



1 September 2017
EMA/CVMP/580683/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of September 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

5 September 2017, 09:00 – 7 September 2017, 13:00 - 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 ongoing 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 July 2017 meeting and the August 2017 meeting via written procedure
- v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 3A)	Tue 5 Sept 2017	16.30-20.00
CVMP interested parties meeting	Wed 6 Sept 2017	17.00-19.00



1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

<ul style="list-style-type: none">Substance EMA/V/MRL/003517/EXTN/0003 <i>Eggs</i>	<p>For decision: Need for oral explanation</p> <p>For adoption: List of outstanding issues</p>
<ul style="list-style-type: none">Substance EMA/V/MRL/004321/FULL/0001 <i>All food producing species</i>	<p>ORAL EXPLANATION – Wednesday 6 September 2017, 14:30</p> <p>For discussion: Applicant's responses to list of outstanding issues and applicant's presentation</p>

1.3 List of questions

<ul style="list-style-type: none">Substance EMA/V/MRL/004828/FULL/0001 <i>Rabbits</i>	<p>For adoption: Scientific overview and list of questions</p>
<ul style="list-style-type: none">Substance EMA/V/MRL/003471/EXTN/0002 <i>Fin fish</i>	<p>For discussion: Draft CVMP EPMAR</p>
<ul style="list-style-type: none">Substance EMA/V/MRL/003647/EXTN/0002 <i>Porcine</i>	<p>For adoption: Scientific overview and list of questions</p>

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

<ul style="list-style-type: none">Product EMA/V/C/004296/0000 <i>New product</i> <i>Bees</i>	<p>For adoption: CVMP opinion, CVMP assessment report, product information</p> <p>For information: Summary of opinion</p>
<ul style="list-style-type: none">Product EMA/V/C/004778/0000 <i>New vaccine</i> <i>Cats</i>	<p>For adoption: CVMP opinion, CVMP assessment report, product information</p> <p>For information: Summary of opinion</p>

<ul style="list-style-type: none"> • Product EMA/V/C/004776/0000 <i>New vaccine</i> <i>Sheep and cattle</i> 	<p>For adoption: CVMP opinion, CVMP assessment report, product information</p> <p>For information: Summary of opinion</p>
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2.2 Oral explanations and list of outstanding issues

<ul style="list-style-type: none"> • Product EMA/V/C/004387/0000 <i>New vaccine</i> <i>Foxes and raccoon dogs</i> 	<p>For decision: Need for oral explanation</p> <p>For adoption: Scientific overview and list of outstanding issues, comments on product information</p>
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2.3 List of questions

<ul style="list-style-type: none"> • Product EMA/V/C/004611/0000 <i>New vaccine</i> <i>Sheep and cattle</i> 	<p>For adoption: Scientific overview and list of questions, comments on product information</p>
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2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

<ul style="list-style-type: none"> • Product EMA/V/C/002836/0000 <i>New antiparasitic product</i> <i>Honey bees</i> 	<p>For endorsement: Request from applicant to extend clock-stop for 1-2 months</p>
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- **For endorsement:** EPAR module scientific discussion for **Innovax-ND-IBD** (EMA/V/C/004422/0000)
- **For endorsement:** EPAR module scientific discussion for **VEPURED** (EMA/V/C/004364/0000)
- **For endorsement:** EPAR module scientific discussion for **Suvaxyn PRRS MLV** (EMA/V/C/004276/0000)
- **For endorsement:** Withdrawal EPAR for **Cheristin** (EMA/V/C/004316/0000)
- **To note:** Updated withdrawal EPAR for **Somnena** (EMA/V/C/004293/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

<ul style="list-style-type: none"> • Simparica EMA/V/C/003991/II/0006 <i>To add new indications</i> 	<p>Rapp: J. G. Beechinor</p> <p>Co-rapp: P. Hekman</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p> <p>For information: Summary of opinion</p>
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<ul style="list-style-type: none"> • RESPIPORC FLU3 EMA/V/C/000153/II/0014 <i>To add a new pack size</i> 	<p>Rapp: E.-M. Vestergaard</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • RHINISENG EMA/V/C/000160/II/0007 <i>Quality</i> 	<p>Rapp: E.-M. Vestergaard</p> <p>For adoption: CVMP opinion</p> <p>For endorsement: Rapporteur's assessment report</p>
<ul style="list-style-type: none"> • Eurican Herpes 205, Purevax RCPCh, Bovalto Ibraxion, Purevax RCP FeLV, Purevax RC, Purevax RCP, BTVPUR AISap 2-4, BTVPUR, Parvoduk and Purevax RCPCh FeLV EMA/V/C/xxxxx/WS1151 <i>Quality</i> 	<p>Rapp: B. Urbain</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>
<ul style="list-style-type: none"> • NEXGARD SPECTRA EMA/V/C/003842/II/0011 <i>Quality</i> 	<p>Rapp: J. G. Beechinor</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>
<ul style="list-style-type: none"> • Fevaxyn Pentofel EMA/V/C/000030/WS1120/0042 <i>Quality</i> 	<p>Rapp: E.-M. Vestergaard</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>
<ul style="list-style-type: none"> • Fevaxyn Pentofel EMA/V/C/000030/WS1142/0043 <i>Quality</i> 	<p>Rapp: E.-M. Vestergaard</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>
<ul style="list-style-type: none"> • Reconcile EMA/V/C/000133/II/0017 <i>Quality</i> 	<p>Rapp: S. Louet</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>

