4 July 2014
EMA/CVMP/410683/2014
Committee for Medicinal Products for Veterinary Use

Committee for medicinal products for veterinary use (CVMP)

Draft agenda of July 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

8 July 2014, 09:00 – 10 July 2014, 13:00

Room CP-02-A

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).

1. Adoption of the Agenda
2. CVMP delegates list of intended participation and identified conflicts of interests
3. Declaration of contacts between members and companies with regard to points on the agenda
4. Adoption of the minutes of the previous meeting
5. Confirmation of topics for rapporteur's meetings and breakout sessions

- **Scientific Advice Working Party** *(CP-02-A)* 8 July 2014 16:30-18:30

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A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 E STABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

• **Substance** EMEA/V/MRL/003660/EXTN/0003 *Rabbits*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For information***: Rapporteur's assessment report; rapporteur's assessment of the responses to the list of questions; rapporteur's EPMAR; peer reviewer's report*;* EU-RL report
• **Substance** EMEA/V/MRL/003158/EXTN/0002 *Porcine species*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For information***: Rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report; EU-RL report
• **Substance** EMEA/V/MRL/003802/FULL/0001 *Fin fish*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For information***: Rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report; peer reviewer's report; EU-RL report; comments
• **Substance** EMEA/V/MRL/003988/FULL/0001 *Bovine species*	***For adoption***: Draft CVMP scientific overview and list of questions ***For discussion***: Rapporteur's assessment report with the critique from the co-rapporteur; rapporteur's scientific overview and list of questions; peer reviewer's report; peer reviewer's report
• **Substance** EMEA/V/MRL/002964/EXTN/0004 *Equidae*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For information***: Revised rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report; EU-RL report

• **Substance** EU/12/199 Modification of ADI & MRL	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For discussion***: Rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report; EU-RL report
• **Substance** EMEA/V/MRL/003044/EXTN/0005 *Eggs*	***For adoption***: Draft CVMP opinion*;* Draft CVMP assessment report ***For discussion***: Rapporteur's assessment of the responses to the list of questions; rapporteur's assessment report; EPMAR; peer reviewers report

A.1.2 Recommendations for extrapolation of established MRLs

- No items

A.1.3 Re-examination of CVMP opinions

- No items

A.2 COMMUNITY MARKETING AUTHORISATIONS

A.2.1 Opinions on applications

• **Product** EMEA/V/C/002802/0000 *New viral vaccine (chickens)*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Draft product information

A.2.2 Variations to Community marketing authorisations

• **COXEVAC** EMEA/V/C/000155/II/0006 *Quality*	Rapp: J.-C. Rouby ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report
• **Easotic** EMEA/V/C/000140/II/0006/G *Quality*	Rapp: J.-C. Rouby ***For adoption***: Draft list of questions
• **NexGard** EMEA/V/C/002729/II/0001 *To change the SPC and the package leaflet due to new clinical data*	Rapp: P. Hekman ***For adoption***: Draft CVMP list of questions
• **Broadline** EMEA/V/C/002700/II/0001 *To add new indications for the target species (cats)*	Rapp: B. Urbain ***For adoption***: Draft CVMP list of questions

• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0002 *To reduce the onset of immunity due to new challenge data*	Rapp: A-M. Brady ***For information***: Letter of withdrawal from Merial

A.2.3 Re-examination of CVMP opinions

- N/a

A.2.4 Lists of questions

• **Product** EMEA/V/C/003797/0000) *New bacterial vaccine (pigs)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, PIQ comments on product information
• **Product** EMEA/V/C/003836/0000) *New cardiovascular product (dogs)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, rapporteurs' and PIQ comments on product information, rapporteurs' assessment and list of questions on the applicant's part of the ASMF and the restricted part of the ASMF
• **Product** EMEA/V/C/003866/0000 *New anti-inflammatory product (horses)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, rapporteurs' and PIQ comments on product information
• **Product** EMEA/V/C/003869/0000 *New viral vaccine (chickens)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, rapporteurs' and PIQ comments on product information

A.3 REFERRALS AND RELATED PROCEDURES

A.3.1 Article 33 of Directive 2001/82/EC

- No items

A.3.2 Article 34 of Directive 2001/82/EC

- No items

A.3.3 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 ***For decision:*** Request from CEVA for an oral explanation ***For discussion***: Presentation on withdrawal period from co-rapporteur

• **All veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses** EMEA/V/A/104 *Indications, dosage and target animal safety*	Rapp: K. Baptiste Co-rapp: C. Muñoz ***For decision***: Need for outstanding issues for an oral explanation ***For discussion:*** Rapporteur's assessment report including co-rapporteur's critique
• **All veterinary medicinal products containing colistin to be administered orally** EMEA/V/A/106 *Indications, prudent use warnings*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

