10 March 2017
EMA/CVMP/171139/2017 draft
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of March 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

14 March 2017, 09:00 – 16 March 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 14 Mar 2017	16.30-20.00

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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

• **Substance** EMEA/V/MRL/004706/FULL/0001 *Rabbits*	***For decision***: Need for a list of questions ***For discussion***: Draft EPMAR

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004099/0000 *New product* *Cattle*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004645/0000 *New vaccine* *Pigs*	***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **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 adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Novem** EMEA/V/C/00086/X/0018 *Extension to add a new strength* *Cattle*	Rapp: F. Hasslung Wikström Co-rapp: E.-M. Vestergaard ***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/004344/0000 *New product* *Chickens*	***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/004387/0000 New vaccine *Foxes and raccoon dogs*	***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 **ORAL EXPLANATION – Tuesday 14 March 2017, 14:30** ***For adoption****:* CVMP assessment report for the re-examination of the CVMP opinion, final CVMP opinion, draft product information ***For discussion:*** Report from the ad hoc expert group (AHEG); applicant's presentation for oral explanation at CVMP ***For information***: Summary of opinion

2.5 Other issues

- ***For endorsement:*** EPAR module scientific discussion for **VarroMed** (EMEA/V/C/002723/0000)
- ***For information:*** Updated EPAR module scientific discussion for **Evalon** (EMEA/V/C/004013/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **NEXGARD SPECTRA** EMEA/V/C/003842/II/0008 *To add new therapeutic indications*	Rapp: J. G. Beechinor Co-rapp: tbc ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **ProZinc** EMEA/V/C/002634/II/0010/G *Quality*	Rapp: R. Breathnach ***For adoption***: CVMP opinion, CVMP assessment report, product information

• **Bravecto** EMEA/V/C/002526/II/0017/G *Quality*	Rapp: G. J. Schefferlie ***For adoption***: CVMP opinion, CVMP assessment report
• **Stronghold** EMEA/V/C/000050/II/0055/G *Quality*	Rapp: H. Jukes ***For adoption****:* CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Comfortis** EMEA/V/C/002233/II/0017 *To change conditions regarding supply and use*	Rapp: *tbc* Co-rapp: T. Hoy ***For adoption****:* List of questions
• **ProteqFlu, Purevax FeLV, Purevax RCP FeLV, Purevax RCPCh FeLV, Oncept IL-2, Proteq West Nile, ProteqFlu-Te, Purevax Rabies** EMEA/V/C/xxxxxx/WS1095 *Quality*	Rapp: B. Urbain ***For adoption****:* List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Porcilis ColiClos** EMEA/V/C/002011/II/0007 *Quality*	Rapp: N. Garcia del Blanco ***For decision***: Clock stop extension

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

• **Denagard 45% and associated names** EMEA/V/A/114 *Tiamulin hydrogen fumarate* *SPC harmonisation*	Rapp: *tbc* Co-rapp: C. Munoz **ORAL EXPLANATION – Wednesday 15 March 2017, 11:30-12:15** ***For discussion***: Presentation from Elanco Animal Health; proposals from Elanco Animal Health for the revised product information

• **Lincocin and associated names** EMEA/V/A/123 *Lincomycin* *SPC harmonisation*	Rapp: C. Munoz Co-rapp: H. Jukes ***For decision:*** Need for list of outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique, draft product information

4.3 Article 35 of Directive 2001/82/EC

• **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. Munoz ***For adoption***: Final CVMP opinion, final CVMP assessment report
• **Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle** EMEA/V/A/119 *Withdrawal periods*	Rapp: *tbc* Co-rapp: S. Louet ***For adoption:*** CVMP opinion, CVMP assessment report
• **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:*** CVMP opinion, CVMP assessment report
• **Veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** EMEA/V/A/089 - Follow-up assessment *Efficacy (dosing regimen for E. coli)*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Follow-up assessment of conditions on marketing authorisations; appointment of rapporteur, co-rapporteur and peer reviewers ***For adoption:*** Timetable for the evaluation