3.2 Oral explanations and list of outstanding issues

<ul style="list-style-type: none"> • Metacam EMA/V/C/000033/II/0127 <i>To register an additional target species</i> 	<p>Rapp: F. Hasslung Wikstrom</p> <p>Co-rapp: G. Hahn</p> <p>For decision: Need for oral explanation</p> <p>For adoption: List of outstanding issues</p>
<ul style="list-style-type: none"> • Vectormune ND EMA/V/C/003829/WS1082 <i>Changes in the product information</i> 	<p>Rapp: F. Klein</p> <p>Co-rapp: E. Werner</p> <p>For decision: Need for oral explanation</p> <p>For adoption: List of outstanding issues</p>

3.3 List of questions

<ul style="list-style-type: none">• Advocate EMA/V/C/000076/II/0039/G <i>To add new therapeutic indications</i>	Rapp: M. Nevalainen Co-rapp: M. Azevedo Mendes For adoption: List of questions
<ul style="list-style-type: none">• Vaxxitek HVT+IBD EMA/V/C/000065/WS1209/G <i>Quality</i>	Rapp: B. Urbain For adoption: Rapporteur's assessment report including list of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

<ul style="list-style-type: none">• Porcilis ColiClos EMA/V/C/002011/II/0007 <i>Quality</i>	Rapp: N. Garcia del Blanco For decision: Clock stop extension
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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

<ul style="list-style-type: none">• Girolan and its associated name Apralan EMA/V/A/122 <i>Apramycin sulfate</i> <i>SPC harmonisation</i>	Rapp: C. Munoz Co-rapp: B. Urbain ORAL EXPLANATION – Wednesday 6 September 2017, 11:30 – 12:30 For discussion: Presentation from Elanco Animal Health
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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

<ul style="list-style-type: none">Seresto EMA/V/A/125 <i>Imidacloprid and flumethrin</i> <i>Efficacy</i>	Rapp: <i>to be appointed</i> Co-rapp: <i>to be appointed</i> For discussion and decision: Notification from Germany under Article 13 of Regulation (EC) No 1234/2008 Appointment of rapporteur, co-rapporteur and peer reviewers
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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
AFTOVAXPUR DOE (EMA/V/C/002292)	15/07/2016 – 14/07/2017
Bovilis BTV8 (EMA/V/C/000148)	06/09/2016 – 05/09/2017
Cardalis (EMA/V/C/002524)	23/07/2016 – 22/07/2017
Dexdomitor (EMA/V/C/000070)	30/08/2016 – 29/08/2017
Emdocam (EMA/V/C/002283)	18/08/2016 – 17/08/2017
Nobilis IB Primo QX (EMA/V/C/002802)	04/09/2016 – 03/09/2017
Nobilis Influenza H5N2 (EMA/V/C/000118)	01/09/2016 – 31/08/2017
Nobivac L4 (EMA/V/C/002010)	16/07/2016 – 15/07/2017
Nobivac Myxo-RHD (EMA/V/C/002004)	07/09/2016 – 06/09/2017
OSURNIA (EMA/V/C/003753)	31/07/2016 – 30/07/2017
Porcilis PCV ID (EMA/V/C/003942)	28/08/2016 – 27/08/2017
Profender (EMA/V/C/000097)	27/07/2016 – 26/07/2017
Proteq West Nile (EMA/V/C/002005)	05/08/2016 – 04/08/2017

Product	Period
Sedadex (EMA/V/C/004202)	12/08/2016 – 11/08/2017
Suvaxyn Aujeszky 783 + O/W (EMA/V/C/000038)	07/08/2016 – 06/08/2017
Suvaxyn PCV (EMA/V/C/000149)	24/07/2016 – 23/07/2017
UpCard (EMA/V/C/003836)	31/07/2016 – 30/07/2017
Vaxxitek HVT+IBD (EMA/V/C/000065)	09/08/2016 – 08/08/2017
Versican Plus L4 (EMA/V/C/003680)	31/07/2016 – 30/07/2017
Versican Plus Pi/L4 (EMA/V/C/003683)	31/07/2016 – 30/07/2017
Versican Plus Pi/L4R (EMA/V/C/003682)	31/07/2016 – 30/07/2017
ZACTRAN (EMA/V/C/000129)	24/07/2016 – 23/07/2017
ZULVAC 1 Bovis (EMA/V/C/002334)	05/08/2016 – 04/08/2017
ZULVAC 1 Ovis (EMA/V/C/002335)	05/08/2016 – 04/08/2017

