7 March 2014
EMA/CVMP/140404/2014
Committee for Medicinal Products for Veterinary Use

Committee for Medicinal Products for Veterinary Use (CVMP)

Draft agenda of March 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

11 March 2014, 09:00 – 13 March 2014, 13:00

Room 4B

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).

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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 4B)*	Tue 11 March 2014	16:30-18:00(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/003044/EXTN/0005 *Eggs*	***For adoption***: CVMP Scientific overview and list of questions ***For discussion***: Rapporteur's assessment report; revised rapporteur's scientific overview and list of questions; peer reviewer's report; peer reviewer's report; report from EU-RL
• **Substance** EMEA/V/MRL/003071/MODF/0002 *Bovine, ovine*	***For discussion***: Rapporteur's assessment report
• **Substance** EMEA/V/MRL/003262/EXTN/0003 *Sheep*	***For decision***: Need for an oral explanation ***For discussion:*** Draft list of outstanding issues, rapporteur's assessment of the responses to the LoQ; rapporteur's EPMAR, peer reviewer's 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/03678/0000 *New viral and bacterial vaccine (dogs)*	***For adoption:*** Draft CVMP opinion; Draft CVMP assessment report; Draft Product information
• **Product** EMEA/V/C/02759/0000 *New viral and bacterial vaccine (dogs)*	***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 spot-on solution for cats from prescription to non-prescription*	Rapp: R. Breathnach ***For adoption***: List of outstanding issues
• **EQUIOXX and Previcox** EMEA/V/C/000142/WS0474/0012/G EMEA/V/C/000082/WS0474/0037/G *Quality*	Rapp: D. Murphy **For adoption**: Draft CVMP opinion; Draft CVMP assessment report
• **AFTOVAXPUR DOE** EMEA/V/C/002292/II/0001 *Addition of a new virus antigen strain*	Rapp: A.-M. Brady Co-rapp: M. Tollis ***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

• **Rheumocam** EMEA/V/C/000121/X/0015 *Extension to include a new strength (horses)*	Rapp: M. Holzhauser-Alberti Co-rapp: E.-M. Vestergaard ***For adoption***: Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/003796/0000 *New viral and bacterial vaccine* (pigs)	***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

• **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 **ORAL EXPLANATION – Wed. 12 March 2014, 11:00** ***For discussion***: Presentation from MAH; rapporteur's assessment report including co-rapporteur's critique

• **AQUACOLI 2 000 000 IU/ml, Solution for use in drinking water or milk** EMEA/V/A/104 *Target species*	***For discussion and decision****:* Notification from the reference Member State (Spain) for an Article 33(4) referral

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 decision***: Need for outstanding issues for an oral explanation ***For discussion***: Rapporteur's assessment with co-rapporteur's comments to responses to list of outstanding issues; updated rapporteur's assessment report following responses to the list of outstanding issues; draft product information

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 decision***: Need for outstanding issues for an oral explanation ***For discussion***: Rapporteur's assessment to responses to list of outstanding issues; updated rapporteur's assessment report following responses to the list of outstanding issues and co-rapporteur's comments
• **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: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: List of questions; Timetable for the procedure ***For discussion and decision***: Notification from Denmark under Article 35 of Directive 2001/82/EC; discussion document ***For information***: List of products concerned Appointment of rapporteur, co-rapporteur and peer reviewers

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:*** Norbonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle – Art. 33(4) referral (EMEA/V/A/098) – Background information for publication
- ***For information:*** Veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys – Art. 35 (EMEA/V/A/089) – Background information for publication

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

• **Product** EMEA/V/C/002746/0000 *New ectoparasiticide* (cats)	**ORAL EXPLANATION – Wed. 12 March 2014** ***For discussion:*** Applicant's presentation; joint rapporteurs' assessment of the responses to the list of outstanding issues; updated scientific overview and benefit-risk assessment; joint rapporteurs' assessment of the responses to the list of outstanding issues on ASMF restricted part; draft D180 product information from applicant, rapporteurs' comments on draft PI
• **Product** EMEA/V/C/002757/000 *New viral vaccine (pigs)*	***For decision***: Need for oral explanation ***For adoption****:* Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information
• **Product** EMEA/V/C/002762/000 *New viral and bacterial vaccine (pigs)*	***For decision***: Need for oral explanation ***For adoption****:* Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion***: Draft product information

• **Product** EMEA/V/C/002761/000 *New bacterial vaccine (pigs)*	***For decision***: Need for oral explanation ***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues ***For discussion:*** Draft product information
• **Product** EMEA/V/C/003681/0000 *New viral 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/003679/0000 *New viral 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/003753 *New otological product* (dogs)	***For decision***: Need for oral explanation ***For adoption***: Updated scientific overview and benefit-risk assessment and list of outstanding issues, list of outstanding issues ***For discussion***: Draft product information; joint rapporteur's assessment of the responses to list of questions on ASMF restricted parts; joint rapporteur's assessment of the responses to list of questions on ASMF restricted parts
• **Product** EMEA/V/C/002590 *New hormonal product (cattle)*	***For endorsement***: Extension of the timeframe for the submission of responses to list of questions upon request from applicant

