10 July 2020
EMA/377609/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of July 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

14 July, 09:00 – 16 July 2020, 13:00 – Adobe Connect (virtual)

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 (virtual)	Monday, 13 July 2020	10:00-13:00 CET

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
  EMEA/V/MRL/003649/EXTN/0002
  Porcine

  For adoption: CVMP opinion including EPMAR, CVMP assessment report

  For information: Summary of opinion

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

  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

- 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/005305/0000
  New product
  Cattle, pigs, sheep

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005076/0000
  New product
  Cattle, pigs, sheep

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

  For information: Summary of opinion

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

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005190/0000
  New vaccine
  Chickens

  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/005384/0000
  New product
  Cattle, pigs, sheep

  For decision: Need for an oral explanation

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

- **Product**
  EMEA/V/C/005184/0000
  New vaccine
  Pigs

  For decision: Need for an oral explanation

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

- **Product**
  EMEA/V/C/005251/0000
  New vaccine
  Dogs

  For decision: Need for an oral explanation

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

2.3 List of questions

- **Product**
  EMEA/V/C/005309/0000
  New vaccine
  Horses

  For adoption: CVMP scientific overview and list of questions, comments on the product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

For endorsement: Withdrawal EPAR scientific discussion for **Tulatrixx** (EMEA/V/C/005364/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Aivlosin**
  EMEA/V/C/000083/II/0080/G
  Quality-related changes

  Rapp: C. Bergman

  ***For adoption*:** CVMP opinion

  For endorsement: Rapporteur's assessment report

- **UpCard**
  EMEA/V/C/003836/II/0005/G
  Quality-related changes

  Rapp: C. Muñoz Madero

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Posatex**
  EMEA/V/C/000122/II/0028/G
  Quality-related changes

  Rapp: S. Louet

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Panacur AquaSol**
  EMEA/V/C/xxxx/WS1837
  ASMF

  Rapp: G. J. Schefferlie

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- **Cytopoint**
  EMEA/V/C/003939/II/0009
  To add a new therapeutic indication

  Rapp: R. Breathnach

  Co-rapp: J. Poot

  For adoption: List of outstanding issues, comments on the product information

3.3 List of questions

- **Cortavance**
  EMEA/V/C/000110/II/0015
  To add a new therapeutic indication

  Rapp: N.C. Kyvsgaard

  Co-rapp: C. Muñoz Madero

  For adoption: List of questions, comments on product information

- **Sevohale**
  EMEA/V/C/004199/II/0006/G
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: List of questions, comments on product information

- **Clynav**
  EMEA/V/C/002390/II/0011
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: List of questions

- **Equilis Prequenza** and **Equilis Prequenza Te**
  EMEA/V/C/xxxx/WS1836
  Quality-related changes

  Rapp: E. Werner

  For adoption: List of questions, comments on product information

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- **Simparica Trio**
  EMEA/V/C/004846/II/0001
  Quality-related changes

  Rapp: R. Breathnach

  For decision: Request from applicant for extension of the clock-stop

- **Advocate**
  EMEA/V/C/000076/II/0043
  To update the SPC

  Rapp: T.-M. Muhonen

  For decision: Request from applicant for extension of the clock-stop

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: F. Hasslung Wikström

  Co-rapp: J. G. Beechinor

  For decision: Request for an extension of the clock-stop

  For adoption: Revised timetable

4.3 Article 35 of Directive 2001/82/EC

- **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof**
  EMEA/V/A/138
  Withdrawal periods

  Rapp: A. Golombiewski

  Co-rapp: L. Nepejchalová

  For adoption: CVMP opinion, CVMP assessment report

- **Betamox LA 150 mg/ml suspension for injection and associated names, and generics products thereof**
  EMEA/V/A/132
  Withdrawal periods

  Rapp: A. Golombiewski

  Co-rapp: P. Hekman

  For adoption: CVMP opinion, CVMP assessment report

- **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

  Rapp: B. Urbain

  Co-rapp: S. Louet

  For decision: Need for further outstanding issues

  For discussion: Rapporteur's assessment report including co-rapporteur's critique

- **Injectable veterinary medicinal products containing vitamin A for use in food producing species**
  EMEA/V/A/141
  Withdrawal periods, user safety

  Rapp: *to be appointed*

  Co-rapp: *to be appointed*

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

  Appointment of rapporteur, co-rapporteur and peer reviewers

  For information: List of products concerned

- **Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines**
  EMEA/V/A/142
  Animal health

  Rapp: *to be appointed*

  Co-rapp: *to be appointed*

  For discussion and decision: Notification from the European Commission under Article 35 of Directive 2001/82/EC

  Appointment of rapporteur, co-rapporteur and peer reviewers

  For information: List of products concerned

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

- **Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus DHPPi, Versican Plus Pi, Versican Plus Pi/L4R, Versican Plus Pi/L4**
  EMEA/V/C/002759/REC/016,
  EMEA/V/C/003678/REC/016,
  EMEA/V/C/003679/REC/011,
  EMEA/V/C/003681/REC/011,
  EMEA/V/C/003682/REC/013,
  EMEA/V/C/003683/REC/012
  Post-authorisation measure

  Rapp: E. Werner

  Co-rapp: G. Kulcsár

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Aftovaxpur DOE (EMEA/V/C/002292)	15.07.2019 – 14.07.2020

