7 November 2017
EMA/CVMP/727215/2017 draft 2
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of November 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

7 November 2017, 09:00 – 9 November 2017, 13:00 - Room 3E

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 with fixed timings

Scientific Advice Working Party (room 3E)	Tue 7 Nov 2017	17.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
  EMA/V/MRL/003141/EXTN/0004
  Fin fish

  For adoption*:* CVMP opinion including EPMAR, CVMP assessment report

  For information*:* Summary of opinion

- **Substance**
  EMA/V/MRL/004113/FULL/0001
  Porcine

  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

- No items

1.4 Re-examination of CVMP opinions

- **Substance**
  EMEA/V/MRL/003135/MODF/0003
  Salmonidae

  For discussion*:* Rapporteurs' assessment report, rapporteurs' EPMAR

1.5 Other issues

- **Substance**
  EMEA/V/MRL/003517/EXTN/0003
  Eggs

  For decision*:* Request to extend the deadline for submission of responses to list of outstanding issues

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- **Product**
  EMEA/V/C/004222/0000
  New anti-inflammatory 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/004440/0000
  New antiparasitic product
  Cats

  For decision: Need for oral explanation

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

2.3 List of questions

- **Product**
  EMEA/V/C/004727/0000
  New product for musculo-skeletal disorders
  Horses
  ***For adoption**:* Scientific overview and list of questions, comments on product information

- **Product**
  EMEA/V/C/004345/0000
  New cardiovascular product
  Dogs
  ***For adoption**:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- **Product**
  EMEA/V/C/004417/0000
  New product acting on the nervous system
  Dogs
  ***For endorsement**:* Request for an oral explanation from the applicant

- ***For adoption:*** EPAR module scientific discussion for **Oxybee** (EMEA/V/C/004296/0000)
- ***For adoption:*** EPAR module scientific discussion for **Bovilis Blue-8** (EMEA/V/C/004776/0000)
- ***For adoption:*** EPAR module scientific discussion for **MiPet Easecto** (EMEA/V/C/004732/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Vectormune ND and NAP**
  EMEA/V/C/003829/WS1082(0006)
  Changes in the product information
  Rapp: F. Klein
  Co-rapp: E. Werner
  For adoption: CVMP opinion, CVMP assessment report, product information

- **ERAVAC**
  EMEA/V/C/004239/II/0002/G
  Quality
  Rapp: C. Muñoz
  For adoption: CVMP opinion, product information
  ***For endorsement**:* Rapporteur's assessment report

- **Exzolt**
  EMEA/V/C/004344/II/0001/G
  Quality
  Rapp: P. Hekman
  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

- **Zolvix**
  EMEA/V/C/000154/II/0023/G
  Quality

  Rapp: E.-M. Vestergaard

  ***For adoption**:* Rapporteur's assessment report including list of questions

- **ERAVAC**
  EMEA/V/C/004239/II/0003/G
  Changes in the product information

  Rapp: C. Muñoz

  ***For adoption**:* List of questions

- **Ingelvac CircoFLEX and Ingelvac PCV FLEC**
  EMEA/V/C/xxxxxx/WS1249/G
  Quality

  Rapp: B. Urbain

  ***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

- **CLYNAV**
  EMEA/V/C/002390/REC/001

  Rapp: N. Garcia del Blanco

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Aivlosin (EMEA/V/C/000083)	09/09/2016 – 10/09/2017
APOQUEL (EMEA/V/C/002688)	12/09/2016 – 13/09/2017
Cerenia (EMEA/V/C/000106)	29/09/2016 – 30/09/2017
COXEVAC (EMEA/V/C/000155)	30/09/2016 – 01/10/2017
ERAVAC (EMEA/V/C/004239)	22/09/2016 – 23/09/2017
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2016 – 09/09/2017
Nobivac Bb (EMEA/V/C/000068)	10/09/2016 – 11/09/2017
Novaquin (EMEA/V/C/003866)	08/09/2016 – 09/09/2017
Palladia (EMEA/V/C/000150)	23/09/2016 – 24/09/2017
Previcox (EMEA/V/C/000082)	13/09/2016 – 14/09/2017
Recocam (EMEA/V/C/002247)	13/09/2016 – 14/09/2017
RHINISENG (EMEA/V/C/000160)	16/09/2016 – 17/09/2017
Trifexis (EMEA/V/C/002635)	19/09/2016 – 20/09/2017
Trocoxil (EMEA/V/C/000132)	09/09/2016 – 10/09/2017
Vectormune ND (EMEA/V/C/003829)	08/09/2016 – 09/09/2017

