9 July 2021
EMA/393347/2021 – draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of July 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

13 July 2021, 09:00 – 15 July 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, 12 July 2021	10:00-13:00 CEST

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
  EMEA/V/MRL/004828/EXTN/0002
  Chickens

  For adoption:
  Revised CVMP opinion including EPMAR, revised CVMP assessment report

  For information:
  Revised 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

- No items

2.2 Oral explanations and list of outstanding issues

- **Product**
  EMEA/V/C/005185/0000
  New vaccine
  Pigs

  For decision:
  Need for an oral explanation

  For adoption:
  CVMP scientific overview and list of outstanding issues

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

  For decision:
  Need for an oral explanation

  For adoption:
  Scientific overview and list of outstanding issues

- **Apoquel**
  EMEA/V/C/002688/X/0019
  To add a new pharmaceutical form
  Dogs

  Rapp: R. Breathnach

  Co-rapp: N. C. Kyvsgaard

  For decision:
  Need for an oral explanation

  For adoption:
  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

- ***For endorsement:***
  EPAR scientific discussion for **Bonqat** (EMEA/V/C/005489/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Ingelvac CircoFLEX** and **Ingelvac PRRSFLEX**
  EMEA/V/C/xxxxxx/WS1921
  To change the product information

  Rapp: P. Pasquali

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

- **Apoquel**
  EMEA/V/C/002688/II/0020
  Quality-related changes

  Rapp: R. Breathnach

  For adoption:
  CVMP opinion

  For endorsement:
  Rapporteur's assessment report

- **Ecoporc Shiga**
  EMEA/V/C/002588/II/0013
  Quality-related changes

  Rapp: N. C. Kyvsgaard

  For adoption:
  CVMP opinion

  For endorsement:
  Rapporteur's assessment report

- **Librela**
  EMEA/V/C/005180/II/0001
  Quality-related changes

  Rapp: F. Hasslung Wikström

  For adoption:
  CVMP opinion

  For endorsement
  Rapporteur's assessment report

- **Locatim**
  EMEA/V/C/000041/II/0021/G
  Quality-related changes

  Rapp: B. Urbain

  For adoption:
  CVMP opinion

  For endorsement:
  Rapporteur's assessment report

- **Nobilis Influenza H5N2**
  EMEA/V/C/000118/II/0016
  Quality-related changes

  Rapp: C. Miras

  For adoption:
  CVMP opinion

  For endorsement:
  Rapporteur's assessment report

- **Porcilis PCV**
  EMEA/V/C/000135/II/0014/G
  Quality-related changes

  Rapp: P. Pasquali

  For adoption:
  CVMP opinion, product information

  For endorsement:
  Rapporteur's assessment report

- **Stelfonta**
  EMEA/V/C/005018/II/0004/G
  Quality-related changes

  Rapp: K. Boerkamp

  For adoption:
  CVMP opinion

  For endorsement:
  Rapporteur's assessment report

- **Vectormune ND**
  EMEA/V/C/003829/II/0015/G
  Quality-related changes

  Rapp: F. Klein

  For adoption:
  CVMP opinion

  For endorsement:
  Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- **Frontpro**
  EMEA/V/C/005126/II/0010
  To change the legal status

  Rapp: K. Boerkamp

  Co-rapp: J. G. Beechinor

  For adoption:
  List of outstanding issues

- **Suvaxyn CSF Marker**
  EMEA/V/C/002757/II/0009
  To amend the therapeutic indication

  Rapp: M. Blixenkrone-Møller

  Co-rapp: B. Urbain

  For adoption:

  List of outstanding issues

- **Bravecto**
  EMEA/V/C/002526/II/0047
  To add a new therapeutic indication

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

  For adoption:

  List of outstanding issues

3.3 List of questions

- **Respiporc FLUpan H1N1**
  EMEA/V/C/003993/II/0013
  To amend the product information

  Rapp: M. Blixenkrone-Møller

  For adoption:
  List of questions

- **Nobivac L4**
  EMEA/V/C/002010/WS2058/0012
  To amend the product information

  Rapp: B. Urbain

  SL: P. Cordero

  For adoption:

  List of questions

- **Credelio**
  EMEA/V/C/004247/II/0018
  Quality-related changes

  Rapp: R. Breathnach

  For adoption:

  List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- **Neocolipor**
  EMEA/V/C/000035/II/0018/G
  Quality-related changes

