29 October 2021
EMA/619106/2021 - draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of November 2021 meeting

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29 October 2021
EMA/619106/2021 – draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

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Draft agenda of November 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

3 November 2021, 09:00 – 5 November 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).

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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)	27 October 2021	10.00-13.00

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- **Substance**
  EMEA/V/MRL/005739/FULL/0001
  Equidae

  For decision: Need for oral explanation

  For adoption*:* CVMP scientific overview and list of outstanding issues, CVMP assessment report

1.3 List of questions

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

  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

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

  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/005528/0000
  New product
  Horses

  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/005816/0000
  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

- ***For endorsement:*** Withdrawal EPAR - scientific discussion for **Aivlosin** (EMEA/V/C/000083/X/0081)
- ***For endorsement:*** EPAR scientific discussion for **Felpreva** (EMEA/V/C/005464/0000)
- ***For information:*** Withdrawal of marketing authorisation of **Coliprotec F4** (EMEA/V/C/003797)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Respiporc FLUpan H1N1**
  EMEA/V/C/003993/II/0013
  Safety-related change

  Rapp: M. Blixenkrone-Møller

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

- **Vaxxitek HVT+IBD and Bovela**
  EMEA/V/C/xxxxx/WS1869
  Quality-related changes

  Rapp: B. Urbain

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

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

  Rapp: R. Breathnach

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Oncept IL-2**
  EMEA/V/C/002562/WS2129/G
  Quality-related changes

  Rapp: C. Miras

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Halagon**
  EMEA/V/C/004201/II/0007
  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

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

  Rapp: N. C. Kyvsgaard

  Co-rapp: J. Poot

  ORAL EXPLANATION – Wednesday, 3 November 2021, 14:00 CEST

  ***For discussion**:* Rapporteur's assessment report of responses to list of outstanding issues, rapporteurs' comments on product information, presentation from the applicant, rapporteur's presentation

- **Veraflox**
  EMEA/V/C/000159/II/0024/G
  Quality-related changes

  Rapp: A. Golombiewski

  For adoption*: L*ist of outstanding issues

  For endorsement: Rapporteur's assessment report

3.3 List of questions

- **Cepedex**
  EMEA/V/C/004376/II/0006
  Quality-related changes

  Rapp: C. Muñoz Madero

  For adoption: List of questions

- **Rabitec**
  EMEA/V/C/004387/II/0007/G
  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 **Circovac** (EMEA/V/C/WS1945)

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
Halocur (EMEA/V/C/000040)	29.10.2020 – 28.10.2021
Zolvix (EMEA/V/C/000154)	04.11.2020 – 03.11.2021

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- **Librela**
  EMEA/V/C/005180

  Rapp: F. Hasslung Wikström

  For adoption: CVMP assessment report on the PSUR for the period 10.11.2020-31.05.2021

- **Credelio Plus**
  EMEA/V/C/005325

  Rapp: R. Breathnach

  For endorsement: Rapporteur's assessment report on the PSUR for the period 14.04.2021-30.06.2021

- **Equilis West Nile**
  EMEA/V/C/002241

  Rapp: E. Werner

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

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

  Rapp: A. C. Golombiewski

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.2021-30.06.2021

- **Meloxoral**
  EMEA/V/C/000151

  Rapp: A. Golombiewski

  For endorsement: Rapporteur's assessment report on the PSUR for the period 20.05.2018-31.05.2021

- **Mirataz**
  EMEA/V/C/004733
  Rapp: S. Louet
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.2021-30.06.2021
- **Nobivac Myxo RHD Plus**
  EMEA/V/C/004989
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2020-31.05.2021
- **Prac-Tic**
  EMEA/V/C/000103
  Rapp: C. Muñoz Madero
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.2018-30.06.2021
- **Vectra Felis**
  EMEA/V/C/002746
  Rapp: A. Golombiewski
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.2021-30.06.2021

- ***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 discussion***: Draft VICH guideline on target animal safety evaluation for veterinary monoclonal antibody products – feedback from Expert Working Group meeting held on 27 October 2021
- ***For discussion***: Possible VICH guidelines for review
- ***For information***: Report from meeting of the Bioequivalence Expert Working Group on 27 September 2021
- ***For information***: Draft agenda for VICH SC meeting to be held on 15, 17-19 November; Draft agenda for VOF meeting to be held on 16 November; progress report bioequivalence expert working group; progress report quality expert working group; progress report BQM expert working group; progress report pharmacovigilance expert working group

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

Documents for information:

6.3: Consideration of alternative intake calculation models for estimation of consumer exposure to residues - minutes from the enlarged expert group's 5th meeting held on 23 September 2021

6.3: Published EFSA opinion on Maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed (link)

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

- 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

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 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

- ***For decision:*** Transfer of (co-)rapporteurships responsibilities from: H. Bergendahl to A. Askdal Bjelland

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 4-5 November 2021; minutes of the CMDv meeting held on 7-8 October 2021

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement:*** Revised procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions in accordance with Regulation (EU) 2019/6
- ***For discussion:*** 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 discussion:*** CVMP draft work plan for 2022
- ***For discussion:*** Draft CVMP Agenda in accordance with Regulation (EU) 2019/6

  For discussion: Appointment of CVMP co-opted members at the December 2021 CVMP meeting; identification of expertise necessary for CVMP to complement its expertise and appointment of co-opted members, CVMP list of expertise 2021
- ***For information:*** EMA Veterinary Info Day #2 to be held on 30 November 2021; draft programme

13. LEGISLATION

- ***For adoption:*** Draft veterinary good pharmacovigilance practice (VGVP) modules on: collection and recording of suspected adverse events for veterinary medicinal products and overview of comments; signal management and overview of comments; veterinary pharmacovigilance communication and overview of comments; pharmacovigilance inspections and overview of comments; pharmacovigilance systems and their PSMF and QMS and overview of comments; draft glossary and overview of comments
- ***For adoption***: Revised templates aligned with Regulation (EU) 2019/6:
  - scientific overview and list of questions and (co-)rapporteur assessment report templates for initial marketing authorisation applications for *pharmaceutical* veterinary medicinal products
  - scientific overview and list of questions; and (co-)rapporteur assessment report templates for initial marketing authorisation applications for *immunological* veterinary medicinal products
- ***For adoption:*** Draft concept paper on the revision of the CVMP recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products
- ***For endorsement:*** Procedure timetables to be utilised for variations requiring assessment
- ***For discussion***: Revised template for variations requiring assessment aligned with Regulation (EU) 2019/6
- ***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
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	14	28 Feb-2 Mar			22-23	22-23				-
Mar 2022	15-17										