13 March 2020
EMA/136373/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of 17-18 March 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

17 March 2020, 09:00 – 18 March 2020, 13:00 – Held virtually, due to travel restrictions because of COVID-19

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 meeting)	Monday, 16 March 2020	14:00-17:00 CET

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
  EMEA/V/MRL/003652/MODF/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

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

  For decision: Need for oral explanation

  For adoption: List of outstanding issues

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

  For decision: Need for oral explanation

  For adoption: List of outstanding issues

1.3 List of questions

- **Substance**
  EMEA/V/MLR/003802/MODF/0002
  Fin fish

  For adoption: 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/005199/0000
  New product
  Cattle, pigs, sheep

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

  For information: Summary of opinion

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

- **Emdocam**
  EMEA/V/C/002283/X/0012
  To add a new strength and new target species

  Rapp: J. G. Beechinor

  Co-rapp: C. Muñoz Madero

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

- **Emdocam**
  EMEA/V/C/002283/X/0013
  To add a new strength and a new pharmaceutical form
  Horses
  Rapp: J. G. Beechinor
  Co-rapp: C. Muñoz Madero
  For adoption: Scientific overview and list of questions, comments on product information
- **Product**
  EMEA/V/C/005325/0000
  New product
  Dogs
  For adoption: Scientific overview and list of questions, comments on product information
- **Product**
  EMEA/V/C/005347/0000
  New vaccine
  Chickens
  For adoption: CVMP scientific overview and list of questions, comments on the product information
- **Product**
  EMEA/V/C/005251/0000
  New vaccine
  Dogs
  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:*** EPAR scientific discussion for **Tulaven** (EMEA/V/C/005153/0000)
- ***For endorsement:*** EPAR scientific discussion for **Tulissin** (EMEA/V/C/005073/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Equisolon** and **Meloxoral**
  EMEA/V/C/xxxx/W1778
  To introduce a new pharmacovigilance system
  Rapp: A. Golombiewski
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report
- **Vectra 3D** and **Vectra Felis**
  EMEA/V/C/xxxx/WS1767/G
  Quality-related changes
  Rapp: A. Golombiewski
  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
  For adoption: List of outstanding issues, comments on the product information

- **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 outstanding issues, comments on the product information

- **ERYSENG PARVO**, **ERYSENG** and **RHINISENG**
  EMEA/V/C/xxxx/WS1686
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption*:* List of outstanding issues

3.3 List of questions

- No items

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

- No items

4.3 Article 35 of Directive 2001/82/EC

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

  Rapp: A. Golombiewski

  Co-rapp: P. Hekman

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

- **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 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

- **Fortekor Plus**
  EMEA/V/C/002804/REC/016
  EMEA/V/C/002804/REC/017
  Recommendation

  Rapp: N. C. Kyvsgaard

  For adoption: Rapporteur's assessment report

- **Nobilis IB Primo QX**
  EMEA/V/C/002802/REC/013
  Recommendation

  Rapp: C. Miras

  For adoption: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
CaniLeish (EMEA/V/C/002232)	14.03.2019 – 13.03.2020
Coliprotec F4 (EMEA/V/C/003797)	16.03.2019 – 15.03.2020
Econor (EMEA/V/C/000042)	12.03.2019 – 11.03.2020
Equisolon (EMEA/V/C/002382)	12.03.2019 – 11.03.2020
Fungitraxx (EMEA/V/C/002722)	12.03.2019 – 11.03.2020
Melosus (EMEA/V/C/002001)	21.02.2019 – 20.02.2020
Novem (EMEA/V/C/000086)	02.03.2019 – 01.03.2020
Pexion (EMEA/V/C/002543)	25.02.2019 – 24.02.2020
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	01.03.2019 – 29.02.2020
ProteqFlu (EMEA/V/C/000073)	06.03.2019 – 05.03.2020
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2019 – 05.03.2020
Purevax RC (EMEA/V/C/000091)	23.02.2019 – 22.02.2020

Product	Period
Purevax RCP (EMEA/V/C/000090)	23.02.2019 – 22.02.2020
Purevax RCP FeLV (EMEA/V/C/000089)	23.02.2020 – 22.02.2020
Purevax RCPCh (EMEA/V/C/000088)	23.02.2019 – 22.02.2020
Purevax RCPCh FeLV (EMEA/V/C/000085)	23.02.2019 – 22.02.2020
Zulvac 1+8 Bovis (EMEA/V/C/002473)	08.03.2019 – 07.03.2020
Zulvac 1+8 Ovis (EMEA/V/C/002251)	14.03.2019 – 13.03.2020

5.4 Renewals

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

  Rapp: C. Muñoz Madero

  Co-rapp: J. G. Beechinor

  For adoption: CVMP list of outstanding issues

- **Porcilis PCV ID**
  EMEA/V/C/003942/R/0004

  Rapp: J. Poot

  Co-rapp: P. Pasquali

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

5.5 Pharmacovigilance - PSURs and SARs

- **Cytopoint**
  EMEA/V/C/003939

  Rapp: R. Breathnach

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.05.2019-31.10.2019

- **Evalon**
  EMEA/V/C/004013

  Rapp: E. Werner

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.11.2018-31.10.2019

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

  Rapp: P. Hekman

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.03.2019-31.08.2019

- **Galliprant**
  EMEA/V/C/004222

  Rapp: K. Baptiste

  For endorsement: CVMP assessment report on the PSUR for the period 01.04.2019-30.09.2019

- **Vaxxitek HVT+IBD**
  EMEA/V/C/000065

  Rapp: B. Urbain

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.09.2016-31.08.2019

- ***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 anthelmintic guidelines: Draft EU comments on:
  - Arithmetic and Geometric Means (dose confirmation studies)
  - VICH GL 7 (general) - Age of Field Isolates and Laboratory Strains
  - VICH GL 7 - Adequacy of infection - Statistical Justification
  - VICH GL 12, 13 ,14, 15, 19, 20 - Adequacy of Infection/Helminth numbers
  - VICH GL 12 (bovine), 13 (ovine), 14 (caprine), 15 (equine) – Faecal egg count reduction test
  - VICH GL16 (porcine) – Claims for *Ascaris suum* L3 larvae
  - VICH GL 19-20 (cats, dogs) - Persistent efficacy
- ***For endorsement:*** Discussion document in the form of a draft concept paper proposing development of further guidance around medicated premixes

6.2 Codex Alimentarius

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 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

- ***For decision:*** Draft CVMP strategy on antimicrobials 2021-2025

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

- 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

- ***To note***: Draft minutes of the 20-21 February 2020 meeting; draft agenda of the meeting to be held on 19-20 March 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information***: European Medicines Regulatory Network Strategy to 2025

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Mar 2020	17-18						24-25		16		
Apr 2020[1]	21-23								21		
May 2020	18-20						12-13	12-14	18		
Jun 2020	16-18				9-10				16		
Jul 2020	14-16						7-8		14		

1 All meetings to be held remotely due to public health measures to slow the spread of COVID-19. This measure is in place until end April 2020, but will be revisited in the light of the development of COVID-19.