A.3.4 Article 39 of Directive 2001/82/EC

- No items

A.3.5 Article 13 of Regulation (EC) No 1234/2008

• **Ubrolexin intramammary suspension for lactating dairy cows** EMEA/V/A/102 *Efficacy and withdrawal periods*	Rapp: J. Bureš Co-rapp: D. Murphy ***For information***: Letter from the MAH for withdrawal of the variation application

A.3.6 Article 78 of Directive 2001/82/EC

- No items

A.3.7 Article 30(3) of Regulation 726/2004

- No items

A.3.8 Article 45 of Regulation 726/2004

- No items

A.3.9 Miscellaneous items

- No items

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

• **Product** EMEA/V/C/002794/0000) *New haematological product* (dogs)	***For decision:*** Need for oral explanation ***For adoption***: Updated scientific overview and benefit-risk assessment list of outstanding issues, product information

• **Product** EMEA/V/C/003796/0000 *New viral and bacterial vaccine* (pigs)	***For decision:*** Need for oral explanation ***For adoption:*** Updated scientific overview and benefit-risk assessment, list of outstanding issues product information
• **Product** EMEA/V/C/002390 *New vaccine* (*Atlantic salmon*)	***For endorsement:*** AHEG - List of candidates
• **Product** EMEA/V/C/002808/0000 *New hormonal product* *(cats)*	***For information***: Withdrawal letter; Draft CVMP opinion; Draft CVMP assessment report

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 GENERAL ISSUES

- No items

C.2 POST-AUTHORISATION MEASURES TO CVMP OPINIONS ON THE GRANTING OF COMMUNITY MARKETING AUTHORISATIONS, ANNUAL REASSESSMENTS

• **ZOLVIX** EMEA/V/C/000154	Rapp: C. Friis Co-rapp: J. Schefferlie ***For adoption***: Rapporteur's recommendation assessment report
• **ZACTRAN** EMEA/V/C/000129	Rapp: C. Friis Co-rapp: J. G. Beechinor ***For adoption***: Rapporteur's recommendation assessment report

C.3 Product anniversary list

Product	**Period**
Circovac (EMEA/V/C/000114)	21.06.2013 – 20.06.2014
Convenia (EMEA/V/C/000098)	19.06.2013 – 18.06.2014
Equilis Prequenza (EMEA/V/C/000094)	08.07.2013 – 07.07.2014
Equilis Prequenza Te (EMEA/V/C/000095)	08.07.2013 – 07.07.2014
Equilis Te (EMEA/V/C/000093)	08.07.2013 – 07.07.2014
Equilis West Nile (EMEA/V/C/002241)	06.06.2013 – 05.06.2014
Equioxx (EMEA/V/C/000142)	25.06.2013 – 24.06.2014
Leucofeligen FeLV/RCP (EMEA/V/C/000143)	25.06.2013 – 24.06.2014

Leucogen (EMEA/V/C/000144)	17.06.2013 – 16.06.2014
Melovem (EMEA/V/C/000152)	07.07.2013 – 06.07.2014
MS-H vaccine (EMEA/V/C/000161)	14.06.2013 – 13.06.2014
Nobilis IB4-91 (EMEA/V/C/000036)	09.06.2013 – 08.06.2014
Porcilis ColiClos (EMEA/V/C/002011)	14.06.2013 – 13.06.2014
Porcilis Pesti (EMEA/V/C/000046)	09.06.2013 – 08.06.2014
Posatex (EMEA/V/C/000122)	23.06.2013 – 22.06.2014
Poulvac E. coli (EMEA/V/C/002007)	15.06.2013 – 14.06.2014
Prilactone (EMEA/V/C/000105)	20.06.2013 – 19.06.2014
Reconcile (EMEA/V/C/000133)	08.07.2013 – 07.07.2014
Suprelorin (EMEA/V/C/000109)	10.07.2013 – 09.07.2014

C.4 Renewals of marketing authorisations

• **Aivlosin** EMEA/V/C/000083/R/0059	Rapp: H. Jukes Co-rapp: E. Lander Persson ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report
• **ZOLVIX** EMEA/V/C/000154/R/0013	Rapp: C. Friis Co-rapp: J. Schefferlie ***For adoption***: Draft CVMP list of outstanding issues
• **Zulvac 8 Bovis** EMEA/V/C/000145/R/0016	Rapp: M. Tollis Co-rapp: I. Malemis ***For adoption***: Draft CVMP list of outstanding issues
• **Zulvac 8 Ovis** EMEA/V/C/000147/R/0016	Rapp: M. Tollis Co-rapp: I. Malemis ***For adoption***: Draft CVMP list of outstanding issues

C.5 Pharmacovigilance - PSURs and SARs

- ***For decision:*** Surveillance of centrally authorised products: recommendations by PhVWP-V

• **Draxxin** EMEA/V/C/000077	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.10-30.11.13
• **Pexion** EMEA/V/C/002543	Rapp: M. Holzhauser-Alberti ***For endorsement***: Rapporteur's assessment report
• **Parvoduk** EMEA/V/C/002740/0000	Rapp: F. Klein Co-rapp: T. Soós ***For discussion***: Post authorisation safety study protocol

