13 January 2014
EMA/CVMP/17499/2014
Committee for Medicinal Products for Veterinary Use

Committee for Medicinal Products for Veterinary Use (CVMP)

Draft agenda of January 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

14 January 2014, 09:00 – 16 January 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.

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this 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**	Tue. 14 Jan 2014	16.30-17.30 (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/003660/EXTN/0003 *Rabbits*	***For adoption***: CVMP Scientific overview and list of questions ***For discussion***: Rapporteur's revised assessment report; rapporteur's status report; 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/02722/0000 *New antifungal product (avian species)*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Product information
• **Product** EMEA/V/C/0002382 *New respiratory product (horses)*	***For adoption***: Draft CVMP opinion Draft CVMP assessment report; Product information
• **Panacur AquaSol** EMA/V/C/002008/X/003 *Extension: new target species (chickens)*	Rapp: P. Hekman Co-Rapp: H.K. Østensen ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Product information

A.2.2 Variations to Community marketing authorisations

• **Profender** EMEA/V/C/000097/II/0025/G *Quality*	Rapp: R. Breathnach ***For adoption***: List of outstanding issues
• **RESPIPORC FLU3** EMEA/V/C/000153/II/0005 *Quality*	Rapp: E.-M. Vestergaard ***For adoption***: List of outstanding issues

• **Proteq Flu** EMEA/V/C/000073/II/0014 *To substitute the strain*	Rapp: J.-C. Rouby ***For adoption***: List of outstanding issues
• **Proteq Flu-Te** EMEA/V/C/000074/II/0017 *To substitute the strain*	Rapp: J.-C. Rouby ***For adoption***: List of outstanding issues
• **MS-H vaccine** EMEA/V/C/000161/II/0005 *Quality*	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/002390 *A vaccine* (*Atlantic salmon*)	***For adoption***: Scientific overview and benefit-risk assessment and list of questions; Comments on product information
• **Product** EMEA/V/C/002590 *New hormonal product* *(cattle)*	***For adoption***: Scientific overview and benefit-risk assessment and list of questions; Comments on product information

A.3 REFERRALS AND RELATED PROCEDURES

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

• **Norbonex 5 mg/ml pour-on solution for beef and dairy cattle** EMEA/V/A/098 *ERA*	Rapp: C. Ibrahim Co-rapp: H. Jukes ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report
• **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: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Request from Vet-Agro Trading Sp. z o.o. for a re-examination of the CVMP opinion Appointment of rapporteur, co-rapporteur and peer reviewers

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

- No items

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

• **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. Persson Co-rapp: A. Wachnik-Święcicka ***For discussion and endorsement***: Revised rapporteur's assessment report with 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

- No items

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

- ***For information***: Informal procedural advice for submission of referral notifications for veterinary medicinal products by Member States (EU/EEA) to the European Medicines Agency

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

• **Product** EMEA/V/C/03678/0000 *New live and inactivated viral and bacterial vaccine (dogs)*	***For decision***: Need for oral explanation ***For adoption***: Updated scientific overview and benefit-risk assessment; List of outstanding issues ***For discussion***: Draft product information
• **Aivlosin** EMEA/V/C/083/X/055 *Extension: new pharmaceutical form*	Rapp: H. Jukes Co-rapp: E. Lander Persson ***For information***: Letter of withdrawal received from the applicant; draft CVMP assessment report

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 GENERAL ISSUES

- No items

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

• **Bovilis BTV8** EMEA/V/C/000148/S/0005 *Annual reassessment*	Rapp: M. Tollis Co-rapp: A.-M. Brady ***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Product information

C.3 Product anniversary list

- **Activyl Tick Plus** (EMEA/V/C/002234) – 09 January 2012 – 08 January 2013
- **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 2012 – 08 January 2013
- **Metacam** (EMEA/V/C/000033) – 07 January 2012 – 06 January 2013
- **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 2012 – 09 January 2013
- **Ypozane** (EMEA/V/C/000112) – 11 January 2012 – 10 January 2013

