15 January 2016
EMA/CVMP/36589/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2016 meeting

Chair: Anja Holm

Vice-chair: David Murphy

19 January 2016, 09:00 – 21 January 2016, 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 19 Jan 2016	16.00-20.00

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1. ESTABLISHMENT OF MAXIMUM RESIDUES LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003200/EXTN/0003 *Bovine tissues and milk*	***For decision***: Need for oral explanation

1.3 List of questions

• **Substance** EMEA/V/MRL/003639/MOD/0002 *Equidae*	***For adoption***: CVMP Scientific overview and list of questions
• **Substance** EMEA/V/MRL/004113/FULL/0001 *Porcine*	**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

- No items

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

• **Product** EMEA/V/C/004239/0000 *New viral vaccine* *Rabbits*	***For adoption:*** Scientific overview and benefit-risk assessment and list of questions, comments on product information
• **Product** EMEA/V/C/004202/0000 *New product for psycholeptic use* *Dogs and cats*	***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)*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For decision**:* Appointment of rapporteur, co-rapporteur and peer reviewers and confirmation of need of an ad-hoc expert group (AHEG) and its composition ***For discussion**:* Request for re-examination from applicant, request for an ad-hoc expert group (AHEG)

2.5 Other issues

- ***For endorsement:*** EPAR module scientific discussion for **Velactis** (EMEA/V/C/003739)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Nobilis IB4-91** EMEA/V/C/000036/II/0021/G *Quality*	Rapp: A-M. Brady ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Panacur AquaSol** EMEA/V/C/002008/II/0010 *Quality*	Rapp: G. J. Schefferlie ***For adoption***: CVMP opinion, CVMP assessment report

3.2 Oral explanations and list of outstanding issues

• **Draxxin** EMEA/V/C/000077/II/0031 *New indication*	Rapp: C. Ibrahim Co-rapp: C. Munoz Madero **ORAL EXPLANATION–Wednesday 20 January 2016, 2:30** ***For discussion**:* Applicant's presentation, draft product information

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

- No items

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 gentamicin presented as solutions for injection to be administered to cattle and pigs** EMEA/V/A/117 *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from Belgium under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers ***For information***: List of products concerned
• **All veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry** EMEA/V/A/110 *Indications, dosage and withdrawal periods*	Rapp: B. Urbain Co-rapp: K. Baptiste ***For decision***: Request from Zoetis for a 1-month delay for the submission of responses to the list of questions

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

• **Suprelorin** EMEA/V/C/000109/REC/022 *Recommendation*	Rapp: E.-M. Vestergaard Co-rapp: M. Mendes ***For adoption***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Activyl Tick Plus (EMEA/V/C/002234)	09/01/2015 – 08/01/2016
Bovela (EMEA/V/C/003703)	22/12/2014 – 21/12/2015
BTVPUR AlSap 1 (EMEA/V/C/002230)	17/12/2014 – 16/12/2015
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	17/12/2014 – 16/12/2015
CORTAVANCE (EMEA/V/C/000110)	09/01/2015 – 08/01/2016
Gripovac 3 (EMEA/V/C/000157)	14/01/2015 – 13/01/2016
MELOXIDYL (EMEA/V/C/000115)	15/01/2015 – 14/01/2016
Metacam (EMEA/V/C/000033)	07/01/2015 – 06/01/2016
NEXGARD SPECTRA (EMEA/V/C/003842)	15/01/2015 – 14/01/2016
Onsior (EMEA/V/C/000127)	16/12/2014 – 15/12/2015
Porcilis PCV (EMEA/V/C/000135)	12/01/2015 – 11/01/2016
Prac-tic (EMEA/V/C/000103)	18/12/2014 – 17/12/2015
RESPIPORC FLU3 (EMEA/V/C/000153)	14/01/2015 – 13/01/2016
Rheumocam (EMEA/V/C/000121)	10/01/2015 – 09/01/2016
SevoFlo (EMEA/V/C/000072)	11/12/2014 – 10/12/2015
Ypozane (EMEA/V/C/000112)	11/01/2015 – 10/01/2016
ZULVAC 8 Bovis (EMEA/V/C/000145)	15/01/2015 – 14/01/2016
ZULVAC 8 Ovis (EMEA/V/C/000147)	15/01/2015 – 14/01/2016

