EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 December 2021
EMA/722972/2021 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2021 meeting

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

3 December 2021
EMA/722972/2021 – draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

7 December 2021, 09:00 – 9 December 2021, 13:00 - Room 15B and 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/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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 session

Scientific Advice Working Party (Webex)	Mon 06 Dec 21	10.00-13.00

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
  EMEA/V/MRL/003363/EXTN/0004
  Chicken eggs

  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

- **Substance**
  EMEA/V/MRL/003477/EXTN/0004
  Fin fish

  For decision: Need for list of questions

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/005579/0000
  New product
  Dogs

  For adoption: CVMP scientific overview and list of outstanding issues

2.3 List of questions

Product
EMEA/V/C/005577/0000
New product
Pigs

For adoption*:* CVMP scientific overview and list of questions

- **Product**
  EMEA/V/C/005860/0000
  New vaccine
  Chickens

  For adoption*:* Scientific overview and LoQ

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For information:*** Decision to cease sending EPARs to CVMP for endorsement
- ***For endorsement:*** EPAR scientific discussion for **CircoMax** (EMEA/V/C/005185/0000)
- ***For endorsement:*** EPAR scientific discussion for **Suiseng Diff/A** (EMEA/V/C/005596/0000)
- ***For endorsement:*** EPAR scientific discussion for **Imoxat** (EMEA/V/C/005597/0000)
- ***For endorsement:*** EPAR scientific discussion for **Zenalpha** (EMEA/V/C/005465/0000)
- **Product**
  EMEA/V/C/005597/0000
  New product
  Cats, ferrets, dogs

  For information*:* Revised product information

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Improvac**
  EMEA/V/C/000136/II/0036
  To change the indication

  Rapp: N. C. Kyvsgaard

  Co-rapp: J. Poot

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

  For information: Summary of opinion

- **Bravecto**
  EMEA/V/C/002526/II/0051
  To add a new therapeutic indication

  Rapp: G. J. Schefferlie

  Co-rapp: R. Breathnach

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

  For information: Summary of opinion

- **Meloxidyl** and **Zeleris**
  EMEA/V/C/xxxxx/WS2038
  Quality-related changes

  Rapp: A. Golombiewski

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Simparica, Felisecto Plus, Simparica Trio, MiPet Easecto and Stronghold Plus**
  EMEA/V/C/xxxxxx/WS2073/G
  Quality-related changes

  Rapp: R. Breathnach

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Vaxxitek HVT+IBD**
  EMEA/V/C/xxxxxx/WS2149
  Quality-related changes

  Rapp: B. Urbain

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Bravecto**
  EMEA/V/C/002526/II/0053
  Quality-related changes

  Rapp: G. J. Schefferlie

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Neocolipor**
  EMEA/V/C/000035/II/0018/G
  Quality-related changes
  Rapp: C. Miras
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report
- **Cytopoint**
  EMEA/V/C/003939/II/0014/G
  Quality-related changes
  Rapp: R. Breathnach
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report
- **Mhyosphere PCV ID**
  EMEA/V/C/005272/II/0001/G
  Quality-related changes
  Rapp: E. Werner
  For adoption: CVMP opinion, product information
  For endorsement: Rapporteur's assessment report
- **Forceris**
  EMEA/V/C/004329/WS2097/0003
  Quality-related changes
  Rapp: C. Muñoz Madero
  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

- **Advocate**
  EMEA/V/C/000076/II/0046
  To add a new therapeutic indication
  Rapp: T.-M. Muhonen
  Co-rapp: J. P. Duarte Da Silva
  For adoption*:* List of questions
- **Suprelorin**
  EMEA/V/C/000109/II/0033
  Quality-related changes
  Rapp: N.C. Kyvsgaard
  For adoption*:* List of questions
- **BTVPUR**
  EMEA/V/C/002231/II/0025/G
  Quality-related changes
  Rapp: C. Muñoz Madero
  For adoption*:* List of questions
- **Porcilis ColiClos**
  EMEA/V/C/0002011/II/0013
  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 **Poulvac E. coli** (EMEA/V/C/002007/II/0018)
- ***For endorsement:*** EPAR scientific discussion for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/II/0013)
- ***For endorsement:*** EPAR scientific discussion for **Apoquel** (EMEA/V/C/002688/X/0019)
- ***For endorsement:*** EPAR scientific discussion for **NexGard Combo** (EMEA/V/C/005094/II/0002/G)

