11 September 2018
EMA/CVMP/579357/2018
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Agenda of September 2018 meeting

Chair: David Murphy

Vice-chair: Helen Jukes

11 September 2018, 09:00 – 13 September 2018, 13:00 - Room 2A

Declaration of interests

In accordance with the Agency's revised policy and procedure on the handling of competing 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 CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP 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. Intended participation and competing interests

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

iv. Adoption of the minutes of the July 2018 meeting and the August 2018 meeting via written procedure

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

Scientific Advice Working Party (room 2A)	Tuesday 11 Sep 2018	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

- No items

1.4 Re-examination of CVMP opinions

- No items

1.5 Other issues

• **Substance** EMEA/V/MRL/004933/FULL/0001 *Bovine*	***For information**:* Letter of withdrawal of the application
• **Substance** EMA/V/MRL/004828/FULL/0001 *Rabbits*	***For information**:* Clock stop extension request

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Inflacam** EMEA/V/C/002497/X/0015 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion
• **Rheumocam** EMEA/V/C/000121/X/0022 *To add a new pharmaceutical form and strength* *Cats*	Rapp: S. Louet Co-rapp: E.-M. Vestergaard ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information**:* Summary of opinion

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/004611/0000 *New vaccine* *Sheep and cattle*	***For decision***: Need for oral explanation ***For adoption***: Scientific overview and list of outstanding issues, comments on product information

• **Product** EMEA/V/C/004329/0000 *New product* *Pigs*	***For decision***: Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on the product information

2.3 List of questions

• **Product** EMEA/V/C/004967/0000 *New product* *Chickens*	***For adoption****:* Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

• **Horse Allo 20** EMEA/V/C/004222/0000 *New product for musculo-skeletal disorder, containing equine adipose-derived mesenchymal stem cells for the treatment of lameness associated to osteoarthritis in adult non-food producing horses* *Horses*	***For adoption****:* List of questions to AHEG ***For endorsement****:* Final list of AHEG members ***For discussion:*** Draft rapporteurs' assessment report for the re-examination of the CVMP opinion
• **Longrange** EMEA/V/C/004291/0000 *New antiparasitic product containing eprinomectin for the treatment of certain specified parasites, and for the prevention of reinfections with certain specified parasites* *Cattle*	***For adoption****:* List of questions to AHEG ***For endorsement****:* Final list of AHEG members ***For discussion***: Draft rapporteurs' assessment report for the re-examination of the CVMP opinion

2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **Cortacare** (EMEA/V/C/004689/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **NEXGARD SPECTRA, NexGard** EMEA/V/C/WS1338/G *To add new therapeutic indications*	Rapp: J. G. Beechinor Co-rapp: P. Hekman ***For adoption****:* CVMP opinion, CVMP assessment report, product information for NEXGARD SPECTRA and NexGard ***For information***: Summary of opinion

• **Econor** EMEA/V/C/000042/II/0052 *To update the SPC due to new preclinical data*	Rapp: H. Jukes ***For adoption**:* CVMP opinion, CVMP assessment report, product information
• **Versican Plus DHPPI**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R**, **Versican Plus L4**, **Versican Plus Pi**, **Versican Plus Pi/L4** and **Versican Plus Pi/L4R** EMEA/V/C/WS1337 *To introduce changes to the SPC and product information*	Rapp: E. Werner **For adoption:** CVMP opinion, CVMP assessment report, product information for: Versican Plus DHPPI, Versican Plus DHPPi/L4, Versican Plus DHPPi/L4R, Versican Plus L4, Versican Plus Pi, Versican Plus Pi/L4, and Versican Plus Pi/L4R ***For information***: Summary of opinion
• **Versican Plus DHPPi** and **Versican Plus Pi** EMEA/V/C/xxxxxx/WS1397 *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion, product information for Versican Plus DHPPi and for Versican Plus Pi ***For endorsement***: Rapporteur's assessment report
• **Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4R** and **Versican Plus Pi/L4** EMEA/V/C/xxxxxx/WS1398 *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion, product information for: Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus L4, Versican Plus Pi/L4R and Versican Plus Pi/L4 ***For endorsement***: Rapporteur's assessment report
• **Versican Plus DHPPi, Versican Plus Pi, Versican Plus Pi/L4, Versican Plus DHPPi/L4, Versican Plus DHPPi/L4R** and **Versican Plus Pi/L4R** EMEA/V/C/xxxxxx/WS1413 *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **Versican Plus DHPPi, Versican Plus Pi, Versican Plus DHPPi/L4R, Versican Plus DHPPi/L4, Versican Plus Pi/L4R** and **Versican Plus Pi/L4** EMEA/V/C/xxxxxx/WS1414 *Quality*	Rapp: E. Werner ***For adoption:*** CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **ZACTRAN** EMEA/V/C/000129/II/0039/G *Quality*	Rapp: E.-M. Vestergaard ***For adoption:*** CVMP opinion ***For endorsement***: Rapporteur's assessment report
• **OSURNIA** EMEA/V/C/003753/II/0008 *Quality*	Rapp: S. Louet ***For adoption**:* CVMP Opinion ***For endorsement***: Rapporteur's assessment report

