27 May 2014
EMA/CVMP/327616/2014
Committee for Medicinal Products for Veterinary Use

Committee for Medicinal Products for Veterinary Use (CVMP)

Draft agenda of June 2014 meeting

Chair: Anja Holm

Vice-chair: David Murphy

3 June 2014, 09:00 – 5 June 2014, 13:00

Room 3A

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** *(Room 3A)* Tue 3 June 2014 16:30-17:15

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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** EU/10/173 *All ruminants*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For discussion***: Revised rapporteur's assessment report; revised rapporteur's EPMAR; comments; peer reviewer's report; EU-RL report, EU-RL review of additional data submitted by the applicant ***For information****:* Summary of opinion
• **Substance** EMEA/V/MRL/003262/EXTN/0003 *Extension to sheep*	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report ***For discussion***: Rapporteur's EPMAR ***For information****:* Summary opinion
• **Substance** EMEA/V/MRL/003923/FULL/0001 *Honey*	***For adoption***: Draft CVMP scientific overview and list of questions ***For discussion***: Revised rapporteur's assessment report including the critique from the co-rapporteur; revised rapporteur's scientific overview and list of questions; comments; comments; peer reviewer's report; peer reviewer's report; EFSA's comments
• **Substance** EMEA/V/MRL/002964/EXTN/0004 *Equidae*	***For adoption:*** Draft CVMP scientific overview and list of questions ***For discussion:*** Rapporteur's assessment report; rapporteur's scientific overview and list of questions; peer reviewer's report; EU-RL report
• **Substance** EMEA/V/MRL/003660/EXTN/0003 *Extension to rabbits*	***For decision:*** Need for an oral explanation ***For discussion****:* 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 *Extension to pigs*	***For decision:*** Need for an oral explanation ***For discussion****:* Rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report*;* EU-RL report
• **Substance** EMEA/V/MRL/003802/FULL/0001 *Fin fish*	***For decision:*** Need for an oral explanation ***For discussion***: Rapporteur's assessment report; rapporteur's EPMAR; peer reviewer's report; EU-RL report
• **Substance** EU/12/199 *Modification of ADI and MRLs*	***For discussion***: Rapporteur's assessment 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/003753/0000) *New otological product* (dogs)	***For adoption***: Draft CVMP opinion; Draft CVMP assessment report; Draft product information
• **Product** EMEA/V/C/003680/0000 *New bacterial vaccine* (dogs)	***For adoption:*** Draft CVMP opinion; Draft CVMP assessment report; Draft product information
• **Product** EMEA/V/C/003683/0000 *New viral and bacterial vaccine* (dogs)	***For adoption:*** Draft CVMP opinion; Draft CVMP assessment report; Draft product information
• **Product** EMEA/V/C/003682/0000 *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

• **Circovac, Eurican Herpes 205, Ibraxion, Purevax RCPCh, Purevax RCPCh FeLV, Purevac RCCh, Vaxxitek HVT+IBD** EMEA/V/C/00114/WS/0546 (0009), EMEA/V/C/00059/WS/0546 (0015), EMEA/V/C/00051/WS/0546 (0013), EMEA/V/C/00092/WS/0546 (0008), EMEA/V/C/00088/WS/0546 (0010), EMEA/V/C/00085/WS/0546 (0010), EMEA/V/C/00065/WS/0546 (0014), *Quality*	Rapp: B. Urbain ***For adoption***: Draft CVMP list of questions
• **COXEVAC** EMEA/V/C/000155/II/0006 *Quality*	Rapp: J.-C. Rouby ***For adoption***: Draft CVMP list of questions
• **Zuprevo** EMEA/V/C/002009/II/006/G *To add a new therapeutic indication*	Rapp: C. Ibrahim Co-rapp: E. Lander Persson ***For adoption***: Draft CVMP list of questions
• **ProteqFlu** EMEA/V/C/000073/II/014 *Strain substitution*	Rapp: J. C. Rouby Co-rapp: E. Werner ***For adoption***: Draft CVMP opinion, Draft CVMP's assessment report
• **ProteqFlu-Te** EMEA/V/C/000074/II/017 *Strain substitution*	Rapp: J. C. Rouby Co-rapp: E. Werner ***For adoption***: Draft CVMP opinion, Draft CVMP's assessment report
• **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 information***: Withdrawal letter from MAH

A.2.3 Re-examination of CVMP opinions

- N/a

A.2.4 Lists of questions

• **Product** EMEA/V/C/003842/0000 *New antiparasiticide* *(dogs)*	***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

- No items

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 colistin to be administered orally** EMEA/V/A/106 *Indications, prudent use warnings*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from EC under Article 35 of Directive 2001/82/EC; discussion document Appointment of rapporteur, co-rapporteur and peer reviewers ***For information*:** List of products concerned; EMA scientific advice to EC on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health

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

- No items

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

• **Resflor injectable solution for cattle** EMEA/V/A/101 *Efficacy*	Rapp: C. Ibrahim Co-rapp: M. Holzhauser-Alberti ***For decision:*** Need for outstanding issues ***For discussion:*** Rapporteur's assessment report including co-rapporteur's critique and annex

