7 February 2014
EMA/CVMP/78423/2014
Committee for Medicinal Products for Veterinary Use

Committee for Medicinal Products for Veterinary Use (CVMP)

Draft agenda of February 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

11 February 2014, 09:00 – 13 February 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 of the information contained in this agenda is considered commercially confidential and therefore is not disclosed. The procedures discussed by the CVMP are on-going and therefore certain aspects are considered confidential. Additional details on these procedures will be disclosed in the CVMP press release and minutes (after the CVMP opinion is adopted). Documents mentioned in the agenda cannot be released at present as they are currently in draft format or are classified as confidential. They will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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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 11 Feb 2014	16:00-20.00 TBC

A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

• **Substance** EMEA/V/MRL/003878/FULL/0001 *Chicken*	***For adoption***: CVMP Scientific overview and list of questions ***For discussion***: Rapporteur's scientific overview and list of questions, rapporteur's assessment report with the critique from the co-rapporteur, comments, peer reviewer's report, EU-RL 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/002740/0000 *Live attenuated vaccine (duck)*	***For adoption***: Draft CVMP opinion Draft CVMP assessment report Draft product information

A.2.2 Variations to Community marketing authorisations

• **Profender** EMEA/V/C/000097/II/0024 *To change the legal status of Profender*	Rapp: R. Breathnach ***For adoption***: Draft CVMP opinion Draft CVMP assessment report
• **Profender** EMEA/V/C/000097/II/0025/G *Quality*	Rapp: R. Breathnach ***For adoption***: Draft CVMP opinion Draft CVMP assessment report
• **Cerenia** EMEA/V/C/000106/II/0022 *Change in posology*	Rapp: C. Friis ***For adoption***: Draft List of questions

A.2.3 Re-examination of CVMP opinions

- No items

A.2.4 Lists of questions

• **Product** EMEA/V/C/003786/0000 *Product for cardiovascular system (cats)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, comments from rapporteurs and PIQ on product information
• **Product** EMEA/V/C/003764/0000 *Product for psycholeptic use (dogs)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions, comments from rapporteurs and PIQ on product information

A.3 REFERRALS AND RELATED PROCEDURES

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

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

• **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 decision***: Need for outstanding issues for oral explanation ***For discussion***: Updated rapporteur's assessment report following responses to the list of outstanding issues; rapporteur's and co-rapporteur's comments following responses to the list of outstanding issues; draft SPCs with rapporteur's and co-rapporteur's comments

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

• **All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses** EMEA/V/A/095 *ERA*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti ***For information:*** Request from the applicant/MAHs for an extension of the clock stop

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

- No items

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

• **Resflor solution injectable** EMEA/V/A/101 *Efficacy*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: List of questions; Timetable for the procedure ***For discussion and decision:*** Notification from reference Member State France under Article 13 of Regulation (EC) No 1234/2008; discussion document. Appointment of rapporteur, co-rapporteur and peer reviewers.
• **Ubrolexin intramammary suspension for lactating dairy cows** EMEA/V/A/102 *Efficacy and withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: List of questions; Timetable for the procedure ***For discussion and decision***: Notification from reference Member State Ireland under Article 13 of Regulation (EC) No 1234/2008; discussion document Appointment of rapporteur, co-rapporteur and peer reviewers.

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

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

• **Product** EMEA/V/C/002590 *Hormonal product (cattle)*	***For adoption***: Request from applicant for extension of the timeframe for the submission of responses to list of questions
• **Product** EMEA/V/C/002794 *Product for blood and blood forming organs (dogs)*	***For decision***: Request from applicant for extension of the timeframe for the submission of responses to list of questions

• **Product** EMEA/V/C/002390 *A vaccine for intramuscular use* (*Atlantic salmon*)	***For decision:*** Mandate of ad-hoc expert group (AHEG) to provide expert advice

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 GENERAL ISSUES

- ***For adoption:*** List of veterinary medicinal products to be included in the 2015 Sampling and Testing Programme

C.2 Specific obligations and follow-up measures to CVMP opinions on the granting of Community marketing authorisations, annual reassessments

• **BTVPUR AlSap 2-4** EMEA/V/C/000139/S/0004 *Annual reassessment*	Rapp: M. Tollis ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Product information

