6 September 2019
EMA/493877/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 10-12 September 2019 meeting

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Committee for Medicinal Products for Veterinary Use

Draft agenda of 10-12 September 2019 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

10 September, 09:00 – 12 September 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 regarding points on the agenda

iv. Adoption of the minutes of the July meeting and the August meeting via written procedure

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 1C)	Tuesday, 10 September 2019	17:30-20:00

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- **Substance**
  EMEA/V/MRL/003131/MODF/0003
  Sheep

  For decision: Need for oral explanation

1.3 List of questions

- **Substance**
  EMEA/V/MRL/005302/FULL/0001
  Horses

  For adoption: CVMP scientific overview and list of questions

- **Substance**
  EMEA/V/MRL/004481/FULL/0002
  Salmonidae

  For adoption: CVMP scientific overview and list of questions

- **Substance**
  EMEA/V/MRL/003649/EXTN/0003
  Cattle

  For adoption: CVMP scientific overview and list of questions

- **Substance**
  EMEA/V/MRL/005009/FULL/0002
  Cattle

  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/004967/0000
  New vaccine
  Chickens

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

  For information*:* Summary of opinion

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

  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/004733/0000
  New product
  Cats

  ORAL EXPLANATION – Tuesday 10 September 2019

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

2.3 List of questions

- **Product**
  EMEA/V/C/005272/0000
  New vaccine
  Pigs

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

- **Product**
  EMEA/V/C/005149/0000
  New vaccine
  Pigs

  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 endorsement:*** EPAR scientific discussion for **Simparica Trio** (EMEA/V/C/004846/0000)
- ***For endorsement:*** Withdrawal EPAR scientific discussion (WEPAR) for **Coliprotec F4/F18** (EMEA/V/C/004225/II/0005)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 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: W. Schlumbohm

  Co-rapp: F. Hasslung Wikström

  For adoption: CVMP opinion, CVMP assessment report

  For information: Product information, summary of opinion

- **Vectra Felis**
  EMEA/V/C/002746/II/0009
  To change the legal status

  Rapp: G. Hahn

  Co-rapp: F. Hasslung Wikström

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

  For information: Summary of opinion

- **Bravecto**
  EMEA/V/C/002526/II/0033/G
  To add new therapeutic indications

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

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

  For information: Summary of opinion

- **Quadrisol**
  EMEA/V/C/000032/II/0038
  To introduce a new pharmacovigilance system

  Rapp: R. Breathnach

  For adoption: CVMP opinion, CVMP assessment report

- **Rhiniseng**
  EMEA/V/C/000160/II/0009
  Quality

  Rapp: M. Blixenkrone-Møller

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Posatex**
  EMEA/V/C/000122/II/0027/G
  Quality

  Rapp: S. Louet

  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

- **Onsior**
  EMEA/V/C/000127/II/0024/G
  To add a new therapeutic indication and to amend the product information due to new clinical data

  Rapp: G. J. Schefferlie

  Co-rapp: N. C. Kyvsgaard

  ***For adoption*:** List of questions

- **Bravecto**
  EMEA/V/C/002526/II/0036
  To add a new therapeutic indication

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

  For adoption: List of questions

- **CLYNAV**
  EMEA/V/C/002390/II/0010
  To extend the duration of immunity

  Rapp: J. G. Beechinor

  For adoption: List of questions

- **Circovac**
  EMEA/V/C/000114/II/0016/G
  Quality

  Rapp: P. Pasquali

  For adoption: List of questions

- **Zulvac SBV**
  EMEA/V/C/002781/II/0006
  Quality

  Rapp: G. Kulcsár

  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

- No items

4.2 Article 34 of Directive 2001/82/EC

- **Ronaxan and its associated names**
  EMEA/V/A/135
  Harmonisation of SPC

  Rapp: *to be appointed*

  Co-rapp: *to be appointed*

  For discussion and decision: Notification from Germany 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 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 discussion: Revised rapporteurs' assessment report including co-critique

- **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 from Norbrook Laboratories Limited for a further extension of the clock stop

  For adoption: Revised timetable

- **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names, and their generic products**
  EMEA/V/A/136
  Withdrawal periods

  Rapp: *to be appointed*

  Co-rapp: *to be appointed*

  For discussion and decision: Notification from France under Article 35 of Directive 2001/82/EC and annex

  Appointment of rapporteur, co-rapporteur and peer reviewers

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

- **BTVPUR**
  EMEA/V/C/002231/REC/021
  Recommendation

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Aivlosin (EMEA/V/C/000083)	09.09.2018 – 08.09.2019
Apoquel (EMEA/V/C/002688)	12.09.2018 – 11.09.2019
Bovilis BTV8 (EMEA/V/C/000148)	06.09.2018 – 05.09.2019
Cardalis (EMEA/V/C/002524)	23.07.2018 – 22.07.2019
Cortacare (EMEA/V/C/004689)	27.08.2018 – 26.08.2019
Dexdomitor (EMEA/V/C/000070)	30.08.2018 – 29.08.2019
Emdocam (EMEA/V/C/002283)	18.08.2018 – 17.08.2019
Exzolt (EMEA/V/C/004344)	18.08.2018 – 17.08.2019
FORTEKOR PLUS (EMEA/V/C/002804)	08.09.2018 – 07.09.2019
Innovax-ND-IBD (EMEA/V/C/004422)	22.08.2018 – 21.08.2019
Nobilis IB Primo QX (EMEA/V/C/002802)	04.09.2018 – 03.09.2019
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2018 – 31.08.2019
Nobivac Bb (EMEA/V/C/000068)	10.09.2018 – 09.09.2019
Nobivac Myxo-RHD (EMEA/V/C/002004)	07.09.2018 – 06.09.2019
Novaquin (EMEA/V/C/003866)	08.09.2018 – 07.09.2019
OSURNIA (EMEA/V/C/003753)	31.07.2018 – 30.07.2019
Porcilis PCV ID (EMEA/V/C/003942)	28.08.2018 – 27.08.2019

