4 December 2020
EMA/661799/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2020 meeting

Chair: D. Murphy - Vice-chair: G. J. Schefferlie

8 December 2020, 09:00 – 10 December 2020, 13:00 – 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 (virtual)	Monday, 7 December 2020	10:00-13:00 CET

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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

- 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/005719/0000
  New product
  Cats

  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/005660/0000
  New product
  Dogs

  For decision: Need for an oral explanation

  For adoption: CVMP scientific overview and list of outstanding issues

- **Aivlosin**
  EMEA/V/C/000083/X/0081
  To add a new target species

  Rapp: C. Bergman

  Co-rapp: A. Golombiewski

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues

2.3 List of questions

- **Product**
  EMEA/V/C/005597/0000
  New product
  Cats, ferrets, dogs

  For adoption: Scientific overview and list of questions

- **Product**
  EMEA/V/C/005596/0000
  New vaccine
  Pigs

  For adoption: Scientific overview and list of questions

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- **Product**
  EMEA/V/C/005427/0000
  Dogs

  For adoption: Request from the applicant for an extension of the clock stop

- ***For endorsement:*** EPAR scientific discussion for **Mhyosphere PCV ID** (EMEA/V/C/005272/0000)
- ***For endorsement:*** EPAR scientific discussion for **CircoMax Myco** (EMEA/V/C/005184/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Circovac**
  EMEA/V/C/000114/II/0017/G
  Quality-related changes

  Rapp: P. Pasquali

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Innovax-ILT**
  EMEA/V/C/003869/II/0006/G
  Quality related changes

  Rapp: E. Werner

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Galliprant**
  EMEA/V/C/004222/II/0014/G
  Quality-related changes

  Rapp: K. Baptiste

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Ubac**
  EMEA/V/C/004595/II/0004
  Quality-related changes

  Rapp: E. Werner

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

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

  Rapp: R. Breathnach

  For adoption: List of outstanding issues

3.3 List of questions

- **Versican Plus Pi/L4R, Versican Plus DHPPi/L4R**
  EMEA/V/C/xxxx/WS1927
  Quality-related changes
  Rapp: E. Werner
  For adoption: List of questions

- **Ingelvac CircoFlex**
  EMEA/V/C/xxxxxx/WS1920/G
  Quality related changes
  Rapp: P. Pasquali
  For adoption: List of questions

- **Stelfonta**
  EMEA/V/C/005018/II/0004/G
  Quality-related changes
  Rapp: K. Boerkamp
  For adoption: List of questions

- **Versican Plus Pi/L4, Versican Plus Pi/L4R, Versican Plus L4, Versican Plus DHPPi/L4R** and **Versican Plus DHPPi/L4**
  EMEA/V/C/xxxxxx/WS1928/G
  Quality related changes
  Rapp: E. Werner
  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- **VarroMed**
  EMEA/V/C/002723/II/0003/G
  Quality-related changes
  Rapp: K. Štraus
  Co-rapp: A. Golombiewski
  For adoption: Request from the applicant for an extension of the clock stop

- ***For endorsement:*** EPAR scientific discussion for **Innovax-ND-IBD** (EMEA/V/C/004422)
- ***For endorsement:*** EPAR scientific discussion for **Zulvac BTV** (EMEA/V/C/004185)
- ***For endorsement:*** EPAR scientific discussion for **Leucofeligen FeLV RCP** (EMEA/V/C/000143)

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

- **Adjusol and its associated names**
  EMEA/V/A/134
  Harmonisation of SPC
  Rapp: C. Muñoz Madero
  Co-rapp: S. Louet
  For adoption: CVMP opinion, CVMP assessment report, product information

4.3 Article 35 of Directive 2001/82/EC

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

  Rapp: A. Golombiewski

  Co-rapp: B. Urbain

  For decision: Need for outstanding issues

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

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

  Rapp: E. Werner

  Co-rapp: F. Klein

  For decision: Need for outstanding issues

  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

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

- 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

- **Cytopoint**
  EMEA/V/C/003939/REC/014.1
  Recommendation

  Rapp: R. Breathnach

  Co-rapp: J. Poot

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Acticam (EMEA/V/C/000138)	09.12.2019 – 08.12.2020
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2019 – 20.11.2020