• **Porcilis PCV M Hyo** EMEA/V/C/003753/II/0008 *Quality*	Rapp: E. Werner ***For adoption**:* CVMP Opinion ***For endorsement***: Rapporteur's assessment report
• **RESPIPORC FLUpan H1N1** EMEA/V/C/003993/II/0004 *Quality*	Rapp: M. Blixenkrone-Møller ***For adoption**:* CVMP opinion, CVMP assessment report, product information ***For information***: Summary of opinion

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

• **ProZinc** EMEA/V/C/002634/II/0015 To add a new target species	Rapp: R. Breathnach Co-Rapp: S. Louet For adoption: CVMP list of questions
• **Aivlosin** EMEA/V/C/000083/II/0072 *Changes to the SPC warnings*	Rapp: H. Jukes ***For adoption**:* CVMP list of questions
• **OSURNIA** EMEA/V/C/003753/II/0009/G *Quality*	Rapp: S. Louet ***For adoption**:* CVMP list of questions
• **Canigen L4, Nobivac L4** EMEA/V/C/xxxx/WS1439/G *Quality*	Rapp: B. Urbain ***For adoption***: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

• **Ecoporc SHIGA** EMEA/V/C/002588/II/0007 *To modify the therapeutic indication*	Rapp: N. Garcia del Blanco Co-Rapp: E. Vestergaard ***For information**:* Letter of withdrawal

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

- 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

- 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

• **CYTOPOINT** EMEA/V/C/003939/ANX/001.1 *Condition*	Rapp: R. Breathnach ***For endorsement***: Rapporteur's assessment report on the recommendation

5.3 Product anniversary list

Product	**Period**
Aivlosin (EMEA/V/C/000083)	09/09/2017 – 08/09/2018
APOQUEL (EMEA/V/C/002688)	12/09/2017 – 11/09/2018
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2017 – 05/09/2018
Cardalis (EMEA/V/C/002524)	23/07/2017 – 22/07/2018
Dexdomitor (EMEA/V/C/000070)	30/08/2017 – 29/08/2018
Emdocam (EMEA/V/C/002283)	18/08/2017 – 17/07/2018
Exzolt (EMEA/V/C/004344)	18/08/2017 – 17/07/2018
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2017 – 07/09/2018
Innovax-ND-IBD (EMEA/V/C/004422)	22/08/2017 – 21/08/2018
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2017 – 03/09/2018
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2017 – 31/08/2018

Product	Period
Nobivac Bb (EMEA/V/C/000068)	10/09/2017 – 09/09/2018
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2017 – 06/09/2018
Novaquin (EMEA/V/C/003866)	08/09/2017 – 07/09/2018
OSURNIA (EMEA/V/C/003753)	31/07/2017 – 30/07/2018
Porcilis PCV ID (EMEA/V/C/003942)	28/08/2017 – 27/08/2018
Previcox (EMEA/V/C/000082)	13/09/2017 – 12/09/2018
Profender (EMEA/V/C/000097)	27/07/2017 – 26/07/2018
Proteq West Nile (EMEA/V/C/002005)	05/08/2017 – 04/08/2018
Recocam (EMEA/V/C/002247)	13/09/2017 – 12/09/2018
Sedadex (EMEA/V/C/004202)	12/08/2017 – 11/08/2018
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2017 – 06/08/2018
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2017 – 23/07/2018
Suvaxyn PRRS MLV (EMEA/V/C/004276)	24/08/2017 – 23/08/2018
Trocoxil (EMEA/V/C/000132)	09/09/2018 – 08/09/2018
UpCard (EMEA/V/C/003836)	31/07/2017 – 30/07/2018
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2017 – 08/08/2018
Vectormune ND (EMEA/V/C/003829)	08/09/2017 – 07/09/2018
VEPURED (EMEA/V/C/004364)	17/08/2017 – 16/08/2018
Versican Plus L4 (EMEA/V/C/003680)	31/07/2017 – 30/07/2018
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2017 – 30/07/2018
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2017 – 30/07/2018
ZACTRAN (EMEA/V/C/000129)	24/07/2017 – 23/07/2018
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2017 – 04/08/2018
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2017 - 04/07/2018

