



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 January 2017
EMA/CVMP/27851/2017 draft
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

17 January 2017, 09:00 – 19 January 2017, 13:00 - Room 2A

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. 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)	Tue 17 Jan 2017	16.30-20.00
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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

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

- No items

1.5 Other issues

<ul style="list-style-type: none">• Substance EMA/V/MRL/004333/FULL/0001 <i>Bovine species</i>	For decision: Update on the submission of the responses to the LoOI
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2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

<ul style="list-style-type: none">• Product EMA/V/C/004316/0000 <i>New antiparasitic product</i> <i>Cats</i>	For adoption: Scientific overview and list of questions, comments on product information
<ul style="list-style-type: none">• Product EMA/V/C/004422/0000 <i>New vaccine</i> <i>Chickens</i>	For adoption: Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

<ul style="list-style-type: none">• RESPIPORC FLUpan H1N1 EMA/V/C/003993/0000 <i>New inactivated viral vaccine for active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v</i> <i>Pigs</i>	Rapp: <i>to be appointed</i> Co-rapp: <i>to be appointed</i> For decision: Appointment of rapporteur, co-rapporteur and peer reviewers For discussion: Request for re-examination from applicant
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2.5 Other issues

<ul style="list-style-type: none"> Product EMEA/V/C/004375/0000 <i>New product for a musculo-skeletal system indication</i> <i>Dogs</i> 	For endorsement: Request for a clock stop extension of two months
<ul style="list-style-type: none"> For endorsement: EPAR module scientific discussion for Coliprotec F4/F18 (EMEA/V/C/004225/0000) 	

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

<ul style="list-style-type: none"> ZULVAC 1+8 Ovis, ZULVAC 8 Ovis, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 1 Bovis, ZULVAC 8 Bovis EMEA/V/C/xxxxxx/WS1040 <i>Quality</i> 	Rapp: E.-M. Vestergaard For adoption: CVMP opinion, CVMP assessment report
<ul style="list-style-type: none"> RESPIPORC FLU3 EMEA/V/C/000153/II/0013/G <i>Quality</i> 	Rapp: E.-M. Vestergaard For adoption: CVMP opinion, CVMP assessment report
<ul style="list-style-type: none"> Clomicalm, OSURNIA, ZOLVIX, Econor, FORTEKOR PLUS, Onsior, Prac-tic EMEA/V/C/xxxxxx/WS1074 <i>Quality</i> 	Rapp: C. Ibrahim For adoption: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

<ul style="list-style-type: none"> NEXGARD SPECTRA EMEA/V/C/003842/II/0008 <i>To add new therapeutic indications</i> 	Rapp: J. G. Beechinor Co-rapp: S. Srcic For adoption: CVMP list of outstanding issues
<ul style="list-style-type: none"> Stronghold EMEA/V/C/000050/II/0055/G <i>Quality</i> 	Rapp: H. Jukes For adoption: CVMP list of outstanding issues

3.3 List of questions

<ul style="list-style-type: none"> Pexion EMEA/V/C/002543/II/0009 <i>Changes to the SPC</i> 	Rapp: S. Louet Co-rapp: H. Jukes For adoption: CVMP list of questions
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<ul style="list-style-type: none"> ZULVAC 8 Ovis, ZULVAC 1+8 Ovis, ZULVAC 1 Bovis, ZULVAC SBV, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 8 Bovis EMEA/V/C/xxxxxx/WS1039 <i>Quality</i> 	Rapp: E.-M. Vestergaard 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

- No items

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"> Veterinary medicinal products containing zinc oxide to be administered orally to food producing species EMEA/V/A/118 (re-examination) <i>ERA and antimicrobial resistance</i> 	Rapp: <i>to be appointed</i> Co-rapp: <i>to be appointed</i> For discussion: Request for re-examination of the CVMP opinion from: - aniMedica GmbH; - Huvepharma N.V.; - DSM Nutritional Products (UK) Ltd. and Provimi Ltd. (<i>joint request</i>); - Andrés Pintaluba S.A., Bio Vet Aps, Calier Portugal S.A., Dunavet-B Zrt., Industrial Veterinaria S.A., Laboratorios Calier S.A., Laboratorios Support Pharma S.L., S.C. Crida Pharm S.R.L., ScanVet Animal Health A/S, Sintofarm S.p.A, Tekro, spol. s r.o., Vepidan Aps, Vetlima S.A., Vetoquinol Biowet Sp. z o. o. and Vetpharma Animal Health, S.L. (<i>joint request</i>). For decision: Appointment of rapporteur, co-rapporteur and peer reviewers
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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

