8 July 2016
EMA/CVMP/477115/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of July 2016 meeting

Chair: David Murphy

Vice-chair: vacant

12 July 2016, 09:00 – 14 July 2016, 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 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 12 Month 2016	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/003298/MODF/0004 *Bovine milk*	***For adoption***: CVMP opinion, CVMP assessment report ***For information:*** Summary of opinion
• **Substance** EMEA/V/MRL/0031518/EXTN/0003 *Extension to ovine species*	***For adoption***: CVMP opinion, CVMP assessment report ***For information:*** Summary of opinion

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/003596/FULL/0002 *Honey*	***For adoption***: CVMP scientific overview and list of questions

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/004239/0000 *New vaccine* *Rabbits*	***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/0003993/0000 *New vaccine* *Pigs*	***For decision***: Need for oral explanation ***For adoption:*** Scientific overview and list of questions, comments on product information

2.3 List of questions

• **EQUIOXX** EMEA/V/C/000142/X/0015 *Extension to add a new pharmaceutical form* *Horses*	Rapp: J. G. Beechinor Co-rapp: M. Azevedo Mendes ***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/004247/0000 *New antiparasitic product* *Dogs*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/004376/0000 *New product for psycholeptic use* *Dogs and cats*	***For adoption:*** Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/004375/0000 *New product for disorders of the musculo-skeletal system* *Dogs*	***For adoption:*** Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **DRAXXIN** EMEA/V/C/000077/X/0029 *Extension to include a new target species* *Cattle, pigs*	Rapp: C. Friis Co-rapp: G. Beechinor ***For adoption**:* Composition of AHEG, list of proposed experts, draft assessment by the rapporteurs, draft LoQ for AHEG ***For discussion**:* Comments from co-rapporteur

2.5 Other issues

- No items

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0002 *Quality*	Rapp: B. Urbain ***For adoption*:** CVMP opinion, CVMP assessment report, product information
• **Comfortis, Trifexis** EMEA/V/C/002233/WS0906/0016/G EMEA/V/C/002635/WS0906/0009/G *Quality*	Rapp: C. Ibrahim ***For adoption*:** CVMP opinion, CVMP assessment report
• **Vectormune ND** EMEA/V/C/003829/II/0004 *Quality*	Rapp: F. Klein ***For adoption**:* CVMP opinion, CVMP assessment report

• **BLUEVAC BTV8** EMEA/V/C/000156/II/0007 *Quality*	Rapp: E. Werner ***For adoption**:* CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Stronghold** EMEA/V/C/000050/II/0055/G *Quality*	Rapp: H. Jukes ***For adoption**:* List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Activyl Tick Plus** EMEA/V/C/002234/II/008 *To add a new therapeutic indication*	Rapp: J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: Request for extension of clock stop

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: C. Ibrahim Co-rapp: C. Muñoz Madero ***For decision***: Request from Elanco Animal Health for a 1-month delay for the submission of responses to the list of outstanding issues
• **Girolan and its associated name Apralan** EMEA/V/A/122 *Apramycin sulfate* *SPC harmonisation*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from Spain under Article 34 of Directive 2001/82/EC and Annex to notification Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

• **Lincocin and its associated names** EMEA/V/A/123 *Lincomycin* *SPC harmonisation*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from the European Commission under Article 34 of Directive 2001/82/EC and Annex to notification Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

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 Madero **Background note**: N/a ***For decision***: Request from Zoetis for a 2-month delay for the submission of responses to the list of outstanding issues
• **Veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** EMEA/V/A/117 *Withdrawal periods*	Rapp: B. Urbain Co-rapp: H. Jukes ***For information***: Letter from Laboratorios Hipra and EMA response
• **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: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from Finland under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

4.4 Article 45 of Regulation 726/2004

• **Velactis** EU/2/15/192/001-004 *Animal safety* *See also 5.5*	Rapp: W. Schlumbohm Co-rapp: E. Lander Persson **ORAL EXPLANATION – Tuesday 12 July, 14:00** ***For adoption***: CVMP opinion, CVMP assessment report ***For discussion***: Rapporteur's revised assessment report; presentation from MAH

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

• **EVALON** EMEA/V/C/004013/ANX/001-002	Rapp: N. Garcia del Blanco Co-rapp: B. Zemann ***For adoption***: Rapporteurs' assessment report

5.3 Product anniversary list

Product	**Period**
Canigen L4 (EMEA/V/C/004079	03/07/2015 – 02/07/2016
Circovac (EMEA/V/C/000114	21/06/2015 – 20/06/2016
Convenia (EMEA/V/C/000098	19/06/2015 – 18/06/2016
Equilis Prequenza (EMEA/V/C/000094	08/07/2015 – 07/07/2016
Equilis Prequenza Te (EMEA/V/C/000095	08/07/2015 – 07/07/2016
Equilis Te (EMEA/V/C/000093	08/07/2015 – 07/07/2016
EQUIOXX (EMEA/V/C/000142	25/06/2015 – 24/06/2016
ERYSENG (EMEA/V/C/002761	04/07/2015 – 03/07/2016
ERYSENG PARVO (EMEA/V/C/002762	08/07/2015 – 07/07/2016
Innovax-ILT (EMEA/V/C/003869	03/07/2015 – 02/07/2016
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143	25/06/2015 – 24/06/2016
LEUCOGEN (EMEA/V/C/000144	17/06/2015 – 16/06/2016
Melovem (EMEA/V/C/000152	07/07/2015 – 06/07/2016
Posatex (EMEA/V/C/000122	23/06/2015 – 22/06/2016
PRILACTONE (EMEA/V/C/000105	20/06/2015 – 19/06/2016
ProZinc (EMEA/V/C/002634	12/07/2015 – 11/07/2016