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

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

- **Versican Plus DHPPi/L4R, Versican Plus Pi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4**
  EMEA/V/C/002759/REC/017,
  EMEA/V/C/003682/REC/014,
  EMEA/V/C/003678/REC/017,
  EMEA/V/C/003680/REC/012,
  EMEA/V/C/003683/REC/013
  Post-authorisation measure

  Rapp: E. Werner

  Co-rapp: G. Kulcsár

  For endorsement: Rapporteur's assessment report

- **Poulvac E. coli**
  EMEA/V/C/002007/REC/016
  EMEA/V/C/002007/REC/017
  Recommendation

  Rapp: E. Werner

  Co-rapp: E. Augustynowicz

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2020 – 20.11.2021
Broadline (EMEA/V/C/002700)	04.12.2020 – 03.12.2021
CircoMax Myco (EMEA/V/C/005184)	09.12.2020 – 08.12.2021
Contacera (EMEA/V/C/002612)	06.12.2020 – 05.12.2021
Draxxin (EMEA/V/C/000077)	11.11.2020 – 10.11.2021
Easotic (EMEA/V/C/000140)	20.11.2020 – 19.11.2021
Enteroporc Coli AC (EMEA/V/C/005149)	09.12.2020 – 08.12.2021
Equip WNV (EMEA/V/C/000137)	21.11.2020 – 20.11.2021
Gumbohatch (EMEA/V/C/004967)	12.11.2020 – 11.11.2021
Imrestor (EMEA/V/C/002763)	09.12.2020 – 08.12.2021
Inflacam (EMEA/V/C/002497)	09.12.2020 – 08.12.2021
Librela (EMEA/V/C/005180)	10.11.2020 – 09.11.2021
Masivet (EMEA/V/C/000128)	17.11.2020 – 18.11.2021
Meloxoral (EMEA/V/C/000151)	19.11.2020 – 18.11.2021
Nobivac DP Plus (EMEA/V/C/005251)	09.12.2020 – 08.12.2021
Nobivac LeuFel (EMEA/V/C/004778)	06.11.2020 – 05.11.2021
Nobivac Myxo-RHD Plus (EMEA/V/C/004989)	19.11.2020 – 18.11.2021

Product	Period
OvuGel (EMEA/V/C/005219)	10.11.2020 – 09.11.2021
Oxyglobin (EMEA/V/C/000045)	29.11.2020 – 28.11.2021
Panacur AquaSol (EMEA/V/C/002008)	09.12.2020 – 08.12.2021
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2020 – 15.11.2021
Porcilis PCV M Hyo (EMEA/V/C/003796)	07.11.2020 – 06.11.2021
Quadrisol (EMEA/V/C/000032)	04.12.2020 – 03.12.2021
Rabitec (EMEA/V/C/004387)	01.12.2020 – 30.11.2021
Rexxolide (EMEA/V/C/005384)	03.12.2020 – 02.12.2021
Simparica (EMEA/V/C/003991)	06.11.2020 – 05.11.2021
Stronghold (EMEA/V/C/000050)	25.11.2020 – 24.11.2021
Suvaxyn Circo+MH RTU (EMEA/V/C/003924)	06.11.2020 – 05.11.2021
Vectormune FP ILT (EMEA/V/C/005482)	09.12.2020 – 08.12.2021
Vectra 3D (EMEA/V/C/002555)	04.12.2020 – 03.12.2021
Virbagen Omega (EMEA/V/C/000061)	06.11.2021 – 05.11.2021
Zycortal (EMEA/V/C/003782)	06.11.2020 – 05.11.2021

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- **Fevaxyn Pentofel** EMEA/V/C/000030

  Rapp: M. Blixenkrone-Møller

  For adoption: CVMP assessment report on the PSUR for the period 01.07.2018-30.06.2021

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

  Rapp: A. Golombiewski

  For adoption: CVMP assessment report on the PSUR for the period 01.01.2021-30.06.2021

