1 June 2015
EMA/CVMP/362586/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of June 2015 meeting

Chair: Anja Holm

Vice-chair: David Murphy

2 June 2015, 09:00 – 4 June 2015, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of declarations of interests, participants in this meeting are asked to declare any 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).

i. Adoption of the Agenda

ii. CVMP delegates list of intended participation and identified conflicts of interests

iii. Declaration of contacts between members and companies with regard to points on the agenda

iv. Adoption of the minutes of the previous meeting

v. Confirmation of topics for rapporteur's meetings and breakout sessions

Scientific Advice Working Party (room 2A)	Tue 2 June 2015	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/003200/EXTN/0003 *Bovine tissues and milk*	***For adoption**:* CVMP Scientific overview and list of questions

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/003836/0000 *New cardiovascular product* *Dogs*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

• **Product** EMEA/V/C/002723/0000 *New antiparasitic product* *Bees*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, rapporteurs' and PIQ comments on product information
• **Product** EMEA/V/C/004013/0000 New vaccine *Chickens*	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, rapporteurs' and PIQ comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/002804/0000 *New cardiovascular product* *Dogs*	***For discussion***: Joint assessment report on responses to list of outstanding issues, draft CVMP assessment report ***For information****:* Draft product information
• **Product** EMEA/V/C/003866/0000 *New anti-inflammatory product* *Horses*	***For discussion***: Joint assessment report on responses to list of outstanding issues, updated SOBRA

- ***For endorsement*****:** EPAR module 6 scientific discussion for **Sileo** (EMEA/V/C/003764/0000)
- ***For endorsement*****:** EPAR module 6 scientific discussion for **Cerenia** (EMEA/V/C/000106/X/0023)
- ***For information*****:** Withdrawal letter from Pfizer Limited for **ProMeris Duo** (EMEA/V/C/000108)
- ***For information*****:** Withdrawal letter from Pfizer Limited for **ProMeris** (EMEA/V/C/000107)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Ingelvac CircoFLEX** EMEA/V/C/000126/II/0019 *To update the product information*	Rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Poulvac E.Coli** EMEA/V/C/002007/II/0006 *To include an additional route of administration*	Rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **COXEVAC** EMEA/V/C/000155/II/0008/G *Quality*	Rapp: J.-C. Rouby ***For adoption***: CVMP opinion, CVMP assessment report
• **BTVPUR AlSap range** EMEA/V/C/xxxxx/WS/0669 *Quality*	Rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **Advocate** EMEA/V/C/000076/II/0026/G *New indication for dogs and change to the local representatives*	Rapp: M. Nevalainen Co-rapp: M. Azevedo Mendes ***For adoption**:* CVMP list of questions
• **Ingelvac CircoFLEX** EMEA/V/C/000126/II/0020 *Quality*	Rapp: M. Tollis ***For adoption**:* CVMP list of questions
• **STARTVAC** EMEA/V/C/000130/II/0003/G *Quality*	Rapp: E. Werner ***For adoption***: CVMP list of questions
• **ZULVAC SBV** EMEA/V/C/002781/II/0002/G *To update the product information*	Rapp: A.-M. Brady ***For adoption***: CVMP list of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- No items

4 REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

• **Coglapix vakcina A.U.V. suspension for injection for pigs** *(Actinobacillus pleuropneumoniae strains serotype 1 and 2)* EMEA/V/A/109 *Efficacy*	Rapp: M. Tollis Co-rapp: G. Kulcsár ***For adoption***: CVMP opinion, CVMP assessment report
• **Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys** *(Amoxicillin)* EMEA/V/A/112 *Bioequivalence and prudent use advice*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For adoption***: List of questions, timetable ***For discussion and decision***: Notification from the United Kingdom under Article 33(4) of Directive 2001/82/EC; appointment of rapporteur, co-rapporteur and peer reviewers.

