12 February 2016
EMA/CVMP/128074/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2016 meeting

Chair: Anja Holm

Vice-chair: David Murphy

16 February 2016, 09:00 – 18 February 2016, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's 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 16 February 2016	16.00-20.00

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/002993/FULL/0002 *Bovine species*	***For adoption***: CVMP opinion including EPMAR, CVMP assessment report ***For information****:* Summary of opinion

1.2 Oral explanations and list of outstanding issues

- No items

1.3 List of questions

• **Substance** EMEA/V/MRL/004321/FULL/0001 *All food producing species*	***For adoption***: 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

• **Poulvac E. coli** EMEA/V/C/002007/X/0008 *Extension to include a new target species* *Chickens*	Rapp: E. Werner Co-rapp: A.-M. Brady ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information****:* Summary of opinion
• **Product** EMEA/V/C/004013 *New vaccine* *Chickens*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion
• **Product** EMEA/V/C/003685/0000 *New vaccine* *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/0004201/0000 *New antiparasitic* Cattle	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/004185/0000 *New vaccine* Sheep	***For adoption**:* Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/0003993/0000 *New vaccine* Pigs	***For adoption:*** Scientific overview and benefit-risk assessment and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **Bravecto** EMEA/V/C/002526/X/0005 *Extension to add a new pharmaceutical form (spot-on solution) for dogs and for a new target species (cats)* *Cats*	Rapp: C. Ibrahim Co-rapp: S. Louet ***For adoption**:* List of questions to AHEG from CVMP ***For endorsement**:* Final list of experts for AHEG ***For discussion**:* Draft rapporteurs' assessment report for the re-examination of the CVMP opinion; rapporteur's appendix to re-examination assessment report

2.5 Other issues

• **Product** EMEA/V/C/004239/0000 *New vaccine* *Rabbits*	***For adoption**:* Timetable for the 2nd phase of the procedure
• **Product** EMEA/V/C/002390 *New vaccine* *Atlantic salmon*	***For endorsement:*** Proposed list of participants for the 2nd AHEG meeting in February 2016, draft CVMP list of questions to AHEG

- ***For endorsement:*** EPAR module scientific discussion for **Imrestor** (EMEA/V/C/002763)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **BTVPUR AlSap 1-8** EMEA/V/C/002231/II/0007/G	Rapp: C. Muñoz Madero Co-rapp: M. Tollis ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **DRAXXIN** EMEA/V/C/000077/II/0031 *New indication*	Rapp: C. Ibrahim Co-rapp: C. Munoz Madero ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Bravecto** EMEA/V/C/002526/II/0010/G *Quality*	Rapp: G. J. Schefferlie **For adoption:** CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Metacam** EMEA/V/C/000033/II/0118/G *Quality*	Rapp: F. Hasslung Wikström ***For adoption***: CVMP list of outstanding issues
• **Versican Plus Pi/L4R/Versican Plus DHPPi/L4R** EMEA/V/C/xxxxxx/WS/0785 *To extend the duration of immunity*	Rapp: E. Werner ***For adoption***: CVMP list of outstanding issues

3.3 List of questions

- No items

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

• **CattleMarker IBR Inactivated emulsion for injection for cattle** *(Infectious bovine rhinotracheitis (IBR) vaccine)* EMEA/V/A/115 *Animal safety*	Rapp: E. Werner Co-rapp: F. Klein ***For decision***: Need for outstanding issues ***For decision***: MAH's request to provide an oral explanation ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 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: S. Louet ***For discussion***: Rapporteur's assessment of the responses to LoOI including co-rapporteur's critique
• **All veterinary medicinal products containing zinc oxide to be administered orally to food producing species** EMEA/V/A/118 *ERA and antimicrobial resistance*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision:*** Notification from The Netherlands and France under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned

