11 June 2021
EMA/308464/2021 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of June 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

15 June 2021, 09:00 – 17 June 2021, 13:00 – Virtual and room 15B

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, 14 June 2021	10.00-13.00 CEST

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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/005427/0000
  New product
  Dogs

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

  For information: Summary of opinion

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

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005309/0000
  New vaccine
  Horses

  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/005465/0000
  New product
  Dogs

  For decision: Need for an oral explanation

  For adoption: CVMP scientific overview and list of outstanding issues

- **Product**
  EMEA/V/C/005464/0000
  New product
  Cats

  For adoption: CVMP scientific overview and list of outstanding issues

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

  For adoption: CVMP scientific overview and list of outstanding issues

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- **Product**
  EMEA/V/C/005538/0000
  New vaccine
  Dogs

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

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **BTVPUR**
  EMEA/V/C/002231/WS2017/0022
  Quality-related changes

  Rapp: C. Muñoz Madero

  ***For adoption*:** CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Porcilis ColiClos**
  EMEA/V/C/002011/II/0012
  Quality-related changes

  Rapp: E. Werner

  ***For adoption*:** CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Eryseng** and **Eryseng Parvo**
  EMEA/V/C/xxxxx/WS1986/G
  Quality-related changes

  Rapp: J. G. Beechinor

  ***For adoption*:** CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Locatim**
  EMEA/V/C/000041/II/0017/G
  Quality-related changes

  Rapp: B. Urbain

  ***For adoption*:** CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Baycox Iron**
  EMEA/V/C/004794/II/0003
  Quality-related changes

  Rapp: G. J. Schefferlie

  ***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

- **NexGard Combo**
  EMEA/V/C/005094/II/0002/G
  To add two new therapeutic indications
  Rapp: A. Golombiewski
  Co-rapp: N. C. Kyvsgaard
  For adoption: List of questions
- **Meloxidyl** and **Zeleris**
  EMEA/V/C/xxxxx/WS2038/
  Quality-related changes
  Rapp: A. Golombiewski
  For adoption: List of questions
- **Neocolipor**
  EMEA/V/C/000035/II/0018/G
  Quality-related changes
  Rapp: C. Miras
  For adoption: List of questions
- **Startvac**
  EMEA/V/C/000130/II/0008/G
  Quality-related changes
  Rapp: E. Werner
  For adoption: List of questions
- **Locatim**
  EMEA/V/C/000041/II/0018
  Quality-related changes
  Rapp: B. Urbain
  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Cortavance** (EMEA/V/C/000110/II/0015)

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

- **Ronaxan and its associated names** (doxycycline)
  EMEA/V/A/135
  Harmonisation of SPC
  Rapp: F. Hasslung Wikström
  Co-rapp: J. G. Beechinor
  For adoption: CVMP opinion, CVMP assessment report, product information for 20 mg, 100 mg and 250 mg

4.3 Article 35 of Directive 2001/82/EC

- **Veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection**
  EMEA/V/A/143
  Rapp: *to be appointed*
  Co-rapp: *to be appointed*
  For discussion and decision: Notification from Germany under Article 35 of Directive 2001/82/EC
  Appointment of rapporteur, co-rapporteur and peer reviewers

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

- **Librela**
  EMEA/V/C/005180/REC/004
  Recommendation

  Rapp: F. Hasslung Wikström

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Baycox Iron (EMEA/V/C/004794)	20.05.2020 – 19.05.2021
Dany's BienenWohl (EMEA/V/C/004667)	14.06.2020 – 13.06.2021
Equilis West Nile (EMEA/V/C/002241)	06.06.2020 – 05.06.2021
Frontpro (EMEA/V/C/005126)	20.05.2020 – 19.05.2021
Leucogen (EMEA/V/C/000144)	17.06.2020 – 16.06.2021
Lydaxx (EMEA/V/C/005199)	18.05.2021 – 17.05.2021
MS-H Vaccine (EMEA/V/C/000161)	14.06.2020 – 13.06.2021
Naxcel (EMEA/V/C/000079)	19.05.2020 – 18.05.2021
Nobilis IB 4-91 (EMEA/V/C/000036)	09.06.2020 – 08.06.2021
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2020 – 13.06.2021
Porcilis Pesti (EMEA/V/C/000046)	09.06.2020 – 08.06.2021
Poulvac E. coli (EMEA/V/C/002007)	15.06.2020 – 14.06.2021

