4 September 2020
EMA/469339/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of September meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

8 September 2020, 09:00 – 10 September 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 or 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 July meeting and the August meeting via written procedure

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (virtual)	Monday, 7 September 2020	12:30-15:30 (CET)

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

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

  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/005180/0000
  New product
  Dogs

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005219/0000
  New product
  Pigs

  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/005149/0000
  New vaccine
  Pigs

  ORAL EXPLANATION – Tuesday, 8 September 2020 – 15:00-16:30

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

2.3 List of questions

- **Product**
  EMEA/V/C/005660/0000
  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/005719/0000
  New product
  Cats

  For decision: Request from applicant for an oral explanation

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

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

  Rapp: R. Breathnach

  Co-rapp: J. Poot

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

  For information: Summary of opinion

- **Nobilis IB Primo QX**
  EMEA/V/C/002802/II/0008
  To amend the product information due to new safety data

  Rapp: C. Miras

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

- **Zycortal**
  EMEA/V/C/003782/II/0008
  Quality-related changes

  Rapp: H. Bergendahl

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Nasym**
  EMEA/V/C/004897/II/0003/G
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Nobivac L4** and **Canigen L4**
  EMEA/V/C/xxxxxx/WS1871/G
  Quality-related changes

  Rapp: B. Urbain

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Suvaxyn Circo+MH RTU** and **Suvaxyn Circo**
  EMEA/V/C/xxxxxx/WS1852/G
  Quality-related changes

  Rapp: F. Klein

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Vectra 3D** and **Vectra Felis**
  EMEA/V/C/xxxxxx/WS1876
  Quality-related changes

  Rapp: A. Golombiewski

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Simparica** and **MiPet Easecto**
  EMEA/V/C/xxxxxx/WS1793
  Quality-related changes
  Rapp: J. G. Beechinor
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report
- **NexGard Spectra, Afoxolaner Merial** and **NexGard**
  EMEA/V/C/xxxxxx/WS1862/G
  Quality-related changes
  Rapp: J. G. Beechinor
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

- **Exzolt**
  EMEA/V/C/004344/II/0011
  To amend the SPC
  Rapp: K. Boerkamp
  For adoption: List of questions, comments on product information
- **Circovac**
  EMEA/V/C/000114/II/0017/G
  Quality-related changes
  Rapp: P. Pasquali
  For adoption: List of questions, comments on product information
- **Comfortis**
  EMEA/V/C/002233/II/0023/G
  Quality-related changes
  Rapp: A. Golombiewski
  For adoption: List of questions, comments on product information
- **Ubac**
  EMEA/V/C/004595/II/0004
  Quality-related changes
  Rapp: E. Werner
  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Clynav** (EMEA/V/C/002390)
- ***For endorsement:*** EPAR scientific discussion for **Aivlosin** (EMEA/V/C/000083)

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 adoption: CVMP opinion, CVMP assessment report

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

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

- **Stelfonta**
  EMEA/V/C/005018/REC/001
  EMEA/V/C/005018/REC/002
  EMEA/V/C/005018/REC/003
  Recommendation