5.4 Renewals

- **Semintra**
  EMEA/V/C/002436/R/0009

  Rapp: R. Breathnach

  Co-rapp: C. Muñoz

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

5.5 Pharmacovigilance - PSURs and SARs

- **Bluevac BTV8**
  EMEA/V/C/000156

  Rapp: E. Werner

  For adoption: CVMP assessment report

- **Leucogen**
  EMEA/V/C/000144
  Rapp: E. Werner
  For endorsement: Rapporteur's evaluation on the PSUR for the period 01.07.14-30.06.17
- **NexGard**
  EMEA/V/C/002729
  Rapp: P. Hekman
  For discussion: Draft CVMP assessment report on the PSUR for the period 11.02.14-28.02.17
- **Poulvac E.Coli**
  EMEA/V/C/002007
  Rapp: E. Werner
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.17-30.06.17
- **Trifexis**
  EMEA/V/C/002635
  Rapp: G. Hahn
  For endorsement: Rapporteur's assessment report on the PSUR for the period 05.01.17-04.07.17
- **Vectra 3D**
  EMEA/V/C/002555
  Rapp: G. Hahn
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.16-30.06.17
- **Velactis**
  EMEA/V/C/003739
  Rapp: W. Schlumbohm
  For endorsement: Rapporteur's assessment report on the PSUR for the period 01.01.17-30.06.17
- ***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***: Joint statement of EU regulators and industry on the further development of VICH guidance on extraneous viruses
- ***For discussion***: Updated draft of JMAFF (Japanese Ministry of Agriculture, Farming and Fisheries) document on 'Definition of "Biologics"'
- ***To note***: 35th VICH Steering Committee meeting to be held on 13-16 November 2017 in Tokyo:
  - Agenda draft 5
  - Progress report from Quality EWG
  - Progress report from ESI - Pharmacovigilance EWG
  - Progress report from BQM EWG
  - Progress report from MRK EWG
  - Progress report from Safety EWG
  - Progress report from Anthelmintics EWG
  - Minutes from the in-person meeting of the Anthelmintics EWG in July 2017
  - Draft agenda for VICH Outreach Forum meeting

- Draft programme for VICH 6th conference to be held in South Africa in February 2019
- Discussion document on the VICH Steering Committee meeting frequency

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For endorsement***: Presentation to HMA from D. Murphy representing CVMP, to be given at the HMA meeting to be held on 29-30 November in Tallinn, Estonia

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)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to be commercially confidential

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 MRLs 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

- ***For information***: Verbal report on the 7th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 30 European countries in 2015; press release link
- ***For decision:*** Procedure for appointment of members for the Antimicrobial Advice Ad hoc Expert Group (AMEG)

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

- ***For endorsement:*** Revised incident management plan for medicines for veterinary use

Documents for information:

8.3: WHO: Call for data on foodborne antimicrobial resistance. Deadline: 31.12.2017
http://www.who.int/foodsafety/DATA_Foodborne_AMR.pdf?ua=1

8.3: WHO: Call for experts on foodborne antimicrobial resistance. Deadline: 31.12.2017
http://www.who.int/foodsafety/Call_for_experts_oct2017.pdf

8.3: Publication of Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals, press release link

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

- ***For endorsement:*** Final report of the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, held on 22-23 June 2017

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

- ***For endorsement***: Procedural advice to applicants / marketing authorisation holders on re-examination of CVMP opinions

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information***: Draft agenda of meeting to be held on 9-10 November 2017; draft minutes of meeting held on 5-6 October 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Draft CVMP work plan 2018
- ***For information***: Verbal report from the chair of the Strategic Planning Group (SPG) on the ad hoc meeting held on 8 November 2017, draft agenda; draft minutes from the SPG meeting held on 4 October 2017
- ***For information***: Update on the release of Common Repository for veterinary submissions in the centralised procedure
- ***For information***: Verbal update on the EMA working group on operational preparedness for veterinary medicines

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

Next meetings of the CVMP and its working parties

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Nov 2017	7-9		22-23		28-29		21-22	28-30	7	30-	
Dec 2017	5-7	7							5	-1	
Jan 2018	16-18			30-31			23-24		16		
Feb 2018	13-15	15	20-21		20-21	28-		27-	13	1-2	
Mar 2018	13-15					-1	20-21	-1	13		