• **Ubrolexin intramammary suspension for lactating dairy cows** EMEA/V/A/102 *Efficacy and withdrawal periods*	Rapp: J. Bureš Co-rapp: D. Murphy ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur critique

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

- No items

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

• **Dapsone** EMEA/V/A/075 *Genotoxicity*	Rapp: M. Holzhauser-Alberti Co-rapp: W. Schlumbohm ***For endorsement:*** CVMP response to question raised by EDQM
• **Lidocaine** EMEA/V/A/092 *Genotoxicity and carcinogenicity*	Rapp: B. Urbain Co-rapp: C. Muñoz Madero ***For discussion***: Revised rapporteur's assessment report

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/002808/0000 *New hormonal product* *(cats)*	**ORAL EXPLANATION – Tue 3 June 2014, 14:00** ***For discussion***: Applicant's presentation; draft D181 product information with rapporteurs' comments; rapporteurs' assessment of the responses to the list of outstanding issues
• **Product** EMEA/V/C/002802/0000 *New viral vaccine* *(chickens)*	**ORAL EXPLANATION – Wed 4 June 2014, 15:30** ***For discussion:*** Applicant's presentation, Draft D181 product information

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

• **Versican Plus DHPPi+L4** EMEA/V/C/003678	Rapp: E. Werner Co-rapp: G. Kulcsár **Background note:** N/a ***For adoption:*** Rapporteur's recommendation assessment report
• **Versican Plus DHPPi+LR4** EMEA/V/C/002759	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption***: Rapporteur's recommendation assessment report
• **NexGard** EMEA/V/C/002729 *REC 007*	Rapp: P. Hekman Co-rapp: D. Murphy ***For adoption***: Rapporteur's recommendation assessment report

C.3 Product anniversary list

Product	Period
Naxcel (EMEA/V/C/000079)	19.05.2013 – 18.05.2014
Improvac (EMEA/V/C/000136)	11.05.2013 – 10.05.2014

C.4 Renewals of marketing authorisations

• **Aivlosin** EMEA/V/C/000083/R/0059	Rapp: H. Jukes Co-rapp: E. Lander Persson ***For adoption***: List of outstanding issues
• **Palladia** EMEA/V/C/000150/R/0007	Rapp: E. Lander Persson Co-rapp: C. Ibrahim ***For adoption:*** Draft CVMP opinion; Draft CVMP assessment report

C.5 Pharmacovigilance - PSURs and SARs

• **ECOPORC SHIGA** EMEA/V/C/002588	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Equilis Te** EMEA/V/C/000093	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.13-31.01.14
• **Gonazon (WD)** EMEA/V/C/000075	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.11-31.01.14
• **Kexxtone** EMEA/V/C/002235	Rapp: C. Munoz-Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Melovem** EMEA/V/C/000152	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.13-31.01.14
• **Nobilis Influenza H5N2** EMEA/V/C/000118	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.13-28.02.14
• **Onsior** EMEA/V/C/000127	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.01.13-31.12.13
• **ProZinc** EMEA/V/C/002634	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 12.07.13-31.01.14
• **Rheumocam** EMEA/V/C/000121	Rapp: M. Holzhauser-Alberti ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14

• **Suprelorin** EMEA/v/c/000109	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **Trifexis** EMEA/V/C/002635	Rapp: C. Ibrahim ***For adoption***: CVMP assessment report on the PSUR for the period 19.04.13-04.01.14
• **ZULVAC 8 Bovis** EMEA/V/C/000154	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14
• **ZULVAC 8 Ovis** EMEA/V/C/000145	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.13-31.01.14

- ***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: revision of anthelmintic guidelines: EU comments on topic 1 and topic 2
- ***For information***: Fixed combination GL: Questionnaire with EU response
- ***For information***: VICH GL52 on Bioequivalence: comments from interested parties and published guideline
- ***For information***: Final EU comments on draft 2 of VICH Metabolism and Residue Kinetics guideline on Residue studies in fish; draft 2 of the guideline; comments
- ***For information***: Draft agenda for the 30th VICH Steering Committee meeting to be held on 23-26 June 2014, in Brussels
- ***For discussion***: VICH discussion document on the future vision from Industry on a globally harmonized pharmacovigilance system to be discussed at the 30th VICH Steering Committee meeting

D.2 Codex Alimentarius

- No items

D.3 Other EU bodies and international organisations

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 **Versican Plus DHPPi L4** (EMEA/V/C/003678/0000)
- ***For endorsement:*** EPAR module 6 scientific discussion for **Versican Plus DHPPi L4R** (EMEA/V/C/002759/0000)

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 5-6 June 2014; minutes of the meeting held on 7-8 May 2014

J. ORGANISATIONAL MATTERS

- ***For discussion***: Discussion document on multinational assessment teams
- ***For information***: Verbal report from the Strategic Planning Group meeting to be held on 4 June 2014; draft agenda; draft minutes of the meeting held on 12 February 2014

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
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		