EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2022
EMA/27915/2022 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2022 meeting

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14 January 2022
EMA/27915/2022 – draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2022 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

18 January 2022, 09:00 – 20 January 2022, 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).

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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 (Webex)	Mon 17 Jan 2022	10.00 - 13.00 CET

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- **Substance**
  EMEA/V/MRL/003652/EXTN/0004
  Chickens

  For decision: Need for oral explanation and list of outstanding issues

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

- No items

2.3 List of questions

- **Meloxoral**
  EMEA/V/C/000151/X/0015
  To add a new pharmaceutical form
  Dogs

  Rapp: A. Golombiewski

  Co-rapp: L. Nepejchalová

  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/005538/0000
  New vaccine
  Dogs

  For decision*:* Request from the applicant for a further extension of the clock stop

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

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

  Rapp: K. Štraus

  Co-rapp: A. Golombiewski

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Credelio**
  EMEA/V/C/004247/II/0019
  To add a new therapeutic indication in dogs

  Rapp: R. Breathnach

  Co-rapp: G. Kulcsár

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

  For information: Summary of opinion

- **Evant**
  EMEA/V/C/004902/II/0002/G
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Purevax RC, Purevax RCPCh Purevax RCPCh FeLV, Purevax RC** and **Purevax RCP FeLV**
  EMEA/V/C/xxxxxx/WS2166/G
  Quality-related changes

  Rapp: B. Urbain

  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

- **Gumbohatch**
  EMEA/V/C/004967/II/0005/G
  To reduce the minimum protective dose and make quality-related changes

  Rapp: J. G. Beechinor

  For adoption: List of questions, comments on product information

- **Bonqat**
  EMEA/V/C/005489/II/0002/G
  Quality-related changes

  Rapp: M. O'Grady

  For adoption*:* List of questions, comments on product information

- **Innovax-ND-ILT**
  EMEA/V/C/005190/II/0003/G
  Quality-related changes

  Rapp: J. Poot

  For adoption: List of questions, comments on product information

- **NexGard Spectra**
  EMEA/V/C/003842/II/0031
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption*:* List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

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 toltrazuril to be administered orally to chickens** EMEA/V/A/144 *Consumer safety*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from the Netherlands under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

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

- No items

5.3 Product anniversary list

Product	Period
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2021 – 08.01.2022
Bovela (EMEA/V/C/003703)	22.12.2020 – 21.12.2021
BTVPUR (EMEA/V/C/002231)	17.12.2020 – 16.12.2021
Cepedex (EMEA/V/C/004376)	13.12.2020 – 12.12.2021
Coliprotec F4/F18 (EMEA/V/C/004225)	09.01.2021 – 08.01.2022
Cortavance (EMEA/V/C/000110)	09.01.2021 – 08.01.2022
Galliprant (EMEA/V/C/004222)	09.01.2021 – 08.01.2022
Halagon (EMEA/V/C/004201)	13.12.2020 – 12.12.2021
Isemid (EMEA/V/C/004345)	09.01.2021 – 08.01.2022
Meloxidyl (EMEA/V/C/000115)	15.01.2021 – 14.01.2022
Metacam (EMEA/V/C/000033)	07.01.2021 – 06.01.2022
Mirataz (EMEA/V/C/004733)	10.12.2020 – 09.12.2021
Neptra (EMEA/V/C/004735)	10.12.2020 – 09.12.2021
NexGard Spectra (EMEA/V/C/000127)	15.01.2021 – 14.01.2022
Onsior (EMEA/V/C/000127)	16.12.2020 – 16.12.2021
Porcilis PCV (EMEA/V/C/000135)	12.01.2021 – 11.01.2022
Prac-tic (EMEA/V/C/000103)	18.12.2020 – 17.12.2021
Respiporc FLU3 (EMEA/V/C/000153)	14.01.2021 – 13.01.2022
Rheumocam (EMEA/V/C/005018)	10.01.2021 – 09.01.2022
SevoFlo (EMEA/V/C/005018)	11.12.2020 – 10.12.2021
Stelfonta (EMEA/V/C/005018)	15.01.2021 – 14.01.2022
Syvazul BTV (EMEA/V/C/004611)	09.01.2021 – 08.01.2022
Ypozane (EMEA/V/C/000112)	11.01.2021 – 10.01.2022
Zulvac 8 Ovis (EMEA/V/C/000147)	15.01.2021 – 14.01.2022

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

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

  Rapp: K. Boerkamp

  For adoption: CVMP assessment report on the PSUR for the period 01.02.2021-31.07.2021

- **Suvaxyn Circo**
  EMEA/V/C/004242
  Rapp: F. Klein
  For adoption: CVMP assessment report on the PSUR for the period 01.09.2020-31.08.2021

- **Cimalgex**
  EMEA/V/C/000162
  Rapp: F. Hasslung Wikström
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.09.2018-31.08.2021

- **Hiprabovis IBR Marker Live**
  EMEA/V/C/000158
  Rapp: B. Urbain
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2021

- **Ingelvac CircoFLEX**
  EMEA/V/C/000126
  Rapp: P. Pasquali
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.09.2018-31.08.2021

- **Isemid**
  EMEA/V/C/004345
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2021-31.07.2021

- **NexGard / Frontpro**
  EMEA/V/C/002729
  EMEA/V/C/005126
  Rapp: K. Boerkamp
  For endorsement: Rapporteur's assessment report on the PSURs for the period 01.09.2018-31.08.2021

- **Solensia**
  EMEA/V/C/005179
  Rapp: R. Breathnach
  For endorsement: Rapporteur's assessment report on the PSUR for the period 17.02.2021-31.08.2021

- **Stronghold Plus / Felisecto Plus**
  EMEA/V/C/004194
  EMEA/V/C/005093
  Rapp: R. Breathnach
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.09.2020-31.08.2021

- **Syvazul BTV**
  EMEA/V/C/004611
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.2021-31.07.2021

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 endorsement:*** Revision of VICH guidelines on efficacy of anthelmintics, draft EU comments

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 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

8.3 Antimicrobial resistance

8.4 Pharmacovigilance

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

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

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

Information relating to limited market classifications and confirmation of eligibility for authorisation according to Regulation (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***: Draft agenda of the CMDv meeting to be held on 20-21 January 2022; minutes of the CMDv meeting held on 09-10 December 2021; minutes of the CMDv-Interested Parties meeting held on 08 October 2021; agenda of the CMDv-Interested Parties meeting to be held on 21 January 2022

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Verbal report from the chair of the Veterinary Domain on the meeting held on 13 January 2022 and agenda and minutes of the 25 November 2021 meeting
- ***For information:*** Annual report on Veterinary Big Data initiative

13. LEGISLATION

- ***For information:*** Verbal update on work progress for the 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***: new highlights of the meeting

ANNEX

	CVMP	SAWP	QWP	SWP	ERAWP	EWP	AWP	IWP	PhVWP	NTWP	J3Rs WG
Jan 2022	18-20	17									-
Feb 2022	15-17	14	28 Feb-2 Mar			22-23					-
Mar 2022	15-17	11 or 14		31	2-3		22-23				-
Apr 2022	11-13	8 or 11		1				28-29			-
May 2022	10-12	6 or 10				17-18	24-25				