10 February 2017
EMA/CVMP/102247/2017 draft
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

14 February 2017, 09:00 – 16 February 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 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. 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 14 Feb 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

• **Substance** EMEA/V/MRL/004481/FULL/0001 *Salmonidae*	***For decision***: Need for oral explanation; list of outstanding issues

1.3 List of questions

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

Information on certain topics discussed under section 1.5 cannot be released at the present time as it is deemed to be confidential

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004247/0000 *New antiparasitic product* *Dogs*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For discussion***: Applicant's query on the product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004185/0000 *New vaccine* *Sheep*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:*Summary of opinion
• **Product** EMEA/V/C/003939/0000 *New dermatological product* *Dogs*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004099/0000 *New product* *Cattle*	**ORAL EXPLANATION – Wednesday 15 February, 11:20-12:05** ***For discussion****:* Applicant's presentation, draft product information, rapporteur's assessment report of responses to LoOI

• **Zactran** EMEA/V/C/000129/X/0034 *Extension to add a new species* *Cattle, pigs*	Rapp: E.-M. Vestergaard Co-rapp: J. G. Beechinor ***For decision***: Need for oral explanation ***For adoption****:* Comments on product information
• **Product** EMEA/V/C/004331/0000 *New antiemetic product* *Dogs, cats*	***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/004417/0000 *New product* *Dogs*	***For adoption****:* Scientific overview and list of questions, comments on product information, assessment of proposed QR code
• **Product** EMEA/V/C/004296/0000 *New product* *Bees*	***For adoption****:* Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004645/0000 *New vaccine* *Pigs*	***For adoption****:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **RESPIPORC FLUpan H1N1** EMEA/V/C/003993/0000 *New inactivated viral vaccine for active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v* *Pigs*	Rapp: N. Garcia Del Blanco Co-rapp: J. G. Beechinor ***For adoption****:* Draft list of questions to AHEG ***For endorsement****:* Final list of AHEG members ***For discussion****:* Draft rapporteurs' assessment report for the re-examination of the CVMP opinion

2.5 Other issues

• **Product** EMEA/V/C/004265/0000 *New product for a musculo-skeletal disorder* *Horses*	***For decision****:* Request from applicant to extend clock-stop for 7 months

- ***For endorsement*****:** EPAR module scientific discussion for **Equioxx** extension (EMEA/V/C/000142/X/0015)
- ***For endorsement*****:** EPAR module scientific discussion for **Stronghold Plus** (EMEA/V/C/004194/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **BTVPUR** EMEA/V/C/002231/II/0008/G *Quality*	Rapp: C. Munoz ***For adoption*:** CVMP opinion, CVMP assessment report, product information

3.2 Oral explanations and list of outstanding issues

• **Activyl Tick Plus** EMEA/V/C/002234/II/0008 *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: List of outstanding issues

3.3 List of questions

• **Activyl** EMEA/V/C/000163/II/0011 *To change conditions regarding supply and use*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption**:* List of questions
• **Nobivac Bb** EMEA/V/C/000068/WS1053/0015 *Quality*	Rapp: N. Garcia del Blanco ***For adoption**:* List of questions
• **Porcilis ColiClos** EMEA/V/C/002011/II/0007 *Quality*	Rapp: N. Garcia del Blanco ***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: C. Ibrahim Co-rapp: C. Muñoz ***For discussion***: Rapporteur's revised assessment report including co-rapporteur's critique
• **Veterinary medicinal products containing zinc oxide to be administered orally to food producing species** EMEA/V/A/118 (re-examination) *ERA and antimicrobial resistance*	Rapp: E.-M. Vestergaard Co-rapp: C. Muñoz **ORAL EXPLANATION – Tuesday 14 February, 14.00-15.30** ***For discussion***: Rapporteurs' joint assessment report; presentations from MAHs/applicants
• **Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle** EMEA/V/A/119 *Withdrawal periods*	Rapp: C. Ibrahim Co-rapp: S. Louet ***For discussion:*** Rapporteur's revised assessment report including co-rapporteur's critique
• **Veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp.** EMEA/V/A/121 *Efficacy*	Rapp: M. Nevalainen Co-rapp: A. Wachnik-Swiecicka ***For discussion:*** Rapporteur's revised assessment report including co-rapporteur's critique, rapporteur's presentation
• **Zanil and associated names, and generic products thereof** EMEA/V/A/124 *Oxyclozanide* *Withdrawal periods*	Rapp: S. Louet Co-rapp: W. Schlumbohm ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

