



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 July 2017
EMA/CVMP/435607/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of July 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

11 July 2017, 09:00 – 13 July 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 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)	Tue 11 Jul 2017	16.30-20.00
--	-----------------	-------------



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/003596/FULL/0002 <i>Honey</i>	<p>For decision: Need for oral explanation</p> <p>For adoption: CVMP list of outstanding issues</p>
<ul style="list-style-type: none">• Substance EMA/V/MRL/004543/FULL/0001 <i>Equidae</i>	<p>For decision: Need for oral explanation</p> <p>For adoption: CVMP list of outstanding issues</p>
<ul style="list-style-type: none">• Substance EMA/V/MRL/004113/FULL/0001 <i>Porcine</i>	<p>For decision: Need for oral explanation</p> <p>For adoption: CVMP list of outstanding issues</p>

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

<ul style="list-style-type: none">• Product EMA/V/C/004375/0000 <i>New product for musculo-skeletal disorders</i> <i>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>
--	---

2.3 List of questions

<ul style="list-style-type: none">• Product EMA/V/C/004242/0000 <i>New vaccine</i> <i>Pigs</i>	<p>For adoption: Scientific overview and list of questions, comments on product information</p>
---	--

<ul style="list-style-type: none"> • Product EMA/V/C/004595/0000 <i>New vaccine</i> <i>Cows and heifers</i> 	<p>For adoption: Scientific overview and list of questions, comments on product information</p>
---	--

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

<ul style="list-style-type: none"> • Product EMA/V/C/004293/0000 <i>New pharmaceutical product</i> <i>Cats</i> Withdrawal of application 	<p>For endorsement: Draft WEPAR</p>
---	--

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

<ul style="list-style-type: none"> • ZULVAC 1+8 Ovis ZULVAC 1+8 Bovis ZULVAC 1 Bovis EMA/V/C/WS1096 <i>Quality</i> 	<p>Rapp: E.-M. Vestergaard</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>
<ul style="list-style-type: none"> • ZULVAC 8 Bovis ZULVAC 8 Ovis EMA/V/C/WS1097 <i>Quality</i> 	<p>Rapp: P. Pasquali</p> <p>For adoption: CVMP opinion, CVMP assessment report</p>

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

<ul style="list-style-type: none"> • Imrestor EMA/V/C/002763/II/0005 <i>Quality</i> 	<p>Rapp: E.-M. Vestergaard</p> <p>For adoption: List of questions</p>
<ul style="list-style-type: none"> • Porcilis PCV M Hyo EMA/V/C/003796/II/0006/G <i>Quality</i> 	<p>Rapp: E. Werner</p> <p>For adoption: List of questions</p>
<ul style="list-style-type: none"> • SevoFlo EMA/V/C/000072/II/0020 <i>To add a new target species</i> 	<p>Rapp: J. G. Beechinor</p> <p>For adoption: List of questions</p>
<ul style="list-style-type: none"> • Hiprabovis IBR Marker Live EMA/V/C/000158/II/0009 <i>Quality</i> 	<p>Rapp: N. Garcia del Blanco</p> <p>For adoption: List of questions</p>

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

<ul style="list-style-type: none">• Comfortis EMA/V/C/002233/II/0017 <i>To change conditions regarding supply and use</i>	Rapp: G. Hahn Co-rapp: T. Høy For information: Applicant's letter for withdrawal of the variation application
--	--

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">• Lincocin and its associated names EMA/V/A/123 <i>Lincomycin</i> <i>SPC harmonisation</i>	Rapp: C. Munoz Co-rapp: H. Jukes For adoption: CVMP opinion, CVMP assessment report, product information
---	---

4.3 Article 35 of Directive 2001/82/EC

<ul style="list-style-type: none">• Zanil and associated names, and generic products thereof EMA/V/A/124 <i>Oxyclozanide</i> <i>Withdrawal periods</i>	Rapp: S. Louet Co-rapp: W. Schlumbohm 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
Canigen L4 (EMA/V/C/004079)	03/07/2015 - 02/07/2017
Circovac (EMA/V/C/000114)	21/06/2007- 20/06/2017
Convenia (EMA/V/C/000098)	19/06/2006 - 18/06/2017
Equilis Prequenza (EMA/V/C/000094)	08/07/2005 - 07/07/2017
Equilis Prequenza Te (EMA/V/C/000095)	08/07/2005 - 07/07/2017
Equilis Te (EMA/V/C/000093)	08/07/2005 - 06/07/2017
EQUIOXX (EMA/V/C/000142)	25/06/2008 - 24/07/2017
ERYSENG (EMA/V/C/002761)	04/07/2014 - 03/07/2017
ERYSENG PARVO (EMA/V/C/002762)	08/07/2014 - 07/07/2017
Innovax-ILT (EMA/V/C/003869)	03/07/2015 - 02/07/2017
LEUCOFELIGEN FeLV/RCP (EMA/V/C/000143)	25/06/2009 - 24/06/2017
LEUCOGEN (EMA/V/C/000144)	17/06/2009 - 16/06/2017
Melovem (EMA/V/C/000152)	07/07/2009 - 06/07/2017
Posatex (EMA/V/C/000122)	23/06/2008 - 22/06/2017
ProZinc (EMA/V/C/002634)	12/07/2013 - 11/07/2017
Reconcile (EMA/V/C/000133)	08/07/2008 - 07/07/2017
Sevohale (EMA/V/C/004199)	21/06/2016 - 20/06/2017
Spirolactone Ceva (EMA/V/C/000105)	20/06/2007 - 19/06/2017
Suprelorin (EMA/V/C/000109)	10/07/2007 - 09/07/2017
Versican Plus DHPPi (EMA/V/C/003679)	04/07/2014 - 03/07/2017
Versican Plus Pi (EMA/V/C/003681)	04/07/2014 - 03/07/2017

