5 October 2020
EMA/523278/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

6 October 2020, 09:00 – 8 October 2020, 13:00 – Adobe connect

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 and 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, 5 October 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/005184/0000
  New vaccine
  Pigs

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

  For information: Summary of opinion

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

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005384/0000
  New product
  Cattle, pigs, sheep

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

  For information: Summary of opinion

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

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005482/0000
  New *vaccine*
  Chickens

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

  For information: Summary of opinion

2.2 Oral explanations and lists of outstanding issues

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

  ORAL EXPLANATION – Tuesday, 6 October 2020 – 14:30-16:00 CET

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

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

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

2.3 Lists of questions

- **Product**
  EMEA/V/C/005489/0000
  New product
  Cats

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

- **Product**
  EMEA/V/C/005465/0000
  New product
  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

- **Product**
  EMEA/V/C/005301/0000
  New vaccine
  Rabbits

  For decision: Request from applicant to extend the clock-stop

- ***For endorsement:*** EPAR scientific discussion for **Tulinovet** (EMEA/V/C/005076)
- ***For endorsement:*** EPAR scientific discussion for **Increxxa** (EMEA/V/C/005305)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Innovax-ND-IBD**
  EMEA/V/C/004422/II/0004
  To extend the duration of immunity

  Rapp: J. Poot

  Co-rapp: E. Werner

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

  For information: Summary of opinion

3.2 Oral explanations and list of outstanding issues

- No items

3.3 Lists of questions

- **Arti-Cell Forte**
  EMEA/V/C/004727/II/0003/G
  Quality-related changes

  Rapp: F. Hasslung Wikström

  For adoption: List of questions

- **Vectormune ND**
  EMEA/V/C/003829/WS1892
  Quality-related changes

  Rapp: F. Klein

  For adoption: List of questions, comments on product information

- **Eravac**
  EMEA/V/C/004239/II/0006
  Quality-related changes

  Rapp: C. Muñoz Madero

  For adoption: List of questions, comments on product information

- **VarroMed**
  EMEA/V/C/002723/II/0003/G
  Quality-related changes

  Rapp: K. Štraus

  Co-rapp: A. Golombiewski

  For adoption: List of questions

- **VarroMed**
  EMEA/V/C/002723/II/0004/G
  Quality-related changes

  Rapp: K. Štraus

  For adoption: List of questions

- **Cytopoint**
  EMEA/V/C/003939/II/0011/G
  Quality-related changes

  Rapp: R. Breathnach

  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Bluevac BTV** (EMEA/V/C/000156)

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

- **Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products**
  EMEA/V/A/140
  Withdrawal periods

  Rapp: A. Golombiewski

  Co-rapp: J. G. Beechinor

  For decision: Need for further outstanding issues

  For discussion: Revised 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 (EC) 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

- **Nobivac Myxo-RHD Plus**
  EMEA/V/C/004989/REC/001
  Recommendation

  Rapp: E. Werner

  Co-rapp: C. Rubio Montejano

  For adoption: Rapporteur's assessment report

- **Purevax RC, Purevax RCP, Purevax RCPCh**
  EMEA/V/C/000091/REC/022
  EMEA/V/C/000090/REC/022
  EMEA/V/C/000088/REC/024
  Recommendation

  Rapp: B. Urbain

  Co-rapp: C. Muñoz Madero

  For adoption: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Apoquel (EMEA/V/C/002688)	12.09.2019 – 11.09.2020
Cerenia (EMEA/V/C/000106)	29.09.2019 – 28.09.2020
Coxevac (EMEA/V/C/000155)	30.09.2019 – 29.09.2020
Eravac (EMEA/V/C/004239)	22.09.2019 – 21.09.2020
Palladia (EMEA/V/C/000150)	23.09.2019 – 22.09.2020
Previcox (EMEA/V/C/000082)	13.09.2019 – 12.09.2020
Recocam (EMEA/V/C/002247)	13.09.2019 – 12.09.2020
Rhiniseng (EMEA/V/C/000160)	16.09.2019 – 15.09.2020
Simparica Trio (EMEA/V/C/004846)	17.09.2019 – 16.09.2020

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- **Baycox Iron**
  EMEA/V/C/004794
  Rapp: J. G. Schefferlie
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2019-31.05.2020
- **Bluevac BTV8**
  EMEA/V/C/000156
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.2019-30.06.2020
- **Nobivac Myxo RHD Plus**
  EMEA/V/C/004989
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 19.11.2019-31.05.2020
- **Respiporc FLUPan H1N1**
  EMEA/V/C/003993
  Rapp: M. Blixenkrone-Møller
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2019-31.05.2020
- **Simparica & MiPet Easecto**
  EMEA/V/C/003991 &
  EMEA/V/C/004732
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-31.05.2020
- **Zycortal**
  EMEA/V/C/003782
  Rapp: H. Bergendahl
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-31.05.2020

- ***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 Concept paper on the development of further guidance around medicated premixes
- ***For adoption:*** VICH Concept paper for the adoption of ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients
- ***For endorsement:*** VICH GL59 "Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use" for sign off at step 5
- ***For information:*** Draft agenda for VICH Steering Committee meeting scheduled to take place on 16-19 November 2020 and VICH Outreach Forum meeting to take place 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

8.3 Antimicrobial resistance

- ***For decision***: Comments received during public consultation on the draft CVMP strategy on antimicrobials for 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 10-11 September 2020 meeting; draft agenda of the meeting to be held on 8-9 October 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Agenda for the virtual Presidency CVMP meeting to be held on 20 October 2020
- ***To note***: CVMP meeting dates for 2022-2024

13. LEGISLATION

- ***For information:*** Verbal update on work progress of the expert group concerning provision of scientific recommendations on an implementing act to Regulation (EU) 2019/6 on the list of antimicrobials reserved for the treatment of certain infections in humans

  Verbal update on work progress of the expert group concerning provision of scientific recommendations on an 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))

- ***For information:*** Agreement from the European Commission to extend the deadline for finalising the scientific advice regarding 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
Oct 2020	6-8								5		
Nov 2020	3-5						24-25		29[1]		
Dec 2020	8-10							14-16	8		
Jan 2021	19-21								19		
Feb 2021	16-18								16		

[1] To be held on 29 October 2020