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

• **Suvaxyn CSF Marker** EMEA/V/C/002757/REC/007	Rapp: M. Blixenkrone-Moller Co-rapp: B. Urbain ***For adoption***: Rapporteur's assessment report
• **Letifend** EMEA/V/C/003865/REC/007	Rapp: C. Munoz Co-rapp: J.-C. Rouby ***For adoption***: Rapporteur's assessment report
• **Circovac** EMEA/V/C/000114/REC/002.1 & 005.1	Rapp: P. Pasquali Co-rapp: N. Garcia del Blanco ***For adoption***: Rapporteur's assessment report
• **NexGard** EMEA/V/C/002729/REC/014	Rapp: P. Hekman Co-rapp: J. G. Beechinor ***For adoption***: Rapporteur's assessment report
• **FORTEKOR PLUS** EMEA/V/C/002804/REC/014	Rapp: E.-M. Vestergaard Co-rapp: C. Munoz ***For adoption:*** Rapporteur's assessment report
• **ZULVAC SBV** EMEA/V/C/002781/ANX/004.2	Rapp: N. Garcia del Blanco ***For adoption:*** Rapporteur's assessment report
• **ProZinc** EMEA/V/C/002634/REC/010	Rapp: R. Breathnach Co-rapp: S. Louet ***For adoption:*** Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Bravecto (EMEA/V/C/002526)	11/02/2016 – 10/02/2017
Comfortis (EMEA/V/C/002233)	11/02/2016 – 10/02/2017
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2016 – 04/02/2017

Product	Period
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2016 – 26/01/2017
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2016 – 12/02/2017
Kexxtone (EMEA/V/C/002235)	28/01/2016 – 27/01/2017
Loxicom (EMEA/V/C/000141)	10/02/2016 – 09/02/2017
NexGard (EMEA/V/C/002729)	11/02/2016 – 10/02/2017
Nobilis OR inac (EMEA/V/C/000062)	24/01/2016 – 23/01/2017
PIRSUE (EMEA/V/C/000054)	29/01/2016 – 28/01/2017
Semintra (EMEA/V/C/002436)	13/02/2016 – 12/02/2017
STARTVAC (EMEA/V/C/000130)	11/02/2016 – 10/02/2017
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2016 – 09/02/2017
ZULVAC SBV (EMEA/V/C/002781)	06/02/2016 – 05/02/2017

5.4 Renewals

• **Poulvac E. coli** EMEA/V/C/002007/R/0012	Rapp: E. Werner Co-rapp: N. Garcia del Blanco ***For adoption***: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Canigen L4 & Nobivac L4** EMEA/V/C/004079 EMEA/V/C/002010	Rapp: B. Urbain ***For discussion and adoption***: CVMP assessment report on the PSUR for the period 01.02.16-31.07.16
• **Bovalto Ibraxion** EMEA/V/C/000051	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13-30.09.16
• **Coliprotec F4** EMEA/V/C/003797	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **Econor** EMEA/V/C/000042	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.15-30.09.16
• **Evalon** EMEA/V/C/004013	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 18.04.16-31.10.16

• **FORTEKOR PLUS** EMEA/V/C/002804	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **Fungitraxx** EMEA/V/C/002722	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **Imrestor** EMEA/V/C/002763	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **Incurin** EMEA/V/C/000047	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13-30.09.16
• **Previcox** EMEA/V/C/000082	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.14-30.09.16
• **ProteqFlu** EMEA/V/C/000073	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **ProteqFlu-Te** EMEA/V/C/000074	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.16-30.09.16
• **Vaxxitek HVT-IBD** EMEA/V/C/000065	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-31.08.16
• **ZULVAC 1+8 Bovis** EMEA/V/C/002473	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.15-30.09.16

- ***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 adoption***: VICH GL56 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal period, for endorsement at step 4 for consultation

- ***For endorsement***: Draft guideline on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use, for circulation to VICH EWG at step 2
- ***For endorsement***: Draft VICH GL50 on harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use, for circulation to VICH EWG at step 5
- ***For endorsement***: Draft VICH GL55 on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use, for circulation to VICH EWG at step 5
- ***For endorsement***: Pharmacovigilance Electronic Standards Implementation EWG – response to Chair's report to the VICH Steering Committee
- ***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
  - minutes of the 33rd VICH Steering Committee held on 21-24 June 2016
  - progress report from Quality Expert Working Group (EWG)
  - progress report from Biologicals Quality Monitoring EWG
  - progress report from Metabolism and Residue Kinetics EWG
  - progress report anthelmintics guidelines revision EWG
  - anthelmintics guidelines revision revised plan
  - progress report on general combination products TF

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

- 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 adoption:*** Draft problem statement on the need to further elaborate on the CVMP/CHMP recommendations on antimicrobials (Antimicrobial Advice Ad Hoc Expert Group (AMEG))
- ***For information:*** Publication of EFSA report on risk for the development of antimicrobial resistance due to feeding of calves with milk containing residues of antibiotics (link)
- ***For information:*** Verbal report on pilot project on dose optimization in the context of SPC harmonization of established veterinary antibiotics and the first meeting held on 20 January 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

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:*** Verbal report of the Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards held on 31 January 2017, final agenda
- ***For information:*** Focus group on field efficacy trials in the context of an EU authorisation for veterinary vaccines

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 Fungitraxx

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 16-17 February 2017; draft minutes of the meeting held on 19-20 January 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: Guidance to applicants on oral explanations
- ***For information***: EMA veterinary medicines Info Day to be held on 16-17 March 2017, draft programme
- ***To note***: CVMP meeting dates for 2019-2021

13. LEGISLATION

Information on certain topics discussed under section 13 cannot be released at the present time as it is deemed to be confidential

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
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	
Jun 2017	13-15			20-21		21-22			13		

**Monday to Wednesday*

***Wednesday to Friday*