5.4 Renewals

• **Zuprevo** EMEA/V/C/002009/R/0010	Rapp: C. Ibrahim Co-rapp: E. Lander Persson ***For adoption***: CVMP renewal assessment report, CVMP opinion, product information
• **CERTIFECT** EMEA/VC/002002/R/0011	Rapp: S. Louet Co-rapp: E. Lander Persson ***For adoption***: CVMP list of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Kexxtone** EMEA/V/C/002235	Rapp: C. Muñoz Madero ***For adoption***: CVMP assessment report on the PSUR for the period 01.02.15 - 31.07.15
• **Nobivac L4** EMEA/V/C/002010	Rapp: B. Urbain ***For adoption***: CVMP assessment report on the PSUR for period 01.02.15 - 31.07.15
• **Profender** EMEA/V/C/000097	Rapp: R. Breathnach ***For adoption:*** CVMP assessment report on the PSUR for the period 01.08.12 - 31.07.15
• **Zolvix** EMEA/V/C/000154	Rapp: C. Friis ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.09 - 31.07.15 (targeted PSUR)
• **Activyl** EMEA/V/C/000163	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.14 – 31.08.15
• **Bovilis BTV8** EMEA/V/C/000148	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15
• **Bravecto** EMEA/V/C/002526	Rapp: G. J. Schefferlie ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15 – 31.08.15
• **Econor** EMEA/V/C/000042	Rapp: H. Jukes ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15
• **Ingelvac CircoFLEX** EMEA/V/C/000126	Rapp: M. Tollis ***For adoption***: CVMP assessment report on the PSUR for the period 01.09.12 – 31.08.15
• **NexGard** EMEA/V/C/002729	Rapp: P. Hekman ***For adoption***: CVMP assessment report on the PSUR for the period 01.03.15 – 31.08.15
• **Nobilis IB4-91** EMEA/V/C/000036	Rapp: A-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15

• **Nobilis IB Primo QX** EMEA/V/C/002802	Rapp: A-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15 – 30.09.15
• **Semintra** EMEA/V/C/002436	Rapp: R. Breathnach ***For adoption:*** CVMP assessment report on the PSUR for the period 01.03.15 – 31.08.15
• **ZULVAC SBV** EMEA/V/C/002781	Rapp: A-M. Brady ***For adoption***: CVMP assessment report on the PSUR for the period 06.02.15 – 31.08.15

- ***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***: GL30 Revision of species and breeds list
- ***For discussion***: Revised draft VICH GL54 on general approach to establish an acute reference dose (ARfD); draft overview of comments received during the public consultation

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- ***For information***: Summary and conclusions from the 81st Joint FAO/WHO Expert Committee on Food Additives (Residues of veterinary drugs) held in Rome on 17–26 November 2015

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

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

- ***For discussion***: 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)
- ***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 15 December 2015

8.4 Pharmacovigilance

- No items

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

- ***For information:*** Verbal update on the first meeting of the ad hoc expert group on RD114 held on 2-3 December 2015; agenda of the meeting

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 21-22 January 2016; minutes of the meeting held on 10-11 December 2015 and Chair's presentation for November and December 2015

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion:*** Revision of the scientific overview template guidance for immunological products
- ***For discussion****:* Draft public CVMP work plan for 2016
- ***For discussion***: Information about the round table with stakeholders on the 10-year anniversary of the micro-, small- and medium-sized-enterprise (SME) office
- ***For information***: CVMP Interested Parties' meeting to be held on 20 April 2016: first announcement/invitation and draft minutes of previous meeting, held on 6 May 2015

13. LEGISLATION

Information on certain topics discussed under section 13 cannot be released at the present time as it is deemed to be confidential

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
Jan 2016	19-21						26-27		19		
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	14-6				1	29-30		1-2	14		