C.4 Renewals of marketing authorisations

• **BTVPUR AlSap 8** EMEA/V/C/000146/R/0010	Rapp: M. Tollis Co-rapp: J.-C. Rouby ***For adoption***: Draft CVMP opinion Draft CVMP assessment report
• **Loxicom** EMEA/V/C/000141/R/0018	Rapp: D. Murphy Co-rapp: S. Srčič ***For adoption***: Draft CVMP opinion Draft CVMP assessment report

C.5 Pharmacovigilance - PSURs and SARs

• **Trifexis** EMEA/V/C/002635/0000	Rapp: C. Ibrahim Co-rapp: H.-K. Østensen ***For decision***: Draft post-authorisation safety study protocol
• **Activyl** EMEA/V/C/000163	Rapp: G.J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **Cardalis** EMEA/V/C/002524	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.13-31.07.13
• **Clomicalm** EMEA/V/C/000039	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.10-31.07.13
• **Gripovac** EMEA/V/C/000157	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.12-31.07.13
• **Kexxtone** EMEA/V/C/002235	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 28.01.13-31.07.13
• **Loxicom** EMEA/V/C/000141	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 11.08.12-10.08.13
• **Melosus** EMEA/V/C/002001	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **Neocolipor** EMEA/V/C/000035	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.10-31.08.13

• **Pexion** EMEA/V/C/002543	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 25.02.13-31.08.13
• **Proteq West Nile** EMEA/V/C/002005	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **RevitaCAM** EMEA/V/C/002379	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 13.02.13-31.08.13
• **Zulvac 1 Bovis** EMEA/V/C/002334	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **Zulvac 1 Ovis** EMEA/V/C/002335	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13

- ***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***: Nomination of expert(s) for:
  - VICH task force for reviewing the draft Concept Paper from IFAH-Europe for the revision of VICH Stability GL 3(R)
  - VICH task force for development of a discussion document for the development of a VICH GL for efficacy studies for combination products
  - VICH task force for scientific review of the issues raised in the draft CP from FDA on the revision of the VICH anthelmintics GLs
- ***For decision***: Proposal for a mandate for the VICH Task Force for Efficacy Studies for Combination Products

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"
- ***For decision***: Request from ECHA to nominate observers to join the Ad Hoc Working Group on the assessment of residues transfer to food (ARTFood) of the Biocidal Products Committee

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

Disclosure of 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

Disclosure of 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

Disclosure of 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

F.3 Other MRL items

Disclosure of 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

- ***For discussion***: Improving the SPC for old antimicrobials
- ***For information***: Verbal report of the Joint ECDC/EFSA/EMA Antimicrobial Consumption and Resistance Analysis EU Expert group meeting held on 17-18 December 2013; draft agenda of the meeting
- ***For information***: EFSA scientific opinion on carbapenem resistance in food animal ecosystems

F.5 Pharmacovigilance

- ***For information:*** Presentation on post-authorisation safety studies

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

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

Disclosure of 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

Disclosure of 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

Disclosure of 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

Disclosure of 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

Disclosure of 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***: Draft agenda of the meeting to be held on 16-17 January 2014; draft minutes of the meeting held on 12-13 December 2013

J. ORGANISATIONAL MATTERS

- ***For discussion***: Draft minutes of the informal CVMP meeting and the joint CVMP/CMDv meeting, held on 21-23 October 2013 in Vilnius, Lithuania
- ***For discussion:*** EMA/IFAH-Europe Info Day to be held on 13-14 March 2014, draft outline of programme

- ***For information***: 2014 an Agency on the move presentation
- ***For information:*** Report from Veterinary SME workshop held on 7 November 2013

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
Jan 2014	14-16	22-23	28-29			28-29		14		
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	27-28	20-21	13-15	6	22-23	
June	3-5		17-18					3		
July	8-10					1-2 (Poss. Adobe)		8		
September	9-11	24-25		30 Sept - 1 Oct	30 Sept-1 Oct	16-17	16-18	9	3-4	
October	7-9		21-22					7		
November	4-6	18-19		25-26		18-19		4	27-28	
December	9-11						2-4	9		