Product	Period
Profender (EMEA/V/C/000097)	27.07.2018 – 26.07.2019
Proteq West Nile (EMEA/V/C/002005)	05.08.2018 – 04.08.2019
Sedadex (EMEA/V/C/004202)	12.08.2018 – 11.08.2019
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07.08.2018 – 06.08.2019
Suvaxyn PCV (EMEA/V/C/000149)	24.07.2018 – 23.07.2019
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24.08.2018 – 23.08.2019
Trocoxil (EMEA/V/C/000132)	09.09.2018 – 08.09.2019
UBAC (EMEA/V/C/004595)	26.07.2018 – 25.07.2019
UpCard (EMEA/V/C/003836)	31.07.2018 – 30.07.2019
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2018 – 08.08.2019
Vectormune ND (EMEA/V/C/003829)	08.09.2018 – 07.09.2019
VEPURED (EMEA/V/C/004364)	17.08.2018 – 16.08.2019
Versican Plus L4 (EMEA/V/C/003680)	31.07.2018 – 30.07.2019
Versican Plus Pi/L4 (EMEA/V/C/003683)	31.07.2018 – 30.07.2019
Versican Plus Pi/L4R (EMEA/V/C/003682)	31.07.2018 – 30.07.2019
ZACTRAN (EMEA/V/C/000129)	24.07.2018 – 23.07.2019
ZULVAC 1 Bovis (EMEA/V/C/002334)	05.08.2018 – 04.08.2019
ZULVAC 1 Ovis (EMEA/V/C/002335)	05.08.2018 – 04.08.2019

5.4 Renewals

- **Suvaxyn CSF Marker**
  EMEA/V/C/002757/R/0006

  Rapp: M. Blixenkrone-Møller

  Co-rapp: B. Urbain

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

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

  Rapp: F. Klein

  Co-rapp: C. Muñoz Madero

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

- **Nexgard Spectra**
  EMEA/V/C/003796/R/0012

  Rapp: J. G. Beechinor

  Co-rapp: M. Turk

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

5.5 Pharmacovigilance - PSURs and SARs

- **Bravecto**
  EMEA/V/C/002526

  Rapp: G. J. Schefferlie

  For adoption: CVMP assessment report on the PSUR for the period 01.03.2018-28.02.2019

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

  Rapp: G. J. Schefferlie

  For adoption: CVMP assessment report on the PSUR for the period 01.12.2018-31.05.2019

- **COXEVAC**
  EMEA/V/C/000155

  Rapp: J.-C. Rouby

  For adoption: CVMP assessment report on the PSUR for the period 01.04.2016-31.03.2019

- **OSURNIA**
  EMEA/V/C/003753

  Rapp: S. Louet

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2018-31.01.2019

- **CYTOPOINT**
  EMEA/V/C/003939

  Rapp: R. Breathnach

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.11.2018-30.04.2019

- **Vectormune ND**
  EMEA/V/C/003829

  Rapp: F. Klein

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.04.2018-31.03.2019

- ***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***: Concept paper for revision of GL22 on reproduction testing to include the extended one generation reproduction toxicity study, for discussion at VICH Steering Committee
- ***For information***: Draft agenda for VICH Steering Committee meeting scheduled to take place on 18–21 November 2019 in Tokyo, Japan

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For decision:*** CVMP expert nomination - request from EFSA to participate as observers at the BIOHAZ panel working group for 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 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

8.3 Antimicrobial resistance

8.4 Pharmacovigilance

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 discussion:*** CMDv request to CVMP/ERA WP for advice on identification of products not eligible to the SPC harmonisation due to Article 72 of Regulation 2019/6
- ***For information***: Draft minutes of the meeting held on 18-19 July 2019; draft agenda of the meeting to be held on 12-13 September 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 11 September 2019, draft agenda of the meeting; minutes from the SPG meeting held on 19 June 2019
- ***For adoption:*** Revised procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur for referral procedures
- ***For endorsement:*** Agenda of informal presidency CVMP/CMDv meeting (to be held during the Finnish presidency) on 25-27 September 2019 at Haikko Manor, Finland
- ***For decision:*** Appointment of CVMP co-opted members at the November 2019 CVMP meeting; identification of expertise necessary to accomplish the mandate and appointment of co-opted members, CVMP list of expertise 2019
- ***For discussion:*** Draft CVMP work plan for 2020

13. LEGISLATION

- ***For endorsement***: Interim report to the Commission on the progress made by the 3 expert groups working on the scientific advice for the implementing act on good pharmacovigilance practice and the expert group working on the scientific advice on the pharmacovigilance master file (PSMF).

- ***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 on signal detection and adverse events and pharmacovigilance inspections and pharmacovigilance system master file and on pharmacovigilance communication

14. ANY OTHER BUSINESS

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

ANNEX

NEXT MEETINGS OF THE CVMP AND ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Sep 2019	10-12						24-25	26-27	10		
Oct 2019	8-10								8		
Nov 2019	5-7						10-20		5		
Dec 2019	3-5								3		