EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 October 2021
EMA/556577/2021 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2021 meeting

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1 October 2021
EMA/556577/2021 – draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of October 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

5 October 2021, 09:00 – 7 October 2021, 13:00 - 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).

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, 4 Oct 2021	10.00-13.00 CEST

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/005597/0000
  New product
  Cats, dogs, ferrets

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

  For information: Summary of opinion

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

  Rapp: R. Breathnach

  Co-rapp: N. C. Kyvsgaard

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

  For information: Summary of opinion

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

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

  For information: Summary of opinion

- **Product**
  EMEA/V/C/005465/0000
  New product
  Dogs

  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/005185/0000
  New vaccine
  Pigs

  ORAL EXPLANATION – Tuesday, 5 October 2021

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

- **Product**
  EMA/V/C/005606/0000
  New product
  Cattle, pigs, sheep

  For decision: Need for an oral explanation

  For adoption: CVMP scientific overview and list of outstanding issues

2.3 List of questions

- **Product**
  EMEA/V/C/005829/0000
  New product
  Dogs

  For adoption: CVMP scientific overview and list of questions

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

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

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

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **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: CVMP opinion, CVMP assessment report, product information

  For information: Summary of opinion

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

  Rapp: B. Urbain

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

- **Vaxxitek HVT+IBD**, **Prevexxion RN+HVT+IBD** and **Prevexxion RN**
  EMEA/V/C/xxxxxx/WS2107
  Quality-related changes
  Rapp: F. Klein
  For adoption: CVMP opinion, product information
  For endorsement: CVMP assessment report

- **Reconcile**
  EMEA/V/C/000133/II/0039
  Pharmacovigilance-related changes
  Rapp: S. Louet
  For adoption*:* CVMP opinion
  For endorsement: CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- **Meloxidyl** and **Zeleris**
  EMEA/V/C/xxxxx/WS2038
  Quality-related changes
  Rapp: A. Golombiewski
  For adoption: List of outstanding issues
  For endorsement: Rapporteur's assessment report

3.3 List of questions

- **Tulissin**
  EMEA/V/C/005073/II/0005
  Quality-related changes
  Rapp: C. Muñoz Madero
  For adoption*:* List of questions

- **Forceris**
  EMEA/V/C/004329/WS2097/0003
  Quality-related changes
  Rapp: C. Muñoz Madero
  For adoption*:* List of questions

- **Evant**
  EMEA/V/C/004902/II/0002/G
  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

- No items

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

- No items

5.3 Product anniversary list

Product	**Period**
Apoquel (EMEA/V/C/002688)	12.09.2020 – 11.09.2021
Cerenia (EMEA/V/C/000106)	29.09.2020 – 28.09.2021
Coxevac (EMEA/V/C/000155)	30.09.2020 – 29.09.2021
Eravac (EMEA/V/C/004239)	22.09.2020 – 21.09.2021
Increxxa (EMEA/V/C/005305)	16.09.2020 – 15.09.2021
Innovax-ND-ILT (EMEA/V/C/005190)	16.09.2020 – 15.09.2021
Mhyosphere PCV ID (EMEA/V/C/005272)	18.09.2020 – 17.09.2021
Nobivac Bb (EMEA/V/C/000068)	10.09.2020 – 09.09.2021
Palladia (EMEA/V/C/000150)	23.09.2020 – 22.09.2021
Previcox (EMEA/V/C/000082)	13.09.2020 – 12.09.2021
Recocam (EMEA/V/C/002247)	13.09.2020 – 12.09.2021
Rhiniseng (EMEA/V/C/000160)	16.09.2020 – 15.09.2021
Simparica Trio (EMEA/V/C/004846)	17.09.2020 – 16.09.2021
Tulinovet (EMEA/V/C/005076)	16.09.2020 – 15.09.2021

5.4 Renewals

- **VarroMed**
  EMEA/V/C/002723/R/0005

  Rapp: K. Štraus

  Co-rapp: A. Golombiewski

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

- **Stronghold Plus**
  EMEA/V/C/004194/R/0008

  Rapp: R. Breathnach

  Co-rapp: K. Boerkamp

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

5.5 Pharmacovigilance - PSURs and SARs

- **Letifend**
  EMEA/V/C/003865

  Rapp: C. Muñoz Madero

  For adoption: CVMP assessment report on the PSUR for the period 01.05.2020-30.04.2021