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

- No items

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

5.1 General issues

- No Items

5.2 Post-authorisation measures and annual reassessments

• **Zulvac SBV** EMEA/V/C/002781/ANX/004.1	Rapp: A.-M. Brady Co-rapp: G. Kulcsar ***For adoption***: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Activyl (EMEA/V/C/000163)	18/02/2015 – 17/02/2016
Bravecto (EMEA/V/C/002526)	11/02/2015 – 10/02/2016
Cimalgex (EMEA/V/C/000162)	18/02/2015 – 17/02/2016
Comfortis (EMEA/V/C/002233)	11/02/2015 – 10/02/2016
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2015 – 04/02/2016
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2015 – 26/01/2016
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2015 – 12/02/2016
Kexxtone (EMEA/V/C/002235)	28/01/2015 – 27/01/2016
Loxicom (EMEA/V/C/000141)	10/02/2015 – 09/02/2016
NexGard (EMEA/V/C/002729)	11/02/2015 – 10/02/2016
Nobilis OR inac (EMEA/V/C/000062)	24/01/2015 – 23/01/2016
PIRSUE (EMEA/V/C/000054)	29/01/2015 – 28/01/2016
Purevax Rabies (EMEA/V/C/002003)	18/02/2015 – 17/02/2016
Semintra (EMEA/V/C/002436)	13/02/2015 – 12/02/2016
STARTVAC (EMEA/V/C/000130)	11/02/2015 – 10/02/2016
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2015 – 09/02/2016
ZULVAC SBV (EMEA/V/C/002781)	06/02/2015 – 05/02/2016

5.4 Renewals

• **MS-H Vaccine** EMEA/V/C/000161/R/0009	Rapp: B. Urbain Co-rapp: G. Kulcsar ***For adoption***: CVMP List of outstanding issues
• **ZULVAC 1 Bovis** EMEA/V/C/002334/R/0010	Rapp: E.-M. Vestergaard Co-rapp: I. Malemis ***For adoption***: CVMP assessment report, CVMP opinion, product information
• **ZULVAC 1 Ovis** EMEA/V/C/002335/R/0011	Rapp: M. Tollis Co-rapp: I. Malemis ***For adoption***: CVMP assessment report, CVMP opinion, product information
• **CERTIFECT** EMEA/V/C/002002/R/0011	Rapp: S. Louet Co-rapp: E. Lander Persson ***For adoption***: CVMP assessment report, CVMP opinion, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Comfortis** EMEA/V/C/002233	Rapp: C. Ibrahim ***For adoption***: Draft CVMP assessment report on the PSUR for the period 01.10.14-30.09.15
• **Aivlosin** EMEA/V/C/000083	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-30.09.15
• **CaniLeish** EMEA/V/C/002232	Rapp: J.-C. Rouby ***For adoption***: CVMP assessment report on the PSUR for the period 01.10.14-30.09.15
• **Coliprotec F4** EMEA/V/C/003797	Rapp: A.-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 16.03.15-30.09.15
• **Equisolon** EMEA/V/C/002382	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 13.03.15-12.09.15
• **Fungitraxx** EMEA/V/C/002722	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-30.09.15

• **Recocam** EMEA/V/C/002247	Rapp: D. Murphy ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-30.09.15
• **ZULVAC 1+8 Bovis** EMEA/V/C/002473	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-30.09.15

- ***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 adoption***: Revised VICH GL50 on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use, for consultation at step 4
- ***For adoption***: VICH GL 55 on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use, for consultation at step 4

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

Information on certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be confidential

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

- ***For adoption:*** Reflection paper on the authorisation of veterinary medicinal products containing (potential) PBT/vPvB substances.

8.3 Antimicrobial resistance

- ***For information:*** Verbal report on the RONAFA (Joint EFSA/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) meeting held on 4-5 February 2016
- ***For information***: Verbal report on the request from the Commission for an update of the 2013 advice on the impact on public health and animal health of the use of antibiotics in animals (colistin) – Antimicrobial Advice ad hoc Expert group (AMEG) meeting to be held on 26 February 2016
- ***For discussion***: Presentation from EUCAST's Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST)

8.4 Pharmacovigilance

Information on certain topics discussed under section 8.4 cannot be released at the present time as it is deemed to be confidential

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information

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***: Draft agenda of the meeting to be held on 18-19 February 2016; draft minutes of the meeting held on 21-22 January 2016

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: Public CVMP work plan 2016
- ***For discussion and endorsement:*** Revision of the scientific overview template guidance for immunological products: Assessor guideline subgroup composition and timelines
- ***For information***: Streamlining of procedure for preparation of Type II variation assessment reports

13. LEGISLATION

14. ANY OTHER BUSINESS

- ***For comments***: Press release of the meeting

ANNEX

NEXT MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	3R's
Feb 2016	16-18	18	23-24	2-3	23-24	11-12			16		
Mar 2016	15-17						22-23	1-3	15	3-4	22
Apr 2016	19-21								19		
May 2016	17-19	19	25-26		31		24-25	31	17	26-27	
Jun 2016	14-16				1	29-30		1-2	14		