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

  Rapp: F. Klein

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.07.2020-30.06.2021

- **Coliprotec F4/F18** EMEA/V/C/004225

  Rapp: E. Augustynowicz

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.08.2020-31.07.2021

- **CircoMax Myco**
  EMEA/V/C/005184
  Rapp: N. C. Kyvsgaard
  For endorsement: Rapporteur's assessment report on the PSUR for the period 09.12.2020-30.06.2021
- **Nasym**
  EMEA/V/C/004897
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2021-31.07.2021
- **Neptra**
  EMEA/V/C/004735
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.2021-30.06.2021
- **NexGard Combo**
  EMEA/V/C/005094
  Rapp: A. Golombiewski
  For endorsement: Rapporteur's evaluation on the PSUR for the period 06.01.2021-31.07.2021
- **Porcilis Porcoli Diluvac Forte**
  EMEA/V/C/000024
  Rapp: J. Poot
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2021
- **Prevexxion RN+HVT+IBD**
  EMEA/V/C/005057
  Rapp: F. Klein
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2021-31.07.2021
- **Profender**
  EMEA/V/C/000097
  Rapp: R. Breathnach
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2018-30.07.2021
- **Reconcile**
  EMEA/V/C/000133
  Rapp: S. Louet
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2021
- **VarroMed**
  EMEA/V/C/002723
  Rapp: K. Straus
  For endorsement: Rapporteur's assessment report on the PSUR for the period 03.08.2020-02.08.2021

- ***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

Information on certain topics discussed under section 6 cannot be released at the present time as it is deemed to be confidential

6.1 VICH

- ***For adoption***: VICH GL18 (R2) on impurities: residual solvents in new veterinary medicinal products, active substances and excipients for release for public consultation at step 4 of the VICH process
- ***For endorsement***: Concept paper proposing development of a VICH GL to parallel ICH Q8 (R2) on Pharmaceutical Development
- ***For discussion***: Report from virtual meetings of the Safety EWG held on 8 and 9 November to discuss the ongoing revisions of GL22 on reproduction studies and GL23 on genotoxicity testing
- ***For information***: Verbal report from VICH Steering Committee meeting held on 15, 17 and 18 November 2021 and VICH Outreach Forum meeting held on 15 November 2021

6.2 Codex Alimentarius

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 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

- No items

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 information***: Eleventh ESVAC report: Sales of veterinary antimicrobial agents in 31 European countries in 2019 and 2020. Trends from 2010 to 2020 (link)

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

9.1 MUMS/limited markets classifications

Information relating to MUMS/limited markets classifications cannot be released at the present time as it is deemed to be commercially confidential

- No items

9.2 Limited market classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of the Regulation (EU) 2019/6

Information relating to limited market classifications and confirmation of eligibility for authorisation according to Regulation 2019 (EU) 2019/6 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 7-8 October and 4-5 November 2021*;* draft agenda of the CMDv meeting to be held on 9-10 December 2021; minutes of the CMDv meeting held on 4-5 November 2021

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Verbal report from the chair of the Veterinary Domain on the meeting held on 25 November 2021 and agenda; minutes of the 3 September 2021 meeting and 25 October 2021 meeting
- ***For adoption:*** Rules on appointment and responsibilities of the CVMP rapporteur, co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6 and peer reviewer
- ***For adoption:*** CVMP draft work plan for 2022
- ***For decision:*** Appointment of CVMP co-opted members at the December 2021 CVMP meeting; nominations received for: Keith Baptiste **(Antimicrobial resistance)**, Christine Schwarz **(Antimicrobial resistance)**, Damien Bouchard **(Antimicrobial resistance)** and Ricardo Carapeto García **(Environmental risk assessment)**

  - Antimicrobial resistance

  - Environmental risk assessment
- ***For information:*** Annual report on Veterinary Big Data initiative

13. LEGISLATION

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	SAWP	QWP	SWP	ERAWP	EWP	AWP	IWP	PhVWP	NTWP	J3Rs WG
Dec 2021	7-9	6									-
Jan 2022	18-20	14 or 17									-
Feb 2022	15-17	14	28 Feb-2 Mar			22-23					-
Mar 2022	15-17	11 or 14			2-3		22-23				-
Apr 2022	11-13	8 or 11						28-29			-