- **Purevax RC**
  EMEA/V/C/000091

  Rapp: B. Urbain

  For adoption: CVMP assessment report on the PSUR for the period 01.03.2018-28.02.2021

- **Purevax RCP**
  EMEA/V/C/000090

  Rapp: B. Urbain

  For adoption: CVMP assessment report on the PSUR for the period 01.03.2018-28.02.2021

- **Purevax RCP FeLV**
  EMEA/V/C/000089

  Rapp: B. Urbain

  For adoption: CVMP assessment report on the PSUR for the period 01.03.2018-28.02.2021

- **Purevax RCPCh**
  EMEA/V/C/000088

  Rapp: B. Urbain

  For adoption: CVMP assessment report on the PSUR for the period 01.03.2018-28.02.2021

- **Purevax RCPCh FeLV**
  EMEA/V/C/000085

  Rapp: B. Urbain

  For adoption: CVMP assessment report on the PSUR for the period 01.03.2018-28.02.2021

- **Apoquel**
  EMEA/V/C/002688

  Rapp: R. Breathnach

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2018-31.05.2021

- **Baycox Iron**
  EMEA/V/C/004794

  Rapp: G. J. Schefferlie

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2020-31.05.2021

- **Bovilis Blue-8**
  EMEA/V/C/004776
  Rapp: E. Werner
  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.07.2020-30.06.2021
- **Clevor**
  EMEA/V/C/004417
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.11.2020-30.04.2021
- **Porcilis AR-T DF**
  EMEA/V/C/000055
  Rapp: M. Blixenkrone-Møller
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2018-31.05.2021
- **Recocam**
  EMEA/V/C/002247
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.04.2018-31.03.2021
- **Respiporc FLUpan H1N1**
  EMEA/V/C/003993
  Rapp: M. Blixenkrone-Møller
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2020-31.05.2021

- ***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 endorsement:*** Draft revision of VICH GL18 Impurities: residual solvents in new VMPs, active substances and excipients, updated to include tertiary-butyl alcohol, cyclopentyl methyl ether, 2-methyltetrahydrofuran and triethylamine – for sign off at Expert Working group level
- ***For endorsement:*** Revision of VICH guidelines on efficacy of anthelmintics, draft EU comments on:
  - VICH GL7 (general)
  - VICH GL12 (bovine)
  - VICH GL13 (ovine)
  - VICH GL14 (caprine)
  - VICH GL15 (equine)
  - VICH GL16 (porcine)
  - VICH GL19 (canine)
  - VICH GL20 (feline)
  - VICH GL21 (poultry)

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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

- 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

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 15-16 July and 9-10 September 2021; draft agenda of the CMDv meeting to be held on 7-8 October 2021; minutes of the CMDv meeting held on 9-10 September; draft agenda of the CMDv-Interested Parties meeting to be held on 8 October 2021; minutes of the CMDv-Interested Parties meeting held on 12 May 2021; agenda of the CMDv Presidency meeting to be held virtually on 14 October 2021

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** Revised procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions
- ***For information:*** Informal presidency CVMP meeting (to be held virtually during the Slovenian presidency) on 13 October 2021; invitation and agenda
- ***For information:*** Info day for micro, small and medium-sized enterprises (SMEs) under the new Veterinary Medicinal Products Regulation; event summary (link) and agenda (link)

13. LEGISLATION

- ***For discussion:*** Concept paper on the revision of the CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products
- ***For discussion:*** Draft veterinary good pharmacovigilance practice (VGVP) modules on: collection and recording of suspected adverse events for veterinary medicinal products; Signal management; Veterinary pharmacovigilance communication; Pharmacovigilance inspections; PhV Systems and their PSMF and QMS; and draft annex glossary.

14. ANY OTHER BUSINESS

- ***For comments***: meeting highlights

ANNEX

	CVMP	SAWP	QWP	SWP	ERAWP	EWP	AWP	IWP	PhVWP	NTWP	J3Rs WG
Oct 2021	5-7	4			20-21	19-20					-
Nov 2021	3-5	27 Oct	22-24	18-19			23-24	17-18	16-17	24	-
Dec 2021	7-9	6									-
Jan 2022	18-20	14									
Feb 2022	15-17										-