Product	Period
Respiporc FLUpan H1N1 (EMEA/V/C/003993)	17.05.2020 – 16.05.2021
Sileo (EMEA/V/C/003764)	10.06.2020 – 09.06.2021
Vectra Felis (EMEA/V/C/002746)	06.06.2020 – 05.06.2021
Zeleris (EMEA/V/C/004099)	15.05.2020 – 14.05.2021

5.4 Renewals

- **Sedadex**
  EMEA/V/C/004202/R/0005

  Rapp: C. Muñoz Madero

  Co-rapp: M. Leitner

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

- **Eravac**
  EMEA/V/C/004239/R/0007

  Rapp: C. Muñoz Madero

  Co-rapp: P. Pasquali

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

5.5 Pharmacovigilance - PSURs and SARs

- **Cerenia**
  EMEA/V/C/000106

  Rapp: N. C. Kyvsgaard

  For adoption: CVMP assessment report on the PSUR for the period 01.01.2018-31.12.2020

- **Prevomax**
  EMEA/V/C/004331

  Rapp: S. Louet

  For adoption: CVMP assessment report on the PSUR for the period 01.01.2018-31.12.2020

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

  Rapp: A. Golombiewski

  For adoption: CVMP assessment report on the PSUR for the period 01.07.2020-31.12.2020

- **Aservo EquiHaler**
  EMEA/V/C/004991

  Rapp: K. Baptiste

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.08.2020-31.01.2021

- **Credelio**
  EMEA/V/C/004247

  Rapp: R. Breathnach

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2020-31.01.2021

- **Equilis Te**
  EMEA/V/C/000093

  Rapp: E. Werner

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2018-31.01.2021

- **Evicto**
  EMEA/V/C/004973

  Rapp: J. G. Beechinor

  For endorsement: Rapporteur's assessment report on the PSUR for the period 19.07.2019-31.01.2021

- **Halagon**
  EMEA/V/C/004201

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.01.2020-31.12.2020

- **HorStem**
  EMEA/V/C/004265

  Rapp: A. Golombiewski

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.2020-31.12.2020

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

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2020-31.01.2021

- **Nasym**
  EMEA/V/C/004897

  Rapp: J. G. Beechinor

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2020-31.01.2021

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

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.2020-31.12.2020

- **Nobivac Myxo RHD Plus**
  EMEA/V/C/004989

  Rapp: E. Werner

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2020-30.11.2020

- **Sedadex**
  EMEA/V/C/004202

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.03.2020-28.02.2021

- **Stelfonta**
  EMEA/V/C/005018

  Rapp: K. Boerkamp

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2020-31.01.2021

- **Stronghold**
  EMEA/V/C/000050

  Rapp: J. G. Beechinor

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.01.2018-31.01.2021

- **Syvazul BTV**
  EMEA/V/C/004611

  Rapp: C. Muñoz Madero

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2020-31.01.2021

- **Ubac**
  EMEA/V/C/004595

  Rapp: E. Werner

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2020-31.01.2021

- **Ypozane**
  EMEA/V/C/000112
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2018-31.01.2021
- **Zactran**
  EMEA/V/C/000129
  Rapp: N. C. Kyvsgaard
  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.02.2020-31.01.2021

- ***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 discussion:*** EU comments on draft guideline on target animal safety evaluation for veterinary monoclonal antibody products

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

Document for information:

6.3: Consideration of alternative intake calculation models for estimation of consumer exposure to residues - minutes from the enlarged expert group's 3rd meeting held on 26 April 2021

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 Therapies & Technologies Working Party (NTWP)

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

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

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 agenda of the CMDv meeting to be held on 17-18 June 2021*;* minutes of the CMDv meeting held on 11-12 May 20211

12. ORGANISATIONAL AND STRATEGIC MATTERS

13. LEGISLATION

- ***For discussion:*** Reflection paper on eligibility criteria for limited markets
- ***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))
- ***For information:*** Publication of the Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council in the Official Journal of the European Union

14. ANY OTHER BUSINESS

- ***For comments:*** new highlights of the meeting

ANNEX

	CVMP	SAWP	QWP	SWP	ERAWP	EWP	AWP	IWP	PhVWP	NTWP	J3Rs WG
Jun 2021	15-17	14			30-1 July	22-23					-
Jul 2021	13-15	12							6-7		-
Sep 2021	7-9	6	22-24				21-22		21-22		-
Oct 2021	5-7	4			20-21	19-20					
Nov 2021	3-5	29/10									