EMEA/V/C/004973/0000)
- ***For adoption:*** EPAR scientific discussion for **Nasym** (EMEA/V/C/004897/0000)
- ***For adoption:*** EPAR scientific discussion for **HorStem** (EMEA/V/C/004265/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **NEXGARD SPECTRA**
  EMEA/V/C/003842/II/0019
  To add a new therapeutic indication

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion, CVMP assessment report, product information

  For information: Summary of opinion

- **NexGard / NEXGARD SPECTRA**
  EMEA/V/C/xxxxxx/WS1559
  To add a new therapeutic indication

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion, CVMP assessment report, product information

  For information: Summary of opinion

- **BROADLINE**
  EMEA/V/C/002700/II/0024
  To add a new therapeutic indication

  Rapp: B. Urbain

  Co-rapp: C. Muñoz

  For adoption: CVMP opinion, CVMP assessment report, product information

  For information: Summary of opinion

- **MS-H Vaccine**
  EMEA/V/C/000161/II/0014/G
  Quality related change

  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
  Update of product information

  Rapp: W. Schlumbohm

  Co-rapp: F. Hasslung Wikström

  ORAL EXPLANATION – Tuesday 16 July 2019, 14:30-15:30

  For discussion: Rapporteurs' assessment of responses to list of outstanding issues

3.3 List of questions

- **Vectormune ND**
  EMEA/V/C/xxxxxx/WS1597
  Quality related change

  Rapp: F. Klein

  For adoption: List of questions

- **Poulvac E. Coli**
  EMEA/V/C/002007/II/0016/G
  Quality related change

  Rapp: E. Werner

  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- No items

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- **Ketamine 100 mg/ml solution for injection**
  EMEA/V/A/133
  Withdrawal period

  Rapp: *to be appointed*

  Co-rapp: *to be appointed*

  For discussion and decision: Notification from France under Article 33(4) of Directive 2001/82/EC

  Appointment of Rapporteur, co-rapporteur and peer reviewers

4.2 Article 34 of Directive 2001/82/EC

- **Adjusol and its associated names**
  EMEA/V/A/134
  Harmonisation of SPC

  Rapp: *to be appointed*

  Co-rapp: *to be appointed*

  For discussion and decision: Notification from European Commission under Article 34 of Directive 2001/82/EC and annex

  Appointment of Rapporteur, co-rapporteur and peer reviewers

4.3 Article 35 of Directive 2001/82/EC

- **Veterinary medicinal products containing paromomycin to be administrated parenterally to pigs**
  EMEA/V/A/129
  Indications, posology, withdrawal periods

  Rapp: B. Urbain

  Co-rapp: S. Louet

  For adoption: CVMP opinion, CVMP 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

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

5.3 Product anniversary list

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15.07.2018 – 14.07.2019
Canigen L4 (EMEA/V/C/004079)	03.07.2018 – 02.07.2019
Circovac (EMEA/V/C/000114)	21.06.2018 – 20.06.2019
CLYNAV (EMEA/V/C/002390)	27.06.2018 – 26.06.2019
Equilis Prequenza (EMEA/V/C/000094)	08.07.2018 – 07.07.2019

Product	Period
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2018 – 07.07.2019
Equilis Te (EMEA/V/C/000093)	08.07.2018 – 07.07.2019
EQUIOXX (EMEA/V/C/000142)	25.06.2018 – 24.06.2019
ERYSENG (EMEA/V/C/002761)	04.07.2018 – 03.07.2019
ERYSENG PARVO (EMEA/V/C/002762)	08.07.2018 – 07.07.2019
Innovax-ILT (EMEA/V/C/003869)	03.07.2018 – 02.07.2019
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25.06.2018 – 24.06.2019
Melovem (EMEA/V/C/000152)	07.07.2018 – 06.07.2019
Nobivac L4 (EMEA/V/C/002010)	16.07.2018 – 15.07.2019
Posatex (EMEA/V/C/000122)	23.06.2018 – 22.06.2019
ProZinc (EMEA/V/C/002634)	12.07.2018 – 11.07.2019
Reconcile (EMEA/V/C/000133)	08.07.2018 – 07.07.2019
Sevohale (EMEA/V/C/004199)	21.06.2018 – 20.06.2019
Suprelorin (EMEA/V/C/000109)	10.07.2018 – 09.07.2019
Versican Plus DHPPi (EMEA/V/C/003679)	04.07.2018 – 03.07.2019
Versican Plus Pi (EMEA/V/C/003681)	04.07.2018 – 03.07.2019

