8 September 2014
EMA/CVMP/543110/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of September 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

9 September 2014, 09:00 – 11 September 2014, 13:00 - Room 3E

Declaration on conflict of interests

In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting are asked to declare any conflict of 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 held on 8-10 July 2014 and of the August 2014 CVMP meeting by written procedure

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 3E)	Tue. 9 Sept. 2014	16.00-20.00
CVMP Strategic planning group (room 3E)	Wed 10 Sept. 2014	08.30-09.30

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 RESIDUES LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003298/MODF/0004	***For decision***: Need for an oral explanation ***For discussion***: Rapporteur's assessment report including the assessment of the responses to the list of questions; rapporteur's EPMAR; peer reviewer's report; EU-RL report

1.3 List of questions

- No items

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/003796/0000 *New viral and bacterial vaccine (pigs)*	***For adoption:*** CVMP opinion CVMP assessment report CVMP product information

2.2 Oral explanations and list of outstanding issues

• **Product** EMA/V/C/0003703/0000 *New viral vaccine (cattle)*	**ORAL EXPLANATION – Wed 10 September 2014, 11:15** ***For discussion***: Applicant's presentation, draft product information, rapporteurs' assessment of responses to the list of outstanding issues
• **Product** EMEA/V/C/002781/0000 *New viral vaccine (sheep, cattle)*	***For decision***: Need for oral explanation ***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues, draft product information

2.3 List of questions

• **Product** EMEA/V/C/003782/0000 *New corticosteroid product* *(dogs)*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information, assessment and list of questions on the ASMF
• **Stronghold** EMEA/V/C/000050/X/051/G *Extension: new strengths* *(cats and dogs)*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/003829/0000 *New viral vaccine* *(chicken)*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/002794/0000 *New haematological product* (dogs)	***For information:*** Request by the applicant for a one-month extension to the oral explanation

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/003764 *New psycholeptic product* *(dogs)*	***For decision**:* Request from the applicant for an extension to the clock stop
• **Product** EMEA/V/C/003684/0000 *New vector vaccine* *(dogs)* **Withdrawal of application**	***For endorsement:*** Draft WEPAR
• **Product** EMEA/V/C/002808/0000 *New hormonal product* *(cats)* **Withdrawal of application**	***For endorsement:*** Draft WEPAR

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Fevaxyn Pentofel** EMEA/V/C/000030/WS/0489/G *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: CVMP opinion CVMP assessment report

• **STARTVAC** EMEA/V/C/000130/II/0002 *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion CVMP assessment report
• **Equilis StrepE** EMEA/V/C/000078/II/0012/G *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion CVMP assessment report
• **Equilis Prequenza Te** EMEA/V/C/000095/II/0012 *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion CVMP assessment report
• **Equilis Prequenza** EMEA/V/C/000094/II/0010 *Quality*	Rapp: E. Werner ***For adoption***: CVMP opinion CVMP assessment report
• **Hiprabovis IBR Marker Live** EMEA/V/C/000158/II/0003/G *Quality*	Rapp: A.-M. Brady ***For adoption***: CVMP opinion CVMP assessment report
• **Circovac, Eurican Herpes 205, Ibraxion, Purevax RCCh, Purevax RCPCh, Purevax RCPCh FeVL, Vaxxitek** EMEA/V/C/XXXXXX/WS/0546 *Quality*	Rapp: B. Urbain ***For adoption***: CVMP opinion CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Equip WNV** EMEA/V/C/000137/II/0018/G *Quality*	Rapp: J.-C. Rouby ***For adoption***: Draft list of outstanding issues

3.3 List of questions

- No items

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Broadline** EMEA/V/C/002700/II/0001 *New indications*	Rapp: B. Urbain ***For decision***: Marketing authorisation holder request of an extension for the response to the list questions and revised timetable

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

• **Suanovil 20, Captalin and associated names** EMEA/V/A/086 *Indications, dosage and withdrawal periods*	Rapp: C. Ibrahim Co-rapp: B. Urbain **ORAL EXPLANATION – Tuesday 9 September 2014, 11.15-12.15** ***For adoption:*** CVMP opinion CVMP assessment report ***For discussion***: Presentation from Ceva Santé Animale