C.3 Product anniversary list

- **Comfortis** (EMEA/V/C/002233) – 11 February 2013 – 10 February 2014
- **Dicural** (EMEA/V/C/000031) – 16 January 2013 – 15 January 2014
- **Fevaxyn Pentofel** (EMEA/V/C/000030) – 5 February 2013 – 4 February 2014
- **Gripovac 3** (EMEA/V/C/000157) – 14 January 2013 – 13 January 2014
- **Hiprabovis IBR Marker Live** (EMEA/V/C/000158) – 27 January 2013 – 26 January 2014
- **Ingelvac CircoFLEX** (EMEA/V/C/000126) – 13 February 2013 – 12 February 2014
- **Kexxtone** (EMEA/V/C/002235) – 28 January 2013 – 27 January 2014
- **Loxicom** (EMEA/V/C/000141) – 10 February 2013 – 9 February 2014
- **Meloxidyl** (EMEA/V/C/000115) – 15 January 2013 – 14 January 2014
- **Nobilis OR Inac** (EMEA/V/C/000062) – 24 January 2013 – 23 January 2014
- **Pirsue** (EMEA/V/C/000054) – 29 January 2013 – 28 January 2014
- **Porcilis PCV** (EMEA/V/C/000135) – 12 January 2013 – 11 January 2014
- **RESPIPORC FLU3** (EMEA/V/C/000153) – 14 January 2013 – 13 January 2014
- **Semintra** (EMEA/V/C/002436) – 13 February 2013 – 12 February 2014
- **STARTVAC** (EMEA/V/C/000130) – 11 February 2013 – 10 February 2014
- **TruScient** (EMEA/V/C/002000) – 14 December 2012 – 13 December 2013
- **ZULVAC 8 Bovis** (EMEA/V/C/000145) – 15 January 2013 – 14 January 2014
- **ZULVAC 8 Ovis** (EMEA/V/C/000147) – 15 January 2013 – 14 January 2014

Updated date ranges from the product anniversary list of the January meeting:

- **Activyl Tick Plus** (EMEA/V/C/002234) – 09 January 2013 – 08 January 2014
- **BTVPUR AlSap 1** (EMEA/V/C/002230) – 17 December 2012 – 16 December 2013
- **BTVPUR AlSap 1-8** (EMEA/V/C/002231) – 17 December 2012 – 16 December 2013
- **CORTAVANCE** (EMEA/V/C/000110) – 09 January 2013 – 08 January 2014
- **Metacam** (EMEA/V/C/000033) – 07 January 2013 – 06 January 2014
- **Onsior** (EMEA/V/C/000127) – 16 December 2012 – 15 December 2013
- **Prac-Tic** (EMEA/V/C/000103) – 18 December 2012 – 17 December 2013
- **ProMeris** (EMEA/V/C/000107) – 19 December 2012 – 18 December 2013
- **ProMeris Duo** (EMEA/V/C/000108) – 19 December 2012 – 18 December 2013
- **Rheumocam** (EMEA/V/C/000121) – 10 January 2013 – 09 January 2014
- **Ypozane** (EMEA/V/C/000112) – 11 January 2013 – 10 January 2014

C.4 Renewals of marketing authorisations

• **Improvac** EMEA/V/C/000136/R/0024	Rapp: E.-M. Vestergaard Co-rapp: A.-M. Brady ***For adoption***: Draft CVMP Opinion; Draft CVMP assessment report
• **Equilis StrepE** EMEA/V/C/000078/R/0010	Rapp: E. Werner Co-rapp: E.-M. Vestergaard ***For adoption***: Draft CVMP Opinion; Draft CVMP assessment report

C.5 Pharmacovigilance - PSURs and SARs

• **Trifexis** EMEA/V/C/002635/0000 Post-authorisation safety study	Rapp: C. Ibrahim Co-rapp: H.-K. Østensen ***For decision***: Draft CVMP comments on draft post-authorisation safety study protocol ***For discussion***: Rapporteurs' comments, rapporteur's comments on draft protocol, comments from PhVWP-V, other comments, response from MAH on case record forms and owner consent forms
• **CaniLeish** EMEA/V/C/002232	Rapp: J.-C. Rouby ***For adoption*:** CVMP assessment report on the PSUR for the period 01.04.13 – 30.09.13