5.4 Renewals

- **Bovela**
  EMEA/V/C/003703/R/0014

  Rapp: F. Klein

  Co-rapp: C. Muñoz

  For adoption: List of outstanding issues

- **Porcilis PCV M Hyo**
  EMEA/V/C/003796/R/0012

  Rapp: E. Werner

  Co-rapp: K. Kivilahti-Mantyla

  For adoption: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- **Bravecto Plus**
  EMEA/V/C/004440

  Rapp: G.J. Schefferlie

  For discussion: Rapporteur assessment report on the PSUR for the period 08.05.2018-30.11.2018

- **Broadline**
  EMEA/V/C/002700

  Rapp: B. Urbain

  For adoption: CVMP assessment report on the PSUR for the period 01.01.2018-31.12.2018

- **Credelio**
  EMEA/V/C/004247

  Rapp: R. Breathnach

  For adoption: CVMP assessment report on the PSUR for the period 01.08.2018-31.01.2019

- **Suprelorin**
  EMEA/V/C/000109

  Rapp: N. C. Kyvsgaard

  For adoption: CVMP assessment report on the PSUR for the period 01.02.2018-31.01.2019

- **CEPEDEX**
  EMEA/V/C/004376

  Rapp: C. Muñoz

  For adoption: Rapporteur assessment report on the PSUR for the period 13.12.2016-28.02.2019

- **Coliprotec F4/F18**
  EMEA/V/C/004225

  Rapp: E. Augustynowicz

  For adoption: Rapporteur's evaluation on the PSUR for the period 01.08.2018-31.01.2019 and annex

- **Dexdomitor**
  EMEA/V/C/000070

  Rapp: F. Hasslung Wikström

  For adoption: Rapporteur assessment report on the PSUR for the period 01.03.2016-28.02.2019

- **Emdocam**
  EMEA/V/C/002283

  Rapp: J. G. Beechinor

  For adoption: Rapporteur's evaluation on the PSUR for the period 01.03.2016-28.02.2019

- **Innovax ND IBD**
  EMEA/V/C/004422

  Rapp: J. Poot

  For adoption*:* Rapporteur's assessment report on the PSUR for the period 01.09.2018-28.02.2019

- **Melosus**
  EMEA/V/C/002001

  Rapp: N. C. Kyvsgaard

  For adoption: Rapporteur's assessment report on the PSUR for the period 01.03.2016-28.02.2019

- **Nobilis Influenza H5N2**
  EMEA/V/C/000118

  Rapp: J.-C. Rouby

  For adoption: Rapporteur's assessment report on the PSUR for the period 01.03.2018-28.02.2019

- **Porcilis PCV ID**
  EMEA/V/C/003942

  Rapp: J. Poot

  For adoption: Rapporteur's assessment report on the PSUR for the period 01.03.2018-28.02.2019

- **Proteq West Nile**
  EMEA/V/C/002005

  Rapp: J.-C. Rouby

  For adoption: Rapporteur's evaluation on the PSUR for the period 01.03.2016-28.02.2019

- **Sedadex**
  EMEA/V/C/004202

  Rapp: C. Muñoz

  For adoption: Rapporteur's evaluation on the PSUR for the period 13.08.2018-12.02.2019