5.4 Renewals

<ul style="list-style-type: none"> Pexion EMA/V/C/002543/R/0010 	Rapp: S. Louet Co-rapp: H. Jukes For adoption: List of outstanding issues
<ul style="list-style-type: none"> Contacera EMA/V/C/002612/R/0009 	Rapp: S. Louet Co-rapp: W. Schlumbohm For adoption: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

<ul style="list-style-type: none"> Bovela EMA/V/C/003703 	Rapp: F. Klein For adoption: CVMP assessment report on the PSUR for the period 01.07.16-31.12.16
<ul style="list-style-type: none"> Versican Plus DHPPi EMA/V/C/003679 	Rapp: E. Werner For adoption: CVMP assessment report on the PSUR for the period 01.08.16-31.01.17
<ul style="list-style-type: none"> ERAVAC EMA/V/C/004239 	Rapp: C. Munoz For endorsement: Rapporteur's assessment report on the PSUR for the period 22.09.16-31.03.17
<ul style="list-style-type: none"> LETIFEND EMA/V/C/003865 	Rapp: C. Munoz For endorsement: Rapporteur's assessment report on the PSUR for the period 01.11.16-30.04.17

<ul style="list-style-type: none"> • Meloxidolor EMA/V/C/002590 	Rapp: C. Munoz For endorsement: Rapporteur's assessment report on the PSUR for the period 22.04.16-22.04.17
<ul style="list-style-type: none"> • Recuvyra (WD) EMA/V/C/002239 	Rapp: E.-M. Vestergaard For endorsement: Rapporteur's assessment report on the PSUR for the period 01.05.16-30.04.17
<ul style="list-style-type: none"> • ZOLVIX EMA/V/C/000154 	Rapp: E.-M. Vestergaard For endorsement: Rapporteur's assessment report on the PSUR for the period 01.05.14-30.04.17

- **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:** Draft EU response to EWG comments regarding the VICH GL22 on studies to evaluate the safety of residues of veterinary drugs in human food: reproduction testing
- **For endorsement:** FDA proposal for modification of EU proposal for a revised testing approach for genotoxicity testing battery for inclusion in VICH GL23 on studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing
- **For endorsement:** Draft EU position on the need for revision of VICH GL18(R) on residual solvents in new veterinary medicinal products, active substances and excipients; draft EU position on the need for revision of VICH GL46 on metabolism study to determine the quantity and identify the nature of residues, and of VICH GL47 on laboratory animal comparative metabolism studies
- **For endorsement:** EU comments on draft VICH guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species
- **For information:** Feedback from the meeting of the VICH Anthelmintics EWG in Rockville, USA on 11-13 July 2017; concluding slides provided by chair of EWG

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)

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:** WHO online consultation on the monitoring and evaluation (M&E) approach to the global action plan

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:** Participation to IABS Conference on next generation sequencing for adventitious virus detection in biologics, to be held on 26-27 October 2017 in Rockville, Maryland/USA

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:** Draft minutes from the FishMedPlus Coalition breakout session held on 12 July 2017; barriers and solutions table with CVMP/EMA responses to the recommendations made by the FishMed Plus Coalition; draft agenda
- **For endorsement:** Draft minutes of the CVMP ad hoc group on veterinary vaccine availability (CADVVA) meeting held on 4 July 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

- **For decision:** Transfer of co-rapporteurship for Zeleris from L. Markus Cizelj

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 from the meeting to be held on 7-8 September 2017, draft minutes of the meeting held on 13-14 July 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- **For endorsement:** CVMP Interested parties meeting to be held on 6 September 2017, draft agenda
- **For discussion:** Verbal report on the CVMP/CMDv Presidency meeting held on 26-27 June 2017 in the Netherlands, recommendations to CVMP; agenda
- **For information:** EMA Veterinary Medicines Division - organisation and appointments
- **For information:** Verbal update on the EMA working group on operational preparedness for veterinary medicines
- **For information:** Multinational assessment teams – Guide for rapporteurs and coordinators, [link](#) to webpage

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
Sep 2017	5-7	7	20-21		12-13		26-27	27-29	5	20	
Oct 2017	3-5			24-25		18-19			3		
Nov 2017	7-9	9	22-23		28-29		21-22	28-30	7	30-1/12	
Dec 2017	5-7								5	30/11-1	
Jan 2018	16-18								16		