- ***For decision:*** Surveillance of centrally authorised products: recommendations by PhVWP-V

• **Activyl** EMEA/V/C/000163	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **Bovilis BTV8** EMEA/V/C/000148	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.13-31.03.14
• **Coxevac** EMEA/V/C/000077	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-31.03.14
• **Emdocam** EMEA/V/C/002283	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **Equilis Prequenza Te** EMEA/V/C/000095	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Equilis Prequenza** EMEA/V/C/000094	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14

• **Equilis StrepE** EMEA/V/C/000078	Rapp: E. Werner **Background note:** N/a ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Melosus** EMEA/V/C/002001	Rapp: E. M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **Nobivac L4** EMEA/V/C/002010	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Proteq West Nile** EMEA/V/C/002005	Rapp: J-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **Purevax Rabies** EMEA/V/C/002003	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **RevitaCAM** EMEA/V/C/002379	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **RHINISENG** EMEA/V/C/000160	Rapp: E. M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-31.03.14
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14
• **Zulvac 1 Bovis** EMEA/V/C/002334	Rapp: E. M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14

• **Zulvac 1 Ovis** EMEA/V/C/002335	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.13-28.02.14

- ***For endorsement:*** List of products and calendar for signal detection analysis

C.6 Supervision and sanctions

- No items

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- ***For endorsement***: VICH Task Force on the revision of anthelmintic guidelines: EU comments on topic 3 - standards for effectiveness
- ***For information***: VICH Steering Committee: verbal report from the VICH SC meeting held on 23-26 June 2014 in Brussels; press release

D.2 Codex Alimentarius

- No items

D.3 Other EU bodies and international organisations

- ***For discussion***: Update on the draft EFSA Opinion on reference points for action for chloramphenicol

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to contain commercially confidential information

E.2 Pharmacovigilance Working Party (PhVWP)

E.3 Efficacy Working Party (EWP)

E.4 Safety Working Party (SWP)

E.5 Immunologicals Working Party (IWP)

E.6 Quality Working Party (QWP)

E.7 Environmental Risk Assessment Working Party (ERAWP)

E.8 Antimicrobials Working Party (AWP)

E.9 Joint CVMP/CHMP AHEG on the application of the 3Rs

E.10 Other Working Party issues

F. SAFETY OF VETERINARY MEDICINES AND RESIDUES

F.1 Appointment of Rapporteurs, Co-rapporteurs and Peer reviewers for the establishment of new MRLs

Information relating to letters of intent for new MRL applications cannot be released at the present time as it is deemed to contain commercially confidential information

F.2 Critical issues related to centralised procedures

Information on critical issues related to MRL centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information

- No items

F.3 Other MRL items

Information on pending MRL related issues cannot be released at the present time as it is deemed to contain commercially confidential information

F.4 Antimicrobial resistance

Information relating to topics on antimicrobial resistance discussed at this meeting cannot be released at present time as it is deemed to be confidential

F.5 Pharmacovigilance

- ***For information***: Live demonstration – new interface to query EVVET data

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

G.1 Eligibility and appointment of Rapporteurs, Co-rapporteurs and Peer reviewers

Information concerning letters of intent and eligibility requests relating to community marketing authorisations cannot be released at the present time as it is deemed to contain commercially confidential information

G.2 Inspections

Information relating to GMP and pharmacovigilance inspections will not be published as it would be undermining the purpose of such inspections

G.3 Regulatory issues

Information relating to certain regulatory issues on community marketing authorisations cannot be released at the present time as it is deemed to contain commercially confidential information

G.4 Miscellaneous items

Information relating to certain miscellaneous items on community marketing authorisations cannot be released at the present time as it is deemed to contain commercially confidential information

H. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to contain commercially confidential information

I. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- ***For information***: Agenda of the meeting to be held on 10-11 July 2014; minutes of the meeting held on 5-6 June 2014

J. ORGANISATIONAL MATTERS

- ***For discussion***: Informal CVMP and Joint CVMP/CMDv meetings, to be held on 22-23 September in Rome, Italy – draft agenda
- ***For discussion and decision***: CVMP agenda – revised structure
- ***For information:*** Update on the EMA policy on the handling of declarations of interests of scientific committees' members and experts, presentation
- ***For information:*** Induction training for Committees, presentation

K. LEGISLATION

- No items

L. ANY OTHER BUSINESS

- ***For information:*** Information on potential issues or procedures that would require CVMP decision(s) via written procedure during August 2014

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES 2014

	CVMP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	JEG 3Rs
July	8-10					1-2		8		
September	9-11	24-25		30 Sept - 1 Oct	30 Sept -1 Oct	16-17	17-19	9	3-4	
October	7-9		21-22					7		28-29
November	4-6	18-19		25-26		18-19		4	27-28	
December	9-11						3-5	9		