9 June 2017
EMA/CVMP/368384/2017 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of June 2017 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

13 June 2017, 09:00 – 15 June 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 13 June 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

• **Substance** EMEA/V/MRL/003517/EXTN/0003 *Chicken*	***For decision**:* Request to extend the deadline for submission of responses to list of questions

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/004422/0000 *New vaccine* *Chickens*	***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
Product EMEA/V/C/004364/0000 *New vaccine* *Pigs*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Product** EMEA/V/C/004344/0000 *New antiparasitic product* *Chickens*	***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion
• **Product** EMEA/V/C/004276/0000 *New vaccine* *Pigs*	***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/004296/0000 *New product* *Bees*	***For decision***: Need for oral explanation ***For adoption**:* Scientific overview and list of outstanding issues, comments on draft product information

2.3 List of questions

• **Product** EMEA/V/C/002774/0000 *New product for musculo-skeletal disorder* *Horses*	***For adoption***: Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- ***For endorsement:*** EPAR module scientific discussion for **Respiporc FLUpan H1N1** (EMEA/V/C/003993/0000)
- ***For endorsement:*** EPAR module scientific discussion for **Prevomax** (EMEA/V/C/004331/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Pexion** EMEA/V/C/002543/II/0009 *Changes in the SPC*	Rapp: S. Louet Co-rapp: H. Jukes ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **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***: CVMP opinion, CVMP assessment report
• **Porcilis PCV** EMEA/V/C/000135/II/0011/G *Quality*	Rapp: P. Pasquali ***For adoption***: CVMP opinion, CVMP assessment report
• **Suvaxyn Circo+MH RTU** EMEA/V/C/003924/II/0005/G *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Eurican Herpes 205, Purevax RCPCh, Bovalto Ibraxion, Purevax RCP FeLV, Purevax RC, Purevax RCP, BTVPUR AlSap 2-4, BTVPUR, Parvoduk, Purevax RCPCh FeLV** EMEA/V/C/xxxxxx/WS1151 *Quality*	Rapp: B. Urbain ***For adoption**:* List of questions
• **Reconcile** EMEA/V/C/000133/II/0017 *Quality*	Rapp: S. Louet ***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

• **Girolan and its associated name Apralan** EMEA/V/A/122 *Apramycin sulfate* *SPC harmonisation*	Rapp: C. Munoz Co-rapp: B. Urbain ***For decision***: Need for oral explanation ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique on MAH's responses to second list of outstanding issues, revised rapporteur's assessment report, draft product information
• **Lincocin and its associated names** EMEA/V/A/123 *Lincomycin* *SPC harmonisation*	Rapp: C. Munoz Co-rapp: H. Jukes ***For decision***: Need for oral explanation ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique on MAH's responses to list of outstanding issues, revised rapporteur's assessment report including co-rapporteur's critique, draft product information

4.3 Article 35 of Directive 2001/82/EC

• **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 further outstanding issues or oral explanation ***For discussion***: Rapporteur's assessment report on applicants/MAHs' responses to list of outstanding issues, revised rapporteur's assessment report, rapporteur's presentation
• **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: H. Jukes Co-rapp: C. Munoz ***For decision***: Need for questions to MAHs ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique; comments from AWP

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
Equilis West Nile (EMEA/V/C/002241)	06/06/2016 – 05/06/2017
MS-H Vaccine (EMEA/V/C/000161)	14/06/2016 – 13/06/2017
Naxcel (EMEA/V/C/000079)	19/05/2016 – 18/05 2017

Product	Period
Nobilis IB 4-91 (EMEA/V/C/000036)	09/06/2016 – 08/06/2017
Porcilis ColiClos (EMEA/V/C/002011)	14/06/2016 – 13/06/2017
Porcilis Pesti (EMEA/V/C/000046)	09/06/2016 – 08/06/2017
Poulvac E. coli (EMEA/V/C/002007)	15/06/2016 – 14/06/2017
Sileo (EMEA/V/C/003764)	10/06/2016 – 09/06/2017
Vectra Felis (EMEA/V/C/002746)	06/06/2016 – 05/06/2017

