4 April 2014
EMA/CVMP/208229/2014
Committee for Medicinal Products for Veterinary Use

Committee for medicinal products for veterinary use (CVMP)

Draft agenda of April 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

8 April 2014, 09:00 – 10 April 2014, 13:00 (*Room 2A*)

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 cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as 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** *(Room 2A)* Tue. 8 April 2014 16:15-18:00 TBC

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A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

• **Substance** EMEA/V/MRL/003071/MODF/0002 *Bovine, ovine species*	***For adoption***: Draft CVMP opinion including EPMAR; Draft CVMP assessment report ***For information***: Rapporteur's assessment report including the critique from the co-rapporteur; peer review report; peer review report; comments
• **Substance** EMEA/V/MRL/002860/FULL/0002 *Equidae*	***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; comments; peer review report; peer review report; report from EU-RL
• **Substance** EMEA/V/MRL/003915/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; comments; peer review report; peer review report; report from EU-RL
• **Substance** EMEA/V/MRL/003044/EXTN/0005 *Eggs* Clarification	***For discussion***: Clarification with regard to the agreed question on the analytical method; correspondence with EU-RL

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/002746/0000 *New ectoparasiticide* *(cats)*	***For adoption:*** Draft CVMP opinion; Draft CVMP assessment report; Product information

A.2.2 Variations to Community marketing authorisations

• **RESPIPORC FLU3** EMEA/V/C/000153/II/0005 *(Quality)*	Rapp: E-M. Vestergaard Co-rapp: B. Urbain ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report

A.2.3 Re-examination of CVMP opinions

- No items

A.2.4 Lists of questions

• **Product** EMEA/V/C/002804/0000 *New cardiovascular product* *(dogs)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions; joint rapporteurs' assessment and list of questions on the applicants and the restricted parts of the ASMF
• **Product** EMEA/V/C/002781/0000 *New viral vaccine* *(cattle and sheep)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions

A.3 REFERRALS AND RELATED PROCEDURES

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

• **Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs** EMEA/V/A/099 (Re-examination) *Efficacy*	Rapp: R. Breathnach Co-rapp: B. Zemann ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report

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

• **Linco-Spectin 100 and its associated names** EMEA/V/A/088 *Harmonisation of SPC*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For adoption***: Draft CVMP opinion; Harmonised product information; Draft CVMP assessment report

• **Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names** EMEA/V/A/091 *Harmonisation of SPCs*	Rapp: M. Holzhauser-Alberti Co-rapp: C. Muñoz Madero ***For adoption***: Draft CVMP opinion; Harmonised product information for Baytril 2.5%, Baytril 5% and Baytril 10%; Draft CVMP assessment report

A.3.3 Article 35 of Directive 2001/82/EC

• **Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC** EMEA/V/A/097 *Indications, dosage and withdrawal periods*	Rapp: C. Muñoz Madero Co-rapp: P. Hekman ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Divergent position
• **All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs** EMEA/V/A/100 *Indications, dosage, antimicrobial resistance*	Rapp: E. Lander Persson Co-rapp: A. Wachnik-Święcicka ***For decision*** Need for outstanding issues for an oral explanation ***For discussion***: Revised rapporteur's assessment report including co-rapporteur's critique following comments from applicants and MAHs
• **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 Madero ***For adoption***: List of questions to AWP

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

- No items

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

- No items

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

- No items

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

• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-Rapp: C. Muñoz Madero ***For adoption***: Revised timetable

A.3.8 Article 45 of Regulation 726/2004

- No items

A.3.9 Miscellaneous items

- ***For information:*** Long-acting formulations for injection containing barium selenate for all food producing species – Art. 35 (EMEA/V/A/077) – Background information for publication

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

• **Product** EMEA/V/C/003680/0000 *New bacterial vaccine* *(dogs)*	***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information
• **Product** EMEA/V/C/003683/0000 *New viral and bacterial vaccine* *(dogs)*	***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information
• **Product** EMEA/V/C/003682/0000 *New viral and bacterial vaccine* *(dogs)*	***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information
• **Product** EMEA/V/C/002802/0000 *New viral vaccine* *(chickens)*	***For adoption:*** Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion:*** Draft product information

• **DRAXXIN** EMEA/V/C/000077/X/0026 *Extension: new strength* *(pigs)*	Rapp: C. Ibrahim Co-rapp: C. Muñoz Madero ***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information
• **Product** EMA/V/C/0003703/0000 *New viral vaccine* *(cattle)*	***For adoption****:* Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion****:* Draft product information
• **Product** EMA/V/C/0003703/0000 *New hormonal product* *(cats)*	***For adoption:*** Updated scientific overview and benefit-risk assessment and list of outstanding issues
• **Product** EMEA/V/C/002390 *New vaccine* (*Atlantic salmon*)	***For adoption****:* Amendment of mandate of ad-hoc expert group (AHEG)

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 and annual reassessments

• **Zolvix** EMEA/V/C/000154/1B/0008/G	Rapp: C. Friis Co-rapp: J. Schefferlie ***For adoption***: Rapporteur's assessment report
• **Bravecto** EMEA/V/C/002526/0000	Rapp: J. Schefferlie Co-rapp: R. Breathnach ***For adoption:*** Rapporteur's assessment report