• **Suprelorin** EMEA/V/C/000109	Rapp: E.-M. Vestergaard ***For adoption*:** CVMP assessment report on the PSUR for the period 01.02.13 - 31.07.13
• **BLUEVAC BTV8** EMEA/V/C/000156	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13 – 30.10.13
• **Bovilis BTV8** EMEA/V/C/000148	Rapp: M. Tollis ***For adoption*:** CVMP assessment report on the PSUR for the period 01.04.13 – 30.09.13
• **Comfortis** EMEA/V/C/002233	Rapp: C. Ibrahim ***For adoption*:** CVMP assessment report on the PSUR for the period 01.10.12 - 31.03.13
• **ECOPORC SHIGA** EMEA/V/C/002588	Rapp: A.-M. Brady ***For adoption*:** CVMP assessment report on the PSUR for the period 09.01.13 – 31.07.13
• **Ibraxion** EMEA/V/C/000051	Rapp: J.-C. Rouby ***For adoption*:** CVMP assessment report on the PSUR for the period 01.10.10 - 30.09.13
• **Netvax** EMEA/V/C/000134	Rapp: A.-M. Brady ***For adoption*:** CVMP assessment report on the PSUR for the period 01.05.13 - 30.10.13
• **Nobivac Myxo-RHD** EMEA/V/C/002004	Rapp: E. Werner ***For adoption*:** CVMP assessment report on the PSUR for the period 01.04.13 - 30.09.13
• **ZULVAC 1+8 Bovis** EMEA/V/C/002473	Rapp: E. M. Vestergaard ***For adoption*:** CVMP assessment report on the PSUR for the period 01.04.13 - 30.09.13
• **ZULVAC 1+8 Ovis** EMEA/V/C/002251	Rapp: M. Tollis ***For adoption*:** CVMP assessment report on the PSUR for the period 01.04.13 - 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 decision***: Request from IFAH Europe for an anthelmintic focus group meeting in the context of the concept paper to revise the VICH guidelines
- ***For endorsement:*** Revised draft VICH GL on the Harmonization of criteria to waive target animal batch safety testing for live vaccines for veterinary use and draft consideration of comments from other regions on the last draft VICH GL on the Harmonization of criteria to waive target animal batch safety testing for live vaccines for veterinary use
- ***For adoption***: VICH GL 53 on Electronic exchange of documents: file format requirements - formal adoption for release for consultation at step 4 of the VICH process

D.2 Codex Alimentarius

- No items

D.3 Other EU bodies and international organisations

- ***For decision:*** Request from EFSA for cooperation on establishing "Reference Points for Actions (RPAs) for non-allowed pharmacologically active substances present in food of animal origins" in relation to nitrofurans

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.

- No items

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

- ***For information:*** Verbal report on the Antimicrobial advice ad hoc expert group (AMEG) meeting held on 23-24 January 2014; agenda of the AMEG meeting and draft minutes
- ***For information:*** Verbal report on the ESVAC annual network meeting and stakeholders meeting to held on 4-5 February 2014; agenda of the annual network meeting; ESVAC expert group meeting and agenda of the stakeholders meeting
- ***For information:*** Preliminary agenda of the Working Group Antimicrobial Resistance meeting organised by DG SANCO in Brussels on 11 February 2014

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.

- ***For decision:*** Transfer of co-rapporteur and peer reviewer responsibilities from T. Soós to G. Kulcsár

G.2 Inspections

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

- No items

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. REQUEST FOR CLASSIFICATION AS MUMS/LIMITED MARKET

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

- ***For discussion***: Update on MUMS policy revision and clarification of criteria for financial incentives for MUMS products for horses

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

- ***For information***: Draft agenda of the meeting to be held on 13-14 February 2014; draft minutes of the meeting held on 16-17 January 2014

J. ORGANISATIONAL MATTERS

- ***For adoption***: Draft minutes of the informal CVMP meeting and the joint CVMP/CMDv meeting, held on 21-23 October 2013 in Vilnius, Lithuania; recommendations from the meeting
- ***For decision***: Request for participation of a CVMP member in a Task Force on Adaptation of timetables in procedures
- ***For discussion:*** EMA/IFAH-Europe Info Day to be held on 13-14 March 2014, draft programme
- ***For information***: Verbal report from the Strategic Planning Group meeting to be held on 12 February 2014; draft agenda; draft minutes of the meeting held on 11 September 2013
- ***For information***: CVMP Interested Parties' Meeting to be held on 7 May 2014: first announcement/invitation and draft minutes of previous meeting, held on 15 May 2013
- ***For information***: 2014 an Agency on the move presentation

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

	CVMP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	JEG 3Rs
Feb 2014	11-13			18-19	4-5		4-6	11	20-21	
Mar 2014	11-13					20-21		11		4
Apr 2014	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		
November	4-6	18-19		25-26		18-19		4	27-28	
December	9-11						3-5	9		