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

• **Resflor injectable solution for cattle** EMEA/V/A/101 *Efficacy*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti **ORAL EXPLANATION – Wednesday 10 September 2014, 15.30-16.30** ***For discussion:*** Presentation from MSD; Rapporteur's assessment of the response to list of outstanding issues, including co-rapporteur's critique

4.6 Article 30(3) of Regulation 726/2004

• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For discussion***: Request for advice from the EC
• **Diclofenac** EMEA/V/A/107 *Risk to vultures and other necrophagous birds*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion***: Request from the EC for a scientific opinion of CVMP; discussion document

4.7 Other issues

- ***For information***: Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names - Article 34 referral (EMEA/V/A/091) – Background information for publication
- ***For information***: Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products - Article 35 referral (EMEA/V/A/097) – Background information for publication
- ***For information***: Veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs - Article 35 referral (EMEA/V/A/100) – Background information for publication

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

5.2 Post-authorisation measures and annual reassessments

• **COXEVAC** EMEA/V/C/000155/S/0007 *Annual reassessment*	Rapp: J.-C. Rouby ***For adoption***: List of questions, draft product information
• **ZOLVIX** EMEA/V/C/000154/REC/025	Rapp: C. Friis ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2013– 31.08.2014
Nobivac Bb for Cats (EMEA/V/C/000068)	10.09.2013 – 09.09.2014
Nobivac L4 (EMEA/V/C/002010)	16.07.2013 – 15.07.2014
Nobivac Myxo-RHD (EMEA/V/C/002004)	07.09.2013 – 06.09.2014

Product	Period
Previcox (EMEA/V/C/000082)	10.09.2013 – 09.09.2014
Profender (EMEA/V/C/000097)	27.07.2013 – 26.07.2014
Proteq West Nile (EMEA/V/C/002005)	05.08.2013 – 04.08.2014
ProZinc (EMEA/V/C/002634)	12.07.2013 – 11.07.2014
Suvaxyn Aujeszky 783 o/w (EMEA/V/C/000038)	07.08.2013 – 06.08.2014
Suvaxyn PCV (EMEA/V/C/000149)	24.07.2013 – 23.07.2014
Trocoxil (EMEA/V/C/000132)	09.09.2013 – 08.09.2014
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2013 – 08.08.2014
ZACTRAN (EMEA/V/C/000129)	24.07.2013 – 23.07.2014
Zulvac 1 Bovis (EMEA/V/C/002334)	05.08.2013 – 04.08.2014
Zulvac 1 Ovis (EMEA/V/C/002335)	05.08.2013 – 04.08.2014

5.4 Renewals

• **Respiporc Flu 3** EMEA/V/C/000157/R/0005	Rapp: E.-M. Vestergaard Co-rapp: B. Urbain ***For adoption***: List of outstanding issues
• **ZOLVIX** EMEA/V/C/000154/R/0013	Rapp: C. Friis Co-rapp: J. Schefferlie ***For adoption***: CVMP opinion CVMP assessment report
• **Gripovac 3** EMEA/V/C/000157/R/0005	Rapp: E.-M. Vestergaard Co-rapp: B. Urbain ***For adoption***: CVMP opinion CVMP assessment report
• **Zulvac 8 Bovis** EMEA/V/C/000145/R/0016	Rapp: M. Tollis Co-rapp: I. Malemis ***For adoption***: CVMP opinion CVMP assessment report

• **Zulvac 8 Ovis** EMEA/V/C/000147/R/0016	Rapp: M. Tollis Co-rapp: I. Malemis ***For adoption***: CVMP opinion CVMP assessment report

5.5 Pharmacovigilance - PSURs and SARs

• **Activyl Tick Plus** EMEA/V/C/002234	Rapp: G.J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Flexicam** EMEA/V/C/000102	Rapp: J.G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.11-30.04.14
• **Meloxoral** EMEA/V/C/000151	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 19.05.13-19.05.14
• **Porcilis AR-T DF** EMEA/V/C/000055	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.13-31.05.14
• **Suvaxyn PCV** EMEA/V/C/000149	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **ZOLVIX** EMEA/V/C/000154	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13-30.04.14
• **Pexion** EMEA/V/C/002543	Rapp: M. Holzhauser-Alberti ***For information:*** Letter on advice to the veterinary surgeons concerning the use of Pexion by Veterinary Medicines Directorate (VMD)(UK), for publication in the Veterinary Record