C.3 Product anniversary list

Product	Period
Advocate (EMEA/V/C/000076)	02.04.2013 – 01.04.2014
BTVPUR Alsap 8 (EMEA/V/C/000146)	17.03.2013 – 16.03.2014

CaniLeish (EMEA/V/C/002232)	14.03.2013 – 13.03.2014
Clomicalm (EMEA/V/C/000039)	01.04.2013 – 31.03.2014
Ecoporc Shiga (EMEA/V/C/002588)	10.04.2013 – 09.04.2014
Eurican Herpes 205 (EMEA/V/C/000059)	26.03.2013 – 25.03.2014
Flexicam (EMEA/V/C/000102)	10.04.2013 – 09.04.2014
Incurin (EMEA/V/C/000047)	24.03.2013 – 23.03.2014
Locatim (EMEA/V/C/000041)	29.03.2013 – 28.03.2014
Rabigen SAG2 (EMEA/V/C/000043)	06.04.2013 – 05.04.2014
Zulvac 1+8 Ovis (EMEA/V/C/002251)	14.03.2013 – 13.03.2014

C.4 Renewals of marketing authorisations

• **LEUCOFELIGEN FeLV/RCP** EMEA/V/C/000143/R/0003	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report;
• **LEUCOGEN** EMEA/V/C/000144/R/0002	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report
• **Suvaxyn PCV** EMEA/V/C/000149/R/0016	Rapp: B. Urbain Co-rapp: E.-M. Vestergaard ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report
• **Melovem** EMEA/V/C/000152/R/0008	Rapp: R. Breathnach Co-rapp: E.-M. Vestergaard ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report

C.5 Pharmacovigilance - PSURs and SARs

• **Comfortis** EMEA/V/C/002233	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the targeted PSUR for the period 11.02.11-31.03.13

• **Apoquel** EMEA/V/C/002688	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 12.09.13-30.11.13
• **BTVPUR AlSap 2-4** EMEA/V/C/000139	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.13-30.11.13
• **Certifect** EMEA/V/C/002002	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.06.13-30.11.13
• **Equip WNV** EMEA/V/C/000137	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 22.11.12-21.11.13
• **Improvac** EMEA/V/C/000136	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.12-30.11.13
• **MS-H vaccine** EMEA/V/C/000161	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.12-30.09.13
• **Oncept IL-2** EMEA/V/C/002562	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13-30.11.13
• **Palladia** EMEA/V/C/000150	Rapp: E. Lander-Persson ***For adoption***: CVMP assessment report on the PSUR for the period 01.12.12-30.11.13
• **Porcilis ColiClos** EMEA/V/C/002011	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13

• **Porcilis Pesti** EMEA/V/C/000046	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 10.12.10-31.12.13
• **Posatex** EMEA/V/C/000122	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.12-30.09.13
• **TruScient** EMEA/V/C/002000	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.07.13-31.12.13
• **Zuprevo** EMEA/V/C/002009	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.12-30.09.13

- ***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***: Revised draft guideline on study design recommendations for residue depletion studies in honey following comments from VICH EWG – revised draft which has been updated to take account of SWP comments
- ***For endorsement***: Draft concept paper for the revision of VICH Stability GL 3(R) to include climatic zones III and IV: draft EU comments on draft summary of discussion and proposal for actions; draft summary table of comments from the regions
- ***For endorsement:*** VICH Task Force on the revision of the VICH Anthelmintics GLs: Draft EU comments on the first topic for discussion: Adequacy of infection
- ***For endorsement:*** VICH TF on Efficacy studies for combination products - draft questionnaire

D.2 Codex Alimentarius

- No items

D.3 Other EU bodies and international organisations

- ***For endorsement***: Workshop organised by the European Chemicals Agency on 24th September 2014 to discuss the outcome of research arising from the European Chemical Industry Council-Long Range Research Initiative (CEFIC-LRI) – nomination of CVMP representative

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

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

F.4 Antimicrobial resistance

F.5 Pharmacovigilance

- No items

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

- ***For endorsement:*** EPAR module 6 scientific discussion for **Panacur AquaSol** (EMEA/V/C/002008/X/0003) concerning the extension to add a food-producing target animal species (chickens)
- ***For endorsement***: Table on dossier requirements for veterinary CAPs
- ***For information:*** Update on e-submission matters

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 April 2014 ; minutes of the meeting held on 13-14 March 2014
- ***For information***: CMDv meeting dates in May 2014

J. ORGANISATIONAL MATTERS

- ***For discussion***: CVMP Interested Parties' meeting, to be held on 7 May 2014 at the EMA; draft agenda and draft minutes of the previous meeting held on 15 May 2013
- ***For discussion***: CHMP initiative concerning multinational assessment teams for future consideration by the CVMP, working instructions for multinational CHMP teams, presentation
- ***For decision***: Rapporteurs meetings via Adobe Connect: recommendations
- ***For information***: Revision of the pre-submission guidance on the Agency website
- ***For information***: An Agency on the move presentation

- ***For information***: Assessment of new application

K. LEGISLATION

- No items

L. ANY OTHER BUSINESS

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

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES 2014

	CVMP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	JEG 3Rs
April	8-10							8		
May	6-8	14-15		13-14		20-21	13-15	6	22-23	
June	3-5		17-18		18-19			3		
July	8-10					1-2 (Poss. Adobe)		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		