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

- No items

4.4 Article 78 of Directive 2001/82/EC

- No items

4.5 Article 13 of Regulation (EC) No 1234/2008

- No items

4.6 Article 30(3) of Regulation 726/2004

- No items

4.7 Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- No Items

5.2 Post-authorisation measures and annual reassessments

• **LEUCOFELIGEN FeLV/RCP** EMEA/V/C/000143/REC/015	Rapp: E. Werner ***For adoption***: Rapporteur's assessment report
• **Coliprotec F4** EMEA/V/C/003797/ANX/001	Rapp: A.-M. Brady ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Improvac (EMEA/V/C/000136)	11/05/2014 – 10/05/2015
Naxcel (EMEA/V/C/000079)	19/05/2014 – 18/05/2015

5.4 Renewals

• **Meloxoral** EMEA/V/C/000151/R/0006	Rapp: H. Jukes Co-rapp: C. Ibrahim ***For adoption****:* List of outstanding issues

• **COXEVAC** EMEA/V/C/000155/R/0009 Re-examination	Re-examination rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For discussion***: Comments from E. Werner
• **BTVPUR AlSap 2-4** EMEA/V/C/000139/R/0006	Rapp: M. Tollis Co-rapp: J.-C Rouby ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Activyl Tick Plus** EMEA/V/C/002234	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **ECOPORC SHIGA** EMEA/V/C/002588	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **Emdocam** EMEA/V/C/002283	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-28.02.15
• **Equilis Te** EMEA/V/C/000093	Rapp: E. Werner ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.01.15
• **Kexxtone** EMEA/V/C/002235	Rapp: C. Munoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.0814-31.01.15
• **Nobilis Influenza H5N2** EMEA/V/C/000118	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.14-28.02.15
• **ProZinc** EMEA/V/C/002634	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15

• **Stronghold** EMEA/V/C/000050	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.12-31.01.15
• **Suprelorin** EMEA/V/C/000109	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.14-31.01.15
• **Suvaxyn PCV** EMEA/V/C/000149	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **Ypozane** EMEA/V/C/000112	Rapp: J. G. Beechinor ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.12-31.01.15
• **ZULVAC 1 Bovis** EMEA/V/C/002334	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15)
• **ZULVAC 1 Ovis** EMEA/V/C/002335	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14-28.02.15
• **ZULVAC 8 Bovis** EMEA/V/C/000145	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15
• **ZULVAC 8 Ovis** EMEA/V/C/000147	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.14-31.01.15

- ***For endorsement:*** List of products and calendar for signal detection analysis

5.6 Supervision and sanctions

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

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement***: Nomination of advisor to support the EU expert in relation to the review of VICH GL23 on genotoxicity testing
- ***For endorsement***: VICH Anthelmintic Guidelines Task Force, EU comments on discussion paper

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information:*** Revisiting the International Estimate of Short-Term Intake (IESTI) - Joint EFSA/FAO/WHO Stakeholder Meeting and Scientific Workshop

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information on certain topics discussed under section 7 cannot be released at the present time as it is deemed to be confidential

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP procedures cannot be released at the present time as it is deemed to be commercially confidential

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs

7.11 Other working party and scientific group issues

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential

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

8.2 Environmental risk assessment

Information on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential

8.3 Antimicrobial resistance

Information on certain antimicrobial resistance related issues cannot be released at the present time as it is deemed to be confidential

- ***For discussion*:** European Commission request for a joint EFSA and EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety, mandate

8.4 Pharmacovigilance

- No items

8.5 Other issues

- No items

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential

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

- ***For information***: Agenda of the meeting to be held on 4-5 June 2015; minutes of the meeting held 7-8 May 2015*;* presentation

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Consultation draft of the EU Medicines Agencies Network Strategy to 2020
- ***For discussion***: Experience gained on multinational assessment teams
- ***For information***: Verbal report from the Strategic Planning Group (SPG) to be held on 3 June 2015, draft agenda, draft minutes from the meeting held on 11 March 2015

13. LEGISLATION

14. ANY OTHER BUSINESS

For comments: Press release of the meeting

ANNEX

OTHER EVENTS OF INTEREST FOR CVMP OR ITS WORKING PARTIES

Assessor trainings, workshops, focus groups, presidency meetings, etc.

Event	Date	Place	Organiser
Training for assessors: Quality	25–26 June 2015	EMA	EMA / QWP
Training for assessors: Quality Assessment of Drug Substances	12–13 October 2015	Estonia	State Agency of Medicines - Estonia
Workshop (with industry): Lifecycle Management	28–29 October 2015	EMA	EMA / QWP / BWP / GMDP IWG
Workshop / Focus group meeting: VeDDRA	tbd	tbd	EMA / EWP
Training for assessors: Benchmark dose approach	2015/ tbd	tbd	EMA / SWP
Training for assessors: Microbiological ADI	2015/ tbd	tbd	EMA / SWP