- ***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***: VICH EWG on Safety: draft guideline on acute reference dose; draft 9 for sign-off at step 2
- ***For endorsement***: VICH EWG on Metabolism and Residue Kinetics: draft revision of VICH GL48 on Marker Residue Depletion Studies for sign-off by EWG at step 5/6; VICH GL49 on Method used in Residue Depletion Studies for sign-off by Expert Working Group at step 5/6
- ***For endorsement***: VICH Expert Working Group on Quality: Task Force on revision of GL3: revised draft concept paper on the revision of (Stability) GL3(R); draft EU response
- ***For endorsement****:* Revised VICH GL23 on genotoxicity testing for formal endorsement prior to final adoption; Discussion of comments received during public consultation
- ***For discussion***: VICH MRK EWG: mission report from the VICH Expert Working Group on Metabolism and Residue Kinetics meeting held on 16-19 June 2014 in Brussels; revised draft guideline on residue studies in honey; revised draft guideline on residue studies in fish
- ***For discussion***: VICH survey on the need for VICH GLs for biotechnological/biological veterinary medicinal products
- ***To note***: VICH Expert Working Group on Electronic Exchange of Documents: draft guideline on electronic file formats (EFF) at step 5; compilation of comments received during public consultation

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

Information relating to topics discussed under point 6.3 at this meeting cannot be released at the present time as it is deemed to be confidential.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

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

- ***For decision:*** Draft CVMP report on inclusion **of substance** in the list of substances not falling within the scope of Regulation (EC) No 470/2009
- ***For decision:*** Draft CVMP report on inclusion **of substance** in the list of substances not falling within the scope of Regulation (EC) No 470/2009
- ***For decision:*** Draft CVMP report on inclusion **of substance** in the list of substances not falling within the scope of Regulation (EC) No 470/2009
- ***For adoption:*** Revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009
- ***For decision:*** Request for clarification on the MRL status of substance
- ***For discussion:*** Comments received during the public consultation on the reflection paper **on injection site residues** – from Danish residue control authority; Portuguese residue control authority; Spanish residue control authority; AECOSAN; EGGVP; EQAC; the Dutch Ministry of Economic Affairs; FVE; IFAH-Europe; Israeli ministry of agriculture
- ***For discussion***: CVMP/SWP Proposals on principles for **extrapolation of MRLs**

8.2 Environmental risk assessment

- No items

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 contain commercially confidential information

- ***For discussion***: Concept paper for the review of the CVMP guidelines on data requirements for veterinary medicinal products for minor use minor species

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/adoption***: Revised Policy for classification and incentives for veterinary medicinal products indicated for MUMS/limited market; Guidance on the classification of veterinary medicinal products indicated for MUMS/limited market

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***: Agenda of the meeting to be held on 11-12 September 2014; minutes of the meeting held on 10-11 July 2014; presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion and adoption***: Informal CVMP and Joint CVMP/CMDv meetings, to be held on 22-23 September in Rome, Italy; Presidency meeting CVMP draft agenda and Presidency meeting CMDv draft agenda
- ***For information***: FVE Correspondence to CVMP dated 16 May 2014 and FVE list “VMPs for aquatic animals”
- ***For information***: Verbal report from the Strategic Planning Group on Road Map meeting to be held on 10 September 2014; draft agenda; draft minutes of the meeting held on 4 June 2014
- ***For information***: CVMP dates 2015

13. LEGISLATION

- No items

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP
September	9-11	24-25		30 Sept - 1 Oct	30 Sept-1 Oct	16-17	17-19	9	4-5
October	7-9		21-22					7	
November	4-6	18-19		25-26		18-19		4	27-28
December	9-11						3-5	9	
Jan 2015	13-15	20-21				27-28		13	
Feb 2015	10-12			3-4				10	19-20