17 April 2020
EMA/CVMP/211697/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of April 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

21 April 2020, 09:00 – 23 April 2020, 13:00 – Adobe virtual meeting

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 (Adobe connect)	Monday 20 April 2020	14:30-16:30 (TBC)

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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

- **Substance**
  EMEA/V/MRL/004828/EXTN/0002
  Chickens

  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

- No items

2.2 Oral explanations and list of outstanding issues

- **Product**
  EMEA/V/C/005094/0000
  New product
  Cats

  For decision: Need for an oral explanation

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

- **Product**
  EMEA/V/C/005148/0000
  New vaccine
  Pigs

  For decision: Need for an oral explanation

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

- **Product**
  EMEA/V/C/005719/0000
  New product
  Cats

  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/005427/0000
  New product
  Dogs

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

- **Product**
  EMEA/V/C/005384/0000
  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/005149/0000
  New vaccine
  Pigs

  For decision: Request to extend the clock-stop

- **Product**
  EMEA/V/C/005132/0000
  New product
  Dogs

  For decision: Request to further extend the clock-stop

- **Product**
  EMEA/V/C/005364/0000
  New product
  Cattle, pigs, sheep

  For information: Letter of withdrawal of the marketing authorisation application

- ***For endorsement:*** EPAR scientific discussion for **Lydaxx** (EMEA/V/C/005199/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Bravecto**
  EMEA/V/C/002526/II/0042
  To lower the minimum age of target animals

  Rapp: G. J. Schefferlie

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

- **Meloxidyl**
  EMEA/V/C/000115/II/0031
  Quality-related changes

  Rapp: C. Bergman

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Imrestor**
  EMEA/V/C/002763/II/0014
  Quality-related changes

  Rapp: N. C. Kyvsgaard

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- **Aivlosin**
  EMEA/V/C/000083/II/0078
  To add a new indication

  Rapp: C. Bergman

  Co-Rapp: A. Golombiewski

  ORAL EXPLANATION – Wednesday 22 April 2020 (11:30-12:00)

  For discussion: Rapporteur's assessment of responses to list of outstanding issues, rapporteurs' comments on the product information

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

  Rapp: C. Muñoz Madero

  For adoption: List of outstanding issues

3.3 List of questions

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

  Rapp: R. Breathnach

  Co-rapp: J. Poot

  For adoption: List of questions, comments on the product information

- **Nobilis Primo IB QX**
  EMEA/V/C/002802/II/0008
  To present new data on the safe use of Nobilis IB Primo QX

  Rapp: C. Miras

  For adoption: List of questions, comments on the product information

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- **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 decision: Request for extension of 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

- No items

4.3 Article 35 of Directive 2001/82/EC

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

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

- **Suvaxyn PRRS MLV**
  EU/2/17/215/001-003
  Animal health

  Rapp: E. Werner

  Co-rapp: F. Klein

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

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

- **Cytopoint**
  EMEA/V/C/003939/ANX/002
  Post-authorisation measure

  Rapp: R. Breathnach

  Co-rapp: J. Poot

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2019 – 01.04.2020
Arti-Cell Forte (EMEA/V/C/004727)	29.03.2019 – 28.03.2020
Bluevac BTV8 (EMEA/V/C/000156)	14.04.2019 – 13.04.2020
Chanhold (EMEA/V/C/004824)	17.04.2019 – 16.04.2020

Product	Period
Clevor (EMEA/V/C/004417)	13.04.2019 – 12.04.2020
Clomicalm (EMEA/V/C/000039)	01.04.2019 – 31.03.2020
Ecoporc Shiga (EMEA/V/C/002588)	10.04.2019 – 09.04.2020
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2019 – 25.03.2020
Evalon (EMEA/V/C/004013)	18.04.2019 – 17.04.2020
Forceris (EMEA/V/C/004329)	23.04.2019 – 22.04.2020
Incurin (EMEA/V/C/000047)	24.03.2019 – 23.03.2020
Letifend (EMEA/V/C/003865)	20.04.2019 – 19.04.2020
Locatim (EMEA/V/C/000041)	29.03.2019 – 28.03.2020
Meloxidolor (EMEA/V/C/002590)	22.04.2019 – 21.04.2020
Neocolipor (EMEA/V/C/000035)	14.04.2019 – 13.04.2020
Procox (EMEA/V/C/002006)	20.04.2019 – 19.04.2020
Purevax FeLV (EMEA/V/C/000056)	13.04.2019 – 12.04.2020
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2019 – 05.04.2020
Veraflox (EMEA/V/C/000159)	12.04.2019 – 11.04.2020

5.4 Renewals

- **Novaquin**
  EMEA/V/C/003866/R/0005

  Rapp: J. G. Beechinor

  Co-rapp: L. Nepejchalová

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

- **UpCard**
  EMEA/V/C/003836/R/0004

  Rapp: C. Muñoz Madero

  Co-rapp: J. G. Beechinor

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

- **Vectormune ND**
  EMEA/V/C/003829/R/0013

  Rapp: F. Klein

  Co-rapp: E. Werner

  For adoption: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

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

  Rapp: G. J. Schefferlie

  For discussion / endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-30.11.2019

- **Baycox Iron**
  EMEA/V/C/004794
  Rapp: G. J. Schefferlie
  For endorsement: Rapporteur's assessment report on the PSUR for the period 20.05.2019-30.11.2019
- **Improvac**
  EMEA/V/C/000136
  Rapp: N. C. Kyvsgaard
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2016-30.11.2019
- **Respiporc FluPan H1N1**
  EMEA/V/C/003993
  Rapp: M. Blixenkrone-Møller
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-30.11.2019
- **SevoFlo**
  EMEA/V/C/000072
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-30.11.2019
- **Zeleris**
  EMEA/V/C/004099
  Rapp: A. Golombiewski
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-30.11.2019
- **Suvaxyn Circo+MH RTU**
  EMEA/V/C/003924
  Rapp: B. Urbain
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2018-30.11.2019
- ***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:*** Nomination of EU expert to join the VICH Metabolism and Residues Kinetics Expert Working Group
- ***For discussion:*** Nomination of EU expert to join the VICH Safety Expert Working Group
- ***For discussion:*** Need for new EU experts to join VICH Bioequivalence EWG

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

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 MRL 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

- ***For adoption:*** Transfer of (co-)rapporteurships responsibilities from T. Høy to A. Bjelland

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 19 March 2020 meeting; draft agenda of the meeting to be held on 23 April 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption:*** CVMP Rules of procedure (EMA/MB/47098/2007–Rev.2)
- ***For information:*** Verbal report from the chair of the CVMP Strategic Planning Group on the meeting held on 20 April 2020; draft agenda of the meeting; draft minutes of the February 2020 meeting

13. LEGISLATION

- ***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 format for the collection of data for antimicrobials used in animals; on rules for oral administration of veterinary medicinal products; and on the list of antimicrobials reserved for the treatment of certain infections in humans

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Apr 2020	21-23								20		
May 2020	18-20						12-13		18		
Jun 2020	16-18								16		
Jul 2020	14-16						7-8		14		
Sept 2020	8-10						22-23		10		