  Rapp: C. Miras

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

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

- No items

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

- **CircoMax Myco**
  EMEA/V/C/005184/REC/002.1.2.3.4
  Recommendation

  Rapp: N. C. Kyvsgaard

  For adoption:
  Rapporteur's assessment report

- **Letifend**
  EMEA/V/C/003865/REC/014
  Recommendation

  Rapp: C. Muñoz Madero

  For endorsement:
  Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Aftovaxpur DOE (EMEA/V/C/002292)	15/07/2020 – 14/07/2021
Canigen L4 (EMEA/V/C/004079)	03/07/2020 – 02/07/2021
Circovac (EMEA/V/C/000114)	21/06/2020 – 20/06/2021
Clynav (EMEA/V/C/002390)	27/06/2020 – 26/06/2021
Convenia (EMEA/V/C/000098)	19/06/2020 – 18/06/2021
Equilis Prequenza (EMEA/V/C/000094)	08/07/2020 – 07/07/2021
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2020 – 07/07/2021
Equilis Te (EMEA/V/C/000093)	08/07/2020 – 07/07/2021
Equioxx (EMEA/V/C/000142)	25/06/2020 – 24/06/2021
Eryseng (EMEA/V/C/002761)	04/07/2020 – 03/07/2021
Eryseng Parvo (EMEA/V/C/002762)	08/07/2020 – 07/07/2021
HorStem (EMEA/V/C/004265)	19/06/2020 – 18/06/2021
Innovax-ILT (EMEA/V/C/003869)	03/07/2020 – 02/07/2021
Leucofeligen FeLV/RCP (EMEA/V/C/000143)	25/06/2020 – 24/06/2021
Melovem (EMEA/V/C/000152)	07/07/2020 – 06/07/2021
Posatex (EMEA/V/C/000122)	23/06/2020 – 22/06/2021

Prevomax (EMEA/V/C/004331)	19/06/2020 – 18/06/2021
ProZinc (EMEA/V/C/002634)	12/07/2020 – 11/07/2021
Reconcile (EMEA/V/C/000133)	08/07/2020 – 07/07/2021
Sevohale (EMEA/V/C/004199)	21/06/2020 – 20/06/2021
Suprelorin (EMEA/V/C/000109)	10/07/2020 – 09/07/2021
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2020 – 03/07/2021
Versican Plus Pi (EMEA/V/C/003681)	04/07/2020 – 03/07/2021

5.4 Renewals

- **Halagon**
  EMEA/V/C/004201/R/0006

  Rapp: C. Muñoz Madero

  Co-rapp: S. Louet

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

5.5 Pharmacovigilance - PSURs and SARs

- ***For adoption:***
  Recommendation for changes to the SPC for **Advocate** as outcome of signal detection activities

  For adoption:
  Recommendation for changes to the SPC for **Kriptazen** as outcome of signal detection activities

- **Vectra 3D**
  EMEA/V/C/002555

  Rapp: A. Golombiewski

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

- **Acticam**
  EMEA/V/C/000138 (WD)

  Rapp: J. G. Beechinor

  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 01.07.2018-22.03.2021

- **Bravecto Plus**
  EMEA/V/C/004440

  Rapp: G. J. Schefferlie

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

- **Chanhold**
  EMEA/V/C/004824

  Rapp: S. Louet

  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 17.04.2019-31.01.2021

- **Evant**
  EMEA/V/C/004902
  Rapp: J. G. Beechinor
  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 01.09.2020-28.02.2021
- **Exzolt**
  EMEA/V/C/004344
  Rapp: K. Boerkamp
  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 01.03.2020-28.02.2021
- **Innovax ND-IBD**
  EMEA/V/C/004422
  Rapp: J. Poot
  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 01.03.2020-28.02.2021
- **Suvaxyn PRRS MLV**
  EMEA/V/C/004276
  Rapp: E. Werner
  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 01.03.2020-28.02.2021
- **Vepured**
  EMEA/V/C/004364
  Rapp: N. C. Kyvsgaard
  For endorsement:
  Rapporteur's assessment report on the PSUR for the period 01.03.2020-28.02.2021

- ***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 endorsement:***
  EU comments on draft VICH 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

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)

7.5 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

- ***For information:***
  Verbal report from the CMDv chair on the CMDv meetings held on 11-12 May and 17-18 June 2021; draft agenda of the CMDv meeting to be held on 15-16 July 2021; minutes of the CMDv meeting held on 17-18 June 2021

12. ORGANISATIONAL AND STRATEGIC MATTERS

13. LEGISLATION

- ***For adoption:*** Reflection paper on eligibility criteria for limited markets, overview of comments received
- ***For adoption:*** Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6; guideline on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species
- ***For adoption:*** Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6
- ***For adoption:*** Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of the Regulation (EU) 2019/6
- ***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:*** Procedural advice for requests for the classification of variations not already listed in Commission Implementing Regulation (EU) 2021/17 or EMA/CMDv Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6

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 Oct	22-24	18-19			23-24		16-17		-
Dec 2021	7-9	6									-