- **Semintra**
  EMEA/V/C/002436
  Rapp: R. Breathnach
  For adoption: Rapporteur's evaluation on the PSUR for the period 01.09.2018-28.02.2019
- **Stronghold Plus**
  EMEA/V/C/004194
  Rapp: R. Breathnach
  For adoption: Rapporteur assessment report on the PSUR for the period 01.09.2018-28.02.2019
- **Suvaxyn Circo**
  EMEA/V/C/004242
  Rapp: F. Klein
  For adoption: Rapporteur's assessment report on the PSUR for the period 01.09.2018-28.02.2019
- **Suvaxyn PRRS MLV**
  EMEA/V/C/004276
  Rapp: E. Werner
  For adoption: Rapporteur's assessment report on the PSUR for the period 01.09.2018-28.02.2019
- **UpCard**
  EMEA/V/C/003836
  Rapp: C. Muñoz
  For adoption: Rapporteur assessment report on the PSUR for the period 01.09.2018-28.02.2019
- **VEPURED**
  EMEA/V/C/004363
  Rapp: N. C. Kyvsgaard
  For adoption: Rapporteur assessment report on the PSUR for the period 01.09.2018-28.02.2019
- ***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:*** VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use for sign off at step 3
- ***For endorsement:*** Nomination of EU expert to join the VICH Expert Working Group on bioequivalence
- ***For endorsement:*** EU comments on draft training slides on VICH GL57 on marker residue depletion studies to establish product withdrawal periods in aquatic species

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For decision:*** Appointment of CVMP representative to participate to the "Pain in Animals Workshop 2019" to be held on 2-3 October in Bethesda, Maryland, USA (link)

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)

- No items

7.3 Safety Working Party (SWP-V)

- No items

7.4 Environmental Risk Assessment Working Party (ERAWP)

- No items

7.5 Efficacy Working Party (EWP-V)

- No items

7.6 Antimicrobials Working Party (AWP)

- No items

7.7 Immunologicals Working Party (IWP)

- No items

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

- ***For information:*** Verbal report on the Strategic Approach to Pharmaceuticals in the Environment meeting held on 7 June 2019 in Brussels.

8.3 Antimicrobial resistance

- ***For information:*** Revised "Reflection paper on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation" and the overview of comments received during the public consultation
- ***For information:*** Antimicrobial advice *ad hoc* expert group (AMEG)'s "Categorisation of antimicrobials" advice: Response from EC regarding the request for a further extension for the deadline to submit the update of the scientific advice

8.4 Pharmacovigilance

- ***For information:*** Bravecto Spot on / Bravecto Plus - use of gloves response from the MAH

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

- ***For decision:*** Transfer of co-rapporteurships responsibilities from I. Malemis to S. Farlopoulos

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***: Verbal report from the CMDv chair on the meetings held in April, May and June; minutes of the meeting held on 20-21 June 2019; draft agenda of the meeting to be held on 18-19 July 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** Informal presidency CVMP/CMDv meeting (to be held during the Finnish presidency) on 25-27 September 2019 at Porvoo, Finland; draft agenda
- ***For endorsement:*** Informal presidency CVMP/CMDv meeting held (during the Romanian presidency) on 6-8 May 2019 at Zamárdi, Hungary; report on conclusions and recommendations of the meeting

- ***For information:*** List of provisions in new veterinary legislation with impact on CVMP work and potentially requiring action
- ***For information:*** Information on potential issues or procedures that would require CVMP decision via written procedure during August 2019

13. LEGISLATION

- ***For adoption:*** Draft scientific recommendation on the list of variations not requiring assessment
- ***For adoption:*** Draft scientific recommendations on the revision of Annex II of Regulation (EU) 2019/6
- ***For adoption:*** Draft report 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 concerning: criteria to designate antimicrobial or groups of antimicrobials reserved for treatment of certain infections in humans; signal detection and adverse events; pharmacovigilance inspections; pharmacovigilance system master file and pharmacovigilance communication
- ***For information:*** Second package of EC requests for scientific advices to the Agency on Regulation (EU) 2019/6 concerning designation of antimicrobials or groups of reserved for treatment of certain infections in humans (Article 37(5)), format of the data to be collected on antimicrobial medicinal products used in animals (Article 57(4)) and rules on oral administration (Article 106(60))

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
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		
Dec 2019	3-5								3		