



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 November 2015
EMA/CVMP/723983/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of November 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

4 November 2015, 09:00 – 6 November 2015, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of declarations of 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 Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee 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. CVMP delegates list of intended participation and identified conflicts of 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 2A)

Wed 4 November 2015 16.00-20.00



1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

<ul style="list-style-type: none">• Substance EMA/V/MRL/004047/FULL/0001 <i>Caprine species, Equidae, fin fish and rabbits</i>	For adoption: CVMP opinion including EPMAR
<ul style="list-style-type: none">• Substance EU/ART27/11/192 <i>Art. 27 Extrapolation to bovine and ovine milk</i>	For adoption: CVMP opinion including EPMAR

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

<ul style="list-style-type: none">• Substance EMA/V/MRL/004268/FULL/0001 <i>All food producing species</i>	For discussion: Rapporteur's assessment report including critique from co-rapporteur; draft EPMAR; peer reviewer reports
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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">• Zactran EMA/V/C/000129/X/0027 <i>Extension to add a new food producing species</i>	Rapp: C. Friis Co-rapp: J. G. Beechinor For adoption: Scientific overview and benefit-risk assessment and list of outstanding issues, product information
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<ul style="list-style-type: none"> • Bravecto EMA/V/C/002526/X/0005 <i>Extension to add a new pharmaceutical form and a new target species</i> 	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ORAL EXPLANATION – Thursday 5 November <i>For discussion:</i> Applicant’s presentation, rapporteurs’ joint assessment of the responses to LoOI; applicant’s proposed product information
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2.3 List of questions

<ul style="list-style-type: none"> • Product EMA/V/C/004199/0000 <i>New anaesthetic product Dogs</i> 	<i>For adoption:</i> Scientific overview and benefit-risk assessment and list of questions, comments on product information
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2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement:*** EPAR module 6 scientific discussion for **Suvaxyn Circo+ MH RTU** (EMA/V/C/003924/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **Zycortal** (EMA/V/C/0003782/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

<ul style="list-style-type: none"> • Vectormune ND EMA/V/C/003829/II/0001 <i>Quality</i> 	Rapp: F. Klein <i>For adoption:</i> CVMP opinion, CVMP assessment report
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3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

<ul style="list-style-type: none"> • Metacam EMA/V/C/000033/II/0118/G <i>Quality</i> 	Rapp: F. Hasslung Wikström <i>For adoption:</i> CVMP list of questions
<ul style="list-style-type: none"> • Trifexis EMA/V/C/002635/II/0008 <i>To add a new indication</i> 	Rapp: C. Ibrahim Co-rapp: T. Høy <i>For adoption:</i> CVMP list of questions

<ul style="list-style-type: none"> • Versican Plus Pi/L4R, Versican Plus DHPi/L4R) EMA/V/C/xxxxxx/WS/0785 <i>Change in the SPC, labelling or PL</i> 	Rapp: E. Werner For adoption: CVMP list of questions
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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

<ul style="list-style-type: none"> • Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys <i>(Amoxicillin)</i> EMA/V/A/112 <i>Bioequivalence and prudent use advice</i> 	Rapp: E.-M. Vestergaard Co-rapp: H. Jukes For adoption: CVMP opinion, CVMP assessment report
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4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

<ul style="list-style-type: none"> • All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses EMA/V/A/095 <i>Environmental risk assessment</i> 	Rapp: C. Ibrahim Co-rapp: S. Louet For decision: Need for outstanding issues For discussion: Rapporteur's assessment report including co-rapporteur's critique
<ul style="list-style-type: none"> • All veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry EMA/V/A/110 <i>Indications, dosage and withdrawal periods</i> 	Rapp: B. Urbain Co-rapp: K. Baptiste For decision: Need for outstanding issues For discussion: Rapporteur's assessment report including co-rapporteur's critique

<ul style="list-style-type: none"> • All veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses EMEA/V/A/116 ERA 	<p>Rapp: <i>to be appointed</i></p> <p>Co-rapp: <i>to be appointed</i></p> <p>For discussion and decision: Notification from Germany under Article 35 of Directive 2001/82/EC</p> <p>Appointment of rapporteur, co-rapporteur and peer reviewers</p> <p>For information: List of products concerned</p>
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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
BTVPUR AISap 2-4 (EMEA/V/C/000139)	05/11/2014 – 04/11/2015
Halocur (EMEA/V/C/000040)	29/10/2014 – 28/10/2015
Virbagen Omega (EMEA/V/C/000061)	06/11/2014 – 05/11/2015
ZOLVIX (EMEA/V/C/000154)	04/11/2014 – 04/11/2015

5.4 Renewals

<ul style="list-style-type: none"> • Procox EMA/V/C/002006/R/0012 	<p>Rapp: E. Lander Persson</p> <p>Co-rapp: T. Soós</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • ZULVAC 1+8 Ovis EMA/V/C/002251/R/0014 	<p>Rapp: M. Tollis</p> <p>Co-rapp: I. Malemis</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • Melosus EMA/V/C/002001/R/0006 	<p>Rapp: E-M. Vestergaard</p> <p>Co-rapp: W. Schlumbohm</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • Activyl EMA/V/C/000163/R/0008 	<p>Rapp: J. G. Schefferlie</p> <p>Co-rapp: R. Breathnach</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • CaniLeish EMA/V/C/002232/R/0004 	<p>Rapp: J.-C. Rouby</p> <p>Co-rapp: M. Tollis</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • Cimalgex EMA/V/C/000162/R/0002 	<p>Rapp: F. Hasslung Wikström</p> <p>Co-rapp: B. Urbain</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • Comfortis EMA/V/C/002233/R/0015 	<p>Rapp: C. Ibrahim</p> <p>Co-rapp: T. Høy</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> • Veraflox EMA/V/C/000159/R/0006 	<p>Rapp: C. Ibrahim</p> <p>Co-rapp: T. Høy</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>