Product	Period
Broadline (EMEA/V/C/002700)	04.12.2019 – 03.12.2020
Contacera (EMEA/V/C/002612)	06.12.2019 – 05.12.2020
Draxxin (EMEA/V/C/000077)	11.11.2019 – 10.11.2020
Easotic (EMEA/V/C/000140)	20.11.2019 – 19.11.2020
Equip WNV (EMEA/V/C/000137)	21.11.2019 – 20.11.2020
Gumbohatch (EMEA/V/C/004967)	12.11.2019 – 11.11.2020
Imrestor (EMEA/V/C/002763)	09.12.2019 – 08.12.2020
Inflacam (EMEA/V/C/002497)	09.12.2019 – 08.12.2020
Masivet (EMEA/V/C/000128)	17.11.2019 – 16.11.2020
Meloxoral (EMEA/V/C/000151)	19.11.2019 – 18.11.2020
Mirataz (EMEA/V/C/004733)	10.12.2019 – 09.12.2020
Neptra (EMEA/V/C/004735)	10.12.2019 – 09.12.2020
Nobivac LeuFel (EMEA/V/C/004778)	06.11.2019 – 05.11.2020
Nobivac Myxo-RHD Plus (EMEA/V/C/004989)	19.11.2019 – 18.11.2020
Oxyglobin (EMEA/V/C/000045)	29.11.2019 – 28.11.2020
Panacur AquaSol (EMEA/V/C/002008)	09.12.2019 – 08.12.2020
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2019 – 15.11.2020
Porcilis PCV M Hyo (EMEA/V/C/003796)	07.11.2019 – 06.11.2020
Quadrisol (EMEA/V/C/000032)	04.12.2019 – 03.12.2020
Rabitec (EMEA/V/C/004387)	01.12.2019 – 30.11.2020
Simparica (EMEA/V/C/003991)	06.11.2019 – 05.11.2020
Stronghold (EMEA/V/C/000050)	25.11.2019 – 24.11.2020
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06.11.2019 – 05.11.2020
Vectra 3D (EMEA/V/C/002555)	04.12.2019 – 03.12.2020
Velactis (EMEA/V/C/003739)	09.12.2019 – 08.12.2020
Virbagen Omega (EMEA/V/C/000061)	06.11.2019 – 07.11.2020
Zycortal (EMEA/V/C/003782)	06.11.2019 – 05.11.2020

5.4 Renewals

- **Evalon**
  EMEA/V/C/004013/R/0003

  Rapp: E. Werner

  Co-rapp: P. Falb

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

- **Lefifend**
  EMEA/V/C/003865/R/0023

  Rapp: C. Muñoz Madero

  Co-rapp: C. Miras

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

5.5 Pharmacovigilance - PSURs and SARs

- **Neptra**
  EMEA/V/C/004735

  Rapp: C. Muñoz Madero

  For adoption: CVMP assessment report on the PSUR for the period 10.12.2019-30.06.2020

- **Vectra Felis**
  EMEA/V/C/002746

  Rapp: A. Golombiewski

  For adoption: CVMP assessment report on the PSUR for the period 01.01.2020-30.06.2020

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

  Rapp: F. Klein

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.07.2019-30.06.2020

- **Cortavance**
  EMEA/V/C/000110

  Rapp: N. C. Kyvsgaard

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2017-31.07.2020

- **Ecoporc Shiga**
  EMEA/V/C/002588

  Rapp: N. C. Kyvsgaard

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2017-31.07.2020

- **Gripovac 3**
  EMEA/V/C/000157

  Rapp: M. Blixenkrone-Møller

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2017-31.07.2020

- **Isemid**
  EMEA/V/C/004345

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2020-31.07.2020

- **Meloxidyl**
  EMEA/V/C/000115

  Rapp: C. Bergman

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2017-31.07.2020

- **Nasym**
  EMEA/V/C004897
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2020-31.07.2020
- **ProZinc**
  EMEA/V/C/002634
  Rapp: R. Breathnach
  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.02.2020-31.07.2020
- **Syvazul BTV**
  EMEA/V/C/004611
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2020-31.07.2020
- **Ubac**
  EMEA/V/C/004595
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2020-31.07.2020
- **Velactis**
  EMEA/V/C/003739
  Rapp: A. Golombiewski
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.2019-30.06.2020

- ***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 adoption:*** VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, for implementation at step 7
- ***For discussion:*** Revision of VICH guidelines on efficacy of anthelmintics, draft EU comments on:
  - VICH GL7 (general) - Arithmetic/Geometric mean
  - VICH GL7 (general) - Age of field isolates and laboratory strains
  - VICH GL7 (general) - Adequacy of infection - statistical justification
  - VICH GL12 (bovines), 13 (ovines), 14 (caprines), and 15 (equines) – Fecal egg count reduction tests (FECRT)
  - VICH GL16 (porcines) - *Ascaris suum* L3 claims
  - VICH GL16 (porcines) - Field studies
  - VICH GL19 (canines) and 20 (felines) - Persistent efficacy
  - VICH GL21 (poultry) - Field studies
- ***For information:*** Verbal report from VICH Steering Committee meeting held on 16-19 November 2020 and VICH Outreach Forum meeting held on 17 November 2020

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)

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

For adoption: Revised "Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation"

- ***For discussion:*** Draft CVMP strategy on antimicrobials for 2021-2025

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

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

- No items

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***To note*:** Draft minutes of the 5-6 November 2020 meeting; draft agenda of the meeting to be held on 3-4 December 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** CVMP draft work plan for 2021
- ***For endorsement:*** Minutes of the Presidency CVMP meeting held virtually under the German Presidency of the EU on 20 October 2020
- ***For information:*** European medicines agencies network strategy to 2025

13. LEGISLATION

- ***For information:*** Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans
- ***For information:*** Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 on the list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which may be used in accordance with these articles subject to certain conditions (Article 107(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
Dec 2020	8-10						29-30	14-16	7		
Jan 2021	19-21								18/19		
Feb 2021	16-18								15/16		
Mar 2021	16-18				23-24		26-27	1-3	15/16		
Apr 2021	13-15								12/13		