5.4 Renewals

• **Bravecto** EMEA/V/C/2526/R/0028	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **CYTOPOINT** EMEA/V/C/003939	Rapp: R. Breathnach ***For adoption***: CVMP assessment report on the PSUR for the period 01.11.17-30.04.18
• **Easotic** EMEA/V/C/000140	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the targeted PSUR for the period 01.01.09-31.12.17
• **Nobilis IB4-91** EMEA/V/C/000036	Rapp: N. Garcia del Blanco ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.17-31.03.18
• **OSURNIA** EMEA/V/C/003753	Rapp: S. Louet ***For adoption***: CVMP assessment report on the PSUR for the period 01.08.17-31.01.18
• **RHINISENG** EMEA/V/C/000160	Rapp: E.-M. Vestergaard ***For adoption***: CVMP assessment report on the PSUR for the period 01.04.15-31.03.18
• **LETIFEND** EMEA/V/C/003865	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.11.17-30.04.18
• **Meloxidolor** EMEA/V/C/002590	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 23.04.17-22.04.18
• **Nobilis IB Primo QX** EMEA/V/C/002802	Rapp: N. Garcia del Blanco ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.04.17-31.03.18
• **Zeleris** EMEA/V/C/004099	Rapp: W. Schlumbohm ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.12.17-31.05.18

- ***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 discussion***: Draft training slides on VICH quality guidelines for comments: VICH stability GL overview introduction, VICH GL3 and GL4, VICH GL5, VICH GL8, VICH GL10, VICH GL11 and VICH GL18

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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 Working Group on the application of the 3Rs (J3RsWG)

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

- No items

8.3 Antimicrobial resistance

- ***For information:*** Additional ESVAC project to estimate the consumption of veterinary antimicrobials sales by the different animal species; data collection protocol 2017
- ***For information:*** Focus group meeting with invited stakeholders on the Pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation to be held on 12 October 2018; draft agenda and invitation sent to CVMP

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 be commercially confidential

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***: Minutes of the meeting held on 19-20 July 2018; draft agenda of meeting to be held on 13-14 September 2018

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For endorsement:*** Recommendations arising from the informal presidency meeting held on 7-8 May 2018 in Madrid, Spain; agenda and minutes of the meeting
- ***For endorsement:*** Informal Presidency CVMP-CMDv meeting (to be held during the Austrian presidency) on 25-26 October 2018 in Helsinki, Finland; draft agenda

- ***For discussion:*** Appointment of CVMP co-opted members at the December 2018 CVMP meeting; identification of expertise necessary to accomplish the mandate and appointment of co-opted members, CVMP list of expertise 2018
- ***For discussion***: Revised draft guidance on 'Appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products'
- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) meeting to be held on 12 September 2018, draft agenda of the meeting; draft minutes from the SPG meeting held on 20 June 2018
- ***For information:*** Follow up to the implementation of EMA Business Continuity Phase (BCP) 3
- ***For information:*** Update on Telematics strategy 2020-2025 concept

13. LEGISLATION

- ***To note***: Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the MRL to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive /2001/82/EC (cascade) (link)

14. ANY OTHER BUSINESS

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

ANNEX

NEXT MEETINGS OF THE CVMP AND ITS WORKING PARTIES

	CVMP	ADVENT	AWP	EWP	IWP	PhVWP	SAWP
Sep 2018	11-13	13	18-19	18-19	20-21	25-26	11
Oct 2018	9-11						9
Nov 2018	6-8					20-21	6
Dec 2018	4-6						4
Jan 2019	22-24						22