30 October 2020
EMA/583050/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of November 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

3 November 2020, 09:00 – 5 November 2020, 13:00 – Adobe Connect (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)	Thursday, 29 October 2020	11:30-15:30 CET

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

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- **Substance**
  EMEA/V/MLR/003802/MODF/0002
  Fin fish

  For adoption: List of outstanding issues

  For discussion: Rapporteurs' assessment report, rapporteur's EPMAR

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- **Product**
  EMEA/V/C/005094/0000
  New product
  Cats

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

  For information:
  Summary of opinion

- **Product**
  EMEA/V/C/005148/0000
  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/005719/0000
  New product
  Cats

  ORAL EXPLANATION – Tuesday, 3 November 2020, 13:30 CET

  For discussion: Draft assessment of written responses, comments on product information

- **Product**
  EMEA/V/C/005354/0000
  New product
  Dogs

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

- **Product**
  EMEA/V/C/005325/0000
  New product
  Dogs

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

- **Product**
  EMEA/V/C/005347/0000
  New vaccine
  Chickens

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

- **Emdocam**
  EMEA/V/C/002283/X/0012
  To add a new strength and a new target species

  Rapp: J. G. Beechinor

  Co-rapp: C. Muñoz Madero

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

- **Emdocam**
  EMEA/V/C/002283/X/0013
  To add a new strength and a new pharmaceutical form
  Horses

  Rapp: J. G. Beechinor

  Co-rapp: C. Muñoz Madero

  For decision: Need for an oral explanation

  For adoption: Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

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

  For adoption: CVMP scientific overview and list of questions, comments on the product information

- **Product**
  EMEA/V/C/005464/0000
  New product
  Cats

  For adoption: CVMP scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Ovugel** (EMEA/V/C/005219/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Advocate**
  EMEA/V/C/000076/II/0043
  To update the SPC

  Rapp: T.-M. Muhonen

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

- **Clynav**
  EMEA/V/C/002390/II/0011
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Sevohale**
  EMEA/V/C/004199/II/0006/G
  Quality-related changes
  Rapp: J. G. Beechinor
  For adoption: CVMP opinion, product information
  For endorsement: Rapporteur's assessment report
- **Equilis Prequenza** and **Equilis Prequenza Te**
  EMEA/V/C/xxxxxx/WS1836
  Quality-related changes
  Rapp: E. Werner
  For adoption: CVMP opinion, product information
  For endorsement: Rapporteur's assessment report
- **Respiporc FLU3, Ecoporc Shiga, Respiporc FLUpan H1N1** and **Rabitec**
  EMEA/V/C/xxxxxx/WS1887
  Quality-related changes
  Rapp: M. Blixenkrone-Møller
  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

- **Suvaxyn CSF Marker**
  EMEA/V/C/002757/II/0008
  Quality-related changes
  Rapp: M. Blixenkrone-Møller
  For adoption: List of questions
- **Gumbohatch**
  EMEA/V/C/004967/II/0004
  Quality-related changes
  Rapp: J. G. Beechinor
  For adoption: List of questions
- **Melosus**
  EMEA/V/C/002001/II/0012
  Quality-related changes
  Rapp: N. C. Kyvsgaard
  For adoption: List of questions
- **Meloxoral**
  EMEA/V/C/000151/II/0011
  Quality-related changes
  Rapp: A. Golombiewski
  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Nobilis IB Primo QX** (EMEA/V/C/002802)
- ***For endorsement:*** EPAR scientific discussion for **Cytopoint** (EMEA/V/C/003939)

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

- **Adjusol and its associated names**
  EMEA/V/A/134
  Harmonisation of SPC

  Rapp: C. Muñoz Madero

  Co-rapp: S. Louet

  For decision: Need for further list of outstanding issues

  For discussion: Revised rapporteurs' assessment report including co-rapporteur's critique following MAHs' responses to the list of outstanding issues; comments on product information

4.3 Article 35 of Directive 2001/82/EC

- **Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products**
  EMEA/V/A/140
  Withdrawal periods

  Rapp: A. Golombiewski

  Co-rapp: J. G. Beechinor

  For adoption: CVMP opinion, CVMP assessment report

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

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 DHPPi/L4, Versican Plus DHPPi, Versican Plus Pi, Versican Plus Pi/L4R, Versican Plus Pi/L4**
  EMEA/V/C/002759/REC/016.1, EMEA/V/C/003678/REC/016.1, EMEA/V/C/003679/REC/011.1, EMEA/V/C/003681/REC/011.1, EMEA/V/C/003682/REC/013.1, EMEA/V/C/003683/REC/012.1
  Post-authorisation measure

  Rapp: E. Werner

  Co-rapp: G. Kulcsár

  For endorsement: Rapporteur's assessment report

- **Gumbohatch**
  EMEA/V/C/004967/REC/007
  Recommendation

  Rapp: J. G. Beechinor

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Halocur (EMEA/V/C/000040)	29.10.2019 – 28.10.2020
Zolvix (EMEA/V/C/000154)	04.11.2019 – 03.11.2020

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- **Bovilis Blue-8**
  EMEA/V/C/004776

  Rapp: E. Werner

  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.07.2019-30.06.2020

- **Bravecto**
  EMEA/V/C/002526

  Rapp: G. J. Schefferlie

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.03.2019-29.02.2020

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

  Rapp: G. J. Schefferlie

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.06.2019-30.11.2019

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

  Rapp: G. J. Schefferlie

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.2019-31.05.2020

- **Mirataz**
  EMEA/V/C/004733

  Rapp: S. Louet

  For endorsement: Rapporteur's assessment report on the PSUR for the period 10.12.2019-30.06.2020

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

  Rapp: A. Golombiewski

  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.2020-30.06.2020

- ***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*:** Development of guidance on *in vitro* dissolution testing and biowaivers for *in vivo* blood BE determinations, EU comments responding to 'critical questions' identified in the concept paper
- ***For endorsement:*** Concept paper proposing development of VICH GLs to parallel ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System)
- ***For endorsement:*** Nomination of an adviser to support the EU expert in the work to develop a VICH guideline on Good Manufacturing Practice for Active Pharmaceutical Ingredients
- ***For information:*** Draft agenda for VICH Steering Committee meeting scheduled to be held on 16-19 November 2020 and VICH Outreach Forum meeting to be held on 17 November 2020, VICH expert working groups progress reports:
  - Bioequivalence EWG progress report
  - Quality EWG progress report
  - Anthelmintic EWG progress report
  - Biologicals EWG progress report
  - Combination products EWG progress report
  - Metabolism and residue kinetics EWG progress report
  - Safety EWG progress report
  - Pharmacovigilance EWG progress report

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 therapy groups and related issues

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

- ***For information:*** Verbal report on the 10th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 31 European countries in 2018

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 meetings held on 10-11 September 2020 and 8-9 October 2020; draft minutes of the 8-9 October 2020 meeting; draft agenda of the meeting to be held on 5-6 November 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** Draft CVMP work plan for 2021
- ***For endorsement:*** Draft minutes and conclusions and recommendations arising from the informal CVMP presidency meeting held virtually on 20 October 2020
- ***For information:*** Verbal report from the chair of the Strategic Planning Group on the meeting held on 29 October 2020 and agenda; minutes of the 7 September 2020 meeting

13. LEGISLATION

- ***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

  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***: Press release of the meeting

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Nov 2020	3-5						24-25		29[1]		
Dec 2020	8-10							14-16	7		
Jan 2021	19-21								19		
Feb 2021	16-18								16		
Mar 2021	16-18							1-3	16		

[1] To be held on 29 October 2020