  Rapp: K. Boerkamp

  Co-rapp: A. Golombiewski

  For adoption: Rapporteur's assessment report

- **Cytopoint**
  EMEA/V/C/003939/REC/014
  Recommendation

  Rapp: R. Breathnach

  Co-rapp: J. Poot

  For adoption: Rapporteur's assessment report

- **Prevexxion RN**
  EMEA/V/C/005058/REC/001
  Recommendation

  Rapp: F. Klein

  Co-rapp: E. Werner

  For adoption: Rapporteur's assessment report

- **Prevexxion RN+HVT+IBD**
  EMEA/V/C/005057/REC/001
  Recommendation

  Rapp: F. Klein

  Co-rapp: E. Werner

  For adoption: Rapporteur's assessment report

- **Vaxxitek HVT+IBD**
  EMEA/V/C/000065/REC/026.03
  Post-authorisation measure

  Rapp: B. Urbain

  Co-rapp: J. Poot

  For adoption: Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
Aivlosin (EMEA/V/C/000083)	09.09.2019 – 08.09.2020
Bovilis BTV8 (EMEA/V/C/000148)	06.09.2010 – 05.09.2020
Cardalis (EMEA/V/C/002524)	23.07.2019 – 22.07.2020
Cortacare (EMEA/V/C/004689)	27.08.2019 – 26.08.2020
Dexdomitor (EMEA/V/C/000070)	30.08.2019 – 29.08.2020
Emdocam (EMEA/V/C/002283)	18.08.2019 – 17.08.2020
Evicto (EMEA/V/C/004973)	19.07.2019 – 18.07.2020
Exzolt (EMEA/V/C/004344)	18.08.2019 – 17.08.2020
Fortekor Plus (EMEA/V/C/002804)	08.09.2019 – 07.08.2020
Innovax-ND-IBD (EMEA/V/C/004422)	22.08.2019 – 21.08.2020
Nasym (EMEA/V/C/004897)	29.07.2019 – 28.07.2020
Nobilis IB Primo QX (EMEA/V/C/002802)	04.09.2019 – 03.09.2020
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2019 – 31.08.2020
Nobivac Bb (EMEA/V/C/000068)	10.09.2019 – 09.09.2020
Nobivac Myxo-RHD (EMEA/V/C/002004)	07.09.2019 – 06.09.2020
Novaquin (EMEA/V/C/003866)	08.09.2019 – 07.09.2020
Osurnia (EMEA/V/C/003753)	31.07.2019 – 30.07.2020
Porcilis PCV ID (EMEA/V/C/003942)	28.08.2019 – 27.08.2020
Profender (EMEA/V/C/000097)	27.07.2019 – 26.07.2020
Proteq West Nile (EMEA/V/C/002005)	05.08.2019 – 04.08.2020
Sedadex (EMEA/V/C/004202)	12.08.2019 – 11.08.2020
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07.08.2019 – 06.08.2020
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24.08.2019 – 23.08.2020
Trocoxil (EMEA/V/C/000132)	09.09.2019 – 08.09.2020
Ubac (EMEA/V/C/004595)	26.07.2019 – 25.07.2020

Product	Period
UpCard (EMEA/V/C/003836)	31.07.2019 – 30.07.2020
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2019 – 08.08.2020
Vectormune ND (EMEA/V/C/003829)	08.09.2019 – 07.09.2020
Vepured (EMEA/V/C/004364)	17.08.2019 – 16.08.2020
Versican Plus L4 (EMEA/V/C/003680)	31.07.2019 – 30.07.2020
Versican Plus Pi/L4 (EMEA/V/C/003683)	31.07.2019 – 30.07.2020
Versican Plus Pi/L4R (EMEA/V/C/003682)	31.07.2019 – 30.07.2020
Zactran (EMEA/V/C/000129)	24.07.2019 – 23.07.2020

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- **Convenia**
  EMEA/V/C/000098
  Rapp: A. Golombiewski
  For adoption: CVMP assessment report on the PSUR for the period 01.01.17-31.12.19
- **Zolvix**
  EMEA/V/C/000154
  Rapp: N. C. Kyvsgaard
  For discussion / endorsement: Rapporteur's assessment report on the PSUR for the period 01.05.2017-30.04.2020
- **Equilis StrepE**
  EMEA/V/C/000078
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.04.2017-31.03.2020
- **Letifend**
  EMEA/V/C/003865
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.05.2019-30.04.2020
- **Forceris**
  EMEA/V/C/004329
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.11.2019-30.04.2020
- ***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:*** VICH GL 59 Harmonisation of criteria to waive laboratory animal batch safety testing for veterinary vaccines for veterinary use – revised draft documents for circulation to the VICH expert working group following public consultation: compilation of comments and responses; revised draft guideline

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For discussion:*** EC mandate to EMA and EFSA to develop common approach on exposure assessment for residues of VMPs, feed additives and pesticides

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

- ***For decision:*** Transfer of (co-)rapporteurship responsibilities from P. Hekman

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

- ***For endorsement***: Revised procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions

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

- ***For information:*** Verbal report from the CMDv chair on the meeting held on 16-17 July 2020; draft minutes of the 16-17 July 2020 meeting; draft agenda of the meeting to be held on 10-11 September 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** Virtual informal presidency CVMP meeting (to be held during the German presidency) to be held on 20 October 2020; draft agenda
- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) on the meeting to be held on 7 September 2020; draft agenda of the meeting; draft minutes of the June 2020 meeting

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
Sept 2020	8-10						22-23	16-18	7		
Oct 2020	6-8								6		
Nov 2020	3-5						24-25		3		
Dec 2020	8-10							14-16	8		
Jan 2021	19-21								19		