<ul style="list-style-type: none">• Simparica EMA/V/C/003991/REC/008-010	Rapp: J. G. Beechinor Co-rapp: P. Hekman For adoption: Rapporteur's assessment report
<ul style="list-style-type: none">• ZOLVIX EMA/V/C/000154/REC/011	Rapp: E.-M. Vestergaard Co-rapp: G. J. Schefferlie For adoption: Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
Acticam (EMA/V/C/000138)	09/12/2015 – 08/12/2016
Imrestor (EMA/V/C/002763)	09/12/2015 – 08/12/2016
Inflacam (EMA/V/C/002497)	09/12/2015 – 08/12/2016
Panacur AquaSol (EMA/V/C/002008)	09/12/2015 – 08/12/2016
SevoFlo (EMA/V/C/000072)	11/12/2015 – 10/12/2016
Cepedex (EMA/V/C/004376)	13/12/2015 – 12/12/2016
Onsior (EMA/V/C/000127)	16/12/2015 – 15/12/2016
BTVPUR (EMA/V/C/002231)	17/12/2015 – 16/12/2016
BTVPUR AISap 1 (EMA/V/C/002230)	17/12/2015 – 16/12/2016
Prac-tic (EMA/V/C/000103)	18/12/2015 – 17/12/2016
Bovela (EMA/V/C/003703)	22/12/2015 – 21/12/2016
Metacam (EMA/V/C/000033)	07/01/2016 – 06/01/2017
Activyl Tick Plus (EMA/V/C/002234)	09/01/2016 – 08/01/2017

Product	Period
CORTAVANCE (EMA/V/C/000110)	09/01/2016 – 08/01/2017
Rheumocam (EMA/V/C/000121)	10/01/2016 – 09/01/2017
Ypozane (EMA/V/C/000112)	11/01/2016 – 10/01/2017
Porcilis PCV (EMA/V/C/000135)	12/01/2016 – 11/01/2017
Gripovac 3 (EMA/V/C/000157)	14/01/2016 – 13/01/2017
RESPIPORC FLU3 (EMA/V/C/000153)	14/01/2016 – 13/01/2017
MELOXIDYL (EMA/V/C/000115)	15/01/2016 – 14/01/2017
NEXGARD SPECTRA (EMA/V/C/003842)	15/01/2016 – 14/01/2017
ZULVAC 8 Bovis (EMA/V/C/000145)	15/01/2016 – 14/01/2017
ZULVAC 8 Ovis (EMA/V/C/000147)	15/01/2016 – 14/01/2017

5.4 Renewals

<ul style="list-style-type: none"> Nobivac L4 EMA/V/C/002010/R/0007 	<p>Rapp: B. Urbain</p> <p>Co-rapp: R. Breathnach</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>
<ul style="list-style-type: none"> Porcilis Coliclos EMA/V/C/002011/R/0006 	<p>Rapp: N. Garcia del Blanco</p> <p>Co-rapp: E. Werner</p> <p>For adoption: CVMP opinion, CVMP assessment report, product information</p>

5.5 Pharmacovigilance - PSURs and SARs

<ul style="list-style-type: none"> Activyl EMA/V/C/000163 	<p>Rapp: G. J. Schefferlie</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.09.15-31.08.16</p>
<ul style="list-style-type: none"> Bovilis BTV8 EMA/V/C/000148 	<p>Rapp: P. Pasquali</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.10.15-30.10.16</p>
<ul style="list-style-type: none"> Bravecto EMA/V/C/002526 	<p>Rapp: G. J. Schefferlie</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.03.16-31.08.16</p> <p>For discussion and decision: Request for extension of deadline from MAH to submit targeted PSUR</p>