5.5 Pharmacovigilance - PSURs and SARs

- **For endorsement:** SevoFlo (EMA/V/C/000072) - Recommendation from PhVWP-V to the MAH following surveillance analysis findings

<ul style="list-style-type: none"> • Acticam EMA/V/C/000138 	<p>Rapp: J. G. Beechinor</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.07.14-30.06.15</p>
<ul style="list-style-type: none"> • Advocate EMA/V/C/000076 	<p>Rapp: M. Nevalainen</p> <p>For endorsement: Rapporteur's assessment report</p>
<ul style="list-style-type: none"> • Porcilis Porcoli Diluvac Forte EMA/V/C/000024 	<p>Rapp: G. J. Schefferlie</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.08.12-31.07.15</p>
<ul style="list-style-type: none"> • Vectra 3D EMA/V/C/002555 	<p>Rapp: C. Ibrahim</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.01.15-30.06.15</p>
<ul style="list-style-type: none"> • Broadline EMA/V/C/002700 	<p>Rapp: B. Urbain</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.01.15-30.06.15</p>
<ul style="list-style-type: none"> • Cerenia EMA/V/C/000106 	<p>Rapp: C. Friis</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.01.15-30.06.15</p>
<ul style="list-style-type: none"> • Certifect EMA/V/C/002002 	<p>Rapp: S. Louet</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.06.14 - 31.05.15</p>
<ul style="list-style-type: none"> • ERYSENG EMA/V/C/002761 	<p>Rapp: D. Murphy</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15</p>
<ul style="list-style-type: none"> • ERYSENG PARVO EMA/V/C/002762 	<p>Rapp: D. Murphy</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15</p>
<ul style="list-style-type: none"> • Hiprabovis IBR Marker Live EMA/V/C/000158 	<p>Rapp: A-M. Brady</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.08.14-31.07.15</p>
<ul style="list-style-type: none"> • Inflacam EMA/V/C/002497 	<p>Rapp: S. Louet</p> <p>For adoption: CVMP assessment report on the PSUR for period 01.07.14-30.06.15</p>

<ul style="list-style-type: none"> • Prac-tic EMA/V/C/000103 	Rapp: C. Muñoz Madero For adoption: CVMP assessment report on the PSUR for period 01.07.14-30.06.15
<ul style="list-style-type: none"> • RevitaCAM EMA/V/C/002379 	Rapp: D. Murphy For adoption: CVMP assessment report on the PSUR for period 01.03.15-31.08.15
<ul style="list-style-type: none"> • Trifexis EMA/V/C/002635 	Rapp: C. Ibrahim For adoption: CVMP assessment report on the PSUR for period 05.01.15-04.07.15
<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 period 01.02.15-31.07.15
<ul style="list-style-type: none"> • Versican Plus Pi EMA/V/C/003681 	Rapp: E. Werner For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15
<ul style="list-style-type: none"> • Versican Plus Pi/L4 EMA/V/C/003683 	Rapp: E. Werner For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15
<ul style="list-style-type: none"> • Versican Plus Pi/L4R EMA/V/C/003682 	Rapp: E. Werner For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15
<ul style="list-style-type: none"> • ZULVAC 8 BOVIS EMA/V/C/000145 	Rapp: M. Tollis For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15
<ul style="list-style-type: none"> • ZULVAC 8 OVIS EMA/V/C/000147 	Rapp: M. Tollis For adoption: CVMP assessment report on the PSUR for period 01.02.15-31.07.15

- **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 information:** Report from the 32nd VICH Steering Committee 25-27, 30 October, Tokyo, Japan

6.2 Codex Alimentarius

Information on certain topics discussed under section 6.2 cannot be released at the present time as it is deemed to be confidential

6.3 Other EU bodies and international organisations

- **For decision:** Nomination of expert to join ECHA ad-hoc working group on the Assessment of Residue Transfer to Food (ARTFood)
- **For information:** Feedback from the EFSA's 2nd scientific conference 'Shaping the future of food safety, together' held in Milan from 14-16 October 2015

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 AHEG on the application of the 3Rs

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

- **For adoption:** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009

8.2 Environmental risk assessment

- No items

8.3 Antimicrobial resistance

- **For adoption:** CVMP Strategy on Antimicrobials 2016-2020
- **For information:** Verbal report on the RONAFA (Joint EFSA/EMA Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety) virtual meeting to be held on 29 October 2015
- **For information:** Verbal report on the forthcoming EC Workshop: "The impact on public health and animal health of the use of antibiotics in animals – Analysis of the EMA scientific advice" to be held on 26 November 2015, draft agenda

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 contain commercially confidential information

- 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

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:** Draft agenda of the meeting to be held on 5-6 November 2015; draft minutes of the meeting held 8-9 October 2015; verbal report from CMDv Chair on September and October 2015 CMDv meetings

12. ORGANISATIONAL AND STRATEGIC MATTERS

- **For information:** Guideline on the principles for preparing assessment reports for veterinary medicinal products, and template guidance for scientific overview and list of questions

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

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

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP
Nov 2015	4-6						24-25		4	
Dec 2015	8-10	10	2-3		1-2			1-3	8	3-4
Jan 2016	19-21								19	
Feb 2016	16-18	18				11-12			16	