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **Cerenia** EMEA/V/C/000106	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.16-31.12.16
• **Canigen L4 & Nobivac L4** EMEA/V/C/004079	Rapp: B. Urbain ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17
• **Melovem** EMEA/V/C/000152	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.02.14-31.01.17
• **NEXGARD SPECTRA** EMEA/V/C/003842	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17
• **Nobilis Influenza H5N2** EMEA/V/C/000118	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.03.16-28.02.17
• **Novaquin** EMEA/V/C/003866	Rapp: J. G. Beechinor ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 09.09.16-08.03.17
• **Porcilis PCV ID** EMEA/V/C/003942	Rapp: P. Hekman ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.09.16-28.02.17
• **Sedadex** EMEA/V/C/004202	Rapp: C. Munoz ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 12.08.16-12.02.17

• **Versican Plus L4** EMEA/V/C/003680	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17
• **Versican Plus Pi** EMEA/V/C/003681	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17
• **Versican Plus Pi L4** EMEA/V/C/003683	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17
• **Versican Plus Pi L4/R** EMEA/V/C/003682	Rapp: E. Werner ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17
• **ZACTRAN** EMEA/V/C/000129	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.08.16-31.01.17

- ***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 adoption:*** VICH GL50 Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use for adoption at step 7
- ***For adoption:*** VICH GL55 Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use for adoption at step 7
- ***For endorsement***: Draft explanation of EU objections (proposed by IFAH-EU in 2012) to extended version of the guideline on use of cell cultures for the detection of extraneous viruses in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines
- ***For decision***: Call for a new expert for the VICH Electronic Standards Implementation Expert Working Group; nominations and CVs

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

- No items

8.3 Antimicrobial resistance

- ***For information:*** Verbal report on pilot project on dose optimization in the context of SPC harmonization of established veterinary antibiotics and on the 2nd meeting held on 29 March 2017; minutes
- ***For information:*** Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) workshop to be held on 12-15 September 2017 in France; programme

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:*** Focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU: draft agenda, draft list of experts, revised concept note, list of questions, presentation
- ***For discussion:*** Draft agenda for a breakout session between CVMP and FishMedPlus Coalition at the July 2017 CVMP meeting, gap analysis final report from FishMedPlus Coalition, list of barriers and solutions

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:*** Verbal report from the CMDv chair on the meetings held on 16-17 March 2017, 11-12 April 2017 and 11-12 May 2017; draft agenda of meeting to be held on 15-16 June 2017; draft minutes of meeting held on 11-12 May 2017

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Requests for supplementary information (RSI) for type II variations
- ***For discussion***: CVMP work planning for 2018
- ***For information***: Verbal report from the chair on the Strategic Planning Group (SPG) meeting to be held on 14 June 2017, agenda; draft minutes from the meeting held on 11 April 2017
- ***For information***: Launch of MNATs in post-authorisation procedures
- ***For information:*** HMA/EMA Task Force on timetables: revised best practice guide on measures improving predictability of submissions/responses and adherence to communicated submission/responses deadlines following public consultation, and overview of comments

- ***To note***: Draft agenda of the informal CVMP/CMDv meeting to be held on 26-27 June 2017 in Rotterdam, the Netherlands

13. LEGISLATION

- ***To note***: Commission Regulation (EU) 2017/880 of 23 May 2017 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (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	J3Rs WG
Jun 2017	13-15			20-21		21-22			13		20
Jul 2017	11-13						18-19		11		
Sep 2017	5-7	7	20-21		12-13		26-27	27-29	5	21-22	
Oct 2017	3-5			24-25		18-19			3		
Nov 2017	7-9						21-22		7		