5 May 2017
EMA/CVMP/287794/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of May 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

10 May 2017, 09:00 – 11 May 2017, 16:00 - Room 3A

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 (room 3A)	Wed 10 May 2017	16.30-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/004479/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

• **Substance** EMEA/V/MRL/004321/FULL/0001 *All food producing species*	***For decision****:* Need for oral explanation ***For adoption***: List of outstanding issues

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

Information on certain topics discussed under section 1.4 cannot be released at the present time as it is deemed to be commercially confidential

1.5 Other issues

• **Substance** EMEA/V/MRL/004481/FULL/0001 *Salmonidae*	***For information****:* Letter of withdrawal of the application
• **Substance** EMEA/V/MRL/004333/FULL/0001 *Bovine*	***For information****:* Letter of withdrawal of the application

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004222/0000 *New anti-inflammatory product* *Dogs*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/004344/0000 *New antiparasitic product* *Chickens*	**ORAL EXPLANATION – Wednesday 10 May 2017, 14:00** ***For discussion***: Rapporteurs' assessment report of responses to LoOI, draft CVMP assessment report, draft product information

• **Product** EMEA/V/C/004422/0000 *New vaccine* *Chickens*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/004222/0000 *New product for musculo-skeletal disorder* *Horses*	***For adoption***: Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004291/0000 *New antiparasitic product* *Cattle*	***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

- ***For endorsement:*** EPAR module scientific discussion for **Zeleris** (EMEA/V/C/004099/0000)
- ***For endorsement:*** EPAR module scientific discussion for **Novem** (EMEA/V/C/00086/X/0018)
- ***For endorsement:*** EPAR module scientific discussion for **Ingelvac PCV FLEX** (EMEA/V/C/004645/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Broadline** EMEA/V/C/002700/II/0013 *To extend the spectrum of efficacy*	Rapp: B. Urbain Co-rapp: C. Munoz ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Activyl** EMEA/V/C/000163/II/0011 *To change conditions regarding supply and use*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Nobivac Bb** EMEA/V/C/000068/WS1053/0015 *Quality*	Rapp: N. Garcia del Blanco ***For adoption***: CVMP opinion, CVMP assessment report

• **Vaxxitek HVT+IBD** EMEA/V/C/000065/WS1149/0020 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Metacam** EMA/V/C/000033/II/0127 *To register an additional non-food producing target species*	Rapp: F. Hasslung Wikström Co-rapp: G. Hahn ***For adoption****:* List of questions
• **Simparica** EMA/V/C/003991/II/0006 *To add new indications*	Rapp: J. G. Beechinor Co-rapp: P. Hekman ***For adoption****:* List of questions
• **NEXGARD SPECTRA** EMA/V/C/003842/II/0011 *Quality*	Rapp: J. G. Beechinor ***For adoption****:* List of questions
• **Vectormune ND and NAP** EMA/V/C/003829/WS/1082(0006) *Changes in the product information*	Rapp: F. Klein Co-rapp: E. Werner ***For adoption****:* List of questions
• **Fevaxyn Pentofel** EMA/V/C/000030/WS/1120 *Quality*	Rapp: E.-M. Vestergaard ***For adoption:*** List of questions
• **Fevaxyn Pentofel** EMA/V/C/000030/WS/1142 *Quality*	Rapp: E.-M. Vestergaard ***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

• **Veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** EMEA/V/A/116 *Environmental risk assessment*	Rapp: G. Hahn Co-rapp: C. Munoz ***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

- No items

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
BLUEVAC BTV8 (EMEA/V/C/000156)	14/04/2016 – 13/04/2017
CERTIFECT (EMEA/V/C/002002)	06/05/2016 – 05/05/2017
Equilis StrepE (EMEA/V/C/000078)	07/05/2016 – 06/05/2017
Evalon (EMEA/V/C/004013)	18/04/2016 – 17/04/2017
Improvac (EMEA/V/C/000136)	11/05/2016 – 10/05/2017
LETIFEND (EMEA/V/C/003865)	20/04/2016 – 19/04/2017
Meloxidolor (EMEA/V/C/002590)	22/04/2016 – 21/04/2017
Neocolipor (EMEA/V/C/000035)	14/04/2016 – 13/03/2017
Oncept IL-2 (EMEA/V/C/002562)	03/05/2016 – 02/05/2017
Procox (EMEA/V/C/002006)	20/04/2016 – 19/04/2017