Product	Period
Reconcile (EMEA/V/C/000133	08/07/2015 – 07/07/2016
Suprelorin (EMEA/V/C/000109	10/07/2015 – 09/07/2016
Versican Plus DHPPi (EMEA/V/C/003679	04/07/2015 – 03/07/2016
Versican Plus Pi (EMEA/V/C/003681	04/07/2015 – 03/07/2016

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

- ***For discussion:*** Signal detection findings from Rapporteur on adverse events reports for **Velactis** - *See also 4.7*

• **COXEVAC** EMEA/V/C/000155	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-31.03.16
• **Dexdomitor** EMEA/V/C/000070	Rapp: F. Hasslung Wikström ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-29.02.16
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.15-29.02.16
• **Nobilis IB 4-91** EMEA/V/C/000036	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.15-31.03.16
• **Nobilis IB Primo QX** EMEA/V/C/002802	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.15-31.03.16
• **Nobivac Bb** EMEA/V/C/000068	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-31.03.16
• **Proteq West Nile** EMEA/V/C/002005	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16
• **Purevax Rabies** EMEA/V/C/002003	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16

• **Suprelorin** EMEA/V/C/000109	Rapp: E-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15-31.01.16
• **Vectormune ND** EMEA/V/C/003829	Rapp: F. Klein ***For adoption***: CVMP assessment report on the PSUR for the period 08.09.15-31.03.16
• **ZULVAC 1 Ovis** EMEA/V/C/002335	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15-29.02.16
• **ZULVAC 1+8 Ovis** EMEA/V/C/002251	Rapp: P. Pasquali ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-31.03.16

- ***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***: Draft EU comments on VICH GL22 on Reproduction testing and inclusion of the extended one generation reproduction toxicity study
- ***For endorsement***: Draft VICH GL56 on Studies to evaluate metabolism and residues kinetics of veterinary drugs in food producing species: study design recommendations for residues studies in honey for establishing MRLs and withdrawal periods, for sign-off at step 2
- ***For information***: Report from 33rd VICH Steering Committee meeting and 7th Outreach Forum meeting

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

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-V 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

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:*** Updated advice of the Expert Advisory Group on Antimicrobial Resistance (AMEG) on the use of colistin products in animals within the European Union; overview of comments received on the publication of the updated advice on the use of colistin during the consultation period
- ***For information:*** Verbal report on the Reduction of the Need for Antimicrobials in Food Producing Animals (RONAFA) teleconference held on 22 June
- ***For information:*** Verbal report on the 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) teleconferences held on 14 June, 28 June, 11 July

8.4 Pharmacovigilance

Information on certain topics discussed under section 8.4 cannot be released at the present time as it is deemed to be confidential

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

- ***For endorsement:*** Presentation by the CVMP representative for the Horizon 2020 project PARAGONE Vaccines for animal parasites - consortium meeting to be held in Ghent, Belgium on 29-30 August, 2016

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

- ***For decision:*** Transfer of rapporteurships from D. Murphy to G. Beechinor

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 CMDv meeting to be held on 14-15 July 2016, draft minutes of the meeting held on 16-17 June 2016; presentation by the CMDv chair

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement:*** Revision of procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC
- ***For decision:*** Election of the vice-chair of CVMP (3-year term) at the July 2016 CVMP meeting
- ***For decision:*** Verbal report on the survey results concerning appointment of rapporteurs for CVMP procedures; summary report, individual responses; next steps
- ***For discussion:*** Appointment of CVMP co-opted members at the October 2016 meeting; identification of expertise necessary for CVMP to accomplish the mandate and appointment of co-opted members, CVMP list of expertise - 2016
- ***For discussion***: Revised VNeeS format requirements guideline coming into force on 1 July 2016 – revision of Exceptions to VNeeS format document

- ***For discussion***: CVMP/CMDv Presidency meeting held on 27-28 June 2016 in the Netherlands; final agenda, presentation on summary and conclusions
- ***For information and discussion:*** Annual report 2015 on the performance of the Agency's scientific procedures: Key Performance Indicators (KPIs) for medicinal products for human and veterinary use
- ***For information***: Verbal report from the Strategic Planning Group (SPG) to be held on 12 July 2016, draft agenda; draft minutes from the meeting held on 16 March 2016
- ***For discussion***: Revision of the documents on dossier submission requirements to commence following the July 2016 CVMP plenary meeting
- ***For information***: Council Decision of 29 May 2016 on the appointment of four Management Board members, including veterinary representative
- ***For information:*** Update on EU Network Training Centre project – Veterinary curriculum
- ***For information:*** Information on potential issues or procedures that would require CVMP decision(s) via written procedure during August 2016

13. LEGISLATION

- ***For information***: Update on development of CVMP recommendations for Methodological principles for the risk assessment and risk management recommendations (*"Volume 8"*)

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	SA WP	SWP	3R's
Jul 2016	12-14						5/6		12		
Sep 2016	6-8		22-23		13-14			19-21	6	22-23	
Oct 2016	4-6	6		11-12		20-21			4		18-19
Nov 2016	8-10				29-30			29-30	8	24-25	
Dec 2016	6-8		14-15					1	6		