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

• **Circovac** EMEA/V/C/000114/REC/003.1	Rapp: P. Pasquali ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Activyl (EMEA/V/C/000163)	18/02/2016 – 17/02/2017
Bovalto Ibraxion (EMEA/V/C/000051)	09/03/2016 – 08/03/2017
CaniLeish (EMEA/V/C/002232)	14/03/2016 – 13/03/2017
Cimalgex (EMEA/V/C/000162)	18/02/2016 – 17/02/2017
Coliprotec F4 (EMEA/V/C/003797)	16/03/2016 – 15/03/2017
Econor (EMEA/V/C/000042)	12/03/2016 – 11/03/2017
Equisolon (EMEA/V/C/002382)	12/03/2016 – 11/03/2017
Fungitraxx (EMEA/V/C/002722)	12/03/2016 – 11/03/2017
Melosus (EMEA/V/C/002001)	21/02/2016 – 20/02/2017
Novem (EMEA/V/C/000086)	02/03/2016 – 01/03/2017
Pexion (EMEA/V/C/002543)	25/02/2016 – 24/02/2017
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	29/02/2016 – 28/02/2017
ProteqFlu (EMEA/V/C/000073)	06/03/2016 – 05/03/2017
ProteqFlu-Te (EMEA/V/C/000074)	06/03/2016 – 05/03/2017
Purevax Rabies (EMEA/V/C/002003)	18/02/2016 – 17/02/2017
Purevax RC (EMEA/V/C/000091)	23/02/2016 – 22/02/2017
Purevax RCP (EMEA/V/C/000090)	23/02/2016 – 22/02/2017
Purevax RCP FeLV (EMEA/V/C/000089)	23/02/2016 – 22/02/2017
Purevax RCPCh (EMEA/V/C/000088)	23/02/2016 – 22/02/2017

Product	Period
Purevax RCPCh FeLV (EMEA/V/C/000085)	23/02/2016 – 22/02/2017
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08/03/2016 – 07/03/2017
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14/03/2016 – 13/03/2017

5.4 Renewals

• **Cardalis** EMEA/V/C/002524/R/0009	Rapp: H. Jukes Co-rapp: C. Munoz ***For adoption***: List of outstanding issues
• **Poulvac E.coli** EMEA/V/C/002007/R/0012	Rapp: E. Werner Co-rapp: N. Garcia del Blanco ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Suprelorin** EMEA/V/C/000109/R/0016	Rapp: E.-M. Vestergaard Co-rapp: M. Azevedo Mendes ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Equisolon** EMEA/V/C/002382	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 13.03.16-12.09.16
• **Comfortis** EMEA/V/C/002233	Rapp: tbc ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.15-30.09.16
• **LETIFEND** EMEA/V/C/003865	Rapp: C. Munoz ***For adoption***: CVMP assessment report on the PSUR for the period 20.04.16-31.10.16
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.16-31.08.16
• **Porcilis Pesti** EMEA/V/C/000046	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 10.12.13-09.12.16

- ***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:*** EU response to latest version of the draft VICH guideline on marker residue depletion studies to establish product withdrawal periods in aquatic species
- ***For endorsement:*** Revision of the VICH anthelmintic guidelines draft EU comments (2nd round) on compiled comments of topics of group 1:
  - topic 1.1 adequacy of infection defining a priori;
  - topic 1.2 minimum numbers of cestodes for equines;
  - topic 1.3 experimental unit as pen in swine and poultry GLs;
  - topic 1.4 updating VICH GL 16;
  - topic 1.5 statistical considerations blocking
- ***For endorsement***: VICH GL50 Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use and VICH GL55 Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use for sign off at step 5
- ***For information***: Report from the 34th VICH Steering Committee, held on 27 February - 2 March 2017 in Buenos Aires
- ***For information***: Presentation on CVMP Strategy on Antimicrobials to 8th VICH Outreach Forum meeting held on 28 February - 1 March 2017

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

Information on certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be confidential

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

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

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

- No items

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 endorsement:*** Report on the stakeholder focus group meeting on the availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards held on 31 January 2017 and Executive summary

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 rapporteurships from C. Ibrahim
- ***For decision:*** Transfer of rapporteurships from S. Srcic

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***: Verbal report from the CMDv chair on the meetings held on 19-20 January 2017 and 16-17 February 2017; draft agenda of the meeting to be held on 16-17 March 2017; draft minutes of the meeting held on 16-17 February 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: CVMP operation and procedures: practical guidance document for CVMP members
- ***For information***: Implementation of Common Repository for Veterinary submissions coordinated by EMA: status update; presentation
- ***For information***: EMA Veterinary Medicines Info Day to be held on 16-17 March 2017: programme
- ***For information***: Integrated CVMP and Working Parties planning for the year 2018

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
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		
Jul 2017	11-13						18-19		11		

**Monday to Wednesday*

***Wednesday to Friday*