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

<ul style="list-style-type: none">• Bravecto EMA/V/C/002526	Rapp: G. J. Schefferlie For adoption: CVMP assessment report on the targeted PSUR for the period 11.02.14-31.12.16
--	--

<ul style="list-style-type: none"> • Bovela EMEA/V/C/003703 	<p>Rapp: F. Klein</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.07.16-31.12.16</p>
<ul style="list-style-type: none"> • Activyl Tick Plus EMEA/V/C/002234 	<p>Rapp: G. J. Schefferlie</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.02.16-31.01.17</p>
<ul style="list-style-type: none"> • Equilis StrepE EMEA/V/C/000078 	<p>Rapp: E. Werner</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.04.14 - 31.03.17</p>
<ul style="list-style-type: none"> • Equisolon EMEA/V/C/002382 	<p>Rapp: E. M. Vestergaard</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 13.09.16-12.03.17</p>
<ul style="list-style-type: none"> • Nobilis IB 4-91 EMEA/V/C/000036 	<p>Rapp: N. Garcia del Blanco</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.10.16 - 31.03.17</p>
<ul style="list-style-type: none"> • Nobilis IB Primo QX EMEA/V/C/002802 	<p>Rapp: N. Garcia del Blanco</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.10.16 - 31.03.17</p>
<ul style="list-style-type: none"> • Masivet EMEA/V/C/000128 	<p>Rapp: G. Hahn</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.12.13-30.11.16</p>
<ul style="list-style-type: none"> • Osurnia EMEA/V/C/003753 	<p>Rapp: S. Louet</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17</p>
<ul style="list-style-type: none"> • Vectormune ND EMEA/V/C/003829 	<p>Rapp: F. Klein</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.10.16 - 31.03.17</p>
<ul style="list-style-type: none"> • Zulvac 1 Bovis EMEA/V/C/002334 	<p>Rapp: E. M. Vestergaard</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.03.16-28.02.17</p>
<ul style="list-style-type: none"> • Zulvac 1 Ovis EMEA/V/C/002335 	<p>Rapp: P. Pasquali</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.03.16-28.02.17</p>
<ul style="list-style-type: none"> • Zulvac SBV EMEA/V/C/002781 	<p>Rapp: N. Garcia del Blanco</p> <p>For endorsement: Rapporteur's assessment report on the PSUR for the period 01.09.16 - 28.02.17</p>

- **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 comments received on concept paper for revision of GL 22 inclusion of the extended one-generation reproductive toxicity study (EOGRTS)

- **For endorsement:** Draft explanation of EU objections to extended version of the guideline on use of cell cultures for the detection of extraneous viruses in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- **For discussion:** Draft proposal for harmonised classification and labelling of theophylline under consideration by ECHA
- **For information:** Final JECFA Guidance document for the establishment of Acute Reference Dose (ARfD) for veterinary drug residues in food - available [here](#)

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

- **For information:** Report of a meeting on developing priorities for WHO activities on antimicrobial resistance and the environment to be held on 5-6 July 2017 in Nieuwegein, the Netherlands; agenda - see agenda point 8.3 Antimicrobial resistance

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 3rd meeting held on 16 June 2017; minutes of the meeting
- **For endorsement:** Comments received on the draft paper on EU clinical breakpoint for veterinary antimicrobial susceptibility testing
- **For information:** Publication of assessment of the risk to public health due to use of antimicrobials in pigs - An example of pleuromutilins in Denmark (26 May 2017) ([link](#))
- **For discussion:** Escmid Study Group for Veterinary Microbiology (ESGVM) Guidelines/consensus papers on antimicrobial use in veterinary infectious diseases
- **For information:** Report of a meeting on developing priorities for WHO activities on antimicrobial resistance and the environment to be held on 5-6 July 2017 in Nieuwegein, the Netherlands; agenda - see agenda point 8.2 Environmental risk assessment
- **For information:** Verbal report on ECDC/EFSA/EMA second joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA II)
- **For information:** European One Health Action Plan against AMR 2017

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 discussion:** FishMed Plus meeting with CVMP to be held on 12 July 2017: barriers and solutions table with EMA and CVMP responses to the recommendations made by the FishMed Plus Coalition; draft agenda
- **For information:** Update from "Focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU", 22-23 June 2017: final programme

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 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 13-14 July 2017; draft minutes of meeting held on 15-16 June 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- **For discussion and decision:** CVMP Interested parties meeting to be held on 6 September 2017 in London, UK; proposals for agenda topics
- **For discussion:** Verbal report on the CVMP/CMDv Presidency meeting held on 26-27 June 2017 in the Netherlands; agenda
- **For discussion/endorsement:** CVMP work planning for 2018, draft work plan; working party priorities 2018
- **For information:** Verbal report from the Strategic Planning Group (SPG) to be held on 12 July 2017, draft agenda; draft minutes from the meeting held on 14 June 2017
- **For information:** Verbal update from the CVMP chair on the EMA working group on operational preparedness for veterinary medicines
- **For information:** Information on potential issues or procedures that would require CVMP decision via written procedure during August 2017
- **To note:** Update on MNATs in post-authorisation procedures
- **To note:** CVMP dates for 2018

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
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		
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	