Product	Period
Purevax FeLV (EMEA/V/C/000056)	13/04/2016 – 12/04/2017
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2016 – 06/05/2017
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2016 – 06/05/2017
Zuprevo (EMEA/V/C/002009)	06/05/2016 – 05/05/2017

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **Bovela** EMEA/V/C/003703	Rapp: F. Klein ***For endorsement***: Revised rapporteur's assessment report
• **BTVPUR** EMEA/V/C/002231	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **BTVPUR Alsap 1** EMEA/V/C/002230	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **Cardalis** EMEA/V/C/002524	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.01.17
• **Convenia** EMEA/V/C/000098	Rapp: G. Hahn ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.14-31.12.16
• **Equilis Prequenza** EMEA/V/C/000094	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.01.17
• **Equilis Prequenza Te** EMEA/V/C/000095	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.01.17
• **Eryseng** EMEA/V/C/002761	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17
• **Eryseng Parvo** EMEA/V/C/002762	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17

• **Innovax ILT** EMEA/V/C/003869	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17
• **Onsior** EMEA/V/C/000127	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.14-31.12.16
• **Porcilis ColiClos** EMEA/V/C/002011	Rapp: N. Garcia del Blanco ***For adoption***: Revised CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.16-31.12.16
• **Sileo** EMEA/V/C/003764	Rapp: F. Hasslung Wikstrom ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.16-31.12.16
• **Simparica** EMEA/V/C/003991	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.16-30.11.16
• **Suvaxyn Aujeszky 783 + O/W** EMEA/V/C/000038	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.14-31.12.16
• **Trifexis** EMEA/V/C/002635	Rapp: G. Hahn ***For adoption***: CVMP assessment report on the PSUR for the period 05.01.16-04.01.17
• **UpCard** EMEA/V/C/003836	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17
• **Velactis** EMEA/V/C/003739	Rapp: W. Schlumbohm ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.16-31.12.16
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17
• **ZULVAC 8 Ovis** EMEA/V/C/000147	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17

- ***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***: VICH GL50 Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use and VICH GL55 Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use for sign off at step 6
- ***For endorsement***: EU comments on preliminary concept paper for a guideline for safety evaluation of biotechnology-derived/biological products
- ***For decision***: Call for a new expert for the VICH Electronic Standards Implementation Expert Working Group; nominations and CVs
- ***For decision***: Call for an adviser on analytical method expert for the VICH Metabolism and Residues Kinetics Expert Working Group; nomination and CV

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information***: Attendance of L. Vesterager Borge at the 2017 Global Animal Health Workshop, Nairobi, Kenya

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

- 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

- ***For information:*** Verbal report on pilot project on dose optimization in the context of SPC harmonization of established veterinary antibiotics and on the 2nd meeting held on 29 March 2017; draft minutes
- ***For information:*** Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) workshop to be held on 12-15 September 2017 in France; programme

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

- No items

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:*** Focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU - draft agenda

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 from G. J. Schefferlie to J. Poot

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 meeting to be held on 11-12 May; draft minutes of meeting held on 11-12 April 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: CVMP operation and procedures: practical guidance document for CVMP members
- ***For information****:* Verbal report from the CVMP chair on the SciCoBo meeting held on 24 April 2017; agenda of the SciCoBo meeting
- ***For information****:* Verbal report on the impact of the triggering of Article 50 of the Lisbon Treaty by the UK
- ***For information****:* CVMP report to HMA
- ***To note:*** EMA and heads of national competent authorities discuss consequences of Brexit. Key principles and working methodology established (press release)
- ***To note:*** Invitation to the informal CVMP/CMDv meeting to be held on 26-27 June 217 in Rotterdam, the Netherlands

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
May 2017	10-11*	15	23-24		30-31		16-17	22-24	10	18-19	
Jun 2017	13-15			20-21		21-22			13		20
Jul 2017	11-13						18-19		11		
Sep 2017	5-7	7	20-21		12-13		26-27	27-29	5	21-22	
Oct 2017	3-5			24-25		18-19			3		

**Wednesday to Thursday*