<ul style="list-style-type: none"> • Broadline EMEA/V/C/002700 	<p>Rapp: B. Urbain</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.01.16-30.06.16</p>
<ul style="list-style-type: none"> • Clomicalm EMEA/V/C/000039 	<p>Rapp: C. Ibrahim</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.08.13-31.07.16</p>
<ul style="list-style-type: none"> • Neocolipor EMEA/V/C/000035 	<p>Rapp: J.-C. Rouby</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.09.13-31.08.16</p>
<ul style="list-style-type: none"> • Nobilis IB4-91 EMEA/V/C/000036 	<p>Rapp: N. Garcia del Blanco</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16</p>
<ul style="list-style-type: none"> • Nobilis IB Primo QX EMEA/V/C/002802 	<p>Rapp: N. Garcia del Blanco</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16</p>
<ul style="list-style-type: none"> • Novaquin EMEA/V/C/003866 	<p>Rapp: J. G. Beechinor</p> <p>For adoption: CVMP assessment report on the PSUR for the period 09.03.16-08.09.16</p>
<ul style="list-style-type: none"> • Osurnia EMEA/V/C/003753 	<p>Rapp: S. Louet</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16</p>
<ul style="list-style-type: none"> • Pexion EMEA/V/C/002543 	<p>Rapp: S. Louet</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.09.15-31.08.16</p>
<ul style="list-style-type: none"> • Semintra EMEA/V/C/002436 	<p>Rapp: R. Breathnach</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.09.15-31.08.16</p>
<ul style="list-style-type: none"> • STARTVAC EMEA/V/C/002436 	<p>Rapp: E. Werner</p> <p>For discussion and adoption: CVMP assessment report on the PSUR for the period 01.09.13-31.08.16</p>
<ul style="list-style-type: none"> • Vectormune ND EMEA/V/C/003829 	<p>Rapp: F. Klein</p> <p>For adoption: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16</p>
<ul style="list-style-type: none"> • Versican Plus DHPPI EMEA/V/C/003679 	<p>Rapp: E. Werner</p> <p>For discussion and adoption: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16</p>

<ul style="list-style-type: none"> • Versican Plus DHPPi L4 EMA/V/C/003678 	Rapp: E. Werner For adoption: CVMP assessment report on the PSUR for the period 01.12.15-31.05.16
<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 the period 01.02.16-31.07.16

- **For endorsement:** List of products and calendar for signal detection

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 VICH GL on general principles for detection of extraneous viruses in veterinary vaccines and defining the testing of seeds and materials of animal origin; draft VICH GL on a list of extraneous viruses that need to be covered
- **For endorsement:** Need for review of VICH safety guidelines
- **For endorsement:** Draft EU response to EWG comments relating to ongoing discussions on the possibility of updating VICH GL22 on reproduction testing to allow use of the extended one generation reproductive toxicity study (EOGRTS)
- **For information:** 34th VICH Steering Committee meeting and Outreach Forum meeting to be held on 27 February to 2 March 2017 in Buenos Aires, Argentina; draft Steering Committee agenda, draft Outreach Forum agenda and minutes of the 33rd VICH Steering Committee held on 21-24 June 2016
- **For endorsement:** PhV Electronic Standards Implementation EWG - comments on industry document on disharmony in the field of pharmacovigilance

6.2 Codex Alimentarius

- **For information:** Feedback from the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) meeting held on 17-21 October 2016 in Houston, USA; report of the meeting

6.3 Other EU bodies and international organisations

- **For information:** Verbal report from the 2nd EMA/JECFA liaison meeting held on 26 September 2016
- **For decision:** EFSA Workshop on Benchmark Dose to be held on 1-2 March 2017 in Brussels; draft programme
- **For information:** EFSA 2nd report on 'Chemicals in food 2016; overview of selected data collection' ([link](#)); detailed report on residues of veterinary medicines ([link](#))

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

- 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

8.3 Antimicrobial resistance

Information relating to items under 8.3 cannot be released at the present time as it is deemed to be commercially confidential

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

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 information:** Network action plan on availability of veterinary vaccines – meeting with industry stakeholders held on 8 December 2016: agenda and draft minutes
- **For decision:** Request for a breakout session between CVMP and FishMedPlus Coalition in the margins of a future CVMP meeting
- **For information:** Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards – 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

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 19-20 January 2017, draft minutes of meeting held on 8-9 December 2016, presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- **For discussion:** CVMP operation and procedures: practical guidance document for CVMP members
- **For discussion:** Guidance to applicants on oral explanations
- **For discussion:** Appointment of rapporteurs for CVMP procedures – next steps; verbal report from the break-out session
- **For information:** Verbal report from the chair on the Strategic Planning Group (SPG) meeting to be held on 18 January 2017, draft agenda; draft minutes from the SPG meeting held on 5 October 2016
- **For information:** Request from Swissmedic for regular observer participation in CVMP meetings

13. LEGISLATION

- **To note:** Commission Implementing Regulation (EU) 2017/12 of 6 January 2017 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 ([link](#))

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	3R's
Jan 2017	17-19			31-1			24-25	31-2	17		
Feb 2017	14-16	16	28-1		21-22	1-2			14	2-3	
Mar 2017	14-16						21-22		14		
Apr 2017	10-12*								10		26-27
May 2017	10-12**	12	23-24		30-31		16-17	22-24	10	18-19	

*Monday to Wednesday

**Wednesday to Friday