Product	Period
Canigen L4 (EMEA/V/C/004079)	03.07.2019 – 02.07.2020
Circovac (EMEA/V/C/000114)	21.06.2019 – 20.06.2020
Clynav (EMEA/V/C/002390)	27.06.2019 – 26.06.2020
Convenia (EMEA/V/C/000098)	19.06.2019 – 18.06.2020
Equilis Prequenza (EMEA/V/C/000094)	08.07.2019 – 07.07.2020
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2019 – 07.07.2020
Equilis Te (EMEA/V/C/000093)	08.07.2019 – 07.07.2020
Equioxx (EMEA/V/C/000142)	25.06.2019 – 24.06.2020
Eryseng (EMEA/V/C/002761)	04.07.2019 – 03.07.2020
Eryseng Parvo (EMEA/V/C/002762)	08.07.2019 – 07.07.2020
HorStem (EMEA/V/C/004265)	19.06.2019 – 18.06.2020
Innovax-ILT (EMEA/V/C/003869)	03.07.2019 – 02.07.2020
Leucofeligen FeLV/RCP (EMEA/V/C/000143)	25.06.2019 – 24.06.2020
Melovem (EMEA/V/C/000152)	07.07.2019 – 06.07.2020
Nobivac L4 (EMEA/V/C/002010)	16.07.2019 – 15.07.2020
Posatex (EMEA/V/C/000122)	23.06.2019 – 22.06.2020
Prevomax (EMEA/V/C/004331	19.06.2019 – 18.06.2020
ProZinc (EMEA/V/C/002634)	12.07.2019 – 11.07.2020
Reconcile (EMEA/V/C/000133)	08.07.2019 – 07.07.2020
Sevohale (EMEA/V/C/004199)	21.06.2019 – 20.06.2020
Spironolactone Ceva (EMEA/V/C/000105)	20.06.2019 – 19.06.2020
Suprelorin (EMEA/V/C/000109)	10.07.2019 – 09.07.2020
Versican Plus DHPPi (EMEA/V/C/003679)	04.07.2019 – 03.07.2020
Versican Plus Pi (EMEA/V/C/003681)	04.07.2019 – 03.07.2020

5.4 Renewals

- **Suvaxyn Circo + MH RTU**
  EMEA/V/C/003924/R/0015

  Rapp: B. Urbain

  Co-rapp: M. Blixenkrone-Møller

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

- **Imrestor**
  EMEA/V/C/002763/R/0015

  Rapp: N. C. Kyvsgaard

  Co-rapp: S. Louet

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

5.5 Pharmacovigilance - PSURs and SARs

- **Activyl Tick Plus**
  EMEA/V/C/002234

  Rapp: G. J. Schefferlie

  For adoption: CVMP assessment report on the PSUR for the period 01.02.2017-31.01.2020

- **Cardalis**
  EMEA/V/C/0002524

  Rapp: C. Muñoz Madero

  For adoption: CVMP assessment report on the PSUR for the period 01.02.2017-31.01.2020

- **Onsior**
  EMEA/V/C/000127

  Rapp: G. J. Schefferlie

  For adoption: CVMP assessment report on the PSUR for the period 01.01.2017-31.12.2019

- **Equilis Prequenza**
  EMEA/V/C/000094

  Rapp: E. Werner

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.02.2017-31.01.2020

- **Equilis Prequenza Te**
  EMEA/V/C/000095

  Rapp: E. Werner

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.02.2017-31.02.2020

- **Eravac**
  EMEA/V/C/004239

  Rapp: C. Muñoz Madero

  For adoption: Rapporteur assessment report on the PSUR for the period 01.04.2019-31.03.2020

- **Exzolt**
  EMEA/V/C/004344

  Rapp: P. Hekman

  For adoption: Rapporteur assessment report on the PSUR for the period 01.09.2019-29.02.2020

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

  Rapp: J. Poot

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.09.2019-29.02.2020

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

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur evaluation on the PSUR for the period 13.02.2019-29.02.2020

- **Suvaxyn Circo**
  EMEA/V/C/004242

  Rapp: F. Klein

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.09.2019-29.02.2020

- **Suvaxyn PRRS MLV**
  EMEA/V/C/004276
  Rapp: E. Werner
  For endorsement: Rapporteur assessment report on the PSUR for the period 01.09.2019-29.02.2020
- **UpCard**
  EMEA/V/C/003836
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur assessment report on the PSUR for the period 01.02.2019-31.01.2020
- ***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:*** Draft concept paper on the development of further guidance on medicated premixes
- ***For endorsement:*** Draft concept paper proposing adoption of ICH Q7: Good manufacturing practice for active pharmaceutical ingredients

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information:*** Verbal report on the expert group to consider alternative intake calculation models for estimation of consumer exposure to residues

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

- No items

8.4 Pharmacovigilance

- No items

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

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 18-19 June 2020 meeting; draft agenda of the meeting to be held on 16-17 July 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Launch (link) of a two-month public consultation of the draft European Medicines Agencies Network Strategy to 2025; deadline for comments (link): 4 September 2020

13. LEGISLATION

- ***For adoption:*** Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products - Scientific problem analysis and recommendations to ensure a safe and efficient administration of veterinary medicinal products via routes other than medicated feed
- ***For adoption:*** Concept paper for the development of a reflection paper on criteria to be developed under Article 40(5) of Regulation (EU) 2019/6

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 2020	14-16						7-8		14		
Sept 2020	8-10						22-23	16-18	10		
Oct 2020	6-8								6		
Nov 2020	3-5						24-25		3		
Dec 2020	8-10							14-16	8		