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

- No items

C.3 Product anniversary list

Product	Period
Activyl (EMEA/V/C/000163)	18.02.2013 – 17.02.2014
Cimalgex (EMEA/V/C/000162)	18.02.2013 – 17.02.2014
Econor (EMEA/V/C/000042)	12.03.2013 – 11.03.2014
Ibraxion (EMEA/V/C/000051)	09.03.2013 – 08.03.2014
Melosus (EMEA/V/C/002001)	21.02.2013 – 20.02.2014
Novem (EMEA/V/C/000086)	02.03.2013 – 01.03.2014
Pexion (EMEA/V/C/002543)	25.02.2013 – 24.02.2014
Porcilis Porcoli (EMEA/V/C/000024)	29.02.2013 – 28.02.2014
ProteqFlu (EMEA/V/C/000073)	06.03.2013 – 05.03.2014
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2013 – 05.03.2014
Purevax Rabies (EMEA/V/C/002003)	18.02.2013 – 17.02.2014
Purevax RC (EMEA/V/C/000091)	23.02.2013 – 22.02.2014
Purevax RCCh (EMEA/V/C/000092)	23.02.2013 – 22.02.2014
Purevax RCP (EMEA/V/C/000090)	23.02.2013 – 22.02.2014
Purevax RCP FelV (EMEA/V/C/000089)	23.02.2013 – 22.02.2014
Purevax RCPCh (EMEA/V/C/000088)	23.02.2013 – 22.02.2014
Purevax RCPCh FelV (EMEA/V/C/000085)	23.02.2013 – 22.02.2014
RevitaCAM (EMEA/V/C/002379)	23.02.2013 – 22.02.2014
Zulvac 1+8 Bovis (EMEA/V/C/002473)	08.03.2013 – 07.03.2014

C.4 Renewals of marketing authorisations

• **LEUCOGEN** EMEA/V/C/000144/R/0002	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: Draft list of outstanding issues
• **LEUCOFELIGEN FeLV/RCP** EMEA/V/C/000143/R/0003	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption***: Draft list of outstanding issues

C.5 Pharmacovigilance - PSURs and SARs

• **Aivlosin** EMEA/V/C/000083	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.12-30.09.13
• **Comfortis** EMEA/V/C/002233	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.13-30.09.13
• **Incurin** EMEA/V/C/000047	Rapp: V. Donini ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.10-30.09.13
• **Econor** EMEA/V/C/000042	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.11-30.09.13
• **Nobilis IB4-91** EMEA/V/C/000036	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.10-30.09.13
• **Procox** EMEA/V/C/002006	Rapp: E. Lander Persson ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13-31.10.13
• **Purevax FeLV** EMEA/V/C/000056	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.10-31.10.13
• **Purevax Rabies** EMEA/V/C/002003	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **Recuvyra** EMEA/V/C/002239	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13-31.10.13

• **Respiporc FLU3** EMEA/V/C/000153	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.12-31.07.13
• **Vaxxitek** EMEA/V/C/000065	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-31.08.13
• **Veraflox** EMEA/V/C/000159	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 01.05.13-31.10.13

- ***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***: Draft EU comments on the revised draft VICH GL23 on genotoxicity testing
- ***For discussion****:* VICH Task force on combination products: update on discussion of CVMP subgroup

D.2 Codex Alimentarius

- No items

D.3 Other EU bodies and international organisations

- No items

E. WORKING PARTIES AND SCIENTIFIC ADVISORY

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 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 27 February 2014 and on the meeting with stakeholders on the Request from the European Commission for advice on the impact on public and animal health of the use of antibiotics in animals (28 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

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 **Vectra 3D** (EMEA/V/C/002555) concerning the initial marketing authorization
- ***For endorsement:*** EPAR module 6 scientific discussion for **Broadline** (EMEA/V/C/002700) concerning the initial marketing authorization
- ***For endorsement:*** EPAR module 6 scientific discussion for **Bravecto** (EMEA/V/C/002526) concerning the initial marketing authorization
- ***For endorsement:*** EPAR module 6 scientific discussion for **NexGard** (EMEA/V/C/002729) concerning the initial marketing authorization
- ***For endorsement:*** EPAR module 6 scientific discussion for **Contacera** (EMEA/V/C/002612/X/0002) concerning the extension to add meloxicam 15 mg/ml oral suspension for an existing target species (horses)

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 endorsement***: MUMS annual report for 2013
- ***For discussion***: Update on MUMS policy revision and clarification of criteria for financial incentives for MUMS products for horses
- ***For information***: Project plan for MUMS policy revision

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

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

J. ORGANISATIONAL MATTERS

- ***For adoption***: CVMP work plan
- ***For discussion***: Preparation for EMA/IFAH-Europe Info Day 2014, to be held on 13-14 March 2014; programme
- ***For information***: Presentation on the CVMP work plan and the WPs for 2014 - EMA/IFAH-Europe Info Day, London 13-14 March 2014
- ***For discussion***: Presentation on recent procedural changes and their implications
- ***For information***: Assessment of new applications (refresher training)
- ***For information***: CHMP initiative concerning multinational assessment teams for future consideration by the CVMP
- ***For information***: Annual Report from the SME Office 2013 – Focus on veterinary SMEs
- ***For information***: 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
March	11-13					20-21		11		4
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		
November	4-6	18-19		25-26		18-19		4	27-28	
December	9-11						3-5	9		